HHS Grants Policy and Administration Manual VERSION 1.02: October 2023

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Chapter 1: Introduction

The U.S. Department of Health and Human Services (HHS) Grants Policy Administration Manual (GPAM) establishes a minimum set of uniform policy requirements for administering HHS financial assistance awards. These policies apply to all awarding agencies while allowing for flexibility in implementation. Information in the GPAM builds upon information in the <u>HHS</u> <u>Grants Policy Statement (GPS)</u>. The GPAM also serves as the basis for monitoring and evaluating award management activities.

HHS implements several parts of the Code of Federal Regulations through the GPAM, including <u>45 CFR part 75</u>, the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, certain provisions of <u>2 CFR 200</u>, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, and others.

The GPAM is an internal HHS resource and may not be cited in public-facing communications or materials, including Notices of Funding Opportunity (NOFOs) and Notices of Award (NoAs). As an internal HHS resource, the GPAM does not apply directly to applicants or recipients. When communicating award policy and requirements to applicants or recipients, reference the HHS Grants Policy Statement (GPS). Do not distribute, cite, or otherwise disseminate the GPAM in public-facing communications or materials.

The GPAM sections align with the stages of the financial assistance award lifecycle and the framework of <u>45 CFR part 75</u>.

Chapter 2: General Information

2.1: Applicability

The GPAM applies to:

- All HHS awarding agencies that have the authority to award financial assistance mechanisms such as grants, loans, scholarships, and cooperative agreements, and
- Discretionary and non-discretionary HHS programs and awards, unless otherwise indicated in statute, regulation, or an approved policy exception. Those programs exempt from specific provisions of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (UAR) are outlined at 45 CFR 75.101(d) and (e).

GPAM users include:

- Grants and program management personnel, and
- Other HHS staff with financial assistance award related responsibilities, including activities such as review, payment, and audit.

2.2: Supersession

The HHS GPAM dated August 11, 2023, supersedes all other HHS internal grants administration guidance issued before this date.

The information in the GPAM is subject to change; GPAM users are encouraged to monitor the HHS <u>GPAM Intranet Web page</u> for pertinent updates. Changes to HHS or government-wide regulation will apply prospectively, with a specific date of adoption. HHS will make conforming changes to the GPAM as soon as possible after adoption and all changes will be communicated to CGMOs, as applicable.

2.3: Supplementation of the GPAM

Awarding agencies operate under distinct missions and legal authorities. The GPAM provides sufficient flexibility to account for these differences while establishing a minimum set of uniform policy requirements for internal HHS award administration throughout the financial assistance award lifecycle. Awarding agencies may supplement the GPAM with awarding agency-specific grants policy guidance, provided the guidance does not contradict HHS policy and is not less restrictive than HHS policy. Please refer to the Exceptions section of this GPAM for detailed language about the exception process for supplemental policies that may contradict or be less restrictive than HHS policy.

2.4: Types of Requirements and Order of Precedence

Requirements may apply to awarding agencies, influencing how the agency administers a program or award. Or, requirements may apply to recipients, addressing program- or award-specific matters, such as what costs and activities the program or award may or may not support. Requirements for applicants and recipients typically fall into one of two categories:

- Programmatic requirements:
- Are specific to a given program or award;
- derive from authorizing or appropriations statutes, as well as implementing program regulations, when applicable;
- establish expectations for the intended impact and results of the program or award; and
- are specified in the Notice of Funding Opportunity (NOFO).
- Administrative requirements:
- Ensure accountability for performance under the award and the expenditure of federal funds;
- complement programmatic requirements;
- establish expectations for program- and award-related business and financial management;
- are specified in the HHS GPS and NOFO; and

• generally apply to all programs, though some may apply only to a particular type of activity or a specific type of recipient.

Order of precedence is critically important to understanding how and when requirements apply to a given program or award.

The below graphic depicts the general order of precedence (also known as order of authority). Note that this list is not exhaustive.

Level of Policy	Examples (Note: This list is not exhaustive.)
1. US Constitution	The foundation of all laws, rules, and policies.
2. Statutes	Program Authorizations and Appropriations
	Federal Grant and Cooperative Agreement Act of 1977
	Federal Funding Accountability and Transparency Act (FFATA) of 2006
	Digital Accountability and Transparency Act (DATA) of 2014
	Grant Reporting Efficiency and Agreements Transparency (GREAT) Act of 2019
3. Regulations	Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HH
	Awards: <u>2 CFR 200</u> (government-wide) & <u>45 CFR 75</u> (HHS)
	Program-specific regulations
4. Policies,	Executive Orders
	OMB Memos
	HHS Grants Policy Statement (GPS)
	HHS Grants Policy Administration Manual (GPAM)
	Agency-Specific Grants Policies
	Agency- and program-specific guidance related to one or more award programs such a Notices of Funding Opportunity (NOFO), FAQs, and other program announcements, e.g., agency guidance, manuals, "Dear Colleague" letters. For non-discretionary awards these might include state or Tribal plans, public assistance or statewide cost allocation plans.
	Requirements specific to an individual award or class of awards, such as a requirement to perform activities described in the recipient's application.

2.4.1: Order of Precedence

GPAM users are encouraged to direct questions regarding order of precedence, including those cases where a conflict appears to exist between requirements, to the appropriate awarding agency CGMO, or their designee. If questions are not resolved at the CGMO level, they may be escalated by the CGMO, or designee, to the HHS Office of Grants, Division of Policy, Oversight, and Evaluation.

2.5: Sources of Requirements

The Office of Management and Budget (OMB) establishes government-wide federal financial assistance guidance through <u>2 CFR part 200</u>, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*. HHS codifies <u>2 CFR part 200</u> into HHS regulation at <u>45 CFR part 75</u>, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards*.

These Uniform Administrative Requirements (UAR) provide the foundation for the HHS Grants Policy Statement (GPS), which serves as terms and conditions of HHS awards, and the HHS GPAM.

Many other applicable public laws, regulations, policy, and guidance, described below and later in this document, also establish requirements.

2.6: Public Policy Requirements

Awarding agencies must manage and administer programs and awards in accordance with U.S. statutory and public policy requirements, including, but not limited to, those protecting public welfare, the environment, and prohibiting discrimination. Awarding agencies must communicate all relevant public policy requirements to recipients, including those in general appropriations provisions, and incorporate them either directly or by reference in the terms and conditions of the award.

<u>45 CFR 75.300(b)</u> sets out that the recipient is responsible for complying with all requirements of the federal award.

More detailed information on government-wide laws and HHS regulations and policies, including potentially applicable appropriations and national public policy requirements, is found in <u>Appendix D</u>.

2.7: HHS Appropriations

HHS typically receives funding via three annual appropriations:

- Labor, HHS, Education, and Related Agencies (HHS appropriations act), covering most HHS awarding agencies and programs
- Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (Agriculture appropriations act), covering the Food and Drug Administration
- Department of the Interior, Environment, and Related Agencies (Interior appropriations act), covering the Indian Health Service, the Agency for Toxic Substances and Disease Registry (within the Centers for Disease Control and Prevention), and the National Institute of Environmental Health Sciences (within the National Institutes of Health)

HHS may also receive funding from supplemental appropriations, such as those that are enacted to address a public health emergency. HHS also receives permanent appropriations

embedded within authorizing statutes that are not subject to annual appropriation, but which do generally have expirations.

Under a continuing resolution (CR), generally the provisions of the prior fiscal year appropriations act remain in effect until a specified date, the passage of a modified CR, or its supersession by the passage of a full-year annual appropriations act. The scope of budget authority provided under a CR will be determined by the language contained in the CR and any subsequent amendment(s).

Awarding agencies may operate under different appropriation terms and conditions, depending on whether one or more of the three appropriations acts under which HHS receives funding are enacted at the start of a fiscal year or are operating via continuing resolution.

Chapter 3: Planning

Planning is a key role in the grants management process that helps to ensure effective program design, appropriate financial management, and good outcomes. An agency first designs the program, including goals, objectives, and expected results, before developing one or more projects or Notices of Funding Opportunity (NOFOs) under the program. Program planning and design is an ongoing and evolving activity that can span multiple fiscal years and is critical for achieving awarding agency objectives.

A program must align with the strategic goals and objectives within the awarding agency's performance plan and should support its performance measurement, management, and reporting. A NOFO should be the result of program planning and should not be the start of the process.

3.1: Financial Assistance Planning

Planning is essential to ensure that awarding agencies:

- Adequately consider the design of financial assistance programs and initiatives;
- Provide sufficient time to develop, submit, and approve concise and informative NOFOs;
- Define overall program implementation strategies that comply with statutory and regulatory requirements, including those outlined in the GPAM;
- Allow adequate time for internal clearance processes;
- Allow applicants adequate time to review published NOFOs, determine whether to apply, develop well-structured applications, and register in the System for Award Management (SAM);
- Allow adequate time for the merit review, award decision-making, risk reviews, and award;

- Develop a competition that is fair and equitable and will likely result in qualified recipients who will be successful in carrying out the purpose of the award and prove to be good stewards of federal funds;
- Effectively balance their own internal workload distribution during the fiscal year; and
- Assign proper staff and resources to make timely and high-quality award decisions.

3.1.1: Minimum Requirements for Financial Assistance Planning

Awarding agencies must employ an annual financial assistance planning process that ensures:

- The awarding office has an effective process for determining the submission timing of required materials by recipients of non-competing continuation awards, evaluation by the awarding office, and issuance of timely awards;
- Financial assistance programs are implemented consistent with the authorizing statute and other applicable statutes and regulations;
- Use of the appropriate award instrument;
- Alternatives to proposed single-source awards or other limitations of competition are considered;
- Forecast reporting;
- NOFOs (and application instructions or guidance used in lieu of, or in addition to the NOFO) are compliant, complete, and in plain language;
- Applicants are provided the maximum amount of time allowable to prepare and submit high-quality applications;
- Adequate time is available for merit review;
- Federal government interests are protected by providing enough time to complete preaward risk assessments and determinations of business management capabilities, to prepare Notices of Award (NoAs), and to allow for the needed level of post-award monitoring; and
- The awarding office provides the NoA to the recipient in advance of the project start date.

To achieve these objectives, the annual financial assistance planning process should:

- Be issued, in writing, by the head of the awarding agency or designee (who must report directly to the head of the awarding agency and have responsibility for grants management functions alone or in combination with programmatic functions);
- Establish program manager (e.g., division directors), project officer (PO), and grants management officer (GMO) responsibilities;
- Require the planning process begin before the passage and allocation of the appropriation from which awards are expected to be made;

- Provide a formal way to obtain detailed information from the awarding agency program office about planned activities, in advance, to allow the GMO to coordinate with the assigned PO;
- Provide for plan updates, at least quarterly, to accommodate changes in programmatic funding priorities or expectations and as needed when appropriations and continuing resolutions are enacted;
- Encourage informal communication between program staff and grants management staff throughout plan development and implementation;
- Include time frames and milestones for the awarding agency's programs;
- Require early indication by program offices of whether a single source or limited competition award is being considered so the PO and the GMO can discuss the basis for the proposed action, and
- Establish appropriate deadlines.

GMO(s) should use the plan to assign activities to grants management specialists, engage POs in discussion on identified issues, and to establish defined milestones.

3.2: Considerations for Planning

3.2.1: Budget Formulation and Appropriations

Each year, awarding agencies are given an opportunity to play a role in the federal budget formulation process by providing recommendations on appropriations related to their programs both during the initial development process and passback. <u>OMB Circular A-11</u> describes this process in full along with information on agency strategic planning and performance measurement.

While NOFOs may be issued prior to the passage of a relevant appropriations act, agencies should reassess estimates once passed. Prior to obligation of funds the appropriation must be legally available (which means that the appropriations bill has become law), the purpose is authorized, the funds are apportioned, the awarding agency obligates funds within the time limits applicable to the appropriation, and the obligation and expenditure are within the amounts Congress has established.

When planning financially for award programs, awarding agencies will consider known appropriations information including previous years' appropriations and a current appropriations act or continuing resolution or the current content of such a bill, if not yet enacted. Awarding agencies should consider the known or expected amount of appropriations by program, as well as the duration of the availability of those appropriations (e.g., no-year, one-year, or other specific limitations).

When considering the overall program budget, agencies also consider breakdowns into categories aligned to specific goals, if any.

The result of this assessment should be a document or other method to clearly articulate and incorporate into NOFOs how much is expected to be allocated to each program and any subcategories of programs along with the floors and ceiling amounts for any single award, if applicable.

3.2.2: Implementing a New Award Program

Sometimes Congress creates a new award program through statute. Each new HHS award program requires an Assistance Listing (AL) number and a public facing AL description of the new program. If a new AL number and description is required, contact the HHS Office of Grants for instructions. Note that multiple NOFOs may be issued under a single program or AL number.

3.2.3: Competition and Eligibility

Fair and equitable competition is an important policy within HHS and across the federal government. Authorizing statutes generally describe eligibility for each HHS financial assistance program. In many cases, ensuring equity means allowing all eligible entities to apply. However, there may be times when based on programmatic needs, available funds, geographic priorities, or other factors that the most effective and equitable choice is to limit the pool of applicants. In these cases, see the section on <u>Exceptions to Maximum Competition</u> for further information.

3.2.4: Selecting the Appropriate Award Instrument

The awarding agency must select the appropriate instrument for a federal award in accordance with the Federal Grant and Cooperative Agreement Act (FGCA) of 1977 (<u>31 U.S.C. §§ 6301-08</u>). In accordance with the FGCA, awarding agencies must utilize procurement contracts for acquisition activities and grants or cooperative agreements for financial assistance relationships. Awarding agencies have inherent authority to contract. In contrast, an awarding agency must have an awarding authority through authorizing legislation (either an authorization act or appropriation act) to award grants or cooperative agreements.

The awarding agency generally has discretion when selecting an award instrument unless the instrument to be used is specified by the authorizing legislation. The determination of the award instrument should be made jointly between the GMO, program officials, and the relevant contracting officer, along with any needed consultation with the Office of the General Counsel (OGC), following discussion of programmatic needs and objectives. In line with the code of federal regulations, federal financial assistance means assistance in the form of grants, cooperative agreements, non-cash contributions or donations of property, direct appropriations, food commodities, and, in some cases, other financial assistance such as loans, loan guarantees, interest subsidies, and insurance.

Most financial assistance awards are in the form of grants and cooperative agreements. The distinction between grants and cooperative agreements is described below:

- A grant is the appropriate awarding instrument when the awarding agency does not anticipate having substantial programmatic involvement.
- A cooperative agreement is the appropriate awarding instrument when the awarding agency is substantially involved. Descriptions of what constitutes substantial

programmatic involvement are included in subsection Use of Cooperative Agreements below.

Other types of financial assistance awards may include loans, fellowships, scholarships, contracts of assistance, and prize challenges.

The awarding agency grants office makes the final determination of the appropriate award instrument for a financial assistance relationship consistent with applicable statutes, regulations, and policies.

The NOFO, NoA, and post-award programmatic and administrative activities must clearly describe which instrument is being used. In the case of a cooperative agreement, awarding agencies must include a very clear statement of how the awarding agency will be substantially involved in the award in the NOFO.

An awarding agency must not develop a preference for a particular award instrument and use it inappropriately to achieve or avoid the requirements of a different process (e.g., the acquisition process) and must not use an award instrument in a way other than required by the Federal Grant and Cooperative Agreement Act of 1977.

3.2.4.1: Use of Cooperative Agreements

The determination to use a cooperative agreement can be made only after concluding that:

- The intended relationship is one of financial assistance rather than acquisition; and
- The awarding agency will have substantial involvement during the period of performance.

The exercise of normal post-award oversight and stewardship responsibilities and functions do not require or justify the use of a cooperative agreement. Examples of normal post-award oversight and stewardship activities that are not considered substantial involvement include:

- Conducting site visits;
- Evaluating progress reports;
- Providing post-award technical assistance;
- Ensuring compliance with public policy requirements or terms and conditions of award;
- Conducting enforcement activities;
- Closer monitoring on the basis of designation of an organization as high-risk; and
- Reviewing and evaluating performance after project completion.

Substantial involvement may include collaboration or participation by awarding agency program staff in activities specified in the award and, as appropriate, decision-making at specified milestones related to performance (e.g., requiring awarding agency approval before undertaking the next phase of a project). Awarding agencies may not use cooperative

agreements to require specific deliverables by set dates and/or mandate budget allocations, as such requirements are inconsistent with a financial assistance relationship.

The awarding agency must provide a written description of the planned substantial involvement in the NOFO and NoA. The substantial involvement must be administered as written to ensure no implied legal liability on the part of the awarding agency. The federal government is generally not liable for any wrongdoing committed by award recipients, and recipients are not afforded coverage under the Federal Tort Claims Act (FTCA), because generally award recipients are not agents of the government.

3.2.5: Pre-applications and Letters of Intent

Awarding agencies may require or encourage applicants to submit letters of intent that indicate their organization's interest in responding to a NOFO. Awarding agencies must limit what is requested in a letter of intent to only the information necessary to determine whether an organization plans to apply. Where a letter of intent is encouraged rather than required, these letters can not to be used as a means of assessing project viability and should not require awarding agency feedback.

Awarding agencies may also require applicants to submit pre-applications. Pre-applications contain detailed information that can be used to determine an organization's eligibility, compare the proposed projects to other proposed projects, and determine applications that are the least likely to be approved for federal funding before applicants incur significant expenses preparing an application. Pre-applications should be reviewed by program staff with the appropriate level of expertise to provide feedback to the applicant. Awarding agency responses to pre-applications must not give an advantage to one applicant over other potential applicants.

Pre-application and letters of intent requirements, if used, must be clearly identified in the NOFO. Use of pre-applications and letters of intent must not be used to circumvent any part of the requirement for merit review.

3.2.6: Program Income Considerations

Awarding agencies must detail any requirements associated with program income in the NOFO.

The awarding agency, in consultation with the Program Official (PO), must determine the following for a particular program, class of awards, or individual award, as appropriate (unless a statute or program regulation requires a particular program income alternative):

- If there is potential for generating program income;
- Which <u>program income alternative(s)</u> to use in aid of federal government stewardship; and
- Whether to place any limits on amounts of program income to be used (e.g., if the deduction or addition alternative is to be used for program income up to a certain dollar amount and another alternative to be used for amounts exceeding that cap).

Applicable program income alternatives applied to all awards under a program must be specified in the NOFO, as well as any related application guidance or budget completion instructions.

See the section <u>Use of Program Income</u> for additional explanation of program income.

The awarding agency may specify post-award requirements for program income by referencing <u>45 CFR 75.307</u>.

3.2.7: Cost Sharing Considerations

All federal awards must have a statutory or regulatory basis to include a requirement for matching or cost sharing, and where matching or cost sharing is required, it must be described in the NOFO.

Awarding agencies must determine the appropriate percentage or amount required for cost sharing or matching based on statutory or regulatory requirements.

If the program authority is ambiguous, in order to maximize the amount of the recipient contribution, the calculation of the required match should be based on the amount of the federal funds awarded, not on the amount of funds obligated by the recipient. Consult with OGC to confirm whether the preferred interpretation is permitted.

Voluntary committed cost sharing or matching may be considered in the merit review process when in accordance with statute or regulation and specified in a NOFO. Note that voluntary committed cost sharing or matching cannot be factored into the merit review process for federal research proposals.

See <u>Communicating Cost Sharing Requirements</u> below.

3.2.8: Performance Management

Awarding agencies should give significant thought to how they will measure and determine how well the recipient performs and how their performance benefits the public. In doing so, awarding agencies should consider how the performance of individual programs and awards might affect Administration and HHS policy priorities and how performance can be measured across multiple programs and initiatives.

The methods used to make this determination should include both output and outcome measures to provide a full picture of a project's impact and value. While individual projects may have additional or differing measures, the core measures and/or performance expectations must be published in the NOFO.

3.2.9: Monitoring Approach

The monitoring approach is determined prior to award and is subject to adjustment after award based on recipient performance and compliance. A monitoring approach includes techniques on how to measure progress towards performance goals and frequency of reporting. The approach should consider the:

• Type of program (e.g., service, research, demonstration);

- Governing statutory and regulatory requirements;
- Type of award instrument;
- Type of recipient(s); and
- Risk-based criteria specific to a program or award.

Consideration must be given to how programmatic performance, financial performance, and other aspects of compliance will be monitored to:

- Establish awarding agency roles, responsibilities, and expectations;
- Identify needed resources; and
- Determine language needed in NOFOs.

3.3: NOFO Development

NOFOs must follow the outline and requirements of <u>45 CFR 75, Appendix I, Full Text of Notice</u> <u>of Funding Opportunity</u>. Awarding agencies may include a summary prior to Section A. The following key information is helpful to developing the NOFO. The full text of the competitive NOFO must be posted at Grants.gov.

3.3.1: Notice of Funding Opportunity (NOFO)

The full text of the notice of funding opportunity is designed so that similar types of information will appear in the same sections of all NOFOs.

NOFO drafts must be provided to awarding agency office of grants, per internal process, for review and approval.

Following publication, if the number or type of questions raised by the public indicates a problem with a NOFO that may have a negative impact on the submission of applications or their evaluation, the Program Official (PO) and the Grants Management Officer (GMO) must jointly consider the need to amend, extend the due date, and/or cancel the NOFO. If the issue is minor, then amending the NOFO is likely appropriate and a decision to extend the due date should be based on whether there is adequate time left for potential applicants to amend their applications. If there is a major flaw in a NOFO, unless very early in the process, canceling and reissuing the NOFO may be the appropriate choice.

All NOFOs for competitive awards must be available to potential applicants through Grants.gov. Awarding agencies may also publish NOFOs in the *Federal Register* or the *NIH Guide for Grants and Contracts* (*NIH Guide*) for submission in Grants.gov, as applicable.

An awarding agency may use supplementary means of making NOFOs available (e.g., distribution through a constituency organization, transmittal through a targeted mailing, or electronic notification directed to the known universe of eligible applicants). Any supplementary notice must be coordinated with the appropriate grants management officer and cannot predate the issuance of the NOFO on Grants.gov.

All awarding agencies are responsible for conducting all processes in a fair and equitable manner to ensure the integrity of the process.

An awarding agency must not give any potential applicants selective advance notification of planned or pending funding opportunities, nor should awarding agencies tailor NOFOs for selected projects that awarding agency staff may have informally discussed with a potential applicant in another forum.

Each NOFO must contain the detail needed for an applicant to understand the funding opportunity and submit a complete and compliant application.

The NOFO must comply with the Plain Writing Act of 2010 (Public Law 111-274) (<u>www.plainlanguage.gov</u>).

3.3.2: Application Deadline, Submission, and Timeliness

Each NOFO must include submission requirements and an application deadline.

To be considered timely, an application must be submitted to Grants.gov on or before the deadline date and time specified in the NOFO. Competing applications that do not meet the deadline specified in a NOFO are considered late and may not be accepted for competition under that NOFO. Agencies can accept late applications at their discretion, provided they are accepted on a consistent and fair basis.

The awarding agency cannot accept an application for review submitted by any means other than specified in the NOFO or by approval from an authorized awarding agency official.

3.3.3: Ease of Understanding Eligibility

Potential applicants must be able to quickly review the NOFO and know whether they are eligible if they meet the requirements of the NOFO. NOFOs must clearly identify and describe the types of entities eligible for funding and other eligibility criteria as required by <u>45 CFR 75</u> <u>Appendix I</u>.

As a reminder, the following types of entities are ineligible for HHS awards, unless expressly authorized by statute:

- Federal entities;
- Individuals (including sole proprietorships); and
- Foreign entities.

3.3.4: Communicating Cost Sharing Requirements

If matching or cost sharing is required by statute or regulation, the NOFO must include the following types of information:

- A citation to the underlying statute or regulation;
- Agency evaluation (i.e., scored evaluation criteria, extra points, preference, etc.) of proposed cost sharing and consequence of failure to include required cost sharing or matching (i.e., application will not receive further consideration);

- A clear statement of the sharing requirement including:
- Whether the amount is negotiable (Note: the amount of matching or cost sharing may not be used as a method of negotiation to increase an applicant's voluntary contributions);
- The minimum percentage/amount or a graduated percentage/amount, if necessary; and
- The method of calculation (percentage of total approved budget or percentage of approved federal share).
- How the matching or cost-sharing requirement applies.
- Limitations on types of costs or contributions that may qualify as matching or cost sharing (e.g., if in-kind contributions will not be acceptable);
- Instructions for applicants to fully identify and document in the application the specific costs or contributions proposed to meet a matching or cost-sharing requirement, the source of the funding or contribution, and how the valuation was determined (if inkind);
- Any special application requirements, for example, whether there is a need for any preaward documentation to establish the applicant's ability to provide the proposed matching or cost sharing; and
- Any applicability of the matching or cost sharing requirement to subrecipients.

There may be cases where statute allows, but does not require, matching or cost sharing. In these cases, the level of matching or cost sharing may vary across individual NOFOs under a single program.

If a NOFO includes a matching or cost-sharing requirement based on a permissive statutory authority (where the statute requires or allows matching or cost sharing but does not specify the minimum/maximum amount) and there are no implementing regulations, the agency must document in writing:

- The reason(s) for requiring matching or cost sharing. Awarding agencies should consider the equity of requiring applicants to cost share when it is a discretionary decision; and
- An explanation of why the specified amount or percentage of matching or cost sharing is being required.

The awarding agency must file this documentation in the grant file.

See Cost Sharing Requirements above for additional information.

3.4: Public Notice

3.4.1: Financial Assistance Forecast

Awarding agencies must provide forecasts of all proposed and/or upcoming funding opportunities (see Pre-Award Chapter, Forecasts for Discretionary Programs for requirements).

3.4.2: NOFO Public Notice Requirement

HHS-wide pre-award requirements are located at <u>45 CFR part 75, subpart C</u>. <u>45 CFR 74.202</u> describes HHS requirements for providing notice of the availability of financial assistance funds to the public.

Awarding agencies must maximize opportunities for competition for discretionary awards by ensuring the widest and earliest possible dissemination of information to the public and to potential applicants.

Except for situations listed below, awarding agencies must make all NOFOs publicly available for at least 60 calendar days. The 60 calendar days is counted from the publication date to the application submission deadline.

If an awarding agency determines that the public availability of a NOFO needs to be fewer than 60 calendar days, the following requirements apply:

- Less than 60 days but more than or equal to 30 days –
- The awarding agency must prepare and retain internal written justification approved by the CGMO and documented in the grant file.
- Less than 30 calendar days –
- The awarding agency must submit an exception request to the Office of Grants for review and approval. The request must include details about the circumstances that necessitate the shortened availability period.

Awarding agencies must report the following to OG by November 1st of each year:

- Number of NOFOs with availability periods of less than 60 days, but 30 or more days in the preceding year.
- Number of NOFOs with availability periods of less than 30 calendar days in the preceding year.

Note that OG can request additional information, as necessary.

3.5: Program Information Documentation

Agencies should maintain a file of information for each program. The program documentation must include information related to a specific NOFO or award cycle, as well as general information, e.g., relevant legal opinions.

Program documentation must include the following, as applicable:

- The program statute, regulations, and program guidance (including documents such as policy information notices, policy/program assistance letters, or program assistance letters);
- A copy of the applicable NOFO(s);

- Any justification for limited competition and approved exception for limiting competition, if applicable;
- Documentation regarding award instrument selection, if applicable;
- Any other approved exceptions that pertain to the NOFO or all recipients under the program, if applicable;
- Office of the General Counsel (OGC) advice and opinions;
- Government Accountability Office (GAO) and Office of the Inspector General (OIG) reports and related correspondence;
- Congressional correspondence related to the program or class(es) of recipients under the program; and
- General documentation that relates to post-award administration of the program, such as single audits or program-specific audits, if any.

An awarding agency must appropriately maintain documentation for each Assistance Listing (AL) number or, as applicable, subprogram(s) under an AL number. The awarding agency must utilize the information in the program documentation file to review and update the AL in SAM.gov at least annually.

Chapter 4: Pre-Award

4.1: Public Notice Requirements

4.1.1: Forecasts for Discretionary Programs

The HHS Office of Grants (OG) requires awarding agencies to provide early information on Notice of Funding Opportunities (NOFOs) by posting advance forecasts on a public website (currently <u>Grants.gov</u>). The forecast provides essential information, including the opportunity number and information about eligibility.

The forecast should provide the public with up to 12 months of notice on potential funding opportunities for the fiscal year. Known forecasts should be posted by August 1 of each year for the following fiscal year. Agencies must post the forecast for unanticipated NOFOs arising throughout the fiscal year as early as possible to maximize public notification. Agencies should immediately remove a forecast from the forecasting module or cancel the forecast if a decision is made to not fund a NOFO when that decision is publicly shareable.

Agencies can find additional information and instructions for posting forecasts to Grants.gov at:

- <u>Create a Forecast</u> or
- Modify a Forecast.

4.1.2: Notice of Funding Opportunity Notifications

Awarding agencies must post competitive discretionary funding opportunities on <u>Grants.gov</u>, including:

- Posting the NOFO developed in compliance with <u>45 CFR part 75, appendix I</u> and the requirements of this chapter; and
- Requiring electronic submission of applications through Grants.gov (or the HHSapproved shared services system interface that links to Grants.gov).

NOFOs are generally issued at least 60 calendar days before the application submission deadline. If an awarding agency determines that the public availability of a NOFO needs to be fewer than 60, but at least 30, calendar days, agencies must document approval detailing the exigent circumstances that necessitate a shortened available period from the agency head or delegate via a written justification. Agencies must maintain this justification in the program information file.

Note: The Exceptions chapter of the GPAM describes requirements for noncompetitive awards, and funding opportunities appropriately treated as exceptions to HHS' equity in competition requirements. HHS encourages all awarding agencies to use their respective grants management systems to post non-competing continuation application guidance and/or receipt of non-competing continuation applications (or equivalent progress reports).

4.1.2.1: Prior Approval for a NOFO Availability Period of Fewer Than 30 Days

Agencies must request prior approval from the Office of Grants, Division of Policy, Oversight, and Evaluation (DPOE) to post NOFOs with availability periods fewer than 30 days. See the Exceptions chapter of the GPAM for more information.

4.1.3: Compliance with Civil Rights Laws

Awarding agencies must notify potential applicants of their responsibilities to administer their programs in compliance with federal civil rights laws that prohibit discrimination. NOFO language addressing compliance with civil rights must be included in the NOFO in line with current published guidance (i.e., annually published NOFO Guidance or Equity Guidance).

4.1.4: Prohibition on Expending Award Funds for Covered Telecommunications Equipment or Services

Section 889(b)(1) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019, Public Law No. 115-232 (2018), prohibits obligating or expending federal award funds on certain telecommunications products and contracting with certain entities for national security reasons. The NOFO must include a notice to the applicants regarding the following sections of <u>2</u> <u>CFR 200.216</u> "Prohibitions on certain telecommunications and video surveillance services or equipment", which became effective on or after August 13, 2020.

Please reference annually issued NOFO Guidance distributed by the OG DPOE for additional guidance about public policy requirements that need to be addressed within NOFOs.

4.2: Application Submission

4.2.1: Applicant Unique Entity Identifier (UEI)

<u>Grants.gov</u> requires each applicant responding to a NOFO to have a unique entity identifier (UEI) issued by the federal System for Award Management (SAM). If the entity does not have a UEI, they must register with <u>SAM.gov</u> to have a UEI issued. The UEI uniquely identifies an entity conducting business with the federal government and is issued and maintained by the U.S. General Services Administration (GSA) through SAM.gov. The UEI is provided upon request and at no charge at SAM.gov. See the Unique Entity Identifier subsection of Appendix C for further information.

All entities applying for HHS awards must register in SAM. To maintain eligibility, recipients must maintain a current SAM registration throughout the life of the award, including annual renewal.

Once SAM registration has been completed and the UEI issued, an applicant may return to their registration in Grants.gov.

Awarding agencies must:

- Include SAM registration requirements for applicants in NOFOs;
- As part of the pre-award process, including any award amendment that adds funds to an existing award, verify that applicants' SAM registrations are current;
- Ensure that no named individuals are debarred within the Excluded Parties section of SAM.gov, and
- Include the award term found at <u>2 CFR part 25, appendix A</u>, which requires the recipient to keep its information current, through at least an annual review, until it submits the final required financial report or receives the final payment, whichever is later.

4.2.2: Electronic Submission

Applicants are required to electronically submit applications through <u>Grants.gov</u> or the HHSapproved shared services system interface that links to Grants.gov. In Grants.gov, applicants create a shared online Workspace where team members of the applicant may simultaneously access and edit the application forms. Once all application forms are completed and files uploaded, the applicant can check for errors and submit the completed Workspace package.

4.2.2.1: Exceptions from Electronic Submission of an Application

An awarding agency may approve certain exception requests from the electronic submission process. An applicant's request could be based on factors such as inability to access the needed technology. To approve the requests, an awarding agency must:

- Specify the point of contact in the NOFO for such requests;
- Provide both the request and the awarding agency response to the applicant by email (or other means, as situationally required) in advance of the closing date and time specified in the NOFO; and

• Apply the exceptions objectively and fairly to all applicants who request such exceptions.

If an awarding agency approves a request for an exception, it must outline the following:

- Specific formatting requirements;
- Submission deadline (this deadline should be the same as the Grants.gov deadline);
- Submission format (i.e., paper copy, email, etc.); and
- Any other details that may differ from those used for electronic submission through Grants.gov.

An awarding agency may not require an applicant to submit more than an original and two hard copies of an application unless the Office of Management and Budget (OMB) has approved a different number of copies as part of Paperwork Reduction Act (PRA) clearance of an application form or format.

If an awarding agency permits the submission of a hard-copy application, the applicant must send the application in sufficient time for it to be received prior to the submission deadline date (applicant must include documentation of mail/delivery service). An awarding agency may not accept hand-delivered applications. Applications that do not meet the application deadline specified in a NOFO are considered late and may not be accepted for competition under that NOFO. Applications submitted to Grants.gov on or before the deadline date and time specified in the NOFO will be considered to have been submitted timely.

4.2.3: Extensions due to Natural Disaster, Mail Service, SAM.gov and Grants.gov Disruptions, or Technical Issues

The Chief Grants Management Officer (CGMO), or other designated awarding agency official (e.g., the head of a central review unit), may authorize an extension of a published application deadline when justified by circumstances such as natural disasters (e.g., floods or hurricanes), widespread disruptions of mail service or other services, or technical issues at Grants.gov or other federal systems. If circumstances affect a defined geographical area, the awarding agency has the option to extend the deadline only for applicants in the affected area.

If an emergency or unanticipated event interrupts federal operation so that Grants.gov or an awarding agency cannot receive applications as specified in the NOFO and the circumstances preclude advance notification of extension of the deadline, applications received by the first business day once government processes resume must be considered timely.

4.3: Reviewing Applications Under Congressional Directives

A Congressional Directive is in an authorization act or appropriations act that requires HHS to make an award(s) to a named recipient(s) or class of recipients for a particular program, project, activity, or geographic area(s). Congressional Directive awards are defined as discretionary awards for the purposes of HHS grants policy and are subject to all requirements that apply to the award and administration of discretionary grants. The authority for each

Congressionally directed award must cite the authorization or appropriations act directing the funds (e.g., Consolidated Appropriations Act, YYYY, [P.L. XXX-XXX]). The House Appropriations Committee calls these funds Community Project Funding, while the Senate Appropriations Committee calls these funds Congressionally Directed Spending. In the past, these types of requests have been commonly referred to as earmarks.

Awarding agencies must follow Congressional direction for a project only when included in statute or incorporated by reference in statute. Therefore, an awarding agency does not have to conduct a merit review and scoring is not required (see the Exceptions Chapter). A Congressionally directed project must meet all requirements, other than competition, which apply to discretionary HHS awards unless otherwise stated in law.

Awarding agencies may choose to conduct a review and must conduct a pre-award risk evaluation used for similar discretionary programs in accordance with <u>45 CFR 75.205</u>. Awarding agencies should also ensure applications are of a significant enough completeness and quality to ensure the recipient can be held accountable for achieving the goals of the project.

4.4: Merit Review

4.4.1: General Policy

Awarding agencies must develop and follow merit review processes for eligible applications received. In the NOFO, agencies must describe or incorporate by reference the review criteria and process they will use to evaluate applications received in response to that NOFO. All applications that meet the eligibility and responsiveness criteria must undergo a merit review. The results of that merit review are advisory in nature only. Program offices and approving officials make final determinations for funding.

In addition to applications, post-award requests for funding that would result in a change to a funded project's scope also must undergo a merit review.

4.4.2: Selecting Reviewers

All merit reviewers must be subject matter experts for the NOFO subject, be sufficiently independent of applying entities, and be able to provide an objective and unbiased evaluation.

Reviewers may be external to the federal government, in which case they are referred to as non-federal personnel, or they may be federal personnel.

Reviewers evaluate an application's scientific/technical aspects through the merit review process, which is an evaluation of the merits of the submitted application(s) based on the criteria/guidelines provided in the NOFO.

Nominations for reviewers may originate at any organizational level. Subordinate program office (PO) and grants management office staff may provide support and advice to merit review panels but cannot be a part of the panel's final recommendation.

At an organizational level, the official responsible for selecting reviewers must be no lower than the head of the cognizant program office, the head of the central review function, or the awarding agency Chief Grants Management Officer (CGMO).

When selecting reviewers and determining whether to use federal or non-federal personnel, the appointing official must consider whether a specific type of reviewer is mandated by statute or regulation.

4.4.3: Independence of Reviewers and Conflicts of Interest

Reviewers must be independent of the applications they review. Awarding agencies must develop a policy that prohibits an appearance of or actual conflict of interest, prejudice, bias, or predisposition in the review process. Prior to the merit review, all reviewers must be informed of the policy and must certify that a conflict of interest does not exist and that they are independent of the applications they review. If there is the appearance of or an actual conflict of interest, awarding agencies shall determine the level of risk based on the size of the competition and number of panels.

A potential reviewer must sign a statement attesting to the absence of a conflict of interest before any review of applications. Further:

- Any circumstances that might introduce any actual or apparent conflict of interest, prejudices, biases, or predispositions into the merit review process must be avoided. Reviewers must inform the cognizant federal review personnel of a potential or real conflict of interest, as soon as they are aware of it, to protect themselves and the awarding agency from allegations of bias or favoritism. Reviewers must take responsibility for evaluating their own and their family's financial interests that relate directly or indirectly to their duties as a reviewer.
- A reviewer may not have any direct relationship with any applicant organization under a NOFO and may not have any conflict of interest with any organization that stands to benefit from a particular applicant organization being selected. Under the merit review process, a reviewer has a conflict of interest in an application if that person, their spouse, parent, minor child, or partner:
- Serves as an officer, director, trustee, partner, or employee of or consultant to any applicant organization, its parent, or any subsidiary organization(s);
- Is negotiating (or has an arrangement concerning) prospective employment (or other similar association) with any applicant organization, its parent, or any subsidiary organization(s); or,
- Has a financial interest, as defined by <u>18 U.S.C. 208</u>, in any application or in any applicant organization, its parent, or any subsidiary organization(s):
- "Parent organization" includes a holding company, trust, or other entity in a higher-level organizational relationship with the applicant organization; and

- "Subsidiary" means an entity under effective control by ownership or otherwise of another organization, and it includes a sub-subsidiary or co-subsidiary of the same parent organization.
- Additionally, no two non-federal individuals reviewing a group of applications may be from the same organization or institution. For this purpose, the terms "organization" and "institution" mean a single campus of a multi-campus university system, a single department or agency of a state or local government, or separate legal entity. These definitions are meant to recognize that:
- An individual's connection with one campus of a university system or one agency or subdivision of a state or local government may be clearly distinct and remote from association with other components of the system or government; and
- A broader prohibition against the use of an individual's service as a reviewer would impair the effective functioning of the review. For example, where it would be necessary to use external sources to obtain needed expertise or where an adequate number of qualified reviewers would not be available.

Each reviewer must assess their particular situation and not merely rely on the above general definitions. These definitions may not be sufficient to avoid a conflict of interest as defined under <u>18 U.S.C. 208</u>, which prescribes criminal penalties in certain situations.

4.4.3.1: Exceptions Related to Conflicts of Interest

The approving official shall not knowingly select a reviewer who has a conflict of interest with any pending application competing under the same NOFO, unless one of the following exceptions applies and is fully documented:

- A non-federal reviewer who has a conflict of interest may be selected and serve on a standing review committee if the approving official decides that without such person(s) it would not be feasible to constitute an adequate committee; or
- A non-federal reviewer who has a conflict of interest may be selected and serve as a reviewer on an ad hoc committee or as a peer reviewer if, with the advice of the Office of the General Counsel (OGC), the approving official documents the following in writing:
- for an ad hoc committee, without such person(s) it would not be feasible to constitute an adequate committee, as long as the determination is made within the terms of <u>18</u>
 <u>U.S.C. 208</u> regarding the significance and substantiality of the individual's interest and, if applicable, the narrow definition of "organization" (see above) is believed to adequately protect the interests of the reviewer and the integrity of the process; or
- for a reviewer, without that individual, an adequate review would not be feasible.

4.4.4: Further Restrictions When Using Federal Personnel as Independent Reviewers

If an awarding agency chooses to use a federal employee as an independent reviewer of one application or a group of applications, they must ensure that none of the following apply:

- The federal employee is responsible for encouraging the submission of application(s);
- The federal employee works for a person who has provided substantive pre-application advice or technical assistance to an applicant, whether as part of a formal technical assistance event (webinar, etc.) or individually (email, phone call, etc.);
- The federal employee may reasonably expect to later serve as, or who works for someone that may serve as, a Project Officer (PO) for an award resulting from the NOFO or application(s);
- The federal employee works for someone who might be substantially involved in the project under a cooperative agreement;
- The federal employee works for the servicing grants management office;
- The federal employee works for someone making post-award project performance and recipient compliance assessments (including audits);
- The federal employee (including special government employees as defined in <u>18 U.S.C.</u> <u>202(a)</u> and <u>5 CFR 2635.102(l)</u>) has a real or apparent conflict of interest in any application. (In the case of state multi-campus institutions of higher education, see <u>5</u> <u>CFR 2640.203(c)</u>); or
- The federal employee also acts as a consultant, whether in a direct relationship with an awarding agency or serving as a consultant to an organization under contract to an awarding agency, who has a conflict of interest with respect to any application.

The above exclusions apply to all federal employees who have performed any of the listed functions within the preceding 12 months immediately prior to the date the review begins, and/or to all individuals currently serving as a line of authority over any individuals with those functions.

4.3.4.1: Financial Disclosure Requirements for Federal Reviewers

Federal reviewers must submit a completed OGE Form 450, OGE Form 278, or other financial disclosure information to identify any actual or apparent conflict of interest and consult with the Office of the General Counsel and the awarding agency ethics adviser, as appropriate, regarding any questions or concerns. The financial disclosure form must be completed prior to selection as a reviewer.

Any federal employee who has a financial conflict of interest must receive a written waiver for any disqualifying financial interest before they may participate in the review.

4.4.5: Use of Consultants

In addition to any of the above review mechanisms, any individual who possesses particular knowledge or expertise pertinent to an application or group of applications may be used as a consultant to review. Use of a consultant is subject to applicable federal regulations and policies, standards of conduct, and conflict of interest statutes. The approving official may approve the use of individual consultants.

4.4.6: Conduct of the Merit Review

Agencies should conduct the merit review of all eligible and responsive applications as soon as possible after the application submission deadline. This includes single-source applications that are required to undergo a review, and applications based on an unsolicited request for funding.

For committees subject to the <u>Federal Advisory Committee Act (FACA)</u>, the specific times and places of committee meetings must be published in the *Federal Register* along with an indication of whether the meeting is open or closed to the public.

4.4.7: Scoring Applications

NOFOs that describe merit review as including an application scoring process will also include criterion-by-criterion items for evaluation. Reviewers must base their scoring on these criteria.

Awarding agencies are prohibited from providing reviewers with additional unpublished criteria or providing guidance that may further interpret the published criteria.

Where applications are scored, awarding agencies must prepare a summary statement of each application's strengths and weaknesses, by criterion, for each scored application. Typically, this summary statement is the information released to applicants.

4.4.8: Documenting Merit Review Results

As soon as possible after the merit review is completed, the central review function or designated official must prepare a list of the applications that includes the results of the review and must sign or co-sign the documentation indicating all applicable requirements have been met. Depending on the merit review process used, this list may include the applications in rank order, results of pass-or-fail criteria, or other categorization used. The purpose of this list is to provide the final decision makers with merit-related information that is adequate to be used, along with other available information, to determine the final slate of applications approved for funding.

4.4.9: Documenting the Merit Review Process

All awarding agencies must maintain records of their merit review process. The process and documentation must protect the confidentiality of the reviewers' identities and their comments and must be handled so it does not reveal the reviewers' individual assessments, scores, or the overall ranking.

All documentation affecting the decision to recommend approval, disapproval, deference, or otherwise to not fund an application must be maintained by the central review function in its files or by the grants management office in the program information file or in the official award file.

Awarding agencies must include all applications in their merit review files or records, whether they were submitted in response to a NOFO or as an unsolicited request for funding.

For each review, agencies must maintain the following information and documentation in a manner that limits access only to authorized individuals:

• Name of the program and copy of the NOFO;

- Date, time, and location of the review;
- Names and affiliations of committee members/chair in attendance;
- Names and affiliations of others in attendance;
- List of all applications received under the NOFO, showing those submitted for review and those deemed ineligible or otherwise disqualified for review (and all documentation supporting the determination);
- Any awarding agency-specific requirements for each application received;
- Evidence of compliance with the conflict-of-interest requirements, including a conflict of interest and confidentiality certification from each reviewer;
- Actions taken to manage conflicts of interest, including documenting any reviewers with conflicts of interest who did not participate in the review of an identified application or other applications in the competition, as applicable;
- Documentation of any selections authorized as an exception to conflict-of-interest requirements;
- Application assignment list (by reviewer and, if applicable, by panel);
- Blank reviewer assessment form/worksheet used to review, score, and comment;
- Review results, including all summary statements sufficient to provide feedback to allow applicants to compete more effectively in future opportunities, and the ranking list (if one was created);
- Final decisions made by the GMO and documentation of any out-of-rank- order decisions made; and
- Copies of notifications to unsuccessful applicants.

4.4.10: Disclosure of Information Related to Merit Review

Unless the authorized awarding agency official asserts any applicable exemptions from the disclosure requirements of the Freedom of Information Act (FOIA) (<u>5 U.S.C. 552</u>), the Privacy Act (<u>5 U.S.C. 552a</u>), HHS implementing regulations (<u>45 CFR Parts 5</u> and <u>5b</u>), or FACA (<u>5 U.S.C. App. 2</u>), certain documents related to the merit review must be made available for public inspection and copying. The following types of merit review-related information generally are not released to the public or may be denied in part:

- Any applications during the period prior to completion of the overall merit review process for the applicable program;
- Applications that are recommended for approval but have not been funded;
- Disapproved and ineligible applications;
- Evaluative portions of summary statements, including scores, rankings, and preferences; and

• A list of specific reviewers for each application.

4.5: Pre-Award Risk Review

4.5.1: General Policy

In accordance with <u>45 CFR 75.205</u>, awarding agencies shall conduct a pre-award risk assessment of each applicant, including those applying for new applications, continuation applications, supplements, and extensions. The pre-award risk assessment determines the risk an applicant poses to meeting federal programmatic and administrative requirements and considers issues such as financial instability, insufficient management systems, non-compliance with prior award conditions, past performance issues, audit findings, history of charging unallowable costs, and/or inexperience.

Each awarding agency must establish procedures to identify and mitigate hazards and potential risks posed by potential recipients prior to funding awards and approving continuations, supplements, and extensions.

Regulations on reviewing and evaluating risk, specific award conditions, and suspension and debarment are located at <u>45 CFR 75.205</u>, <u>45 CFR 75.207</u>, and <u>2 CFR part 376</u>.

Awarding agencies are required by 45 CFR 75.205 to review information available through any OMB-designated repositories of governmentwide eligibility qualification or financial integrity information. This includes suspension and debarments, as outlined in <u>2 CFR part 180</u>. Awarding agency staff must use the SAM.gov Responsibility and Qualification information for reporting and verification requirements. As a result, while agency risk review procedures may include a variety of sources and requirements, it must involve a review of Entity Information on <u>SAM.gov</u>, including:

- Responsibility and Qualification (formerly Federal Awardee Performance and Integrity Information System), which acts in part as the integrity and performance system established by OMB and the U.S. General Services Administration. It includes government-wide data with specific information related to the integrity and performance of recipients and is comprised of information from various sources on the eligibility of recipients to receive award funds from the federal government. Awarding agencies must conduct this review for any award where the federal share will exceed the simplified acquisition threshold over the period of performance.
- Exclusions, which includes information related to suspensions and debarments at <u>SAM.gov</u>.

4.5.1.1: Sources of Risk Review Information

While there are minimum requirements for risk reviews set by regulation and awarding agencies above, there are other sources of information that may provide a fuller picture of applicant risk. They include, but are not limited to:

• Single Audit information at the <u>Single Audit Clearinghouse</u>.

- <u>Do Not Pay (DNP)</u>, operated by the Department of Treasury and governed by OMB, provides a robust source of multiple data points to help determine initial eligibility of applicants (and continued reviews of awardees) to receive federal funds. Data sources include the credit alert system, the death master file (and other sources of death information), list of excluded individuals and entities, foreign assets control, UEI records, SAM exclusion records, incarceration data, and the Treasury Offset Program's Debt Check.
- Credit reports.
- Advisories issued by the HHS Office of Inspector General, such as those posted on the HHS OIG Advisory Opinions webpage.
- An applicant's indication that it is indebted to the federal government.

4.5.1.2: System for Award Management

Earlier in the Pre-award section of this document, the System for Award Management (SAM) was introduced as the system applicants use to obtain a Unique Entity Identifier (UEI). SAM is also the system awarding agencies must use to determine whether an organization or individual recommended for an award is suspended, debarred, disqualified, or voluntarily excluded from receiving federal contracts, certain subcontracts, and certain types of federal financial and non-financial assistance and benefits.

SAM contains an up to date "List of Excluded Individuals/Entities", and organizations and individuals disqualified by agencies based on violation of particular statutes or Executive Orders (EOs) under their cognizance. SAM's list includes the name of the suspending/debarring agency; the basis for the exclusion; the start (action date) and end dates (termination date) of the exclusion; and current status.

With the exception of any HHS OIG exclusions, which have the same scope as a suspension or debarment under <u>2 CFR part 180</u>, <u>2 CFR part 376</u> or the Federal Acquisition Regulation (FAR), a disqualification may have narrower applicability, which will be specified in SAM.

OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) at <u>2 CFR part 180, subpart D</u>, require federal officials to check SAM before they:

- enter into a primary tier covered transaction, which includes grants, cooperative agreements, scholarships, fellowships, contracts of assistance, loans, loan guarantees, subsidies, insurance, payments for specified use, donation agreements and any other non-procurement transactions between a federal agency and a person;
- approve a principal in a primary tier covered transaction;
- approve a lower-tier (any transaction between a participant and a person other than a procurement contract for goods or services, regardless of type, under a primary covered transaction) participant when agency approval is required; or,

• approve a principal in a lower-tier transaction if agency approval of the principal is required.

The appropriate grants official must check SAM before doing any of the following:

- making a new or renewal award, or adding funds to an award pursuant to a noncompeting continuation award or supplemental award;
- awarding a replacement grant or making an award to another organization based on the transfer of a principal investigator (PI) or project director (PD);
- approving a successor-in-interest; or
- approving a replacement PI/PD or change in key personnel when a recipient requests prior approval for a change of PI/PD or other key person.

For new or renewal awards, the appropriate grants official must determine if the applicant has indicated in its application that it or any of its principals:

- are presently suspended, debarred, voluntarily excluded, or disqualified;
- have been convicted within the preceding three years of any of the offenses listed in <u>2</u> <u>CFR 180.800(a)</u>; or had a civil judgment rendered against the organization or the individual for one of those offenses within that time period; and/or
- are presently indicted for, or otherwise criminally or civilly charged by a governmental entity (federal, state or local) with, commission of any of the offenses listed in <u>2 CFR</u> <u>180.800(a)</u>; or have had one or more public transactions (federal, state, or local) terminated within the preceding three years for cause or default).

If the application does not identify any of the above circumstances and the appropriate grants official's check of SAM and other available information indicates otherwise, this may be considered a false "certification." An awarding agency must act against an organization on that basis to reconcile the difference and make the decision whether to issue the award.

4.5.1.3: Effect of Inclusion in the System for Award Management Excluded Parties List

Awarding agencies must not issue an award to a recipient that is debarred, suspended, or otherwise excluded from or ineligible for participation in federal programs or activities. Additionally, if the awarding agency has determined that the PI/PD or other key personnel are not eligible, it must not issue an award until the recipient submits acceptable candidates for the position(s).

In making these determinations, a full understanding of the exclusion type will inform whether the awarding agency cannot make the award or whether mitigating actions may allow for award with specific award conditions:

• If the SAM review indicates that an organization or individual is suspended, debarred, or proposed for debarment under <u>48 CFR 9.4</u> or voluntarily excluded (see <u>2 CFR 180.940</u>), the appropriate grants official must determine whether the exclusion type extends to federal financial assistance awards. If the individual checking SAM is unable to

determine the effect of the exclusion, the appropriate grants official must contact the federal agency responsible for the exclusion. Checking the exclusion type is crucial because the exclusion may not be final, may apply to a limited number of agencies, or have other narrower scope, e.g., a disqualification.

• If an awarding agency is not precluded from making an award (e.g., a key person other than the PI/PD is not debarred or suspended and the exclusion does not pertain to the award), the appropriate grants official may proceed with the award but must seek replacement of the key person or, as appropriate, consider whether to impose specific award conditions.

4.5.2: Risk-Related Specific Award Conditions

If during a pre-award risk review, a potential recipient is found to pose a risk, the awarding agency must either make the award with specific award conditions that address the risk or not make the award. See <u>45 CFR § 75.207</u>.

- If the awarding agency decides to accept the risk and issue an award, the awarding
 agency must include on the Notice of Award (NoA) one or more specific award
 conditions appropriate for addressing the underlying risk that are both achievable and
 enforceable.
- The awarding agency must maintain a process for assigning specific award conditions to recipients that have a history of non-compliance with terms and conditions, do not meet expected performance goals, or are otherwise not responsible. The process must include strategies for working to address deficiencies.
- The awarding agency must notify the recipient of the additional award conditions, why they are being imposed, the action needed to remove them (if applicable), and the process to request reconsideration of the additional requirements.
- All specific award conditions must be promptly removed, through a revised NoA, once the recipient meets the conditions.
- If the awarding agency determines the risk posed on one award may also apply to other awards (i.e., financial systems risk), the awarding agency should apply the same specific award conditions to all awards to the recipient. The awarding agency must also check the HHS award database (<u>TAGGS</u>) for other active awards and notify other awarding agencies of the identified risk.
- An awarding agency that receives a notification about recipient risk from another awarding agency or external awarding agency must consider whether they should apply specific award conditions to the recipient's active award(s) with their agency.
- Recipients may not appeal specific award conditions under HHS or awarding agency award appeals procedures.

4.6: Notifications and Documentation

4.6.1: Notifying Unsuccessful Applicants or Deferred Applications

Awarding agencies must notify all applicants that have been disapproved, approved but unfunded, or deferred.

- Disapproved applications include those that are disqualified as well as those that are ineligible.
- Approved but unfunded applications are those that received a recommendation for funding, but funds were not available, or a decision was made to not prioritize the project. Deferred applications are also approved but unfunded applications, however, the awarding agency expects to be able to fund them at a later time.

Awarding agencies must send written notifications to all unfunded applicants within 30 days after their approving official signs the funding memorandum.

The grants or central review office notifies all applicants for deferred applications and includes any additional requirements and deadlines necessary to make a final funding decision.

4.6.2: Documentation

The awarding agency must document and include in all affected official award files all information, including correspondence, used to identify risk and to impose specific award conditions.

Chapter 5: Award

Once an awarding agency has determined a proposed list of potential recipients and conducted its pre-award risk assessment for each entity on the list, the agency may determine that it is ready to begin the award process.

It is important to note that for discretionary programs, an awarding agency is not required to make an award to any recipient even if it has submitted a responsive and meritorious application. An awarding agency may decide not to issue an award, but it must fully document the basis for doing so, including all deficiencies. This discretion does not extend to non-discretionary awards, which must be awarded as stated in legislation.

5.1: Pre-Approval Processes

5.1.1: Award File

An awarding agency must create a file for each award. The award file, which may be electronic, is an official, formal file and must contain a complete record of the history of an award.

The awarding agency must maintain, in a format that is retrievable by the award identifier for the time period required, all appropriate materials and documentation to support decisions in the award process.

If any of the information in an award file is maintained in two or more different electronic systems, the awarding agency must include a cross reference in a single location that shows where all documents are housed.

5.1.2: Program Office Recommendations for Funding

5.1.2.1: Applications Recommended for Funding

The program office recommends applications for funding based on multiple factors including the following:

- Results of a merit review;
- Any post-merit review considerations published in the NOFO that would affect an applicant's rank order or priority for funding;
- Program office technical recommendations;
- Opinions from other reviews required by executive order, statute, or regulation; and/or
- Advice from other federal officials, advisory bodies, consultants, or others as documented in the NOFO.

5.1.2.2: All Other Applications

The recommending official must prepare and send to the appropriate grants official the approval listing, or separate listings, indicating those applications that are:

- not approved for funding,
- approved but unfunded (including whether they will be held for consideration for funding in the next review cycle), or
- deferred.

For each application not approved for funding, the listing must contain a statement of the reasons directly affecting the approving official's decision.

5.1.3: Funding Approaches

For each award, the awarding agency must select the appropriate funding strategy.

5.1.3.1: Full Funding

An award may be fully funded at the outset subject to the following:

- The awarding agency CGMO receives approval from ASFR through OG's DPOE to use full funding for all awards with periods of performance that exceed 36 months. These requests may be for a single award or for a class of awards.
- If a period of performance is fully funded at the outset, then the budget period and the period of performance must be the same duration.
- Programmatic and financial (expenditure) reporting is required at least annually. Other reports are required on the basis specified in the NoA.

5.1.3.2: Incremental Funding

A period of performance must have multiple budget periods if incremental funding is used.

Each NOFO must contain the expected period of performance duration and the expected number and length of budget periods.

The overall duration of a period of performance or any individual budget period(s) may vary based on the nature of the approved project, consistent with any limitations in statute or this section. For example, an awarding agency may determine that a different number and/or length of budget periods than specified in the NOFO is appropriate and request an applicant to provide a revised budget after award selection. The terms and conditions listed in each NoA must address the specific period during which the recipient may expend federal funds under an award and any expanded authorities for extending that period through a no-cost extension or automatic carryover.

Generally, if an award includes multiple budget periods, a recipient may charge to the award only costs resulting from obligations incurred during the budget period, unless:

- Pre-award costs have been authorized; and/or _____
- An unobligated balance remains at the end of the previous budget period, and the awarding agency has approved carryover of funds from the prior budget period or automatic carryover is permitted through an expanded authority. The unobligated balance may be used to offset the amount of federal funding for a non-competing continuation, or at the agency approval, added to the amount otherwise approved for the new budget period. In either case, the funds may only be used for purpose(s) for which they were awarded.
- After award, the duration of a period of performance or budget period(s) may be changed and/or funds added beyond those previously obligated for an award only through a non-competing continuation, supplemental, renewal or a no-cost extension.

5.2: Award Selection

After the program office submits the proposed list of awards, the Chief Grants Management Officer (CGMO), or their designee(s) has the authority to sign and issue Notices of Awards (NoAs) and may provide grant staff with the authority to sign and issue NoAs based on the agency's organizational structure.

5.2.1: Review of Budgets, Organizational Management Systems, and Financial Capability

Prior to award, and at any time when additional funds are provided to a recipient, awarding agencies must ensure the recipients' financial management practices, procedures, and systems provide for effective control and accountability of funds, in accordance with <u>45 CFR 75.205</u>. As a result, before award, the awarding agency must evaluate each applicant's management systems, proposed budget, and financial capability. The grants management office, in

consultation with the program office, leads this evaluation. They also lead any negotiations necessary to resolve scope of work, budget, or award terms, and conditions issues.

The grants management office must perform a thorough review and evaluation of the applicant's proposed budget for allowability, allocability, consistent application of costs, and reasonableness. For applications that include a categorical budget, agencies must conduct a budget review. The program office may assist, when requested, by assessing the impact and reasonableness of proposed costs based on the technical aspects of the project funded by the award.

Awarding agencies may determine it is necessary to conduct an in-depth pre-award review of the organization's business management systems. When this type of review is done, the grants management office will make the final determination that an applicant can manage federal funds.

The awarding agency must conduct a financial capability review of newly established organizations, organizations that have not received an award from a federal agency within the preceding 36 months, and organizations that are experiencing financial difficulty as evidenced by financial reports or risk evaluations. In these instances, the appropriate awards official evaluates the organization's financial statements and verifies that the organization's financial stability can support its operations with minimal risk of using federal funds for non-authorized purposes.

The grants management office, in consultation with the program office, makes the final decision to award an application based on the reviews consistent with published policies.

A federal agency may provide financial assistance only to the extent authorized by law and available appropriations. An obligation of funds and the incurring expenses more than the amounts appropriated, or before the funds have been appropriated, constitute an Anti-Deficiency Act violation by the awarding agency.

5.3: Requirement to Issue Notices of Award (NoA)

An awarding agency must issue a Notice of Award (NoA) to a recipient for any action that does one or more of the following:

- Obligates federal funding, whether under a new, non-competing continuation, renewal, or supplemental award;
- NoAs must comply with <u>45 CFR § 75.210</u>, unless specifically exempted by <u>45 CFR §</u> <u>75.101(d) or (e)</u>.
- NoAs must still be issued for those programs not subject to <u>45 CFR § 75.210</u>, and must, at a minimum, specify the period of performance and the continuous nature of the award to ensure that it does not appear that the period of performance has expired.

- NoAs must specifically states that the award is made pursuant to a Congressional Directive authorized and appropriated, for example the Consolidated Appropriations Act, 2022 [P.L. 117-103].
- De-obligates federal funds;
- Changes the approved budget that require prior approval;
- Changes the period of performance (either reducing or extending);
- Changes the recipient from one named entity to another such as successor-in-interest or transfer, or a change to the recipient entity's legal name;
- Changes the principal investigator or project director;
- Adds, removes, or changes award conditions, including specific award conditions to include change in risk status of the award; and/or
- Changes the project scope (with or without an associated budgetary impact).

5.4: Periods of Performance

As a matter of law, HHS and its awarding agencies are bound by appropriations laws. The NoA is the instrument under which the awarding agency obligates funding, and thus must be executed in accordance with all applicable appropriations laws. However, the appropriations law designation regarding availability of funding applies only to the government; it does not flow down to recipients once the funds are awarded. To effectively manage HHS awards, HHS policies for the funding of awards are based on a period of performance system.

The expected period of performance duration and the expected number and length of budget periods must be described in each NOFO. The terms and conditions of each award must address the specific period during which the recipient may obligate federal funds under an award and any expanded authorities for extending that period through a no-cost extension or automatic carryover. Whichever funding method is selected, it should be consistent with the nature of the project and the funding programs, and not based solely on the availability of appropriations.

Post-award, an awarding agency may change the duration of a period of performance, budget period(s), and/or add funds beyond those previously obligated for an award only through a non-competing continuation, supplemental, competing continuation, renewal award or a no-cost extension.

5.5: NoA Development

The NoA is the legal document issued to the recipient that indicates an award has been made and it constitutes the legal obligation of funds from the awarding agency.

5.5.1: Contents of the NoA *5.5.1.1: General Information Page One*

Page One of the NoA must include the following, using the official format:

(Top of Page One: Operating Division, FAIN Number, and Federal Award Date)

- 1. Recipient Name
- 2. Congressional District of Recipient
- 3. Payment System Identifier
- 4. Employer Identification Number (EIN)
- 5. Data Universal Numbering System (DUNS), if applicable
- 6. Recipient's Unique Entity Identifier (UEI)
- 7. Project Director or Principal Investigator
- 8. Authorized Official
- 9. Awarding Agency Contact Information
- 10. Program Official Contact Information
- 11. Award Number
- 12. Unique Federal Award Identification Number (FAIN)
- 13. Statutory Authority
- 14. Federal Award Project Title
- 15. Assistance Listing Number
- 16. Assistance Listing Program Title
- 17. Award Action Type
- 18. Is the Award R&D?
- 19. Budget Period Start Date End Date
- 20. Total Amount of Federal Funds Obligated by this Action
- 21. Authorized Carryover
- 22. Offset
- 23. Total Amount of Federal Funds Obligated this Budget Period
- 24. Total Approved Cost Sharing or Matching, where applicable
- 25. Total Federal and Non-Federal Approved this Budget Period
- 26. Project Period Start Date End Date
- 27. Total Amount of Federal Award including Approved Cost Sharing or Matching this Project Period
- 28. Authorized Treatment of Program Income
- 29. Grants Management Officer Signature
- 30. Remarks

5.5.1.1.2: Other General Content Requirements

In addition to the requirements set forth in <u>45 CFR 75.210</u> and those on Page One, each NoA must include the following:

- NoA iteration number or another method to distinguish the current NoA from previous NoAs during the current budget period;
- Governing program regulations, if any;

- Whether the award is a grant or cooperative agreement;
- Categorical budget, if applicable, reflecting only federal funds;
- Amount of funding proposed for each potential future budget period within the anticipated period of performance;
- Value and type of direct assistance (e.g., staff, equipment), if any;
- Reference to the approved application by submission date, or reference to an amended application or correspondence amending the application;
- Accounting and appropriation data and other information required for fiscal administration of the award, including:
- obligating document number (if different from the award number);
- applicable appropriation and fiscal year;
- Treasury Account Fund Symbol (TAFS);
- Budget Account Classification Structure (previously the Common Accounting Number (CAN));
- Object class codes(s);
- PMS vendor number; and
- the federal award issuance date.

5.5.1.2: Terms and Conditions of the Award

All terms and conditions must:

- Reflect current government-wide, HHS, and awarding agency requirements and policies;
- Not vary from established requirements unless exception procedures have been followed;
- Be written in plain language;
- Provide an indication of which expanded authorities are available to the recipient, if applicable; and
- Not repeat in full text, policies, or material addressed in regulations or other documents incorporated by reference, unless required by statute or regulation (e.g., the award term implementing the Trafficking Victims Protection Act of 2000 in <u>2 CFR 175.15</u>)

5.5.1.2.1: General Terms and Conditions

General terms and conditions are those that are administrative and include public policy requirements applicable to the award. Each NoA must incorporate the general terms and conditions by reference. The reference should be to the website at which the awarding agency maintains the general terms and conditions.

It is important to note that the recipient is legally and financially responsible for all aspects of this award including funds provided to subrecipients, in accordance with <u>45 CFR 75.351</u> – <u>75.352</u>, Subrecipient monitoring and management. This is sometimes referred to as "flow-down".

The general terms and conditions must include:

- HHS awards regulations that apply to the award and the public policy requirements found in Appendix D of the GPAM;
- Payment information, including the name, telephone number, URL, and geographic location of the paying office;
- Reporting requirements, including the name of the form/format, any formatting instructions, due date(s), submission instructions and, as applicable, a website for further information;
- If appropriate, a submission schedule for a non-competing continuation application (unless addressed as a reporting requirement);
- Roles and responsibilities of the designated program office and grants official;
- How any program income earned under the award must be used; and
- Indication that the federal award amount may be adjusted (e.g., based on total allowable costs incurred, the value of third-party in-kind contributions or a Congressional rescission occurring after the award is made).

The following types of boiler-plate language must be included in the general terms and conditions, whether in full text or incorporated by reference to the HHS GPS, or as found elsewhere in the award form/format:

- Statement that the award is subject to terms and conditions detailed in the award and to those cited and incorporated by reference;
- Statement indicating the following: "Recipients of HHS awards must comply with all terms and conditions of their awards, including (a) requirements of the authorizing statute(s) and implementing regulation(s) for the program(s) under which the award is funded; (b) applicable appropriations acts provisions; (c) terms and conditions included in the HHS Grants Policy Statement in effect at the time of a new, non-competing continuation, competing continuation renewal, or supplemental award, including the requirements of applicable HHS regulations; (d) any policies specific to the award; and (e) any requirements included in the NOFO."
- Explicit language that funding of non-competing continuation awards is based on the availability of funds, satisfactory progress by the recipient, and an awarding agency determination that continued funding of the award is in the best interests of the federal government;

- Order of precedence to be followed in the event the award includes conflicting or otherwise inconsistent requirements;
- Statement to the effect that, by drawing or otherwise obtaining funds for the award from the award payment system or office, the recipient accepts the terms and conditions of the award and agrees to perform in accordance with the requirements of the award; and
- The following statement: "The HHS Office of the Inspector General (OIG) maintains a toll-free number (1-800- HHS-TIPS [1-800-447-8477]) and website (https://oig.hhs.gov/fraud/report-fraud/) for receiving information concerning fraud, waste, abuse, and mismanagement under HHS programs. Information also may be submitted by mail to Office of the Inspector General, Department of Health and Human Services, Attn: HOTLINE, 330 Independence Ave., SW, Washington DC 20201. Such reports are treated as sensitive material and submitters may decline to give their names if they choose to remain anonymous."
- Information items of note for the recipient in a "Remarks" section, if applicable, e.g., if
 matching or cost sharing includes unrecovered indirect costs, the agency should include
 instructions for the recipient to put an explanation that the claim for less than full
 allowable indirect costs is intentional in the "Remarks" section of the Federal Financial
 Report (FFR). Remarks are not terms and conditions.

5.5.1.2.2: Specific Award Conditions

The NoA must include any specific award conditions that have been identified during the preaward review process, as well as HHS-wide regulations applicable to the terms and conditions of a federal award. See specific award conditions at <u>45 CFR 75.207</u>.

Specific award conditions may apply to one recipient or a class of recipients. Awarding agencies are permitted to implement applicant-specific award conditions either at the time of a new or competing continuation renewal award or during the post award administration process in accordance with 45 CFR 75.207, based on the risk assessment of the applicant. However, when a recipient's ability to draw funds is being restricted, the action must be coordinated with HHS' Payment Management Services (PMSvc)/Payment Management System (PMS) or other paying office to ensure that the recipient does not draw down funds without authority or more than the amount authorized.

Any specific conditions must be promptly removed once the circumstances that prompted them have been corrected.

5.5.1.3: Additional Required Terms and Conditions

Awarding agencies must include the following terms and conditions when applicable:

• Statement of the nature and extent of the awarding agency's anticipated substantial programmatic involvement in a cooperative agreement, recipient responsibilities, and terms and conditions appropriate for the level and type of awarding office involvement (e.g., rights in data and research results, use of equipment);

- Review and approval requirement of sponsored survey instruments under the Paperwork Reduction Act (cooperative agreements are always considered sponsored and require PRA clearance);
- Identification of any key personnel in addition to the PI/PD or co-PI(s);
- Requirements based on the merit review or awarding agency business and financial review;
- Approved single award exception;
- Conditions associated with key personnel that are suspended, debarred, or otherwise excluded from or ineligible for federal assistance programs or activities;
- Term indicating inclusion of allowable pre-award costs; and
- Other award terms that may be required in a specific situation.

5.5.1.3.1: Costs

The NoA must incorporate any specific award term related to allowability of costs and must clearly articulate the applicable indirect cost rate(s).

5.5.1.3.2: Establishing Budget Period Duration at Time of Award

Budget periods are generally 12 months in length, at time of new award (or competing continuation renewal award) and are funded by the annual appropriation. The maximum length of a budget period is five years at the outset. If an award is comprised of a single budget period, the starting and ending dates must correspond with the period of performance.

A budget period other than 12 months in length may be appropriate:

- Based on the type of project, if it will take less than 12 months to complete, such as a conference; or more than 12 months for initial start-up such as a new demonstration or research project;
- To establish a more advantageous anniversary date, such as to align awarding agency workload;
- If the period of performance is not evenly divisible into 12-month budget periods a longer or shorter budget period may be awarded at either the start or end of the project;
- Funding for a portion of a previously approved budget period is awarded through a successor-in-interest, replacement, or transfer to another recipient; or
- To address other extenuating circumstances.

Awards must not be funded using budget periods of less than 12 months as a means of controlling recipient performance or reducing the project's budget because of overall program budget limitations.

Awarding agencies must consider the risk of awarding a budget period exceeding 18 months, such as effort required to terminate the award mid budget period if the recipient fails to perform and document the analysis and decision in the award file.

5.5.1.3.3: Period of Performance Duration

It is HHS awards policy that, regardless of the appropriation type (one-year, multi-year, or noyear), a period of performance may not exceed five years at the outset. This policy is based on considerations such as time constraints on the relevance of the NOFO and length of time between merit reviews of a project. It is not based on the account closure statute, 31 U.S.C. § 1552; however, that statute does affect the length of a fully funded period of performance. A period of performance may consist of a single budget period (not exceeding five years if funded from an annual appropriation) or multiple budget periods subject to any limitations in statute or this chapter on overall length and funding approach.

If a period of performance is comprised of multiple budget periods, the recipient must submit an application or performance/progress report, as specified by the awarding agency, as a prerequisite to each non-competing continuation award.

Awarding agencies are not required to fund all budget periods within a period of performance past the current budget period. Each NoA contains language indicating that future budget periods will be supported "subject to the availability of funds." Support for the next, and any succeeding budget period(s), may also be denied based on:

- A documented lack of progress;
- Unsatisfactory performance (e.g., non-compliance with terms and conditions of the award);
- Program priority changes; and/or
- Reduction or elimination of the appropriated funds for the program.

An awarding agency may award an additional period of performance based on a competing continuation renewal process.

5.5.1.3.4: Information for Subawards

Awarding agencies must include in the NoA the requirement for recipients to ensure selected subrecipients have a UEI number as established in <u>2 CFR part 25, Appendix A</u>.

5.6: Notice of Award Approval and Notifications

5.6.1: Approval of Notice of Award

An authorized grants management officer with the authority to obligate federal funds must sign the NoA unless there are exigent circumstances requiring that the NoA be signed by the head of the awarding agency or the head of the cognizant regional office.

If the notification is issued in paper format due to emergency or other problems, it must be signed by the authorized grants management officer.

5.6.2: Congressional Notification Hold

5.6.2.1: Requirement

The annual Appropriations Act requires that HHS inform the House and Senate Appropriations Committees about certain awards before issuing them. The HHS Congressional Liaison Office (CLO), Office of the Assistant Secretary for Legislation (ASL) is responsible for providing the information to the appropriate Congressional committees according to both ASL and legislative requirements.

- Discretionary awards: HHS awarding agencies must delay all new or competitive awards, including supplements, five business days prior to issuing the NoA to the recipient. This delay ensures the Committees on Appropriations receives the statutorily required three full business days to review information.
- Non-discretionary awards: All monetary allocations under non-discretionary award programs must be delayed three business days following congressional notification prior to issuing the NoA to the recipient.

5.6.2.2: Awarding Agency Responsibilities

The notification must be provided by the responsible grants management office to <u>grant.fax@hhs.gov.</u> and, unless otherwise specified by CLO, must include the following:

- Name of the recipient;
- Congressional district(s) of the recipient and place of performance (if different) (note: if applicable, foreign awards may have no associated district);
- Type of award (e.g., new, renewal, supplemental);
- Approved period of performance; and
- Amount obligated by the current action.

The CLO notification requirement does not apply to:

- Awards to individuals;
- Non-competing continuation awards;
- Supplemental awards of any dollar value if they are not required to undergo merit review;
- Awarding agency actions that do not involve the obligation of funds; or
- De-obligation of awarding agency funds.

5.6.2.1: Waivers

Congressional notification can be waived in two situations, per statute.

• Emergency response grants at any time of the year - The Office of Grants must approve waivers for emergency response grants. Awarding agencies must submit a written justification memo to the Office of Grants for review and approval.

• Grant awards made during the last 10 business days of the fiscal year, or if applicable, of the program year - The Office of Grants will provide annual notification to HHS awarding agencies that identifies the final 10 business days of the applicable fiscal year.

5.7: Issuance of NoAs

Upon expiration of the congressional notification period, the awarding agency issues the NoA to the recipient.

At this time, the awarding agency may make any appropriate announcements. Awarding agencies must comply with all relevant HHS-established press clearance processes.

5.7.1: Removing Conditions of Award

After award, there are sometimes conditions that must be cleared prior to all or part of the work beginning under the award. In such cases, the awarding agency must modify or remove the condition prior to the specified work beginning. Additionally, the awarding agency must describe the actions that must be taken, and the specific portions of the work affected and may withhold funds for any part of the work not yet cleared. Examples include National Environmental Policy Act (NEPA) reviews and Institutional Review Board (IRB) reviews for human subjects research.

5.7.2: Acceptance of NoAs

A recipient indicates acceptance of an award and its associated terms and conditions by drawing down or requesting award funds from the designated HHS payment system or office.

Recipients may not appeal inclusion of award terms and conditions or denial of a request to change the award terms and conditions.

Once the recipient accepts the award, the terms and conditions of the NoA are binding unless the grants management officer issues a revised NoA formally modifying the award.

5.7.2.1: Failure to Draw Down Funds

If a recipient has shown no attempt to receive funds either by drawing down funds or requesting reimbursement within 90 days of the start of the budget period, the awarding agency must determine the cause of the delay, contacting the recipient as necessary. The awarding agency must then determine appropriate next steps including immediate corrective action or termination.

If the recipient has still not adequately justified the lack of drawn down funds or requested reimbursement within 120 days of the start of the budget period, the awarding agency must initiate formal corrective action or termination unless prohibited by statute or program regulations.

5.7.3: State Single Point of Contact Notification

Every state is permitted to designate a State Single Point of Contact (SPOC). The SPOC acts as a single point of contact between a state process and all federal agencies to foster intergovernmental partnership and strengthen federalism by relying on state and local

processes for the coordination and review of proposed federal financial assistance. If the approving official does not accept the recommendations of a SPOC under <u>EO 12372</u>, the awarding agency must notify the SPOC as specified in <u>45 CFR 100.10</u>.

Chapter 6: Post-Award

6.1: Application of the Cost Principles

A recipient must apply the appropriate cost principles in <u>45 CFR 75 subpart E</u> and federal grants administration requirements based on their entity type. Additionally, entities receiving a subaward must also use the appropriate cost principles for their entity type, which may not be the same as those that apply to the recipient. Each entity must apply the appropriate cost principles consistently across all awards. <u>45 CFR part 75 subpart E</u> is applied uniformly to all recipient types, unless otherwise stated.

The cost principles apply to both direct and indirect cost considerations.

The GMO is the official responsible for making final determinations on specific questions related to the cost principles, including reasonableness, allocability, and allowability.

6.2: Adjustments to Awards

6.2.1: Prior Approvals

Awarding agency CGMOs or their designee must review and approve or deny recipient prior approval requests. Actions requiring prior approval are described in <u>45 CFR 75.308</u>.

Prior approval requests include budgetary and programmatic changes sought by the recipient and require timely review and response by the awarding agencies to ensure continuity of projects.

The awarding agency must review each request for prior approval and notify the recipient if prior approval is not required. If the request does not require prior approval, the awarding agency must respond in a timely fashion indicating so. If prior approval is required, the awarding agency must respond with approval, denial, or next steps in writing within 30 calendar days of receipt of the request. Prior approval requests from recipients must be in a formal written documentation (regardless of delivery medium: system submission, email, or mailed/courier service), and must be:

- Signed by an Authorized Organizational Representative (AOR) of the recipient and include any necessary supporting documentation; and
- Submitted to the awarding agency sufficiently in advance of making the proposed change, to allow adequate time for review.

The awarding agency's Chief Grants Management Officer (CGMO) or authorized designee must approve the request in writing before the recipient, or subrecipient, undertakes any of the activities contained in the recipient's request.

CGMOs/GMOs may approve retroactive requests, as necessary.

A recipient cannot appeal disapproval of a prior-approval request.

Actions requiring prior approval are described in the following subsections and include budgetary and programmatic changes requested by the recipient.

6.2.1.1: Expanded Authority

Expanded authority allows a recipient to make specific changes to the approved award without prior approval under certain circumstances. If authorized by the awarding agency, the NoA must identify or reference the expanded authority provided under the award. HHS financial award recipients are required to establish and maintain organizational policies that demonstrate compliance with applicable federal requirements. Through monitoring, the awarding agency must ensure that recipients:

- Follow their own requirements,
- provide required notifications to the awarding agency in a timely manner,
- and receive approval for changes consistent with successful and cost-effective project completion.

For non-research grants, expanded authorities are approved by reference in the NoA;

For research grants, the expanded authorities listed below (pre-award costs, one-time extension, carryover of unobligated funds) are automatic, unless the NoA states otherwise. he awarding agency is authorized to waive prior written approvals except for a change in scope of the program. In line with the items in <u>45 CFR 75.308(c)(1)(ii)-(xi)</u>, such waivers may include authorizing recipients to do any one or more of the following:

- <u>Pre-Award Costs.</u> Incur project costs 90 calendar days before the awarding agency makes the award. Expenses more than 90 calendar days pre-award require prior approval from the awarding agency. All costs incurred before the awarding agency issues the NoA are at the recipient's risk (i.e., the awarding agency is under no obligation to reimburse such costs if for any reason the recipient does not receive an award, costs are in conflict with the Cost Principles or if the dollar amount of the award is less than anticipated and inadequate to cover such costs).
- <u>Carryover of Unobligated Funds</u>. Projects operating under expanded authority may carry over the unobligated funds from one budget period to the subsequent next budget period within a given period of performance if the expanded authority includes automatic carryover of unobligated federal funds, as set out in the NoA. If not operating under expanded authority, please refer to Use of Unobligated Balances for guidance on carry over of funds.
- Awarding agency approval is required to carry over an unobligated balance, in whole or in part, to any budget period other than the next successive budget period.

- Additionally, a recipient may not use the expanded authority to automatically carry over any unobligated balance of funds still restricted by the Notice of Award.
- <u>One-Time Extension</u>. Initiate a one-time extension of the period of performance by up to 12 months unless expanded authority does not apply as outlined below. Any additional extensions will require prior approval. The recipient's expanded authority to initiate a first no-cost extension without prior approval does not apply if: The terms and conditions of the federal award do not authorize or otherwise prohibit the extension. The extension requires additional federal funds. The extension involves any change in the approved objectives or scope of the project.

For one-time extensions, the recipient must notify the awarding agency in writing with the supporting reasons and revised period of performance at least ten calendar days before the end of the period of performance specified in the award. Recipients may not request a one-time extension of their period of performance merely for the purpose of using unobligated balances. While agency approval is not required for these one-time extensions, the awarding agency must record the extension date through issuance of a revised NoA so it can be transmitted to <u>USAspending</u>, the official open data source of federal spending information.

6.2.2: Program Plan Revisions Requiring Prior Approval

For non-construction awards, recipients must request prior approval for the following activities, except if otherwise waived in the NoA:

45 CFR 75	Activity/Requirement	Additional HHS Policy Clarification
Citation		
<u>.308(c)(1)(i)</u>	Change in the scope or the objective	
	of the project or program (even if	
	there is no associated budget revision	
	requiring prior written approval).	
<u>.308(c)(1)(ii)</u>	Change in a key person specified in	Replacement of the principal
	the application or the federal award.	investigator (PI), project director (PD),
		or other key personnel as specified in
		the NoA.
<u>.308(c)(1)(iii)</u>	The disengagement from the project	
Y	for more than 3 months, or a 25%	
	reduction in time devoted to the	
	project, by the approved project	
	director or principal investigator.	

<u>.308(c)(1)(iv)</u>	The inclusion, unless waived by the	
	federal awarding agency, of costs that	
	require prior approval in accordance	
	with <u>45 CFR part 75, subpart E</u> or <u>45</u>	
	CFR part 75, Appendix IX, or <u>48 CFR</u>	,
	part 31, as applicable.	
<u>.308(c)(1)(v)</u>	The transfer of funds budgeted for	
	participant support costs as defined	
	in <u>45 CFR 75.2</u> to other categories of	
	expense.	
. <u>308(c)(1)(vi)</u>	Unless described in the application	Includes:
	and funded in the approved federal	Transferring or changing the recipient
	award(s), the subawarding,	organization from one recipient to
	transferring or contracting out of any	another.
	work under a federal award, including	Involvement of a foreign component,
	fixed amount subawards as described	including:
	in <u>45 CFR 75.353</u> .	 project staff or individuals
	This provision does not apply to the	employed by a foreign organization
	acquisition of supplies, material,	> in any activity that may involve the
	equipment, or general support	population, environment,
	services.	resources, or affairs of a foreign
		country. Awarding agencies must
		obtain concurrence from
		Department of State before
		awarding funds to foreign or
		international organizations or
		domestic organizations with a
		foreign component;
		 any research within a foreign
		country involving the use of human
		subjects or vertebrate animals; and
		 foreign travel by project staff to
		carry out purpose of the award.
.308(c)(1)(vii)	Changes in the approved cost-sharing	
	or matching provided by the	
	recipient.	
.308(c)(1)(viii)	The need arises for additional federal	
<u></u>	funds to complete the project.	
<u>.308(c)(1)(ix)</u>	The inclusion of research patient care	
	costs in research awards made for the	
	performance of research work.	
	performance of research work.	

<u>.308(c)(1)(x)</u>	The provision of subawards by a pass- through entity on fixed amounts up to the Simplified Acquisition Threshold, provided that the	
	subawards meet the requirements	
	for fixed amount awards in 45 CFR	
	<u>75.201</u> .	
<u>.308(c)(1)(xi)</u>	The recipient wishes to dispose of, replace, or encumber title to real property, equipment, or intangible property that are acquired or	
	improved with a federal award. See 45 CFR <u>75.318</u> , <u>75.320</u> , <u>75.322</u> , and <u>75.323</u> .	

6.2.2.1: Transfer of Substantive Programmatic Activity

Awarding agency prior approval is required for a recipient to transfer substantive programmatic work to a subaward. This prior approval is intended to ensure that:

- The proposed arrangement(s) is consistent with applicable statutory authorities;
- The recipient maintains an appropriate role in the project or program, i.e., the recipient maintains a substantive role in the project/program consistent with the approved application;
- The proposed arrangement(s) is required for the efficient and effective accomplishment of award objectives; and
- It is appropriate for the work to be transferred away from the direct recipient.

Awarding agencies must ensure that, unless the recipient is a pass-through entity, the recipient is not simply serving as a conduit for passing funds to other parties and, as applicable, any limitations related to the amount of pass-through are observed.

6.2.3: Budget Revisions Requiring Prior Approvals *6.2.3.1: Budget Revisions*

The recipient must request prior approval under the following circumstances, unless otherwise waived through the expanded authorities described in a previous section.

45 CFR 75 Citation	Activity/Requirement	Additional HHS Policy Clarification
<u>.308(e)</u>		For awards exceeding the simplified
	option, restrict the transfer of	acquisition threshold, awarding agencies
	funds among direct cost categories	may require prior approval for rebudgeting

or programs, functions, and	among direct cost categories or programs,
activities for federal awards in	functions, and activities in which the
which the federal share of the	transfer of funds exceeds 10% or more of
project exceeds the simplified	total costs of the most recently approved
acquisition threshold and the	award (budget period). If granted, such
cumulative amount of such	approval should be noted in the NoA.
transfers exceeds or is expected to	Awarding agencies must also review and
exceed 10% of the total budget as	approve of significant rebudgeting among
last approved by the awarding	direct cost categories or programs, functions
agency. The federal awarding	and activities of 25 percent or more of total
agency cannot permit a transfer	costs of the last approved budget period for
that would cause any federal	all federal awards. Please see the section on
appropriation to be used for	Significant Rebudgeting that immediately
purposes other than those	follows these charts for additional
consistent with the appropriation.	information.

6.2.3.2: Budget Revisions for Construction Awards

For construction awards, the recipient must request prior approval for the following budget activities:

45 CFR 75 Citation	Activity/Requirement	Additional HHS Policy Clarification
<u>.308(g)(1)</u>	The revision results from changes in the scope or the objective of the project or program.	
<u>.308(g)(2)</u>	The need arises for additional federal funds to complete the project.	
<u>.308(g)(3)</u>	A revision is desired which involves specific costs for which prior written approval requirements may be imposed consistent with applicable cost principles listed in <u>45 CFR part 75,</u> <u>subpart E</u> .	
<u>.308(g)(4)</u>	No other prior approval requirements for budget revisions may be imposed unless an exception has been approved by OMB.	Any additional prior approval request must be submitted through a deviatio request by the awarding agency to the HHS Office of Grants.

<u>.308(g)(5)</u>	When a federal awarding agency makes	
	a federal award that provides support	
	for construction and non- construction	
	work, the federal awarding agency may	
	require the recipient to obtain prior	
	approval from the federal awarding	
	agency before making any fund or	
	budget transfers between the two types	
	of work supported.	

In addition to the budget-related prior approval requirements noted in the chart, recipients of construction awards must also request prior approval for a change in key personnel specified in the application or the federal award.

6.2.3.3: Significant Rebudgeting

Rebudgeting refers to the transfer or moving of funds between direct cost budget categories within an approved budget. It is considered significant when proposed expenses in a single direct cost budget category increase or decrease from the approved budget amount for that budget period by 10% for awards that exceed the simplified acquisition threshold, or by 25% for awards that are below the simplified acquisition threshold. Recipients below the simplified acquisition threshold may transfer up to 25% cumulatively within and between approved direct cost categories an aggregate total per budget period without prior approval.

Once the significant rebudgeting threshold is reached, the recipient must request prior approval for all additional changes during that budget period. In response, the awarding agency must determine if there has been a change in scope while conducting the appropriate budget modification review. If so, the awarding agency must instruct the recipient to submit a request for prior approval of a change in scope with significant rebudgeting; or if not, the awarding agency must conduct the appropriate process to modify the award. Significant rebudgeting alone does not constitute a change in scope. The agency must instruct the recipient to submit an additional prior approval change in scope request with the appropriate documentation for the awarding agency to assess the request, if applicable.

6.2.3.4: Retroactive Requests for Budget Changes

If a recipient enacts a budget change before receiving prior approval from the awarding agency, they do so at their own risk.

Recipients may request retroactive approval of a budget change. If an awarding agency receives such a request, they may consider and approve or deny it. If the awarding agency denies a request for retroactive approval, their denial must indicate the underlying basis for the decision.

If the recipient implements the change without prior approval, and the retroactive request for approval is denied, the recipient assumes responsibility for any costs that were not approved, and for completing the project utilizing the current terms and conditions of the award.

6.2.4: Extensions to Awards

Additional time and funds may be provided after an award is made. There are two types of extensions:

- No-cost extensions: If the award's period of performance is extended without additional funds it is considered a no-cost extension. A no-cost extension of the period of performance, or the final budget period of a period of performance, is typically initiated by the recipient to allow time to fully complete the work on the project.
- Extensions with supplemental funding: If the extension involves additional funds, it is an extension with supplemental funding. This may be initiated by either the awarding agency or the recipient.

6.2.4.1: No-Cost Extensions

The awarding agency must ensure the following before issuing an approval for a no-cost extension:

- The extension does not violate limitations detailed in the authorizing statute, regulation, the time period of availability of the appropriation, or statements in the NOFO or NoA that limit or prohibit no-cost extensions.
- The length of extension is justified to complete approved project activities or permit the orderly end of the award activities. If the awarding agency determines a shorter time period than requested by the recipient is necessary, the awarding agency should only approve the time it deems necessary.
- The extension is justified on the basis of time required to complete existing project activities or permit the orderly end of award activities. The extension may not be approved solely because funds remain unobligated at the end of the period of performance.
- There is no change in scope.
- The recipient is demonstrating satisfactory progress at the time when they request the no-cost extension.
- There are no alerts or compliance concerns for the recipient issued by Office of the Inspector General.
- The recipient must continue submitting required financial and performance reports per the schedule outlined in the NoA throughout any extensions.

6.2.4.2: Extensions with Supplemental Funding

Additional funds beyond those originally awarded may be requested by a recipient or be made available by an awarding agency.

Requirements that pertain to awarding supplemental funds vary based on:

- Who is initiating the request (recipient or awarding agency).
- Whether the additional funds are for activities within the currently approved award scope, or for activities that represent a change in scope.
- For requests initiated by an awarding agency, the extent of competition planned.

6.2.4.3: Recipient Initiated Requests – No Change in Scope

A recipient may request funds as an add-on to a current budget period, for:

- Costs within the scope of the currently approved project, i.e., for the same level or type of activity or services, based on an unexpected increase in current-year costs (e.g., increased labor or supply costs); or
- Additional effort that is considered "within scope", e.g., expanding service to additional clients in the same location.

An additional merit review is not required if the awarding agency deems that the increase in funding will have no effect on the project's scope.

Supplemental funding within the scope of the currently approved award may be chargeable to the appropriation available at the time of the original obligation if the appropriation has not expired and funds were available at the time the obligation was made.

6.2.4.4: Recipient Initiated Requests – Change in Scope

If a recipient requests an award of additional funds under an ongoing project for the expansion or change of the project's scope (e.g., planned use of human subjects or animals where such use was not contemplated at the time of award, or a change in population or area served), the request must:

- Undergo merit review regardless of the amount of the request;
- Be treated as a new obligation and charged to an appropriation current at the time the awarding agency issues the award. The request may be for costs related to the current budget period only or may cover a multi-year period within the approved period of performance, resulting in an anticipated increase in the approved budget for future years. Future year amounts, if eventually awarded, must be charged to a then-current appropriation; and
- Not result in an extension of the period of performance unless the results of the merit review indicate the effort could not be completed without such an extension; if this is the case, then the awarding agency must also prepare a single-source justification. If, however, merit review indicates that the work to be performed under the extension is meritorious but not critical to completion of the current project, this action is not considered an extension (see <u>Sole-Source Award Exceptions</u> section of GPAM).

6.2.4.5: Awarding Agency-Initiated Requests

The following table indicates the requirements applicable to awarding agency-initiated requests to supplement ongoing awards:

Awarding Agency Initiated Request	Funding Activity and Scope	Requirements
Offers additional funding	Within scope	The recipients may be notified
non-competitively to all		in a manner deemed
current recipients in the		appropriate by the awarding
same amount or using		agency, and the funds may be
another pre-determined		added without merit review.
amount, (e.g., percentage of		
current funding). Recipients		
received their initial award	\sim	
on a competitive basis.		
Offers additional funding	Within scope or a change in	Single source justifications and
non-competitively to a single	scope	merit review are required.
recipient, or a subset of all		
current recipients with the		
capacity to do the activity.		
Offers additional funding	Within scope or a change in	A NOFO and merit review are
competitively to all current	scope	required.
recipients (i.e., competitive		
supplemental funding		
opportunity open to all		
current recipients).	Y	
Recipients received their		
initial award on a		
competitive basis.		
Offers additional funding	Within scope or a change in	A limited competition
competitively to a subset of	scope	justification, a NOFO, and merit
all current recipients with the		review are required.
capacity to do the activity		

In all cases when there is a change in scope, the awarding agency must use an appropriation available at the time it issues the supplemental award.

6.2.5: Non-Competing Awards

Awarding agencies must provide recipients with specific instructions for completing and submitting non-competing continuation applications.

At a minimum, the awarding agency's non-competing continuation instructions must specify the following:

- Required means of submission;
- Required forms and documentation to be submitted, including instructions;
- Due date for submission (generally expressed as no later than "x" calendar (or business) days before the end date of the budget period), and consequences of a late submission;
- Approved funding level for the upcoming budget period;
- Requirements to request any budget or project revisions;
- Instructions on unobligated balances that exceed the expanded authority. A
 requirement that the recipient must provide its estimated unobligated balance
 separately from the approved budget for the upcoming budget period (e.g., in a
 carryover request) and explain why an unobligated balance exists. If the recipient does
 not operate under the expanded authority for carryover, the recipient must:
- Indicate how the recipient will use the unobligated funds;
- If applicable, provide a revised budget and budget narrative;
- Indicate the impact on the project if the funds are used to offset new funding; and
- If applicable, indicate how the recipient will meet the increased amount of matching or cost sharing.

6.2.5.1: Review of Non-Competing Continuations

The appropriate grants official and the program officer must review the non-competing continuation application and provide a recommendation for continuing or discontinuing the award. The review must be documented and included in the official award file.

As a prerequisite to continued funding, the appropriate grants official must perform the following activities:

- Determine whether the recipient has submitted all required or applicable certifications and assurances;
- Review recipient and key personnel information in the required Office of Management and Budget-designated repositories of government-wide data such as the System for Award Management (SAM) and make awarding decisions accordingly;
- Review the non-competing continuation application budget, if applicable. The appropriate grants official should analyze the categorical budget, if applicable, to ensure that costs are in accordance with the cost principles and that any rebudgeting of funds complies with HHS's grants policy on rebudgeting. Please see the above section on significant rebudgeting for further detail. At a minimum, the budget review must:
- Identify any changes between the requested budget and the originally approved budget,

- Analyze changes in the types/effort of personnel, salary levels, fringe benefits or use of consultants, or any proposed equipment purchases or alteration and renovation costs;
- Ensure that any salary or fringe benefit increases are consistent with the organization's established policies and applied regardless of the source of funding, and comply with any statutory limits applicable to the award; and
- Determine whether all personnel positions have been filled; if they have not, assess the financial impact of the unfilled positions on the project budget.
- Review the PO's comments on the recipient's progress;
- Review the most recent Federal Financial Report (FFR) and other available financial information for continuing unliquidated obligations, unusual expenditure patterns, significant program income, and matching or cost sharing;
- Determine whether any prior approvals are necessary;
- Determine, in consultation with the PO, whether any estimated unobligated balance should supplement the new award as carryover or be used as an offset; and
- Review any other available information to determine compliance with award conditions.

6.2.5.2: Continuation of Funding

The recipient must submit a non-competing continuation application (i.e., progress report) each year as a prerequisite to continued funding if a period of performance is comprised of multiple budget periods.

The initial NoA identifies the period of performance, which may include multiple 12-month budget periods. For a multi-year period of performance, the awarding agency may provide continued funding in the approved amount(s) unless:

- The recipient is not making satisfactory progress as described in the NOFO and NoA terms and conditions;
- The recipient has not complied with the terms and conditions of the previous budget period;
- Program priorities change, per new or revised legislation; or
- The amount available to the awarding agency for funding has been reduced or eliminated.

6.2.5.6: Not Awarding Continuation Support for Lack of Funding or Program Changes

The awarding agency may allow the recipient to spend previously obligated funds by extending the current budget period if the awarding agency will no longer continue to fund a project because of a change in program priorities or lack of appropriations, as allowed under law. Such an extension must be for the purpose of allowing for closure of the work under the project and may not be for the sole purpose of spending remaining funds. Additionally, deciding to allow the recipient to extend the budget period, the awarding agency should consider the policy implications that led to not awarding continuation support, including the intent of Congress.

In the case that the awarding agency determines *continuation of support* will not be awarded:

- The current budget period becomes the last budget period of the period of performance; and
- A no-cost extension is granted to allow additional time for completion of the project.

If the appropriation is reduced and the awarding agency reduces rather than ceases support, the awarding agency must renegotiate non-competing continuation awards. The recipient organization is not required to go through the competitive process.

Note: It is an enforcement action when an awarding agency chooses to terminate an award for non-compliance with the terms and conditions of award, as distinct from not awarding continuation support. See Not Awarding Continuation Support and Terminating an Award in this chapter.

6.2.6: Changes in Recipient Organizational Status

Consistent with appropriations law requirements and HHS grants policy, an awarding agency may effect a change in recipient organizational status under discretionary awards in one of the following sets of changed circumstances:

- The principal investigator (PI) or project director (PD) named on the award(s) is transferring to a different organization and all parties agree to transfer responsibility for the award to the new organization.
- An individual that receives a fellowship from a recipient is transferring to a new organization, or to a division or campus and the transfer requires a change to the Entity Identification Number (EIN) (i.e., new recipient). A move that does not result in a change to the EIN, such as a new department, generally is not a change in recipient. The appropriate grants official makes the final decision whether a change of recipient has occurred.
- Successor in interest or recipient name change.

6.2.6.1: Transfer of an Award

A transfer application cannot be accepted for review in the absence of a relinquishing statement from the original recipient.

The relinquishing statement and transfer application must be submitted to the grants official before the anticipated start date for the new recipient organization, and as far in advance of the transfer as possible, given the circumstances of the specific situation.

In determining whether to approve a transfer, the appropriate grants official, in consultation with the program officer, will consider:

• Eligibility and risk evaluation of the new recipient to receive the award;

- Time remaining in the period of performance against the time needed to complete the project;
- Remaining funding against the budget needed to complete the project;
- The effect of the transfer on the timely and successful completion of the project as currently approved;
- Proposed scope or objective changes that may delay the transfer, pending negotiations and prior awarding agency approval of scope and budgetary revisions;
- Adequacy of facilities and resources available to the new recipient; and
- Any other relevant considerations.

The merits of authorizing the transfer of an award or a proposed change in the PI must be given careful consideration by program and grants management personnel.

Partial relinquishments may be permitted, depending on circumstances, after consultation with the Office of the General Counsel.

Please Note: An awarding agency must not transfer, nor issue either a successor-in-interest or a replacement award if a Congressionally directed award is terminated or relinquished.

6.2.6.2: Relinquishing Statement

The relinquishing statement from the original recipient must include, as applicable, the following information:

- Date of the relinquishing statement;
- Name and address of original recipient;
- Name of PI/PD;
- Award number(s);
- Statement of relinquishment of interest in the award(s) and future claims to remaining unobligated balances;
- Effective date of the end of support to the current recipient;
- A list of all items of non-expendable personal property (equipment) with an original acquisition cost of \$5,000 or more purchased in whole or in part with award funds, which will be transferred;
- An estimated status of funds awarded for the currently active budget period as of the effective date of the end of support; and
- The signature of the Authorized Organizational Representative (AOR).

If the original recipient does not agree to the transfer of all equipment acquired primarily under the award, the awarding agency may:

• Approve the request not to transfer the equipment; or

• Exercise its right to transfer title to the equipment as provided in <u>45 CFR 75.320</u>.

6.2.6.3: Transfer Application

At a minimum, the transfer application from the new organization must include the following:

- Cover page signed by the AOR of the new organization, including its Unique Entity ID (UEI);
- Research plan/project narrative detailing the new, proposed scope of the project or the originally approved plan and a statement indicating that no change is anticipated. The proposed revised scope is not binding on the awarding agency, but can be part of negotiations between the awarding agency and proposed recipient;
- Budget for the current year and any future years, which reflect the remaining time, tasks, and resources;
- Comprehensive progress report, provided by the original recipient, covering the period between award issuance and the time of the proposed transfer. This report fulfills the requirement at closeout for a final performance progress report from the original recipient. The original recipient must also submit any other relevant closeout reports, such as tangible or real property reports;
- Any required project-specific assurances, certifications, or verifications, e.g., review of the project by the receiving organization's Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC);
- Updated biographical sketches for the PI/PD and existing key personnel, and biographical sketches for a new PI/PD, if appropriate, or any proposed new key personnel; and
- Detailed list of any award-funded equipment being transferred to the new recipient (inclusion of this list in the application from the new recipient indicates its acceptance of title to that equipment).

If the awarding agency approves the application, it may make an award to the new recipient without competition for a period not to exceed the remainder of the previously approved period of performance.

The amount for each remaining budget period in the period of performance will be calculated as follows:

- The award for the first budget period after transfer is complete will be up to the amount of direct funds available at time of transfer; i.e., amount of relinquished direct funds, plus associated indirect/facilities and administrative (F&A) costs at the new recipient's negotiated rate.
- For any remaining budget periods after the initial budget period after transfer is complete, the award amount will be the direct cost amount previously recommended

under the original award plus indirect/F&A costs based on the new recipient's negotiated rate.

If the awarding agency does not approve the transfer of the project to a new organization, then either the original recipient must continue the project, or the project should be terminated (unilateral or by mutual agreement).

6.2.6.4: Replacement Award

Change of recipient may also be accomplished by ending the original award, through the enforcement action of termination (unilateral or by mutual agreement) and awarding a replacement award for the same work plan, through a non-competitive process.

The award may be replaced following consultation with the OGC to ensure that use of the replacement award process is legally justified.

A replacement award may be awarded for a single budget period of no more than 18 months and must not commit to future years of support.

A replacement award may be made without the need for competition or merit review if all the following circumstances apply:

- The program office documents a continuing need to provide assistance for the project;
- The time required to obtain competition would seriously jeopardize the success of the project or put at risk the physical or mental health of the people the project serves;
- There will be no significant change in the scope or objectives (including any reduction) of the previously approved project or activity. The replacement award must serve or propose to serve the same group or community population the original award served;
- The proposed replacement recipient is eligible to receive the award; and
- The proposed recipient has the facilities and resources to successfully complete the project.

The appropriate grants official, in consultation with the PO, must request the following minimum information to ensure that the proposed recipient organization can demonstrates the willingness to undertake the legal obligations of an award:

- Cover page signed by the AOR of the proposed recipient, including its Unique Entity ID;
- Detailed budget and narrative for the full duration of the replacement award, formatted as per awarding agency guidelines;
- Narrative, prepared in accordance with awarding agency instructions, indicating how the organization will meet programmatic requirements. This narrative should be in a level of detail that allows the awarding agency to prepare a single source justification;
- Any required project-specific assurances, certifications, or verifications;
- Description of the facilities and other resources available to carry out the project; and

• Biographical sketch for anyone that will be considered a key person, e.g., the PI/PD.

A replacement award must be issued in a timely manner. An awarding agency may issue a replacement award whether or not the original recipient has exhausted or forfeited its appeal rights.

Any hiatus of more than three months between the original and the replacement award must be justified and documented in the official award file. If a replacement award results from the termination of an award for failure to comply with terms and conditions of the award, the NoA for the replacement award must incorporate a condition that notifies the new recipient of the possibility that the replacement award may be terminated if the original recipient is successful in an appeal.

The awarding agency should seek to obtain a relinquishing statement for a replacement award from the recipient whose funding has been terminated or withheld, particularly in those situations where the award has been terminated at the original recipient's request.

If a replacement award cannot be issued, a new competitive award may be made to a new recipient for the same or similar services covering the affected service area. Each budget period may be funded from the appropriation for the fiscal year in which the new award (and any subsequent non-competing continuation award) is made.

If, at the expiration of the 18-month period, the awarding agency determines there is a continuing need to provide assistance for the project/services covered by the replacement award, it must follow the procedures that govern the requirements for competition and merit review, respectively.

6.2.6.5: Issuing an Amended Notice of Award

Following a determination that a change of recipient (whether a transfer or a replacement award) meets the requirements of this chapter, the awarding agency must issue an amended NoA to the original recipient organization:

- Reflecting the revised budget period and/or period of performance end dates;
- Removing any future-year support;
- Stating the federal and non-federal share, if applicable; and
- De-obligating any funds remaining from the original award. If the de-obligated amount is based on an estimate and the amount subsequently changes, a further amendment may be necessary. In some situations, the awarding agency may have difficulty in obtaining complete and reliable financial information, resulting in the possibility of multiple amendments (e.g., a termination for failure to comply with award terms and conditions). To avoid this, the awarding agency should advise the original recipient of the amount intended to be de-obligated prior to issuing a NoA to the new recipient and provide the original recipient a deadline for submission of a finalized financial reporting.

The awarding agency must issue a NoA to the new recipient that includes the following:

- New award number and (as applicable) the EIN for the new recipient assigned by Payment Management Services (PMSvc);
- New starting and ending dates of the budget period and period of performance:
- For a transfer, these dates are an indication of the length of the budget period after the transfer is complete, based on time remaining in the applicable budget period or the original award, and, as applicable, any future years of support remaining in the current approved period of performance; and
- For a replacement award, these dates can encompass the duration of the budget period/period of performance if it is 18 months or less;
- Direct cost amount representing:
- Balance reported on the relinquishing statement;
- Estimated amount remaining; or
- If the change of recipient occurs on the anniversary date of the project, the previously committed direct cost level for the applicable budget period and any future years;
- Applicable indirect/F&A costs;
- If an estimated relinquished amount is used, an indication that the amount awarded is subject to change as a result of the closeout of the original award and may be adjusted downward; and
- A list of any real property or title to equipment that is being transferred to the new recipient and any associated requirements, A revised NoA must be issued once the awarding agency has obtained a definitive list of all real property or titles to equipment which have been transferred to the new recipient.

The awarding agency also must close out the award to the original recipient organization. Please see the section Closeout of Awards for detailed information.

6.2.6.6: Change in Recipient Status

Recipients are responsible for advising the awarding agency if they are involved in a successorin-interest (SII) or name change situation as this may affect one or more aspects of their awards (e.g., registration in the System for Award Management (SAM) or designated payee). Advance consultation between the recipient and the awarding agency will help to ensure payments are not interrupted. The awarding agency must advise the recipient on the formal documentation required and the time it will take to put into effect the change, as well as coordinate within the awarding agency or between awarding agencies, as appropriate.

6.2.6.7: Successor in Interest (SII)

Following legislative or other legal action such as a merger, divestiture, or other corporate change, an awarding agency can recognize a Successor in Interest (SII) when it is consistent with the interests of the awarding agency to ensure continuation of financial and administrative

functions. Otherwise, the awarding agency should terminate the award. At least one of the impacted awarding agencies must implement recognition of an SII.

Upon receipt of a formal notification of a planned or actual change in recipient status, the awarding agency must review the information provided for completeness and to ensure the eligibility and suitability of the organization. The awarding agency will consult with Office of General Counsel (OGC) and other awarding agencies, as needed. The awarding agency has the right to and should seek clarification or additional information from the organization as it deems necessary.

When it is consistent with the interests of an awarding agency to recognize an SII, the awarding agency (or, if multiple awarding agencies have active awards with a recipient, the lead or cognizant awarding agency, i.e., the awarding agency with the largest amount of award funding to that recipient) must request receipt of a letter signed by both the original recipient's AOR and the new recipient's AOR. The letter must address the following:

- Stipulate that the transfer will be properly completed in accordance with applicable law;
- Indicate that the original recipient relinquishes all rights and interests in all the affected awards, to include subawards or subcontracts awarded by the original recipient;
- Document that the new recipient agrees to accept all award obligations and liabilities of the original recipient;
- Request that the awarding agency(ies) modify its/their records to reflect the new recipient as the recipient of record;
- State the expected effective date of the transfer;
- Provide the new recipient's Taxpayer Identification Number/Employer Identification Number and UEI number;
- Include verification of the new recipient's compliance (or intent to comply) with applicable requirements, including continued accountability for property acquired under the award(s) and compliance with human subjects and animal welfare requirements. This includes evidence that the new recipient understands the requirements;
- Include a list of all affected HHS awards (active and pending) with the following information for each or for the new organization, as applicable:
 - Award number;
- Name of PI/PD;
- Current budget period and period of performance; and
- Copy of the current negotiated indirect cost/F&A rate agreement for the new recipient.

If the SII will occur during a budget period rather than on the anniversary date of the award, the original recipient also must provide estimated levels of current-year direct and indirect/F&A costs remaining as of the SII effective date. The estimate may be reported on the Relinquishing

Statement or an equivalent relinquishing statement for each affected award or may be itemized by award number as an attachment to the letter.

In all cases, prior to the execution of an SII, the appropriate grant official must ensure that the transfer will be properly completed in accordance with applicable law. To that end, the appropriate grants official should request that the new recipient submit the following documents:

- Properly authenticated copy of the instrument that transfers the assets such as a bill of sale, certificate of merger, or decree of court;
- Certified copy of the new recipient's Board of Trustees resolutions authorizing the transfer of assets, if applicable;
- Properly authenticated copy of the certificate and articles of incorporation of the new recipient; and
- Opinion of counsel for the original recipient and the new recipient that the transfer was properly completed in accordance with applicable law and the effective date of transfer.

Prior to executing an SII, the lead awarding agency must determine whether the successor organization is listed as an excluded party in the System for Award Management (SAM) and review past performance and ethics in SAM.gov Responsibility and Qualification. If the new recipient organization is subject to specific award conditions, applicable documentation should be modified to show both the original and the new name of the organization to ensure appropriate linkage between organizational names.

The awarding agency must consult with Payment Management Services (PMSvc) on the need to obtain a new EIN. If it is determined that a new EIN is needed, the awarding agency will notify the new recipient organization of the need for it to obtain a new EIN.

Upon review, receipt acknowledgement, and acceptance of the information provided by the original and new recipients to the awarding agency and OGC, the appropriate grants official will sign the SII agreement for awards on behalf of all affected awarding agencies and return it to the original and new recipients for their signatures. The awarding agency also must provide a copy to the CGMO of each affected awarding agency, who will distribute the information within the awarding agency.

Each awarding agency with an affected award(s) must issue a revised NoA(s) to show the transferee as the recipient of record.

6.2.6.8: Name Change

For name changes that do not affect the rights and obligations of the recipient, the recipient must provide written notification (see requirements below) to the affected awarding agencies and must include the effective date of the change. Name changes can be processed at any time, but no later than the next award action (e.g., non-competing continuation award) and the organization will submit a face page, as specified by the awarding agency, with the new information as part of that action.

For a name change to be properly placed into effect, the awarding agency must receive and acknowledge acceptance of the following documents:

- Copy of the instrument that effected the name change, authenticated by a proper official of the state having jurisdiction; and
- Opinion of counsel for the recipient that the change of name was properly completed in accordance with applicable law.

Receipt of the above documents and acknowledgment of acceptance by the awarding agency via a Notice of Award will constitute a name change agreement.

6.3: Payments

There are three types of payment methods available to awarding agencies: (1) advance, (2) reimbursement, and (3) working capital advance.

Payments to states are subject to the Cash Management Improvement Act (CMIA), the Department of the Treasury implementation at <u>31 CFR part 205</u>, and the <u>Treasury Financial</u> <u>Manual (TFM) 4A-2000 Overall Disbursing Rules for All Federal Agencies.</u>

HHS-wide payment regulations are located at 45 CFR 75.305.

The awarding agency must determine and include the appropriate payment method- advance, reimbursement, or working capital advance- in the terms and conditions of the award. Advance payment is the default payment method for HHS discretionary awards, as described below. The reasons awarding agencies may need to alternatively use reimbursement or working capital advances as payment methods are also described in this subsection.

All awarding agencies must use the HHS Program Support Center's Payment Management System (PMS), operated by Payment Management Services (PMSvc) to make funding available to recipients.

Awarding agencies are required to set up payment subaccounts within the Payment Management System (PMS) for PMSvc all new awards, to improve the ability of awarding agency grants management staff to monitor advance payments, including comparison with expenditures, per the Office of Grants sub accounting policy.

The awarding agency must not withhold payments for proper charges made by recipients at any time during the period of performance unless:

- Recipient is subject to specific award conditions under <u>45 CFR 75.207</u>;
- Recipient is subject to enforcement provisions under <u>45 CFR 75.371</u>;
- Recipient has failed to comply with the approved project objectives or the terms and conditions of the; and/or
- Recipient or subrecipient is delinquent on a debt to the United States.

An awarding agency must not require a recipient, excluding states, to maintain a separate bank account for award funds.

Recipients must be able to account for the receipt, obligation, and expenditure of award funds.

6.3.1: Advance Payment

The recipient must be paid in advance, provided the recipient maintains written procedures that minimize the time elapsing between the transfer of funds and disbursement by the recipient, and financial management systems that meet the standards for fund control and accountability as established in <u>45 CFR part 75</u>.

Advance payments must be limited to the minimum amounts needed and be timed to be in accordance with the actual, immediate cash requirements of the recipient in carrying out the purpose of the approved program or project.

When the advance payment method is used, the funds must be maintained in an insured, interest- bearing account unless one of the following apply:

- Recipient receives less than \$120,000 in federal awards per year;
- The best, reasonably available, interest-bearing account would not be expected to earn interest in excess of \$500 per year on federal cash balances;
- Depository would require an average or minimum balance so high as to make it not feasible for use; or
- A foreign government or banking system prohibits or precludes interest bearing accounts.

Any interest earned up to \$500 per year may be retained by the recipient for administrative expense; however, any interest earned beyond \$500 per year must be remitted annually to HHS's Payment Management System as instructed on Program Support Center website-the Returning Funds/Interest.

6.3.2: Reimbursement Payment

The reimbursement method is used for recipients that do not comply with the requirement to minimize the time elapsing between the transfer of funds from the federal government and disbursement of funds for award purposes; when the awarding agency sets a specific condition per <u>45 CFR 75.207</u>; or when the recipient requests payment by reimbursement.

The reimbursement method may also be used on any federal award for construction, or if the major portion of the construction project is accomplished through private market financing or federal loans, and the federal award constitutes a minor portion of the project.

The awarding agency must require the recipient to submit the reimbursement request to the awarding agency for review and referral to PMS at least two weeks before the cash is needed. Note: award payments are not subject to the Prompt Payment Act and HHS is not liable for payment of interest to a recipient for late payment when using the reimbursement method.

When the reimbursement method is used, the awarding agency must make payment within 30 calendar days after receipt of the billing submission, unless the awarding agency reasonably believes the request to be improper.

The awarding agency must reconcile the reimbursement request with information provided on the performance reports for awards paid using the reimbursement method.

6.3.3: Working Capital Advance

If the awarding agency has determined that reimbursement is not feasible because the recipient lacks sufficient working capital, the awarding agency may provide cash on a working capital advance basis. Under this method, the awarding agency must advance cash payments to the recipient to cover its estimated disbursement needs for an initial period generally geared to the recipient's disbursing cycle. Subsequently, the awarding agency must pay the recipient for its actual cash disbursements. For more information, consult the CGMO.

6.3.4: Payments to States

Awarding agencies must ensure that states under a Treasury State Agreement account for the receipt, obligation, and expenditure of federal award funds.

Awarding agencies should ensure, through evaluation and monitoring, that states exercise sound cash management in funds transfers to subrecipients.

To the extent that the Treasury State Agreement does not address use of resources before requesting cash advance payments, the provisions of <u>45 CFR 75.305(b)(5)</u> apply to awards to states.

6.4: Program Income

Recipients are encouraged to earn income to defray program costs where appropriate. Some of this income may fall under the definition of program income and be subject to regulations in <u>45</u> <u>CFR 75.307</u>.

Program income is gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the federal award during the period of performance except as provided in <u>45 CFR 75.307(f)</u>.

6.4.1: Use of Program Income

If the awarding agency does not specify in its regulations or the terms and conditions of the federal award, or give prior approval for how program income is to be used, the deduction method described below must be applied when using and accounting for program income.

6.4.1.1: Deduction. The default method for program income is deducting it from total allowable costs to determine the net allowable costs. Program income must be used for current costs unless the awarding agency authorizes in writing otherwise. Program income that a recipient did not anticipate at the time of the federal award must be used to reduce the federal award and recipient contributions rather than to increase the funds committed to the project.

6.4.1.2: Addition. Program income may be added to the federal award by the federal agency and the recipient. The program income must be used for the purposes and under the terms and conditions of the federal award.

6.4.1.3: Cost Sharing or Matching. Program income may be used to meet cost sharing or matching requirements with prior approval from the awarding agency. The amount of the award remains the same.

6.5: Cost Sharing or Matching

Cost sharing or matching is the portion of project costs not paid by federal funds (unless otherwise authorized by federal statute). Cost sharing or matching may include the value of allowable third-party in-kind contributions, as well as expenditures by the recipient. <u>45 CFR</u> <u>75.306</u> governs cost sharing or matching.

6.5.1: Cost Sharing and Matching Requirements

A recipient must provide the required cost sharing or matching by the end of the applicable budget period or period of performance, per the terms of the NoA. This includes any voluntary cost sharing or matching that the recipient stated in its application.

HHS will only accept cost sharing or matching contributions from allowable sources.

The awarding agency shall accept, as part of the recipient's cost sharing or matching, any shared costs or matching funds and all contributions, including cash and third-party in-kind contributions, when such contributions meet all the following criteria:

- Contributions can be verified from the recipient's records;
- Contributions are not included as cost sharing or matching for any other federal award;
- Contributions are necessary and reasonable for accomplishment of project or program objectives;
- Contributions are allowable under <u>45 CFR part 75, subpart E</u>;
- Contributions are not paid by the federal government from another federal award, except where federal statutes or authorities applicable to that award specifically allows;
- Contributions are provided for in the approved budget when required by the awarding agency; and
- Contributions conform to other provisions of <u>45 CFR 75.306</u>, as applicable.

Other sources of cost sharing or matching contributions may be:

- A non-federal source, (e.g., funds from a state or local government, private non-profit foundation, or private individual);
- Program income, with prior approval of the awarding agency;
- Unrecovered indirect costs as part of cost sharing or matching only with prior approval of the awarding agency. Unrecovered indirect costs are the difference between the

amount charged to the federal award and the amount which could have been charged to the federal award under the recipient's approved negotiated indirect cost rate.

Cost sharing or matching requirements are not allowable from the following sources:

- Costs paid by another federal award or subaward unless the authorizing statute permits those costs to be used as matching or cost sharing.
- However, this limitation does not apply to fee or profit earned by a recipient or subrecipient from a contract awarded under another federal grant or other type of assistance award.
- Costs or contributions used to satisfy a matching or cost-sharing requirement on another federal grant or procurement contract.

Cost sharing or matching may be provided as either direct and/or indirect costs, unless otherwise restricted by statute or regulation. The following scenarios guide how recipients may charge cost sharing or match costs:

- If a recipient treats a type of cost as an indirect cost for purposes of the organization's indirect cost rate, then contributions to an award in that category cannot be treated as a direct cost.
- A recipient may not count the use of facilities or equipment already owned by the recipient as a direct cost contribution if the cost or value of such use is reflected in the applicable indirect cost rate as depreciation or use charges.
- If a recipient has established special or multiple indirect cost rates, the requirement for consistent classification of costs applies to the activities covered by each rate.

Third-party in-kind contributions, including volunteer services, may satisfy a cost sharing or matching requirement only when payment for them would be an allowable cost if the recipient, subrecipient, or cost-type contractor receiving the contributions were to pay for them. Charges for such contributions must be fair, reasonable, and properly justified.

Recipients must document in their records all costs and contributions used to satisfy a matching or cost-sharing requirement. These costs and contributions are subject to audit.

Under federal research proposals, voluntary committed cost sharing or matching is not expected. Voluntary cost sharing or matching cannot be used as a factor during the merit review of applications or proposals but may be considered if it is both in accordance with the awarding agency regulations and specified in a NOFO. More specific rules related to cost sharing and matching for research proposals are found at <u>45 CFR 75.306(a)</u>.

If a recipient fails to provide some or all the required cost sharing or matching, the awarding agency can do the following:

• Reduce the award amount during pre-award;

- Make a downward adjustment of award funds during the budget period or period of performance (as applicable); or
- Disallow costs during post award.

6.5.2: Third-party In-kind Contributions as Indirect Costs

If an otherwise allowable third-party in-kind contribution would be considered an indirect cost, it can be counted as matching or cost-sharing only if the recipient (or subrecipient or cost-type contractor) utilizes its regular indirect cost rate, or a de minimis rate, for allocating to individual projects or programs the value of such contributions.

A third-party in-kind contribution to a fixed-price contract under an award, i.e., one in which the contractor is paid a previously agreed-on fixed amount, regardless of the actual costs of the contract, may count towards satisfying a cost sharing or matching requirement only if it results in:

- An increase in the services or property provided under the contract (without additional cost to the recipient or subrecipient); or
- A cost savings to the recipient or subrecipient.

6.5.3: Valuation of Donated Services

Professional or technical personnel, consultants, or other skilled or unskilled labor may provide volunteer services toward carrying out the activities funded under an award. Rates for volunteers must be consistent with established rates paid for similar work by the recipient or subrecipient or market rates if no similar category has been used by the recipient prior to the funded project. Market rates must be consistent with those paid for similar work in the labor market in which the recipient would compete for the kind of services involved. In either case, a reasonable amount for fringe benefits may be included in the valuation.

When an employer other than the recipient, subrecipient, or cost-type contractor provides services of an employee free of charge in the employee's normal line of work, these services must be valued at the employee's regular rate of pay.

6.5.4: Valuation of Donated Supplies, Equipment, Buildings, and Land

Donated supplies from a third party must be valued at the market value (i.e., the amount for which the supplies can be sold on the given market) of the supplies at the time of donation.

If a third party donates the use of equipment or space in a building but retains the building title, the treatment of the donated property depends upon the purpose of the federal award or subaward as follows:

- If the purpose of the federal award is to assist the recipient in the acquisition of equipment, buildings or land, the aggregate value of the donated property may be claimed as cost sharing or matching.
- If the purpose of the federal award is to support activities that require the use of equipment, buildings or land, normally only depreciation charges for equipment and

buildings may be made. However, the fair market value of equipment or other capital assets and fair rental charges for land may be allowed, provided that the awarding agency has approved the charges.

• If the awarding agency requires an appraisal, the NoA (or equivalent) must specify that the recipient must impose this requirement on subrecipients and contractors.

6.5.5: Other Matching and Cost Sharing Requirements

6.5.5.1: Changes to Amount

If a post-award amendment (e.g., a supplemental award), changes the amount of federal funding awarded, the awarding agency must determine if the cost sharing or matching amount must be recalculated. An awarding agency must also make this determination if project costs are reduced during the period of performance.

6.5.5.2: Meeting Match or Cost Sharing Requirements

Recipients must follow any requirements that restrict the types of expenditures or purposes that can be used as match. However, in determining if a recipient met a cost-sharing or matching requirement, agencies should apply the required percentage to the overall amount of actual and allowable costs (inclusive of third-party in-kind contributions). It is not necessary to ensure that the requirement is met within each of the currently approved cost categories.

The final calculation of the amount of cost sharing or matching and the assessment of recipient compliance with the cost sharing or matching shown on the NoA, must be based on actual, allowable costs (inclusive of the value of in-kind and third-party in-kind contributions). As noted in the Considerations for Planning section, if the program authority is ambiguous, to maximize the amount of the recipient contribution, agencies may calculate the required match amount based on the amount of the federal funds awarded, not on the amount of funds obligated by the recipient. Consult with OGC to confirm whether the preferred interpretation is permitted.

If a recipient provides matching or cost sharing exceeding what is required under the award (or equivalent notification under non-discretionary programs), the excess amount is not subject to the requirements of <u>45 CFR 75.306</u> unless the amount is used to offset otherwise unallowable matching or cost-sharing amounts.

See NOFO requirements at Planning, Cost Sharing Requirements sections of the GPAM.

6.5.5.3: Timing of Match or Cost Share

Recipients are not required to provide their cost sharing or matching before drawing down federal funds unless directed by an authorized statute.

If a recipient is not providing matching or cost sharing at an acceptable rate or cannot provide required cost sharing or matching, the awarding agency grants official, in consultation with the program officer, must:

- Assess the reasons;
- Review statements and assurances contained in the application or plan; and

• Determine the flexibility the awarding agency has, if any, in modifying the requirement and the necessity for additional actions, e.g., conversation to reimbursement payment.

6.6: Real and Personal Property, Intangible Property, and Equipment

The HHS-wide regulations concerning real and personal property, intangible property, and equipment are located at:

- 45 CFR 75.318 Real property;
- <u>45 CFR 75.322</u> Intangible property and copyrights;
- <u>45 CFR 75.320</u> Equipment;
- <u>45 CFR 75.439</u> Equipment and other capital expenditures; and
- <u>45 CFR 75.436</u> Depreciation.

The recipient is responsible for the day-to-day management of real property, equipment, and supplies the recipient acquires or uses under an award, whether title is vested in the recipient or remains with HHS.

Recipients must maintain written policies and procedures that address acquisition, classification, and management of all equipment and supplies, whether associated with federal awards or other recipient activities.

Awarding agencies must assess the adequacy of those policies and procedures before award and during the period of performance.

While acquisition and maintenance of equipment, generally, is an allowable cost, a recipient cannot acquire real property with federal financial assistance funds unless the underlying program statute authorizes the use of federal funds for such purpose. Agencies must have specific statutory authority to provide support for construction or modernization activities (except Minor Alteration & Renovation (A&R)).

A recipient must categorize the property at the time of acquisition and make the determination of whether the unit is intended to be used as equipment or to be affixed to the land in such a way that it becomes a permanent structure. Equipment that will be permanently attached or fixed to the land must be classified as real property.

6.6.1: Award Terms and Conditions

The awarding agency and recipient's rights and responsibilities related to acquisition, use, management, and disposition accountability for equipment and supplies must be clearly spelled out in the terms and conditions of the award. Terms and conditions must include requirements for prior approval for rebudgeting into the equipment category or review of the proposed procurement to acquire the equipment (consistent with <u>45 CFR 75.327</u>) and, as applicable:

- Recipient requirement to submit periodic tangible personal property reports using the SF 428, Tangible Personal Property Report or other Office of Management and Budget (OMB) approved information collection tool;
- Property management requirements related to specific award conditions;
- Generation of program income as a result of using property acquired under an award;
- Indication of whether equipment will be considered exempt;
- Recipient requirement to maintain insurance beyond what it normally maintains for its own operations as an allowable direct cost (including specification of any limitations on self-insurance and the need to demonstrate the cost-effectiveness of the insurance);
- Adequate protection of federal interests in the property during and after the period of performance;
- Be appropriate for the recipient both as a type of entity, for example, a state, and in relation to the specific capabilities of the organization to manage property;
- Be consistent with the purpose of the project or program; and
- Have a benefit consistent with the cost of administration both by the recipient and the awarding agency.

Unless the recipient is designated as an excluded party in SAM.gov or statutory or programmatic requirements apply, the awarding agency may not impose additional management or disposition requirements. An excluded party designation will allow an awarding agency to place more restrictive conditions on awards, but property classification (i.e., real versus personal property) cannot be changed on the basis of that designation.

6.6.2: Real and Personal Property

Property represents a resource to the recipient that not only enables that recipient to meet the objectives of the award, but which will, in most cases, remain with the recipient for authorized purposes after the award completion. Property can be either real property or personal property. See Definitions of Real Property, Personal Property, and Intangible Property in Appendix B.

6.6.3: Intangible Property

Intangible property is property having no physical existence, such as trademarks, copyrights, patents and patent applications, and property, such as loans, notes and other debt instruments, lease agreements, stock and other instruments of property ownership.

HHS is committed to providing the public with robust access to information resulting from federally funded awards. Under an award and subject to additional terms and conditions permitted by the award statute and regulations, title to intangible property, which includes copyrights in works made or obtained under the award, belongs vests with the recipient, subject to a nonexclusive license to the government.

The awarding agency must communicate in writing requirements for intangible property and designate requirements that will flow down to subawards.

Title to intangible property purchased or otherwise acquired under an award or subaward vests in the recipient.

The recipient must use that property for the originally authorized purpose and must not encumber the property without approval of the awarding agency (45 CFR 75.230(e)).

The federal government has the right to obtain, reproduce, publish, or otherwise use the data produced under a federal award, and to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes (45 CFR 75.322(d)).

6.6.3.1: Patents and Inventions

Inventions conceived or first actually reduced to practice under HHS awards to recipients are governed by the requirements of the <u>Bayh-Dole Act, 35 U.S.C. 200-212</u>, and implementing regulations, <u>37 CFR part 401</u>.

The regulations at <u>37 CFR part 401</u> allow recipients (and, as applicable, subrecipients and contractors under awards) to take title to inventions conceived or first actually reduced to practice during the performance of an award, as long as they comply with the requirements of the <u>Bayh-Dole Act</u>, which include: reporting, making efforts to commercialize the subject invention through patent or licensing, formally acknowledging the federal government's support in all patents that arise from the subject invention, and formally granting the federal government a license to use the subject invention.

Recipients must also provide details about all inventions that have been licensed but not patented and include details on income resulting from HHS-funded inventions and patents.

Unpatented research products or resources—research tools (i.e., devices, technologies, procedures, biological materials, reagents, computer systems, computer software, analytical techniques, etc.)—may be made available through licensing to vendors or other investigators. Income earned from any resulting fees must be treated as program income.

The awarding agency must use appropriate enforcement actions when a recipient fails to comply with inventions, patents, and resource sharing requirements.

6.6.3.2: Copyrights

A recipient may, without prior approval from the awarding agency, assert copyright in any work that is subject to copyright protection, and which was developed, or for which ownership was acquired, under an award.

Awarding agencies reserve a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use the work for federal purposes, and to authorize others to do so.

In general, recipients own the rights to data produced under an award. Pursuant to <u>45 CFR</u> <u>75.322(d)</u>, whether the awarding agency funded all or part of the project resulting in the data, the federal government has the right to obtain, reproduce, publish, or otherwise use the data first produced under an award; and authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes. Data developed by a subrecipient is also subject to this policy and recipients must ensure that any agreements with subrecipients or vendors include an acknowledgement of the federal government's rights. Specific terms and conditions relating to data rights and sharing must be stated in the applicable Notice of Funding Opportunity (NOFO) and Notice of Award (NoA).

6.6.3.3: Sharing of Research Tools and Data

HHS policy encourages the sharing of data and other research tools produced or developed by investigators under HHS awards, such as cell lines, certain types of animals (e.g., transgenic mice), and computer programs. Sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health.

Awarding agencies must ensure that recipients are advised of the following:

- If a subaward results in research data or tools, the recipient shall include a provision in any subaward that requires the subrecipient to make available that data or research tools. As appropriate and upon request, the awarding agency may request for the data and research tools to be shared.
- The recipient shall protect the rights and privacy of individuals who participate in HHSsponsored research and ensure that the identity of individual subjects cannot be deduced, e.g., resources involving human cells or tissues must not identify original donors or subjects, either directly or through identifiers such as codes linked to the donors or subjects. See <u>42 USC 241(d)</u> in reference to certificates of confidentiality related to protection of privacy of individuals who are research subjects.

6.6.3.4: Publications and Acknowledgment of Support

Recipients must acknowledge HHS support in publications. The Stevens Amendment, among other requirements apply. See the Award Chapter in GPAM for more information.

6.6.3.5: Royalties and Licensing Fees

A recipient may pursue commercial application of intellectual property developed under an award and require payments for the use of such property.

Recipients have no obligation to report program income earned from license fees and royalties for copyrighted material, patents, patent applications, trademarks, and inventions made under a federal award unless the Notice of Award (NoA) provides otherwise.

Recipients are permitted to pay royalties to others as an allowable direct cost under an award.

6.6.3.6: Debt Instruments When Recipients Act as Creditors

Under certain programs, recipients are allowed or are required to enter into financing arrangements with third parties. Under such circumstances, the terms and conditions of the NoA must be consistent with the program's governing statutory or regulatory provisions and must address the recipient's role with respect to the third parties, the awarding agency's role, and any required provisions to be included in agreements with third parties.

Awarding agencies must monitor the recipient's reporting of financing arrangements with third parties, to ensure the proper utilization of federal funds.

6.6.4: Equipment

See Definitions of Equipment, General Purpose Equipment, and Special Use Equipment in the Definitions section of Appendix B.

6.6.4.1: Title to and Use of Equipment

Purchasing equipment under a federal award offers limited transparency; therefore, prior to issuing an award the awarding agency must:

- Adequately review the proposed budget for the following:
- Proper classification and allowability of proposed equipment;
- Consistency with program goals and objectives; and
- The need for the proposed equipment in order to carry out the award-supported project;
- Ensure that an applicant/recipient has adequate property management, procurement management, and financial management systems meeting the standards set forth in <u>45</u> <u>CFR 75.316</u>;
- Identify potential issues related to equipment, such as possible generation of program income; and
- When warranted by audit findings or other known issues related to property, proceed with administrative corrective actions, to possibly include referring the known issues to HHS' Office of Recipient Integrity Coordination (ORIC) for possible suspension and debarment actions.

Under a research award to a non-profit institution of higher education or to a non-profit organization whose principal purpose is conducting scientific research, the awarding agency must use the special authority provided in the Federal Grant and Cooperative Agreement Act of 1977 (<u>31 U.S.C. 6306</u>) to vest title to equipment to the recipient without further accountability (except for those obligations in <u>45 CFR 75.320</u>). This property is considered "exempt federally-owned property," unless the recipient is subject to specific award conditions.

6.6.4.2: Equipment Acquired by the Recipient

The following circumstances regulate when an awarding agency can place limitations or controls on recipient acquisition or management of equipment acquired under an award:

- <u>45 CFR 75.320</u>–.<u>321</u> and <u>45 CFR 75.439</u> authorize any limitations;
- The program's authorizing legislation or implementing regulations include limitations or controls beyond those in the HHS financial assistance management regulations; or
- The awarding agency has identified concerns during the merit review process or equivalent review process.

6.6.4.3: Equipment Provided by the Awarding Agency

If provided under a program with direct assistance authority, equipment may be purchased by, or on behalf of, the awarding agency specifically for the award.

When an awarding agency provides a recipient any federally owned property for use on an award, the property must be in excess of the awarding agency's needs and the awarding agency has not declared the property as surplus or excess under the Federal Management Regulation (FMR). This federally owned property includes equipment acquired under procurement contracts with the awarding agency or awards where the awarding agency has exercised its right to require the recipient to transfer title to the federal government.

After the awarding agency has coordinated with the Chief Grants Management Officer (CGMO), contracting officer (if the recipient acquired the equipment under an HHS procurement contract), and the awarding agency (or other cognizant agency) property management staff, the awarding agency may authorize a recipient to use federally owned equipment. The awarding agency shall execute a revocable license agreement that allows the recipient to use the equipment while the awarding agency continues to retain title.

An authorized representative of the recipient and an awarding agency official (generally the awarding agency Executive Officer), shall sign a revocable license agreement.

The recipient must return the equipment when the awarding agency determines that it is needed for other purposes.

The revocable license agreement must also stipulate that the use to which the recipient puts the property must not permanently damage it for future federal government use.

6.7: Procurement and Cost Principles

6.7.1: Procurement Governance by Type of Recipient Organization

Recipients may charge routine goods and services necessary for the performance of the award, to either direct or indirect costs. However, the type of recipient may determine the procedure and the assignment of activities. The following regulations apply to the recipient type:

6.7.1.1: States

When procuring goods or services, states must follow the same policies and procedures they use for procurements from their non-federal funds, as indicated in <u>45 CFR 75.326</u>.

States must ensure that every contract or other acquisition vehicle includes applicable clauses required by federal statutes and executive orders and their implementing regulations, including the contract provisions contained in <u>45 CFR part 75, Appendix II</u>. 84 The adequacy of state contracts, (e.g., whether they were awarded consistent with state procurement requirements), should be monitored as part of post-award monitoring. See the Oversight and Monitoring Chapter of GPAM.

(Note: If an award to a state has a subrecipient that is not a state, the subrecipient is not subject to the state procurement standards.)

6.7.1.2: Local Governments and Indian Tribal Governments

Recipients may use their own procurement procedures that reflect applicable state and local laws and regulations, provided that the procurements conform to applicable federal statutes and the standards identified in 45 CFR 75.327 through 45 CFR 75.335.

6.7.1.3: Institutions of Higher Education, Hospitals, Other Non-profit Organizations, and For- Profit Organizations

Recipients may use their own procurement procedures that reflect applicable state, tribal, and local laws and regulations, provided that the procurements conform to applicable federal statutes and the standards identified in <u>45 CFR 75.327</u> through <u>45 CFR 75.335</u>.

6.7.1.4: Federal Institutions

Federal institutions must follow the Federal Acquisition Regulation.

6.7.1.5: Foreign Organizations

Given the differences in foreign organization types and any applicable governing requirements of foreign countries, HHS grants administration policy may be used as guidance. Depending on the extent of acquisition under a foreign award, the awarding agency may require its review of all proposed procurements exceeding a certain dollar amount or for certain types of services and/or may add specific terms and conditions to its awards that address the procurement of such goods and services.

6.7.2: Eligibility of Organizations for Subawards

A recipient may not make a subaward to an organization unless the organization has obtained a Unique Entity Identifier from SAM.gov.

As provided in <u>2 CFR part 180</u> and implemented in <u>2 CFR part 376</u>, the recipient must check the System for Award Management (SAM) as follows to ensure that it does not make a subaward to an entity that is debarred, suspended, or ineligible:

- For all first-tier subawards regardless of potential value. Agencies must also require first tier- subrecipients and lower-tier subrecipients to check SAM.gov; and
- For all first-tier procurement contracts with a value of \$25,000 or more and all lower tiers of subcontracts under covered non-procurement transactions (<u>2 CFR 376.220</u>).

Contracts under awards must be advertised, evaluated, and awarded consistent with the requirements of the recipient's procurement system and applicable statutes and regulations of the jurisdiction in which the recipient conducts business.

6.7.3: Flow Through or Flow Down Requirements

Terms and conditions in a recipient's NoA flow down to all subrecipients, unless the NoA specifically indicates otherwise.

Awarding agency staff monitoring recipients or auditors will look to the recipient's agreement/contract to determine whether the recipient included appropriate and applicable requirements.

The federal grants regulations (<u>45 CFR part 75, subpart E</u>) must be used as the basis for determining allowable costs under subawards and covered cost-reimbursement contracts. These regulations are not required to be applied to contractors under fixed-price type contracts.

A recipient must apply the appropriate cost principles in <u>45 CFR part 75, subpart E</u> and federal financial assistance administration requirements specific to the type of entity receiving the subaward, which may not be the same as those that apply to the recipient.

6.8: Oversight and Monitoring

Awarding agencies perform post-award monitoring to ensure the successful performance and administration of the award. Post-award monitoring is the ongoing activity that extends through the period of performance and closeout. Monitoring includes oversight of day-to-day activities, activities performed at specified intervals, and periodic evaluations of recipient performance required by statute or policy.

HHS-wide regulations on financial, performance and property monitoring, and reporting requirements are located at <u>45 CFR part 75, subpart D</u>.

Each awarding agency conducts the appropriate post-award monitoring for all awards on a regular basis. The use of a cooperative agreement, instead of a grant, does not absolve the awarding agency from its monitoring responsibilities. Such monitoring responsibilities are separate from the federal substantial involvement in a cooperative agreement.

Awarding agencies must ensure proper stewardship of federal funds and that the recipient has accomplished program objectives. The information obtained through post-award monitoring informs decisions related to certain aspects of continued performance (e.g., funding levels) and whether there are needs for additional actions to increase the potential for successful performance or to protect federal interests.

The intention of post-award monitoring is to ensure the recipient is:

- Making progress in achieving the objectives of the federal award, consistent with performance goals or milestones included in the NoA, general activities at a given level of effort, and/or specific project activities;
- Minimizing the time elapsing between the transfer of funds and disbursement;
- Providing required matching or cost sharing consistent with their programmatic performance, if required;

- Maintaining adequate administrative and financial systems;
- Using and accounting for federal or award-generated resources, such as program income or property, in accordance with the terms and conditions of award;
- Communicating to the awarding agency developments that may have a significant impact on timeframes for completing activities and meeting performance goals of the federal award; and
- Complying with other terms and conditions of award, e.g., allowable costs and public policy requirements, such as research integrity, appropriate treatment of human subjects, protection of the environment, and other potential areas of risk.

6.8.1: Documentation

All monitoring must be documented by the awarding agency.

Program and grants management offices must document the adequacy of recipient performance and compliance at least annually during the period of performance.

Program and grants management offices must document, in writing, site visit or desk review results, including findings, as soon as possible after completion of the review. Awarding agencies must share findings and items in need of action or correction with the recipient in a suitable time frame and, as appropriate, require development of a corrective action plan by the recipient.

6.8.2: Responsibilities

Monitoring is a joint responsibility of the awarding agency's grants and program offices. The awarding agency must designate an appropriate grants and program official (PO) as responsible for the post-award monitoring of each award. This designation must be:

- Part of required pre-award documentation and included in the official award file; and
- Updated when a new grants official or PO is assigned to an award.

The grants management office is responsible for the administrative and financial monitoring while the program office monitors recipient compliance with programmatic requirements.

6.8.3: Annual Assessment of Recipient Performance and Compliance

Annual assessments must consist of a review, statement, and signed acknowledgement of the annual performance report. The statement should indicate the recipient's overall progress (acceptable or otherwise) and whether there are known issues. The assessment should include information obtained by telephone, email, or other sources. The annual assessment must be consistent with the monitoring approach adopted for the program and federal award-specific considerations.

The grants management office focuses on assessing the administrative and financial aspects of the federal award. The assessment may include, but is not limited to, a review of:

• Federal financial reports;

- Performance reports;
- The recipient organization's single audit (if applicable);
- Compliance with award requirements;
- The type and frequency of prior approval requests; and
- Adherence to matching or cost sharing commitments.

The program office should provide an annual programmatic assessment to the grants management office. This programmatic assessment should consist of a signed acknowledgement of the annual progress report. This acknowledgment should include a review of and a statement on the recipient's overall progress (acceptable or otherwise) and whether there are known issues.

Any need for specific award conditions, technical assistance, or enforcement actions resulting from the annual assessment must be documented in the award file and addressed as soon as identified to avoid additional problems that may affect recipient performance and/or cause loss of resources.

6.8.4: Post-Award Monitoring Considerations for Program Income

The awarding agency must:

- Monitor a recipient's earning and use of program income through the end of the period of performance of the award as part of post-award monitoring;
- Ensure the recipient has appropriate fiscal controls in place to account for, track, and report program income;
- Review the Federal Financial Report (FFR) to ensure all line items are complete and that the uses of the reported amounts are consistent with the terms and conditions of the award and the expected level of reportable program income; and
- Fund non-competing continuation awards consistent with the program income alternative(s) specified in the original award, unless the recipient requests a change that the awarding agency deems necessary.

The awarding agency is not required to monitor the disposition of program income earned by recipients after the period of performance of a federal award unless specified in HHS regulations or terms and conditions of the award.

6.8.5: Subrecipient Management

Unless prohibited by statute, regulation, or program guidance, a recipient may authorize federal funds to another entity to provide support for the performance of any portion of the project or program.

• A recipient intending to transfer performance of any portion of the work under an award must indicate this information, to the extent known, at the time of the application.

• Awarding agency prior approval is required for the transfer of substantive programmatic work from a recipient to a subaward or contract once the period of performance has commenced.

The recipient, as the awardee organization, is legally and financially responsible for all aspects of an award including funds provided to subrecipients and contracts, in accordance with <u>45 CFR</u> <u>75.351</u> – <u>75.352</u>, Subrecipient and contracts, in accordance with 45 CFR 75.351 – 75.352, Subrecipient monitoring and management.

As part of post-award monitoring, awarding agencies must assess recipient compliance with the requirements for subrecipient reporting and reporting of executive compensation. If a subrecipient or contractor fails to comply with requirements of an award, the recipient is responsible for any repayment or other required action. See the Oversight and Monitoring chapter of GPAM.

6.8.5.1: Oversight and Subrecipient Monitoring by a Pass-Through Entity

Awarding agencies have no direct, legal relationship with subrecipients.

A pass-through entity is a recipient identified on a Notice of Award (NoA) that provides a subaward for some portion of its award to <u>subrecipients</u> to carry out part of a <u>federal program</u>. Pass-through entities are responsible for:

- Monitoring subrecipient activities and compliance with the terms and conditions of the award throughout the lifecycle of subaward activity;
- Making pre-award decisions concerning subawards and managing the day-to-day operations of subaward-supported activities; and
- Monitoring subrecipients to ensure compliance with applicable federal requirements and the achievement of performance goals.

The pass-through entity is responsible for any subrecipient non-compliance issues. If, for example, the awarding agency disallows costs under an award that were incurred under a subrecipient, the pass-through entity is responsible for repayment or offset. In turn, the pass-through entity should take whatever remedies are available to it with respect to its subrecipient for those disallowed costs.

A pass-through entity may impose reporting requirements or require prior approval for an activity even if it is not required by the awarding agency, or use a different threshold, if it would allow the pass-through entity to meet its obligations to the awarding agency.

6.8.5.2: Making Determinations Between Subrecipients and Contractors

Federal funds may be awarded by the recipient to either a subrecipient or a contractor. These two distinct relationships are defined in <u>45 CFR 75.351</u>. Unless otherwise specified in statute or regulation, all types of organizations are eligible as subrecipients or contractors under awards.

Recipients must use judgment in deciding between a subaward and contract. In general, under a subaward, the subrecipient receives federal funds for the purpose of carrying out a portion of

a Federal award. A contract is a for the purpose of obtaining goods and services for the non-Federal entity's own use. <u>45 CFR 75.351</u> provides guidance in deciding between a subaward and contract.

In determining whether an agreement between a pass-through entity and another recipient casts the latter as a subrecipient or a contractor, the substance of the relationship is more important than the form of the agreement. All of the characteristics listed in <u>45 CFR 75.351</u> may not be present in all cases, and the pass-through entity must use judgment in classifying each agreement as a subaward or a contract. However, the awarding agency may supply and require recipients to comply with additional guidance to support these determinations provided such guidance does not conflict with this section.

An awarding agency may not:

- Decide whether a recipient enters into either a subrecipient or contractor relationship;
- Participate in selecting subrecipients or contractors under awards;
- Specify a particular entity to receive a subrecipient or contract under an award;
- Direct a recipient to award procurement contracts or subrecipients to particular organizations;
- Suggest the use of specific contractors or subrecipients;
- Use recipient subrecipients or recipient acquisitions to circumvent HHS award competition policies; or
- Interfere with the recipient's selection decisions or use language in communications
 with applicants or recipients that implies awarding agency approval of a subaward or
 contract. An awarding agency is not a party to the subaward or contract and must avoid
 the appearance of endorsement or use language that could create potential liability for
 the awarding agency.

6.9: Reporting and Other Award Deliverables

Recipients must complete financial, performance, and other reports after award. The recipient shall complete the reports per the terms and conditions as outlined in their NoA.

Awarding agencies may increase the frequency of required reporting by applying specific award conditions to a particular recipient, based on an analysis of the following factors:

- Risk criteria in <u>45 CFR 75.205;</u>
- The <u>recipient's</u> history of compliance with general or specific terms and conditions of a <u>federal award;</u>
- The <u>recipient's</u> ability to meet expected <u>performance goals</u>; or
- History of entity Responsibility and Qualification in SAM.gov.

The awarding agency shall do the following: 90

- Require recipients to use standard, Office of Management and Budget (OMB) approved, government-wide reporting forms and formats and instructions for post-award reporting, to the maximum extent practical;
- Identify in the NOFO the general post-award reporting requirements that will apply to awards made under the NOFO;
- If applicable, identify the forms, formats, or data sets for reporting, including standard form number or reference to a website where the material is accessible;
- Obtain approval from OMB, when required under the Paperwork Reduction Act, for any reporting requirements which differ from standard reporting requirements or instructions; and
- Identify in each NoA, the general terms and conditions that address reporting requirements, which are consistent with information in the NOFO, including:
- Type or name of report and required form or format;
- Frequency of submission;
- Specific office or appropriate grants official, program official, or other to whom a report(s) must be submitted, if applicable;
- Means of and specific location for submission;
- Due date (either by date, number of days after an event, or time period); and
- Language indicating that delinquent, incomplete, or incorrect reports may delay certain actions such as issuance of non-competing continuation awards or result in enforcement actions.

6.9.1: Performance Reports

Due dates for performance or progress reports may be based on dates of the budget period, e.g., under an award with a budget period beginning May 1, a quarterly report covering the period May through July and due August 30, or on a schedule consistent with that for the Federal Financial Report (FFR).

Recipients must submit a performance/progress report at least annually. If an award has a budget period greater than 12 months, the recipient must submit a performance/progress report during each 12-month period (or portion thereof). Reporting frequency continues through any extension periods.

Performance reports must contain the following:

- A comparison of actual accomplishments compared to objectives for the period reported, which may include costs per quantifiable accomplishment or trend data and analysis, as appropriate;
- Reasons why performance goals were not met, if relevant; and

• Additional information as appropriate, including an explanation of cost overruns or high costs.

6.9.2: Federal Financial Report (FFR) – Expenditure Report

Established reporting frequency continues throughout no-cost extension periods. An awarding agency can waive the interim expenditure report and require submission of the SF-270, Request for Advance or Reimbursement in its place.

If at any time a recipient discovers that they have overcharged an award and there is a balance owed to the awarding agency, they can submit a revised FFR to the awarding agency for review.

If, upon review of a revised FFR, an awarding agency determines that there is a balance due, it can be recouped through an adjustment in the Payment Management System (PMS) if the award is still active or completed but not closed out. Please see section titled Financial Reconciliation upon Completion of Award for additional information.

The grants management officer may not accept a revised interim FFR submitted by the recipient that claims additional expenditures after one year from the end of the reporting period (regardless of when the original report was actually submitted). Revised FFRs submitted within the required time frame must be accompanied by a written explanation of the need for the revision. An additional claim that is timely must represent allowable costs under the award.

See <u>Financial Reconciliation upon Completion of an Award</u>, <u>Improper Payments</u>, and <u>Debt</u> <u>Collection</u> sections of GPAM.

6.9.3: Reporting on Property

6.9.3.1: Tangible Personal Property

If an awarding agency provides federally owned property to a recipient, the awarding agency must require that the recipient submit an SF-428, Tangible Personal Property Report, to the awarding agency no less frequently than annually. The awarding agency, at its discretion, may require interim property reports. The recipient must submit a final Tangible Personal Property Report at closeout.

6.9.3.2: Real Property

The SF-429, Real Property Status Report is a multi-purpose form that awarding agencies may require for general reporting about real property acquired or constructed under an award, as well as for recipients to make a request related to acquisition or improvement of real property or to request disposition instructions per <u>45 CFR 75.318</u>.

The awarding agency must require that the recipient submit reports at least annually on the status of real property in which the awarding agency retains an interest, unless the awarding agency's interest in the real property extends 15 years or longer. In those instances where the awarding agency's interest attached is for a period of 15 years or more, the awarding agency, at its option, may require the recipient to report at various multi-year frequencies (e.g., every two years or every three years, not to exceed a five-year reporting period; or an awarding agency may require annual reporting for the first three years of an award and thereafter require reporting every five years).

6.9.6.3: Patents and Inventions

The government-wide requirements concerning patents and inventions under awards are contained in <u>37 CFR part 401</u>, Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements, and reporting requirements are set forth at <u>37 CFR 401.14</u>.

A recipient's failure to comply with invention reporting requirements and any associated awarding agency's policies may result in the loss of patent rights, imposition of enforcement actions, or inclusion of specific conditions in awards.

6.9.4: Subaward Reporting and Reporting of Executive Compensation

The Federal Funding Accountability and Transparency Act of 2006, as amended (referred to as both FFATA and the Transparency Act), as implemented in <u>2 CFR part 170</u>, requires prime recipients to report on first tier subawards (i.e., subrecipients) and executive compensation for the prime and first-tier subrecipients. It is important to note that the disclosed compensation is the full amount, not that charged to a federal award.

- Recipients must report each subaward obligation of \$30,000 or more in federal funds.
- Recipients must report total compensation for each of their five most highly compensated executives for the preceding completed fiscal year, if—
- the total federal funding authorized to date under this award is \$30,000 or more;
- in the preceding fiscal year, the recipient received-
 - 80% or more of their annual gross revenues from federal procurement contracts (and subcontracts) and federal financial assistance subject to the Transparency Act, as defined at <u>2 CFR 170.320</u> (and subawards); and
 - \$25,000,000 or more in annual gross revenues from federal procurement contracts (and subcontracts) and federal financial assistance subject to the Transparency Act, as defined at <u>2 CFR 170.320</u> (and subawards); and
 - The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at the Executive Compensation page of the SEC website.)

These reporting requirements apply to all awards and subawards over \$30,000. If a first tier subaward was funded prior to October 1, but the subaward amount increases to the threshold of \$30,000, then these reporting requirements apply.

Awards include financial assistance to all recipients, with the following exceptions:

• transfers of title to federally owned property provided in lieu of money, even if the award is called financial assistance;

- Cooperative Research and Development Agreements (CRADAs), pursuant to the Federal Technology Transfer Act of 1986, as amended (15 U.S.C. 3710a);
- federal awards to individuals who apply for or receive awards as natural persons (i.e., unrelated to any business or non-profit organization he or she may own or operate in his or her name);
- any classified federal awards;
- any technical assistance, which provides services in lieu of money; and
- any award funded in whole or in part with Recovery funds, as defined in section 1512 of the American Recovery and Reinvestment Act of 2009 (P.L. 115-5).

If the recipient had a gross income from all sources under \$300,000, it is exempt from reporting subawards and subrecipient executive compensation.

6.9.5: Lobbying Disclosure Reports

In accordance with <u>45 CFR part 93</u>, a recipient is required to submit to the awarding agency a lobbying disclosure (SF-LLL) for each payment (or agreement to make payment) to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered federal action. Covered federal actions include contracts, grants, cooperative agreements, loans, loan guarantees, and loan insurance. This report is required only if the recipient has information to report. It is not required on any periodic basis and no report is required if the recipient did not conduct lobbying activities as identified above.

6.9.6: Delinquent Reports

Regardless of the frequency of required reporting, awarding agencies and the appropriate GMO are responsible for conducting follow-up with recipients regarding delinquent reports. GMO follow up actions must occur no later than 30 days after the established report due date and must be documented in the official award file.

If the recipient consistently has reporting delinquencies, and late reports are not submitted or the recipient provides no adequate explanation for the delay, the GMO must take appropriate steps to mitigate the recipient's noncompliance, such as withholding of payment until the report is received. The awarding agency may move to close out the award if the awarding agency does not receive the report prior to when closeout of the award is required.

6.10: Awarding Agency Responsibilities for Award Information Collection and Reporting

The awarding agency must include all reports in the official award file, including all reports the awarding agency collects, regardless of how it collects the reports or where the reports are submitted.

Each awarding agency must:

- Collect and provide the required data to HHS's Tracking Accountability in Government Grants System (<u>TAGGS</u>) to meet the statutory requirements for transparency in financial spending; and
- Meet the requirements of FFATA by providing information about federal financial assistance awards of \$30,000 or more to the public through <u>USAspending.gov</u>.

The Data Quality Database Application (DQDA) is a business support tool that monitors and tracks awarding agencies' awards submission statuses to their respective grants management systems per OMB Circular A-123 and the Open Government Initiative.

For more information on these systems, see <u>Appendix C</u>.

6.11: Improper Payments and Debt Collection

6.11.1: Improper Payments

Improper payments result when funds are awarded to recipients exceeding the amount authorized by law or when recipients use funds for unauthorized grant purposes. If the appropriate grants official makes a final determination that funds were awarded to, or used by, a recipient in excess of that authorized by law, such determination gives rise to a legally enforceable debt owed to the US government, and the awarding agency must take affirmative actions to recover the amounts improperly paid. Actions to recover improper payment must be initiated immediately upon the issuance of a final determination by the appropriate grants official, which may occur during performance of the award or after award closeout.

Examples of grant official final determinations that give rise to legally enforceable debts owed to the government include:

- determinations that recipients used grant funds in excess of the authorized federal share;
- determinations that grant funds were used for unauthorized grant purposes;
- determinations that recipients used grant funds for unauthorized expenditures outside of the grant award period of performance, or other reasons.

For questions on Single Audit-related improper payments, contact <u>auditresolution@HHS.gov</u>.

For questions on debt collection and management, contact <u>DebtManagement@hhs.gov</u>.

6.11.2: Debt Determinations

The awarding agency must coordinate its actions related to improper payments with the cognizant finance/debt collection office(s) and with the Office of the General Counsel (OGC), if required, and follow the established process for subsequent determinations. The established process should include the following steps.

6.11.2.1: Initial Determination Letter

The awarding agency will seek finance/debt collection office and OGC review of an initial determination letter to the recipient, which must include supporting documentation, including:

- the amount and reason for the improper payment;
- inclusion and/or reference to any explanation(s) previously provided to/by the recipient; (i.e., such as a Management Decision Letter);
- an opportunity to submit additional explanation and/or documentation supporting the questioned payment(s); and
- the agency's reason for not accepting the explanation as well as deadlines for response.

If contacted by the recipient, the awarding agency or other federal individual whose name is specified in the initial determination letter must respond promptly, generally within 30 days of the communication from the recipient.

6.11.2.2: Final Determination Letter

After established deadlines for the recipient to respond to the initial letter, the awarding agency will develop and seek finance/debt collection office and OGC review of a final determination letter, which will be sent to the recipient by the appropriate grants or audit resolution official. Only the official with the delegated authority to determine a debt on behalf of the awarding agency is authorized to issue a final determination letter. The letter must be sent to the recipient's last known address by a means that allows the awarding agency to validate when it was sent and received.

The following requirements for the debt determination letter are based on the claims collection standards at <u>45 CFR 30.11(b)</u> with some supplementation:

- Identifying information, including the recipient's name, award number, EIN, and audit report number (if applicable), and the period covered by the report;
- Amount due, including the basis for the determination (e.g., findings of an on-site review, Office of Management and Budget (OMB) single audit report), and how the amount owed was determined. This information should be supported by any applicable statutory or regulatory citations;
- Specific information necessary for the recipient to identify the transaction or behavior at issue and how the amount of debt was estimated;
- Date by which payment should be made, which generally shall be no later than 30 calendar days from the date the final determination letter is sent;
- Statement that the amount due, if not paid or appealed by the due date, will be considered delinquent and is subject to late charges and enforced collection under <u>45</u> <u>CFR part 30</u>;
- Applicable standards at <u>45 CFR 30.18</u> for imposing interest, administrative costs, and penalties on delinquent debts;
- Appeal rights that the recipient has for review of the final awarding agency determination and how to exercise them, including applicable timeframes, as well as a statement that, unless the underlying authority for the award program specifically

prohibits the awarding agency from taking any enforcement action during an appeal by the recipient, under <u>45 CFR 30.18</u>, interest and other late payment charges will continue to accrue on unpaid amounts during any period of review;

- Recipient's right to enter into a reasonable repayment agreement as provided in <u>45 CFR</u> <u>30.17</u> and the HHS representative's willingness to discuss with the recipient alternate forms of repayment;
- Available actions that the awarding agency's financial office may take under <u>45 CFR part</u> <u>30</u> to enforce collection of delinquent debts, to include:
- Making an offset for the debt from any federal payments owed to the recipient, including income tax refunds;
- Referring the debt to a private collection contractor;
- Reporting the debt to a credit reporting agency;
- Referring the debt to the U.S. Department of Justice for litigation; and
- Referring the debt to the U.S. Department of the Treasury for collection action, which may result in an additional collection fee being assessed and added to the amount due.
- Recipient's (or its authorized organizational representative's) right to inspect and copy all the relevant and non-privileged HHS records pertaining to the debt or to request and receive copies of those records;
- Name, address, and telephone number of a contact person (this should ordinarily be the appropriate grants or audit resolution official, who coordinates with the awarding agency office of finance/PMSvc, as necessary);
- Name and address of the collection office to which payment is to be remitted; and
- Statement indicating that until the debt is repaid, or satisfactory repayment arrangements are made, the recipient is not eligible to receive federal government loans or loan guarantees (awards, cooperative agreements, and contracts are not considered to be loans) (see source: 31 U.S.C. 3720B(a)).

The awarding agency must send a copy of the debt final determination letter to the office that is responsible for recording the receivable on behalf of the awarding agency, which may be the awarding agency's office of finance or Payment Management Services (PMSvc) and advise them of the filing/resolution of an appeal, if any, because follow-up actions are deferred until the appeal is decided.

The determination letter may serve as both notification of debt obligation and a repayment agreement, depending upon the specificity and any negotiation with the recipient. The awarding agency may request additional information only if there is a need to negotiate the repayment schedule with the recipient. Once the final determination letter is sent, no further negotiation or submission of documentation regarding the debt is permitted.

The appropriate grants official must maintain evidence of the transmission of the final determination letter to the recipient in the official award file along with a copy of the final determination letter.

6.11.2.3: Results of Final Debt Determination

After issuing a final debt determination letter, the amount owed constitutes a debt to the United States, subject to any rights of appeal that may be available to the recipient. The recipient must remit that amount to the awarding agency, even if the debt results from an improper payment to or by a subrecipient and whether or not the recipient is able to collect any amounts due from a subrecipient. See Debt Collection in this chapter.

6.12: Debt Collection

Unless the program legislation specifically provides for recovering award funds from a recipient, agencies must collect such amounts using certain enforced collection tools.

All debt collection activities covered in the Debt Collection Improvement Act of 1996 must be performed by federal officers and employees who by virtue of their employment are legally responsible for the collection of federal money. Collection of legally enforceable debts arising from HHS financial assistance programs must be carried out in accordance with the requirements of the Federal Claims Collection Act,, as amended, 31 U.S.C. 3711-3720E, and the joint Department of the Treasury and Department of Justice implementing regulations at 31 CFR parts 900-904 (the Federal Claims Collection Standards) and the HHS implementing regulation at <u>45 CFR part 30</u>. Debt collection activities undertaken pursuant to <u>45 CFR part 30</u> are the responsibility of the awarding agency's designated debt collection office.

6.12.1: Interest, Penalties, and Administrative Costs

Once the debt obligation is determined, the awarding agency, or the appropriate HHS office, is authorized, and, in many cases, required to collect amounts due and to charge interest and penalties for non-compliance and administrative costs on the delinquent debts, in accordance with <u>45 CFR 30.18</u>. Interest accrues beginning on the date the awarding agency's final determination letter is mailed; however, interest will not be charged if the amount due is paid within 30 days of that date.

Except as provided in <u>45 CFR 30.18(h)(2)</u>, an administrative review (e.g., an appeal) will not suspend the assessment of interest, penalties, and administrative costs on the amount owed. While under appeal, the recipient may pay the amount due or be liable for any interest or related charges on the uncollected debt.

If an appeal is not successful and the recipient has not paid the amount in dispute, the designated HHS debt collection official may collect any amount determined to be due plus applicable interest, penalties, and administrative costs (as provided in <u>45 CFR subpart 30.18</u>). The interest, penalties, and administrative costs start from the date the awarding agency's final determination letter is mailed and ends when the debt is repaid. The date of delinquency for an installment payment is the due date specified in the payment agreement.

The finance office will compute interest charges using the prevailing rate established annually by Treasury in effect on the postmark (or similar) date of the determination letter and remains fixed for the duration of the indebtedness. The applicable rate of interest is available at the HHS website for <u>Interest Rates on Overdue and Delinquent Debts</u>. A different rate may be specified by statute or a repayment agreement or imposed as allowed by <u>45 CFR 30.18(b)(2) or (3)</u>.

Administrative costs are the costs incurred by HHS for processing and handling delinquent debts and include costs of personnel and supplies, costs associated with hearings or administrative review, and any costs associated with use of a collection agency. Unless otherwise established by statute or a repayment agreement, HHS will charge the prevailing rate established annually by Treasury on the amount of a debt that is delinquent for more than 90 days. The recipient must pay interest as well as any applicable administrative costs or penalties from non-federal sources. Interest, penalties, and administrative charges may be waived only by authorized HHS officials in accordance with <u>45 CFR 30.18(g)</u>.

When an administrative offset (pursuant to <u>45 CFR 30.12</u>) is to be taken under an HHS award, if the recipient has a single HHS award, HHS will convert the recipient to reimbursement payment. The offset will be accomplished by not reimbursing the recipient for claimed costs in an amount equal to the debt (plus applicable interest, penalties, and administrative costs). Alternatively, the awarding agency may withhold the repayment amount from payments due or requested under another award(s), whether as an advance or reimbursement payment.

When imposing any administrative offset on a recipient, the appropriate grants official must consider the potential effect of offset on performance of the affected award(s) and available alternatives to minimize the potential for an adverse financial impact, e.g., reduction in scope. If the grants official finds that the effect on the recipient's project/program is unacceptable, e.g., public health could be affected or patients would not receive services, the appropriate grants official must document the effect in writing and provide that documentation to the cognizant office of finance/PMSvc.

When carrying out the administrative offset by not paying claimed costs under a reimbursement request, the appropriate grants official must ensure that a recipient's request for reimbursement includes actual allowable costs incurred. If the grants official finds that the recipient has claimed unallowable costs in its reimbursement request(s), that amount becomes an additional debt. The appropriate grants official also must ensure that the recipient meets any matching or cost-sharing requirements, where the requirement amount is based on the approved budget and allowable costs.

If a recipient is delinquent on a debt owed to the federal government (whether another HHS awarding agency or another federal agency), the appropriate grants official may take an appropriate action; these may include suspension or termination of awards to that recipient or withholding of payment. Depending on the circumstances of the indebtedness, the appropriate grants official also may consider the need for referring the recipient to the HHS Suspension and Debarment Official for consideration of whether suspension or debarment is appropriate.

Chapter 7: Enforcement Actions and Addressing Noncompliance

Every award contains a provision for enforcement, suspension, and/or termination of the award. Awards are subject to regulations, oversight, and audit. Agencies use reports and other information to gauge the success or non-compliance of projects. Programs establish systems and procedures for oversight and audits.

As discussed in previous sections, HHS awarding agencies must take the appropriate pre- and post-award actions to minimize the incidence of recipient actions that require enforcement. Sometimes these actions do not result in recipient compliance.

Only after all other actions to improve a recipient's compliance or performance are deemed unsuccessful, the grants office, in consultation with the program office, is authorized to take appropriate actions if recipients fail to perform the requirements of the awards.

If the appropriate grants official detects deficiencies in business integrity, project performance, financial management, internal controls, or data that may affect the federal program, the official may use a variety of actions as remedies for non-compliance and enforcement for alleged violations.

If applicable, the awarding agency must initiate enforcement actions within 30 days of a documented finding(s), which includes all relevant information, correspondence, and views regarding the compliance or performance issue, or after other actions to improve a recipient's compliance or performance have not been successful. Agencies should begin enforcement actions as quickly as possible if the related issue could be a serious threat to public health or welfare.

HHS enforcement action and noncompliance regulations are as follows:

- Enforcement and appeals are located at <u>45 CFR 75.371-75.380</u>; <u>42 CFR part 50</u>, <u>45 CFR part 16</u>, and program regulations;
- Suspension and debarment are located at <u>2 CFR part 180</u> and <u>2 CFR part 376</u>; and
- Debt collection is located at <u>45 CFR part 30</u> and 31 U.S.C. 3720B(a).

When planning for enforcement actions, agencies shall take into account the following:

- Level of enforcement action needed, consistent with the type, duration, and significance of the non-compliance or other findings and the HHS awarding agency's programmatic needs
- The combination of enforcement actions available

Awarding agencies have the discretion to determine whether to take an enforcement action, and the appropriate action to be taken, unless:

- Authorizing statutes and regulations set limits on the awarding agency's authority; and/or
- An office outside of the awarding agency has authority to undertake a compliance or enforcement action, e.g., Department of Justice or Office of the Inspector General.

The appropriate grants official's final decision to take an enforcement action must be completed in collaboration with the:

- Appropriate program officials (as necessary, the program office director); and
- Other officials in the awarding agency such as Office of the General Counsel (OGC) or HHS (inclusive of the Assistant Secretary for Legislation (ASL) and the Office of Budget) may be included in collaboration efforts, if necessary.

Final determination on whether to take an enforcement action is the responsibility of the Chief Grants Management Officer (CGMO). The recipient may be notified of a pending enforcement action by a designated grants management officer.

The CGMO may request that a higher-level awarding agency program or management official co-sign the notification.

If an enforcement action is deemed necessary, the following conditions must be addressed, and the action must:

- Be consistent with the type, duration, and significance of the non-compliance or other findings and the awarding agency's programmatic needs;
- Include a plan for continued assistance to beneficiaries if immediate action is necessary (e.g., the project poses a threat to the health of beneficiaries or research subjects);
- Be consistent with the recipient's willingness and ability to correct the non-compliance or to address or change other situations; and
- Ensure that correctable deficiencies are resolved and that the action does not engage in a cycle of recipient non-compliance concerning the same issues.

The awarding agency may use a single enforcement action, or a combination of actions that may increase the severity of actions over time if non-compliance or other performance issues continue. The types of enforcement actions that may be used consist of, but are not limited to:

- Disallowing all or part of the cost of the activity or action not in compliance;
- Temporarily withholding cash payments;
- Converting to the reimbursement payment method;
- Wholly or partly suspending or terminating the award;
- Withholding further awards for the program or project; and/or
- Initiating government-wide recipient suspension and debarment.

7.1: Disallowing Costs

Costs, including those used as matching contributions, may be determined to be unallowable based on the requirements in the applicable cost principles, eligible programmatic activities as stated in the NOFO, the HHS Grants Policy Statement, and specific terms and conditions cited in an award that may indicate disapproval of a cost/activity.

Costs may be disallowed at any time during the period of performance or at closeout based on audit findings, information in reports, or on other bases. If an awarding agency disallows costs, the recipient must repay the awarding agency using non-federal funds. If the repayment is made through an offset of award funds, the recipient will be required to maintain project activities at the previously approved level. Expenditures from non-federal funds in the amount of the offset will be subject to the federal cost principles and all other requirements that would apply to the expenditure of federal funds.

See the Debt Collection chapter of GPAM. Cost disallowances may be appealed.

7.2: Temporarily Withholding Cash Payments

Temporarily limiting the recipient's ability to make drawdowns (advance payment system), or receive payments (reimbursement payment system), referred to as withholding a payment, may be used as an enforcement action, provided:

- It is coordinated between the appropriate grants official and the designated paying office. The paying office cannot unilaterally override or change the awarding agency decision;
- This type of enforcement action generally is used to achieve compliance with a specific requirement within a reasonable period, such as submission of a report; and
- Payment withholding cannot exceed 60 days.

Withholding of cash payments may not be appealed under the HHS or Public Health Service (PHS) administrative awards appeals procedures.

Once the awarding agency lifts the restriction and takes no further enforcement action, the recipient can draw funds or receive the payment to cover the period during which the restriction was in effect.

7.3: Converting Recipient to the Reimbursement Payment Method

Another action available is converting a recipient to a reimbursement payment method when an award originally provided for advance payment. Awarding agencies would do this to address a systemic cash management issue that will take longer to resolve than the period allowed for payment withholding (longer than 60 days).

A recipient cannot appeal a conversion to the reimbursement payment method.

Once the recipient corrects all deficiencies and monitoring indicates compliance, the awarding agency may allow the recipient to resume advance payment. If the deficiency continues beyond a reasonable period, as defined in the notification letter, additional enforcement action(s) may be considered.

During the life of an award, awarding agencies may not employ a strategy of repeatedly switching a recipient back and forth between the reimbursement and advance payment methods, as a means of obtaining compliance.

7.4: Suspension of Award Activities

If an awarding agency determines that a recipient is not complying with the terms and conditions of its award(s), the agency can partly or wholly suspend award activities. While a post-award suspension of activities is in effect, it applies only to the award(s) or portion of the award specified by the awarding agency.

If temporarily withholding payment or less severe enforcement actions do not achieve the desired result, the awarding agency can temporarily suspend award activities pending corrective action by the recipient. The post-award suspension of award activities period should be commensurate with the corrective action needed but must not exceed 120 days at the outset. Termination should also be considered.

If the recipient is not making sufficient progress in correcting the identified deficiencies, both grants and program staff must agree on the appropriate extension period to avoid the need for termination.

The notice of post-award suspension of award activities must clearly indicate:

- What program or project activities, if any, will take place during the suspension period;
- What costs the awarding agency will reimburse if the enforcement action is ultimately lifted and the award resumed;
- What corrective actions must occur during the enforcement action; and
- The awarding agency's intent to terminate the award if the recipient does not meet the conditions of the enforcement action.

The recipient may not appeal a post-award suspension of award activities.

7.5: Terminating an Award

The awarding agency should terminate an award only when all other possible enforcement actions have been exhausted and there is no reasonable expectation that the recipient will complete the necessary corrective actions. The only exception occurs when an immediate termination action is needed to protect public health or welfare, or the federal government's interests. Note that termination as an enforcement action is not applicable to non-discretionary programs.

As part of a termination action, the awarding agency must consider what actions it might take in the event of future awards to that recipient. The final costs of a terminated award may be negotiated if the recipient has non-cancelable obligations. Obligations incurred in anticipation of a termination or incurred in violation of award terms and conditions are not allowable.

The awarding agency may unilaterally terminate an award for material failure to comply with the terms and conditions of the award, without first providing for post-award suspension. A recipient may appeal this type of termination. When an awarding agency terminates a federal award prior to the end of the period of performance due to the recipient's material failure to comply with the award terms and conditions, the awarding agency must report the termination to SAM.gov Responsibility and Qualification (formerly FAPIIS).

If non-compliance issues affect multiple awards and termination of all awards to the recipient is not viable (e.g., programmatic needs cannot be met), the awarding agency should consider other actions, such as withholding payment, to try to achieve compliance across all affected awards. Termination remains an option.

The awarding agency may terminate an award at the request of the recipient or by mutual agreement between the awarding agency and the recipient. This action is often referred to as termination for convenience.

If a recipient requests termination, in whole or in part, the awarding agency should take the necessary action to comply with that request. This may include planning for continuation of services or other ongoing needs and/or considering a replacement award. If a recipient requests termination of only a portion of an award, the awarding agency may decide to terminate the remainder of the award if in the best interest of the program. When the awarding agency terminates the entire award, as requested by the recipient, it is considered a termination for cause and such termination is appealable by the recipient.

7.6: Initiating Government-Wide Suspension and Debarment

Government-wide suspension and debarment activities are used to safeguard federal funds by disallowing awards to organizations and/or their principals (also termed "individuals" for the remainder of this chapter) based on a lack of business honesty or integrity.

The term "suspension" in suspension and debarment has a different meaning than "suspending award activities". For purposes of this subsection, the definition of "suspension" is that provided in <u>2 CFR 180.1015</u>.

Awarding agencies may do business only with those organizations and provide funding for individuals that have a satisfactory record of business ethics and integrity. There are processes in place that:

• Awarding agencies must follow to identify organizations and individuals that do not have a satisfactory record of business ethics and integrity; and

• HHS must follow to afford due process if seeking to suspend or debar an organization or individual.

The government-wide suspension and debarment processes affect (or have the potential to affect) awarding agencies in multiple ways:

- Awarding agency may not make a new, renewal, non-competing continuation, or supplemental award to an organization that is suspended or debarred, whether because of action by HHS or another federal agency;
- Awarding agency may not knowingly provide funding to an entity to fund an individual (e.g., the principal investigator (PI) or project director (PD)) who is suspended or debarred, whether or not the individual's organization is suspended or debarred; and
- After award, if the awarding agency determines that, since the time of its original award, an organization or any of its funded individuals has been suspended or debarred, the awarding agency must take appropriate action concerning the ongoing award.

Each executive agency has a designated suspending and debarring official, who has the authority to impose suspension or debarment should cause arise. (See <u>2 CFR 180.930</u> and <u>180.1010</u>) Information on the suspension and debarment official (SDO) is available from the Office of Acquisitions on the <u>HHS website</u>.

Pursuant to <u>2 CFR 180.135</u> and <u>2 CFR 376.137</u>, only the HHS SDO has the authority to grant an exception to let a suspended or debarred organization or individual participate in a covered transaction. Awarding agencies must ensure that the suspension and debarment information is included in the System for Award Management (SAM).

A federal agency may debar an organization or any of its individuals for any of the following reasons:

- Conviction or civil judgment for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public or private agreement or transaction, violation of federal or state antitrust statutes, including those proscribing price fixing between competitors, allocation of customers between competitors, and bid rigging; commission of embezzlement, theft, forgery, bribery, falsification of data, or destruction of records, making false statements, tax evasion, receiving stolen property, making false claims, or obstruction of justice; or commission of any other offense indicating a lack of business integrity or business honesty that seriously and directly affects present responsibility (Source: <u>2 CFR 180.800 (a)</u>);
- Violation of the terms of a public agreement (including an award) or transaction so serious as to affect the integrity of an agency program, such as willful failure to perform in accordance with the terms of one or more public agreements or transactions; a history of failure to perform or of unsatisfactory performance of one or more public agreements or transactions; or a willful violation of a statutory or regulatory provision or requirement applicable to a public agreement or transaction; and

Other reasons, such as knowingly doing business with an ineligible organization as defined in <u>2 CFR 180.110(c)</u>, except as permitted under <u>2 CFR 180.135</u>; failure to pay a debt(s); violation of the provisions of the Drug-Free Workplace Act of 1988; or, any other cause of so serious or compelling a nature that it affects present responsibility.

Upon conviction or civil judgment, the standard of proof for debarment is met. However, in any other debarment action, the awarding agency must establish the cause for debarment by a preponderance of the evidence (<u>2 CFR 180.850</u>).

Additionally, for HHS, pursuant to <u>2 CFR 376.935</u>, any organization or individual excluded from participation in Medicare, Medicaid, and other federal health care programs under Title XI of the Social Security Act, 42 U.S.C. 1320a–7, 1320a–7a, 1320c–5, or 1395ccc, and implementing regulations at <u>42 CFR part 1001</u>, is prohibited from participating in all federal government procurement and non-procurement programs.

The length of a debarment is based on the seriousness of the cause(s) on which the debarment is based. Generally, debarment will not exceed three years (or five years if based on violation of the Drug-Free Workplace Act); however, if circumstances warrant, the HHS SDO may impose a longer or shorter period of debarment.

Debarment can be preceded by a suspension if immediate action is necessary to protect the public interest. A suspension generally may continue until the conclusion of legal or debarment proceedings that are initiated at the time of, or during, the suspension. However, if proceedings are not initiated during that time, a suspension may not exceed 12 months (with the possibility of a 6-month extension).

A non-compliance issue may be severe enough to warrant government-wide suspension or debarment of an individual or award recipient.

The awarding agency must refer suspension or debarment issues at this level to the Office of Recipient Integrity Coordination (ORIC) within the Office of Acquisitions, Assistant Secretary for Financial Resources (ASFR). While still an enforcement action, it has multiple facets and may involve various determinations in different phases of the process, including:

- Pre-award at the time of a new or renewal award as to whether an entity or any of its principals are currently suspended or debarred;
- Prior to award of a noncompeting continuation or supplemental award whether an entity or any of its principals has been suspended or debarred following the awarding agency's new or renewal award;
- Information on how to treat any ongoing awards if an entity has already been suspended or debarred;
- Information on how the recipient is complying with suspension and debarment requirements, if applicable; and

• Based on recipient's history with the awarding agency, including previous enforcement actions, specific award conditions, and other available information to recommend suspension or debarment of an entity or any of its principals.

7.7: Written Notifications of Enforcement Actions to Recipients

Recipients should be informed of the intention (initial notification) of the awarding agency to use enforcement actions, and the final decision (notification implementing the action) concerning the selection of the actions. Both notifications must be addressed in writing to the authorized organizational representative (AOR). If immediate enforcement action(s) must occur to protect public health or welfare or the interests of the federal government, an initial notification is not required.

The awarding agency must send the written notifications by certified mail, return receipt requested, or by other method that allows for confirming receipt of notification.

In the case of an immediate post-award suspension of award activities, the awarding agency notification must indicate whether the action will be followed by a termination or whether there is any expectation of corrective action by the recipient.

The notification of a proposed enforcement action must clearly specify the following:

- The enforcement action being proposed;
- The non-compliance or other reason for the proposed action and the statutory, regulatory, policy provision, or term or condition that is the basis for that determination;
- The award number of the potentially affected award(s);
- Corrective actions needed, as appropriate;
- The due date for the recipient's written response, including the information required (e.g., submission of delinquent reports, or corrective action plan), which generally is 30 days from the date of the awarding agency's written notification, but can be sooner for payment withholding or later for withholding of support;
- The potential consequences of continued non-compliance, including a notification that terminations for cause will be reported to SAM.gov Responsibility and Qualification; and
- The intended effective date of the enforcement action in the absence of a satisfactory response.

If the awarding agency does not receive a response from the recipient to its initial written notification, the awarding agency must proceed with the enforcement action. Prior to implementing the enforcement action, the appropriate grants official must notify the recipient in writing of the following:

- A summary of the initial notification letter, including the non-compliance issue and all relevant background and basis of the awarding agency decision, reference to the pertinent statutes, regulations, or other governing documents;
- A specific indication of the action the awarding agency is taking, its scope (e.g., full or partial termination), and the effective date;
- Award number(s) of the affected award(s);
- The due date for compliance for a temporary action such as withholding of payment or post-award suspension of award activities;
- The effect on the recipient's ability to incur reimbursable costs;
- The effect on financial and performance reporting (e.g., for a termination, the due date for the final FFR, performance, and other reports);
- The proposed adjusted funding amount, if a final amended Notice of Award (NoA) will be needed, if a recipient's appeal right has lapsed and no appeal has been filed or accepted;
- Any accounting instructions (e.g., for return of unexpended funds and due date); and
- Any appeal rights.

Chapter 8: Appeals

8.1: Post-Award Appeals

Appeals procedures differ depending on the nature and severity of the dispute, the financial assistance program or issue. Awarding agencies must attempt to promptly resolve disputes or issue final decisions in matters affecting the interests of recipients. Therefore, awarding agencies and recipients should consider resolving disputes using alternative dispute resolution (ADR) techniques, when feasible, to avoid a potentially lengthy appeal. ADR includes mediation, ombudsman services, and neutral evaluation. Any attempt at ADR or dispute avoidance should be undertaken in consultation with the Alternative Dispute Resolution Division of the Departmental Appeals Board (DAB) or the OGC.

For cases in which dispute avoidance or ADR efforts are unsuccessful and an appeal is made, final decisions should be issued as quickly as possible; however, those decisions adverse to the recipient should not be issued until it is clear the matter cannot be resolved through further exchange of information and views.

Appeals processes vary according to the type of grant program or issue. A Public Health Service (PHS) grant has a first-level appeal at the awarding agency level prior to being submitted to the DAB. Appeals for non-PHS grants and determinations by the Cost Allocation Services (CAS) are submitted directly to the DAB.

8.2: Public Health Service (PHS) Grants

The appeals procedures established by <u>42 CFR part 50</u>, subpart D address the Public Health Service (PHS) grants under the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Toxic Substances and Disease Registry, the Food and Drug Administration, and the Office of the Assistant Secretary for Health. For these recipients, a firstlevel appeal may be filed with the awarding agency as a preliminary process before submitting a formal appeal to DAB. As provided in <u>42 CFR 50.402</u>, the PHS grant appeals procedures apply to all types of grants other than block grants, which are covered by the appeals procedures specified in <u>45 CFR 96.52</u>. The awarding agency must comply in a timely manner with the requirements of <u>42 CFR part 50</u>, subpart D.

For the first-level appeal, the head of the agency, or their designee, shall appoint review committees to review adverse determinations made by officials for programs under their jurisdiction. DAB will determine whether a recipient has satisfied this prerequisite. Even as a second level of review, DAB provides *de novo* review, i.e., they do a complete review of the case and are not constrained by the other board's or official's decision.

8.3: Other Appeals

Appeals procedures for non-PHS and other types of programs are as follows:

- For other non-PHS programs, grant appeals must be submitted to DAB and follow procedures established in <u>45 CFR part 16 Appendix A</u> distinguishes processes for discretionary and non-discretionary grants.
- Appeals heard by the DAB also may arise from determinations by the CAS, related to cost allocation plans, negotiated indirect or facilities and administrative cost rates, and other rates.
- For any appeals reviewed by the DAB, the awarding agency must comply in a timely manner with the requirements of 45 CFR part 16 and requests by the DAB for information and documentation. The recipient has a right to a prompt resolution. In addition, awarding agency personnel must participate in hearings or other DAB activities, as requested.
- Unless otherwise specified by statute or regulation (e.g., instances where, the DAB issues a recommended decision that will not become final until affirmed, reversed, or modified by the Secretary), the DAB decision is the final administrative decision of HHS and cannot be appealed by either the recipient or the awarding agency to any other HHS office, official (e.g., the Secretary), or function. The DAB decision must be implemented by the awarding agency, whether the decision upholds the awarding agency's position or is adverse to the awarding agency.
- Any further recourse would be with the courts. The costs of pursuing an administrative appeal or court suit may be allowable as provided in the applicable cost principles.

8.4: Discretionary Grants

Under either the HHS or PHS grant appeals procedures, a recipient may appeal the following types of actions under discretionary grants (as listed in <u>45 CFR part 16, Appendix A</u> and <u>42 CFR</u> <u>50.404</u>) after receipt of a final written decision from the awarding agency, resulting in:

- termination, in whole or in part, of a grant for failure of the recipient to carry out the approved project in accordance with the applicable law and the terms and conditions of the award or for failure of the recipient otherwise to comply with any law, regulation, assurance, term, or condition applicable to the award;
- a determination that disallows a cost charged to the grant or that the recipient has otherwise failed to discharge its obligation to account for grant funds. This includes requiring return or off-set of funds already received, but does not apply to determinations of award amount, disposition of unobligated balances, or selection of an option for disposition of program income;
- a denial of a non-competing continuation award (withholding of support) under the period of performance system where the denial is for failure to comply with the terms of a previous award; and
- a determination that an award is void. (Note: This appeal right does not extend to situations where an organization does not "accept" an award through drawdown of funds or signature.)

These appeal rights are available whether the decision is made during the period of performance or after it ends, e.g., disallowance of costs resulting from a Single Audit received after closeout of an award.

Appeal rights do not extend to actions that are temporary or time-limited, e.g., withholding payments or post-award suspension. Nor do they extend to other types of decisions, e.g., disapproval of a prior-approval request, or a decision not to make a supplemental award requested by a recipient.

8.5: Non-discretionary Grants

DAB reviews the following types of final written decisions in disputes arising in HHS programs authorizing the award of non-discretionary grants:

- disallowances under Titles I, IV, VI, X, XIV, XVI(AABD), XIX, and XX of the Social Security Act, including penalty disallowances such as those under sections 403(g) and 1903(g) of the Act and fiscal disallowances based on quality control samples;
- disallowances in non-discretionary grant programs administered by the Public Health Service, including Title V of the Social Security Act;
- disallowances in the programs under sections 113 and 132 of the Developmental Disabilities Act;

- disallowances under Title III of the Older American Act;
- decisions relating to repayment and withholding under block grant programs as provided in 45 CFR 96.52 (Decisions resulting from repayment hearings under 45 CFR 96.51(a) may be appealed by either the state or the Department); and
- decisions relating to repayment and withholding under State Legalization Impact Assistance Grants as provided in <u>45 CFR 402.24</u> and <u>402.25</u>.

In some of the disputes related to non-discretionary awards, there is an option for review by the head of the awarding agency prior to appeal to the DAB. However, in contrast to the PHS grant appeals procedures for discretionary awards, this avenue does not have to be exhausted first.

8.6: Cost Allocation and Rate Disputes

DAB reviews final written decisions in disputes that may affect many HHS programs and awarding agencies because they involve cost allocation plans or rate determinations. These include decisions related to cost allocation plans negotiated with state or local governments and negotiated rates such as indirect cost rates, fringe benefit rates, computer rates, research patient care rates, and other special rates.

8.7: Final Written Decision

Each final written awarding agency decision must receive OGC concurrence. After that, decisions for discretionary awards must be signed by the appropriate grants official, or other management official determined by the awarding agency. For non-discretionary awards, the final written decision must be signed by the individual with the delegated authority to make such decisions. In all cases, the decision may be brief but, must include:

- a complete statement of the background and basis of the awarding agency's decision, including reference to the pertinent statutes, regulations, or other governing authorities;
- an identification of the award(s) affected or other indicator of the scope of the decision; and
- enough information to enable the recipient or a third-party reviewer to understand the issue(s) in dispute and the position of the awarding agency.

Chapter 9: Closeout of Awards

HHS follows the federal award closeout provisions at 2 CFR 200.344 rather than the HHS-specific closeout provisions at 45 CFR 94.381.

Upon the completion date of the award, recipients have 120 calendar days to liquidate all financial obligations and submit all financial, performance, and other reports required in the Terms and Conditions of the Award, or receive approval, with a fixed due date, for an extension

for the submission of a report(s) from the awarding agency. An award expires at midnight, local time for the recipient, on the completion date noted on the latest Notice of Award (NoA). If the award has been extended based on the expanded authority that allows for a unilateral 12-month no-cost extension, the award expires on the date on which the extended period of performance ends (as shown in the required notification from the recipient) (<u>2 CFR</u> <u>200.308(e)(2)</u>).

The closeout process for each HHS discretionary award must be completed no later than one year after the completion date of the period of performance unless otherwise directed by authorizing statutes.

Closeout may extend beyond one year if any of the following circumstances apply:

- There is a pending decision in an HHS appeal (whether to the awarding agency or to the Departmental Appeals Board),
- There is one or more unresolved monetary findings related to that award in an audit; or
- The awarding agency is a party to an open legal action.

The awarding agency may grant an extension for the submission of a report(s) provided a written request from the recipient with sufficient justification for warranting the extension is received by the awarding agency in an amount of time that they determine is adequate to process the request.

If the awarding agency does not receive acceptable final reports within the one-year time frame and determines that it cannot complete a closeout with the cooperation of the recipient, the awarding agency must complete a unilateral closeout. A unilateral closeout letter must be sent to the recipient by a means that allows for substantiation of the dates sent by the awarding agency and received by the recipient.

The awarding agency must also report the recipient's failure to comply with the terms and conditions of the award to the SAM.gov Responsibility and Qualification in accordance with <u>45</u> <u>CFR 75.212</u>. If the awarding agency decides that other enforcement actions are necessary, the type of action and its scope must be commensurate with the program needs and action(s) (or inaction(s)) of the recipient.

The awarding agency must ensure that, if applicable, appropriate information concerning the recipient was reported to the SAM.gov Responsibility and Qualification in accordance with <u>45</u> <u>CFR 75.212</u>.

Following closeout, the awarding agency must retain the entire official award file or archive it in accordance with HHS and awarding agency requirements and in a manner that allows access and retrieval of the file and its contents, when necessary.

The awarding agency must ensure that any additional requirements after the closeout, such as audits or program income, have been appropriately managed.

The following activities must be completed by the awarding agency:

- Receive and review all required final reports for completeness, accuracy, and acceptability. If upon review, reports are found to contain errors, omissions, or are otherwise not acceptable, they must be returned to the recipient for revision with a new due date for submission;
- Respond to a recipient's request for property or equipment disposition instructions, if applicable, consistent with the regulatory timeframe for response (see <u>45 CFR 75.318</u> <u>75.320</u>);
- Review the final cash balance on the award to ensure it is commensurate with project activities;
- Proactively communicate with PMSvc information relating to the status of the award including, as appropriate, notification of no-cost extension(s);
- Make any required funding adjustments and notify the recipient of any amount due;
- Take the necessary action to close the award in the Payment Management System (PMS) (i.e., generate a closed code [TC-059] as indicated under "Document Status") or other paying office system and the respective grant system;
- Appropriately document closeout actions in the official award file;
- Ensure that the award is closed out in the financial system;
- Perform unilateral closeout if a recipient has not submitted timely and acceptable final reports; and
- Collect any amounts determined, either at closeout or later, to be due the federal government, including costs disallowed in audit report(s) after closeout.

9.1: Financial Reconciliation Upon Completion of an Award

In performing the financial reconciliation, the awarding agency must ensure that the amount authorized for expenditure, the amount disbursed by the paying office, and the amount spent by the recipient are all reconciled.

Using the FFR, and other information as indicated, the awarding agency must review the following items:

- Unliquidated obligations: The recipient may not include any unliquidated obligations in the final FFR;
- Matching or cost-sharing requirements. Review and make any adjustments to the federal share based on actual, allowable costs after reviewing lines 10.i through 10.k of the FFR; and
- Cash disbursements.

If payments are made as advances, recognize an advance as an expense or reimbursement of expenditures within the same reporting period as the drawdown.

If payments are made as reimbursements, review and compare the latest SF-270 with the reported expenditures and unobligated balance and approve any final reimbursement payment amount due the recipient.

Adjustments to the federal funding amount may need to occur. In addition, the awarding agency should issue an amended NoA or make an appropriate closing entry in PMS or other payment systems to reflect the final authorized amount of federal funding.

9.2: Property Considerations

The disposition of property is not required as part of closeout. If a recipient continues to use the property after closeout, as permitted in <u>45 CFR 75.318</u>, <u>75.320</u>, and <u>75.321</u>, this will not affect the awarding agency's ability to close out the award. Specifics related to the disposition of federally owned property are outlined in <u>45 CFR 75.319</u>.

For any tangible personal or real property acquired or improved under the award, it must be determined whether:

- the recipient will continue to use the property after closeout;
- the recipient is requesting disposition instructions; or
- the awarding agency wants to exercise its right to transfer title; and
- any reimbursement due to the awarding agency.

If a recipient requests disposition instruction, the awarding agency must:

- have the recipient validate that the property has been disposed of as indicated;
- if applicable, ensure that the sales proceeds are credited in accordance with the terms and conditions of the award; and
- work with the cognizant awarding agency or federal property office to determine the handling of any property owned by the federal government.

All the above actions may be completed after closeout.

During and after closeout, the awarding agency must:

- Track the recipient's compliance with any continuing accountability requirements and associated reporting for the duration specified in the authorizing statute, program regulations, or terms and conditions of the award; and
- Determine the recipient's intent with respect to any inventions conceived or first actually reduced to practice under the award for research and research-related awards. Utilization report for patents and inventions are required after closeout, as specified in <u>37 CFR part 401</u>, and in the terms and conditions of the award.

9.3: Unilateral Closeout

The following actions must be taken if an awarding agency elects to close out an award unilaterally:

- Review the financial documents to determine discrepancies;
- Send a letter to the recipient(s) specifying, at a minimum:
- Awarding agency is unilaterally closing out the award based on non-receipt of acceptable final reports;
- Federal funding amount at which the awarding agency will close the award;
- For multiple-award reporting of advance payments, or for reimbursement payments, any reported discrepancies will be treated as disallowed costs; and
- Recipient is considered to be non-compliant with the terms and conditions of its awards and the awarding agency must report the recipient to the SAM.gov Responsibility and Qualification. The awarding agency may also consider the use of other enforcement actions in accordance with <u>45 CFR 75.371</u>.

Because unilateral closeout may result in an appeal by the recipient or determination of a debt, the awarding agency must coordinate a unilateral closeout letter with the cognizant finance/debt collection office(s), Payment Management Services (PMSvc), and the Office of the General Counsel, as necessary.

9.4: Closeout of an Award Program

There may be instances where an awarding agency is required to closeout an entire program, not just the individual awards. The required program closeout actions will depend on the rationale for discontinuing the program, and any explicit guidance provided by Congress, Office of Management and Budget, the HHS or awarding agency Office of Budget, and/or the Office of the General Counsel. This section assumes that the closeout of one or more programs does not constitute discontinuation of a grants management office's entire portfolio. The grants management office will work in conjunction with other divisions within the awarding agency, but its focus will be the integrity of the award's files, and the awards management processes.

Programs may be closed out for the following reasons:

- Authorizing legislation for the program expires and is not renewed by Congress or continued by appropriation;
- Congress provides no appropriation for the program, even if the authorizing legislation has not expired;
- A court ruling requires that the program be discontinued; or
- Other circumstances, e.g., time-limited programs, such as those under the American Recovery and Reinvestment Act (Recovery Act or ARRA).

Once the program closure(s) and their final dates have been established, the Grants Management Office will be responsible for the following, as applicable:

- Federal Assistance Listing: archive, or provide the necessary information to identify the closure of the program, in the Federal Assistance Listing, or work with the office under whose responsibility falls;
- Existing awards under the closed program: Assess the impact on existing awards, as applicable:
- Existing awards may be allowed to continue until their scheduled completion date;
- The awarding agency may be precluded from providing additional funding under existing awards, effectively withholding support at the end of the current budget period;
- There may be instances, such as those for the Recovery Act, which require that no awards go beyond a specified date. In those instances, and awarding agency may be precluded from providing additional time or funding for an award;
- Closeout all awards as provided in the GPAM; and
- Ensure that the designated individual(s) remain responsible for tracking compliance with continuing accountability requirements.
- Files: The official award files must be treated in the same manner as for any other closed out award;
- Delegations of authority: The Chief Grants Management Officer (CGMO) must rescind any GMO delegations pertaining to the closed programs, as necessary;
- Notifications: The awarding agency must notify the following, as applicable:
- Affected recipients to ensure that they are aware of the cessation of the program, and any details which affects their awards.
- The Division of Grants (DG), the servicing grant system, Payment Management Services (PMSvc) and any other paying office to ensure that information about the program is modified and deleted, and any changes based on the volume of program transactions are adjusted to recognize the elimination of this workload;
- Department Appeals Board (DAB) about the circumstances surrounding the discontinuation of the program if the awarding agency believes recipients may try to appeal any decisions; and
- Awarding agency webmaster to ensure that any publicly accessible web sites containing information about the discontinued program are managed accordingly;
- OMB Compliance Supplement, <u>45 CFR part 75, appendix XI</u> (previously known as the Circular A-133 Compliance Supplement), in conjunction with DG, to determine at what point expenditures by recipients under the closed program no longer require coverage;

- Support services contracts: The awarding agency must determine the effect that the closed program will have on any support services contracts, whether or not they also serve other awarding agency programs. The awarding agency will work with the contracting officer's representative and the cognizant contracting officer to determine what, if any, actions (e.g., reduce the scope of current contracts, decide not to exercise future options) need to be taken; and
- Other: The grants management office must work closely with the awarding agency Budget Office to reconcile any aggregate program expenditures, and any related costs.

Chapter 10: Audits

10.1: Purpose

The purpose of an audit is to provide the federal awarding agency with information about the management of federal funds received by an award recipient. Several types of audits are discussed in this chapter.

The U.S. Department of Health and Human Services (HHS)-wide regulations on single audit and review requirements are located at <u>45 CFR part 75, subpart F</u>.

Government-wide auditing standards and guidance can be found in the Government Accountability Office's (GAO) Generally Accepted Government Auditing Standards (GAGAS), also known as the <u>Yellow Book</u>.

10.2: Single Audit

A single audit is an organization-wide audit in which the auditor samples and tests program and management practices, in accordance with GAGAS, the Uniform Guidance, and the Compliance Supplement to determine whether the organization has complied with the terms and conditions of selected awards.

All awarding agencies must ensure recipients are aware of the single audit requirements that apply to their organization and their responsibilities related to audits of subrecipients.

10.2.1: Key Roles and Partners

Awarding agencies must work closely with other HHS offices that have responsibilities related to audits. The following are key roles within the Assistant Secretary for Financial Resources (ASFR) office and the awarding agencies that are pertinent to the audit process:

ASFR office key roles include:

- <u>Single Audit Accountable Official (SAAO)</u> HHS Assistant Secretary for Financial Resources.
- Office of Grants, Division of Policy, Oversight, and Evaluation (DPOE) Director Manages Compliance Supplement update; and
- <u>Audit Resolution Division (ARD) Director</u> Manages all other Key Management Single Audit Liaison (KMSAL) responsibilities.

Additionally, at the awarding agency level, there is an audit resolution liaison who coordinates with other audit personnel.

10.2.2: Entities Required to Have a Single Audit

Single or program specific audit requirements apply to any non-federal entity, whether recipient or subrecipient, which expends \$750,000 or more in federal awards in its fiscal year. Single or program-specific audits must meet the requirements of the Single Audit Act, <u>45 CFR</u> <u>75, subpart F</u> – Audit Requirements, and applicable sections of the Compliance Supplement.

By policy, the single audit standards are applied to foreign and international organizations as follows:

- Foreign and international organizations that, in a given recipient fiscal year, spend an amount equal to or exceeding the single audit threshold must conduct either a financial-related audit or a single audit.
- Based on a risk assessment, the awarding agency may specify in the terms and conditions of award that the awarding agency will conduct any audit as deemed necessary.
- Domestic recipients with foreign components must comply with the single audit requirements.

10.3: Commercial Recipient Audit Requirements

Commercial recipients and subrecipients have the following options regarding audits:

- An award received under only one HHS program requires a financial-related audit of that particular award, in accordance with Government Auditing Standards as defined in the <u>Government Auditing Standards</u>, (Yellow Book). Awards received under multiple HHS programs require a financial related audit of all HHS awards in accordance with Government Auditing Standards; or
- Perform an audit that meets the requirements of <u>45 CFR part 75, subpart F</u>.

Commercial recipients that receive less than \$750,000 in HHS awards in a given year are exempt from requirements for a non-Federal audit for that year (<u>45 CFR 75.501(j)</u>). These recipients must still be able to provide records to awarding agencies upon request.

In the case that a pass-through entity has a for-profit subrecipient on an award, the pass-through entity is responsible for establishing requirements to ensure compliance by the for-profit subrecipient (<u>45 CFR 75.501(h)</u>).

Note that audits for commercial recipients are not submitted to FAC. Rather, commercial recipient audits are submitted directly to the HHS Audit Resolution Division (ARD), which tracks completed audits through the Single Audit Resource Center (SARC) database.

10.4: Audit Costs

The cost of a single audit is an allowable cost, which generally is covered by the entity's negotiated indirect cost rate because of the organization-wide nature of the audit.

Organizations that do not reach the single audit threshold in one or more years must maintain recipient records for review or audit by federal officials or others acting on behalf of the awarding agency.

10.5: Program-Specific Audits

An auditee may undergo a program specific audit if federal award expenditures occurred under only one federal award program.

A recipient that expends \$750,000 or more under a single program during its fiscal year can opt for the program-specific audit.

An auditee may elect a program-specific audit when:

- Expenditures are under only one federal program; and
- The federal program's legislation, regulations, and award terms and conditions do not require a financial statement audit of the recipient.

Recipients of federal research and development (R & D) programs cannot choose to conduct program-specific audits, unless:

- All expenditures were from the same federal agency; or
- All expenditures were from the same federal agency and the same pass-through entity, for subrecipients; and
- The federal agency or pass-through entity approves of a program-specific audit in advance.

10.6: Awarding Agency Responsibilities

10.6.1: Audit Requirements

The awarding agency must clearly specify audit requirements in the terms and conditions of the award (in the full terms and conditions text) or incorporate the requirements by reference (meaning the award terms and conditions clearly mandate compliance with requirements that are spelled out in another document that is cross-referenced in the terms and conditions).

The requirements must state the consequences of not submitting audit reports in a timely manner and the pass-through entity's responsibility to inform their subrecipients of these requirements. Additionally, all awarding agencies must ensure auditees and auditors adhere to the requirements outlined in <u>45 CFR 75.508-75.512</u> (auditees) and <u>45 CFR 75.514-75.520</u> (auditors); and any other awarding agency-specific requirements.

Awarding agencies must:

- Ensure, through monitoring and evaluation, that recipients:
- Keep accurate financial records;
- Take action on any past audit findings (see <u>45 CFR 75.508</u>);
- Have internal controls established to ensure compliance with the terms and conditions of awards; and
- Safeguard sensitive information (see <u>45 CFR 75.303</u>);

- Determine the availability of the most recent required audit report and review it for possible effect on the pending and current awards;
- Designate an audit resolution liaison; and
- The appropriate awarding agency official must delegate the authority to sign management decision letters to the audit resolution liaison.

10.7: Single and Program-Specific Audit Report Submission

10.7.1: Federal Audit Clearinghouse (FAC)

The FAC operates on behalf of the US Office of Management and Budget (OMB) and is responsible for receiving, processing, and distributing Single Audit packages. The FAC manages a database of completed audits that is available to federal agencies as well as the public.

10.7.2: Use of the Audit Report

Awarding agencies must review current and previous audit reports before making any type of award as part of pre-award risk assessment, and at least annually as a regular part of monitoring and closeout. A pass-through entity must access and review the audits from FAC before awarding any subawards.

10.7.3: Recipients with Delinquent Audit Reports

The single audit report is delinquent if a recipient does not submit the report within 30 calendar days after receipt of the auditor's report(s) or within 9 months of the end of the auditee's fiscal year, whichever is earlier. The awarding agency or designated lead awarding agency must follow up with the recipient to obtain the delinquent report and document the corresponding award(s) file.

Delinquent audits are assigned to a lead awarding agency based on the level of funding. In deciding the next steps of a delinquent audit that affects other awarding agencies, the lead awarding agency is responsible for coordinating with other affected awarding agencies and offices as necessary. All other awarding agencies shall adhere to the lead awarding agency's decision with respect to their own awards to the recipient.

Awarding agencies may impose specific award conditions and/or sanctions as remedies for noncompliance if a recipient fails to comply with audit requirements (see <u>45 CFR 75.371</u>).

Awarding agencies may consult <u>Audit Resolution Division (ARD)</u> of the HHS Office of Finance to seek additional guidance.

10.8: Audit Findings

An audit finding is an instance of non-compliance identified by an auditor as per <u>45 CFR</u> <u>75.516(a)</u>. Audit findings are generally in response to non-compliance with statutes, regulations, or terms and conditions of an award. Types of audit findings include the following:

• <u>Monetary audit findings</u> – An audit report cites a questionable cost.

- <u>Management findings (procedural findings)</u> There are significant deficiencies in internal controls as well as material noncompliance with laws, regulations, contracts, or award terms and conditions.
- <u>Repeat findings</u> A finding that was identified in the previous single audit report that has not been corrected.

Awarding agencies must work closely with recipients to ensure optimal resolution of audit findings.

Corrective actions may be completed over a timeframe acceptable to the audit resolution liaison. If the corrective action plan calls for a modification to an award(s), that action must be taken by the appropriate grants official.

Subsequent audits can be used to determine if recipients have appropriately implemented corrective actions.

An award may be closed out prior to the submission of the Single Audit submission covering the final year of that award. If an audit report submitted after closeout of an award identifies questioned costs or other findings that would affect the closeout, the awarding agency must act on the findings and recover funds if there are disallowed costs.

10.9: Audit Resolutions and Management Decisions

10.9.1: Audit Resolution

Audit resolution is defined as the awarding agency's follow-up with recipients on audit findings to ensure appropriate and timely corrective actions are taken.

10.9.2: Cooperative Audit Resolution

Cooperative audit resolution is used as a structured technique that brings together the appropriate stakeholders that could contribute to discussions about single audit findings and proposed corrective actions.

The awarding agency must correspond with the recipient during the audit resolution process.

10.9.3: Management Decisions

10.9.3.1: Responsibility for Management Decisions

The awarding agency must issue a management decision on all assigned audit findings within six months of the date the FAC accepts the single audit report package. Pass-through entities must issue a management decision for findings on subawards. For cross-cutting single audit findings (findings that apply to more than one program and thus require involvement of multiple awarding agencies), the Audit Resolution Division (ARD) shall work with affected awarding agencies to issue a management decision.

10.9.3.2: Requirements for Management Decisions

A management decision must clearly state:

• The finding reference number;

- Whether or not the audit finding is sustained and the reasons for the decision; and
- Whether the recipient must repay any disallowed cost(s).

A management decision should specify:

- A timetable for corrective action; and
- Describe the process for appealing a decision when an awarding agency disallows costs.

Failure by an awarding agency to determine the disallowed amount of questioned costs shall not delay a management decision letter beyond the required six-month timeframe.

10.9.3.3: Disallowed Costs

Determinations of cost allowability and deficiencies in management systems resulting from audit findings must be based on the applicable statute(s), regulations, cost principles, and other terms and conditions of the award.

The basis for the determination of a disallowed amount must be adequately documented.

Awarding agencies, through monitoring and evaluation, must ensure recipients reimburse for all disallowed costs. The responsibility to establish a debt continues even if the audit covers an award(s) that was completed or terminated prior to receiving the audit report. The awarding agency shall make, in writing, the first demand for payment no later than 30 days after the official determination that the debt exists and is owed. Only the official with the delegated authority to determine a debt on behalf of the awarding agency is authorized to issue a final determination letter.

Disallowed amounts are federal debts subject to the HHS claims collection regulation at <u>45 CFR</u> <u>part 30</u>. See the Debt Collection chapter of GPAM. The collection of debts based on disallowed amounts may be completed over a timeframe acceptable to the audit resolution liaison.

10.10: Compliance Supplement

The Compliance Supplement helps auditors understand the federal program's objectives, procedures, and compliance requirements subject to the audit as well as audit objectives and suggested audit procedures for determining compliance with the requirements.

The latest Compliance Supplement is found on Whitehouse website for the <u>Office of Federal</u> <u>Financial Management.</u>

10.10.1: Program-Specific Compliance Supplements and Updates to Supplements

After an agreement is made to include a program in the Compliance Supplement, the awarding agency is responsible for drafting the program-specific compliance supplements for inclusion in the annual update of the Compliance Supplement.

Awarding agencies are responsible for:

- Determining the need for changes to program supplements during subsequent updating cycles;
- Justifying changes to program supplements;
- Providing information to the KMSAL (OG/DPOE) on a schedule established by the KMSAL (OG/DPOE); and, as applicable; and
- Recommending removal of programs from the Compliance Supplement.

Awarding agencies must have a Compliance Supplement liaison who coordinates with program officials within the agency to compile required data and documentation for consideration. The liaison works closely with the DPOE Compliance Supplement coordinator and is responsible for reviewing programs to determine whether they require some additional compliance guidance based on the type of funding and visibility.

The program-specific supplement must be prepared in accordance with Office of Management and Budget (OMB) guidelines and must be updated annually on the schedule specified by the KMSAL (OG/DPOE). OG/DPOE provides schedules to awarding agencies that are directly dependent on OMB guidance. Therefore, if OMB changes the timing of the release of the Compliance Supplement process or their guidance or instructions, then HHS will also have to adjust its timeframes, guidance, and process.

The update process for the Compliance Supplement has three phases, based on OMB guidance:

- Phase 1 The DPOE Compliance Supplement coordinator contacts the awarding agency's Compliance Supplement liaison and if the liaison knows which programs will be included in the Compliance Supplement, the liaison should obtain the names and contact information of the program officials.
- Phase 2 HHS determines for each program in the previous year's Compliance Supplement whether changes are required or if minor edits, significant rewrites, or deletion are required. Additionally, HHS determines whether they should add new programs to the Compliance Supplement.
- Phase 3 HHS submits the narrative drafts and their corresponding cover pages, checklists, and supporting documentation to the OMB for inclusion in the new Compliance Supplement document.

10.11: Other HHS Audits and Requirements

Other entities that conduct audits and related oversight or audit-related activities include the following:

 HHS Office of Inspector General (OIG) conducts and supervises audits, investigations, evaluations, and inspections audits to examine the performance of HHS programs and/or recipients receiving federal funds and provides independent assessments of HHS programs and operations. • Government Accountability Office (GAO) is the audit, evaluation, and investigative arm of Congress. GAO conducts audits on federal programs and policies to provide accountability improve the performance and accountability of the federal government and determines whether awarded entities are spending federal funds efficiently and effectively. GAO studies are initiated at the request of congress, as mandated in public law or congressional committee reports, or at the discretion of the Comptroller General of the United States.

10.12: HHS OIG and GAO Roles

10.12.1: HHS OIG Audit Roles

The HHS OIG may audit recipients, awards, and programs and operates based on the following offices and functions (see <u>www.oig.hhs.gov</u> for more information):

- The Office of Audit Services (OAS) conducts independent audits of HHS programs and/or HHS recipients and contractors. These audits examine the performance of HHS programs and/or recipients in carrying out their responsibilities and provide independent assessments of HHS programs and operations.
- The Office of Evaluation and Inspections (OEI) conducts national evaluations of HHS programs from a broad, issue-based perspective. The evaluations offer practical recommendations to improve the efficiency and effectiveness of HHS programs, with a focus on preventing fraud, waste, and abuse.
- The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries.

10.12.2: GAO Audit Roles

The GAO conducts audits to improve the performance and provide accountability to federal programs to determine whether awarded entities are spending federal funds efficiently and effectively. GAO audits usually target a specific issue in a program or a particular grants management function of the awarding agency.

10.13: HHS OIG and GAO Interplay, Collaboration, and Lifecycle Timeframe

10.13.1: HHS OIG and GAO Interplay

Awarding agencies must have a GAO and HHS OIG liaison(s) to coordinate with the GAO/OIG, Assistant Secretary for Legislation (ASL), and other awarding agencies to respond to inquiries quickly and thoroughly.

The Assistant Secretary for Legislation (ASL) serves as the HHS's audit liaison with GAO. If there are fewer than three awarding agencies involved in an engagement, the ASL may delegate interactions with GAO to the respective agency liaisons. Agency liaisons develop, review and coordinate responses to requests for information, reports and, where applicable, findings. If

three or more awarding agencies are involved, then the ASL plays a coordinating role in the engagement. The HHS OIG and GAO often request official government records and documents associated with their audits. Awarding agencies must provide auditors and reviewers with the information requested to fulfill its statutory responsibilities in an expeditious manner while respecting HHS and executive branch policy and operational requirements.

10.13.2: Collaboration

An OIG or GAO audit is a collaborative effort with awarding agencies and may result in resolution actions to address concerns. Awarding agencies must ensure these actions are consistent with law, regulation, and policy and include written justification containing, when applicable, the legal basis for decisions not agreeing with the audit recommendation. Prior to an awarding agency planning any additional audits, the awarding agency must review existing audits. Additional audits must build on, but not duplicate, audit work already completed. Per <u>45</u> <u>CFR 75.503</u>, if the awarding agency conducts or arranges for additional audits, the awarding agency must arrange for the full cost of those additional audits, consistent with other applicable federal statutes and regulations.

ASFR's Office of Finance (OF), Division of Payment Integrity Improvement (DPII) tracks all OIG and GAO engagements across HHS. The Assistant Secretary is the designated audit follow-up official for HHS per <u>OMB Circular A-50</u>.

10.13.3: Engagement Lifecycle Timeframe

The timeframes for OIG and GAO audit reviews vary based on the scope and source requirements of the audit(s) with the following engagement lifecycle used to conduct the audits:

- <u>Start notice</u> Otherwise known as the notification letter, the official notification from the GAO or OIG of an audit review. The notification includes the scope, objectives, and, potentially, the source of the audit/evaluation engagement. If necessary, OIG may reach out for a pre-notification meeting to help with scoping their audit.
- <u>Entrance conference</u> The entrance conference allows the GAO or OIG to explain the review/evaluation, including the timeframe, and gather preliminary information that may shape the audit or review.
- <u>Data gathering</u> This work is the main bulk of activity and includes data gathering related to the scope and objectives of the review or evaluation. Data gathering can be accomplished through document requests and/or interviews.
- <u>Exit conference</u> The exit conference provides an opportunity to review the statement of facts or preliminary draft report and to provide final information to the GAO or OIG if necessary.
- <u>Draft report</u> The draft report is the last opportunity for the awarding agency to review and comment on the work of the GAO or OIG before publication of the work. The awarding agency can provide both general and technical comments on the draft report. General comments are included in the published report.

- <u>Final report</u> The final report (or in some cases, a summary) is publicly available. If there are no recommendations for the awarding agency, the report is closed.
- <u>Follow-up</u> If there are recommendations, the awarding agency is responsible for following up with the GAO or OIG to close out (either as implemented or unimplemented) the recommendations

Chapter 11: Exceptions

Formerly known as deviations, exceptions are instances when awarding agencies deviate from HHS policy or regulation for a justifiable reason. Awarding agencies should use exceptions only after a thorough risk analysis. When conducting a risk analysis, an awarding agency should examine the impacts of the contemplated exception for HHS, the awarding agency, the program, and potential recipients. Under no circumstances may an exception override a statutory or regulatory requirement unless the statute or regulation expressly provides such flexibility.

Before seeking approval for an exception, and in addition to the risk analysis, awarding agencies are encouraged to thoroughly review whether the needed flexibility is already allowed in the statute, regulation, or policy, or whether an alternative approach (e.g., a change to the program design) could yield the intended outcome.

11.1: Circumstances That Are Not Exceptions Include:

- Applying less restrictive requirements on a class basis to small awards where the federal share for each award is not expected to exceed the current simplified acquisition threshold per award for the budget period (see the Post-Award section for more information on the threshold);
- Applying one or more expanded authorities on a class basis as provided in <u>45 CFR part</u> <u>75</u>;
- Determining, on a class basis, the types and required frequency of financial and progress reports;
- Applying more restrictive requirements by using specific award conditions for a single award, as needed and at any point during the life of the award, in accordance with <u>45</u> <u>CFR 75.207</u>;
- Choosing a program income alternative based on a project-by-project assessment of potential income;
- Choosing an award payment method; or
- Applying a specific statutory requirement that differs from the requirements of the HHS awards administration regulations or policies.

11.2: Limited Competition Exceptions

To encourage equity in competition, HHS policy expects awarding agencies to maximize competition. However, under certain circumstances, awarding agencies may limit competition to less than all statutorily eligible entities or to a single source.

Exceptions to maximum competition are permitted when the:

- U.S. President or HHS Secretary declare a disaster or emergency;
- HHS Secretary declares a public health emergency;
- Director or direct report of an awarding agency (such as the CGMO), provides approval via a written communication that demonstrates the awarding agency established justified programmatic need to award a single source instead of maximizing competition;
- HHS Deputy Assistant Secretary for Grants, or their direct report, provides approval via a written communication that demonstrates the awarding agency established justified programmatic need for a limited competition approach; or
- Unsolicited request for funding meets all requirements described below in Unsolicited Request for Funding Exception.

The appropriate approving official as indicated below must approve the exception to maximum competition prior to the awarding agency publishing an associated NOFO.

Limiting competition may be a permissible policy choice when a statute or regulation requires broad eligibility and specific, identifiable programmatic or policy needs cannot be addressed through other mechanisms; e.g., criteria that are reviewed and scored and other funding considerations. Consult with the Office of the General Counsel to assess the risk of challenge.

An awarding agency is not required to get an exception if it is initiating supplements to a limited pool of existing recipients that were initially awarded as part of a competition, when the supplemental funding is offered to all recipients in that cohort, and where there is no change to the scope of the awards. For example, an exception would not be required for a NOFO competition geared towards existing recipients of a current award for a second award that carries out the next phase of a project.

11.3: Exception Request and Approval Policy

This section covers the framework for the request and approval policy for all exceptions, including limiting competition. More information on other types of exceptions mentioned in the framework will follow this section.

Awarding agencies should only request exceptions through the appropriate channels, as described below. Note that who must approve an exception depends on the level and type of exception requested, and that if an exception is approved, awarding agencies must maintain

documentation of their request and the approval in the official award file of each affected award.

11.3.1: Awarding Agency Head Approvals

The awarding agency head, or CGMO may approve the following exception:

• Sole-source (e.g., only one entity is qualified to carry out the award)

11.3.2: Awarding Agency Chief Grants Management Officer (CGMO) Approvals

The CGMO or higher may approve the following exceptions:

- With delegated authority from the awarding agency head, single-source awards (more than one entity may be qualified, but only one is invited to apply (such as with a replacement award) or one entity submits an unsolicited application); and
- Single case exceptions, unless prohibited by regulation.

11.3.3: HHS Office of Grants (OG)/Division of Policy, Oversight, and Evaluation Approvals

An awarding agency must submit a formal exception request to the Division of Policy, Oversight, and Evaluation (DPOE) when an awarding agency seeks to:

- Issue policy, guidance, or terms and conditions that alter HHS grants policy;
- Use full funding for all awards with periods of performance that exceed 36 months
- Limit maximum competition for a Notice of Funding Opportunity (NOFO);
- Administer class exceptions;
- Receive exceptions from government-wide or HHS regulations. For exceptions to government-wide regulations, where allowed, DPOE must make the request of OMB on behalf of HHS and the awarding agency(ies);
- Receive exceptions that support innovative program designs. The innovative design must apply a risk-based, data-driven framework that alleviates select compliance requirements and hold recipients accountable for good performance. OG must make the request of OMB on behalf of the awarding agency(ies). <u>See 2 CFR 200.102(d)</u>; or
- If a class exception decision will impact budget forecasting, the awarding agency must confer with the OPDIV and ASFR OB regarding the budgetary impact and include a statement affirming this occurred in the official exception request.

11.3.4: Implementation of Approved Exceptions

- If an exception request requires language in a Notice of Funding Opportunity (NOFO) or an award term or condition, the awarding agency will not publish either the NOFO Forecast or NOFO until the approving authority approves.
- The awarding agency/applicant/recipient may not engage in the activity for which the exception is sought until the exception is approved in writing.

- Awarding agencies must apply class exceptions consistently to all awards as described in the approval. If a class exception decision will impact budget forecasting, the awarding agency must confer with the OPDIV and ASFR OB regarding the budgetary impact and include a statement affirming this occurred in the official exception request.
- Finally, if the program has sought the same or similar request in the past, the awarding agency should consider submitting a legislative proposal to allow for the change or needed flexibility, rather than continuing to manage the program through exceptions.
- If awarding agencies want to submit such a legislative proposal, they should refer to <u>OMB Circular A-19</u>, *Legislative Coordination and Clearance*, for instructions on the timing and preparation. A well-written legislative proposal expedites the review process and enables departmental officials, the Secretary, the OMB, and congressional staff to make informed decisions. These proposals must be specific, succinct, and persuasive.
- The proposal should: (1) describe the current practice/situation and how the current law could be improved to enhance the performance of the program or administrative operation; (2) explain why an administrative remedy is not warranted or feasible; and (3) discuss the specific consequences of changing the law (e.g., what programs would benefit and any potentially negative consequences). If supporting data would provide further evidence of the need for a change in the law, it should succinctly be incorporated into the proposal or submitted as a brief attachment.

11.4: Additional Exception Types and Requirements

11.4.1: OMB Innovative Program Design Exception

To allow for innovation, <u>2 CFR 200.102 (d)</u> and <u>OMB Memorandum 13-17</u> allow federal awarding agencies to request exceptions in support of innovative program designs that apply a risk-based, data-driven framework to alleviate select compliance requirements and hold recipients accountable for good performance.

The innovative outcome-focused award design models described in <u>OMB Memorandum 13-17</u> include Pay for Success, tiered-evidence awards, Performance Partnerships and Waiver Demonstrations, and using competitive awards to promote use of evidence in formula awards. The goals for these models include encouraging a greater share of funding to support approaches with strong evidence of effectiveness and building more evaluation into award-making so the government keeps learning more about what works. In addition to these specific models, M-13-17 also encourages federal agencies to pursue other strategies to increase cost-effectiveness in high-priority programs.

11.4.2: Sole Source Award Exception

A sole source approach is permitted when only one entity is qualified to carry out the award. A sole source exception must be approved by the head of the awarding agency or direct report.

In addition to all required documentation listed below as part of the single source justification, the sole source justification must also include the following:

- Intended award instrument and rationale for any change in award instrument from a prior award.
- Name of the intended recipient.
- Basis for the program office judgment that the named entity is the only entity that can carry out the project.
- Qualifications of the intended recipient and evidence supporting the conclusion that they are the only entity that can carry out the project.
- Whether the funded activity is a new activity or a continuation of an ongoing activity, and if ongoing, whether activity has been conducted by the intended recipient or another organization.

Although objective or merit review and scoring is not required for a sole-source award, awarding agencies may choose to conduct a review and must conduct a pre-award risk evaluation used for similar discretionary programs in accordance with 45 CFR 75.205. HHS awarding agencies should also request an application and ensure it is of a significant enough completeness and quality to ensure the recipient can be held accountable for achieving the goals of the project.

11.4.3: Single Source Award Exception

A single source award requires written justification to solicit an application from a single source when the awarding agency can justify it is in the best interest of the public and/or programmatic need. The justification must be approved by the Awarding Agency Head or a designee who has responsibility for grants management functions.

The single source award justification should include:

- Program title, Assistance Listing (AL) Number, and statutory authority for the project;
- Purpose of the award (e.g., research or services), if not apparent from the statutory authority or AL number;
- Description of the project;
- Proposed period of performance and anticipated award amount;
- Intended award instrument (grant or cooperative agreement) and the rationale for any change in award instrument from a prior award;
- Name of the intended recipient;
- Name of the Program Officer (PO); and,
- The basis for the program office's judgment that the named entity is the only entity from which it should request an application. This part of the determination must address all applicable considerations, including:
- the timing of the project;

- the qualifications of the organization or specified individuals that may be involved;
- prior or ongoing relationships with the intended recipient;
- whether the activity to be funded is a new activity or a continuation of an ongoing activity, and, if the latter, whether the ongoing activity is with the intended recipient or another organization;
- if the justification is based on the unique qualifications of an organization or individuals to carry out the specified project, it must include evidence supporting that conclusion (e.g., journal articles, conference proceedings, Web search).

11.4.4: Single Source Justifications for Multiple Awards

In some situations, the awarding agency may prepare a single source justification that covers multiple single source awards. For example, if an awarding agency plans to make an award to a foreign entity when only one entity in a country can meet the requirements of the program, and the awarding agency will make similar awards in multiple countries, it must be treated in accordance with the single source application requirements of this section.

Each period of performance requires a separate justification. For example, if an awarding agency awarded the initial period of performance on a single source basis, the program office must receive approval to solicit a renewal application on a single source basis.

The written justification must include sufficient information to allow those reviewing it to decide. (Refer to required documentation for all requests above.)

11.4.5: Public Notice for Single and Sole Source Awards

An awarding agency must publish a public notice for each single or sole source award in the *Federal Register*, a public press release, or the NIH Guide for Grants and Contracts. The approved justification will serve as the basis for the program office to prepare the notice. An awarding agency must publish the notice concurrently with the expiration of the congressional liaison office and appropriation notifications, or immediately. The one exception is for emergency awards for which the awarding agency must publish the notice as far in advance as possible but no later than concurrently with award issuance.

The notice must include at least the following:

- recipient's name;
- purpose of the award;
- amount of the award;
- approved period of performance;
- basis for the award; and
- name and contact information of the cognizant awarding agency official.

11.4.6: Emergency Award Exception

Although an emergency award is one that cannot be planned and applies to declared national or public health emergencies, the awarding agency program office should provide its grants office as much advance notice as possible of their intent to solicit such an application for such an award and discuss, among other things:

- The feasibility of meeting the emergency need through a supplement to an ongoing award(s) rather than a new award(s);
- Any required exceptions from the pre-award process;
- Publication of forecast as early as possible to maximize public notification; and
- The planned funding approach and period of performance, which should be consistent with the nature of the identified emergency (for all emergency awards).

The following requirements also apply to emergency awards:

- An awarding agency may allow applicants 30 calendar days or fewer to prepare the application. The awarding agency must keep documentation on file justifying the shorter application time frame;
- The applicants must adhere to the established deadline for submission unless the GMO authorizes an extension;
- The applicants must use Office of Management and Budget (OMB)-approved application forms, as specified by the awarding agency; and
- The applications must undergo merit review, unless merit review is not required by statute, or if the Chief Grants Management Officer (CGMO), or other official responsible for the merit review function, determines that it is not feasible to perform merit review. In that case, an alternate form of review is acceptable. Documentation of the decision not to conduct a merit review must be placed in the official award file.

When soliciting an application on an emergency *single-source* basis, an awarding agency:

- Is not required to publish a NOFO;
- Does not have to require the applicant submit its application through Grants.gov; and
- May provide advice and assistance to the applicant during the application preparation phase.

Along with all information in the Required Documentation portion of this section, awarding agencies must include the following in their written justification:

- Nature of the emergency, including its scope and duration;
- Potential need for additional related single-source awards in out years, and whether those potential out year funds would be on an emergency or a non-emergency basis; and

• A copy of the presidential or secretarial emergency/disaster declaration/announcement and, if applicable, an approved decision memo.

11.4.7: Congressionally Directed Funding Exception

A Congressional Directive is an authorization act or appropriations act that requires HHS to make an award(s) to a named recipient(s) for a particular program, project, activity, or geographic area(s). Congressional Directive awards are also defined as discretionary awards made under the Congressional Directive language.

Awarding agencies must follow Congressional direction for a project only when included in statute or incorporated by reference in statute. Therefore, an awarding agency does not have to conduct a merit review and scoring is not required. A Congressionally directed project must meet all requirements other than competition that apply to HHS awards unless otherwise stated in law.

Awarding agencies may choose to conduct a review and must conduct a pre-award risk evaluation used for similar discretionary programs in accordance with <u>45 CFR 75.205</u>. Awarding agencies should also ensure applications are of a significant enough completeness and quality to ensure the recipient can be held accountable for achieving the goals of the project.

For more information on identifying Congressional Directives in an appropriations act see <u>Executive Order 13457</u>.

11.4.8: Non-Statutory Congressional Guidance Exception

In accordance with <u>Executive Order 13457</u>, if a Congressional report includes language that appears to be non-statutory congressional guidance, the awarding agency must determine its options in consultation with the awarding agency Budget Office and the Office of the General Counsel (OGC), as appropriate. If the awarding agency decides to make an award pursuant to non-statutory congressional guidance, it must treat the award either as a solicited single-source application or as a limited competition.

- An awarding agency must have a written justification to solicit an application from a single source when the decision is within awarding agency discretion.
- Single-source justifications for non-statutory Congressional guidance may be approved at a level no lower than the CGMO.

11.4.8.1: Unsolicited Request for Funding Exception

For an unsolicited request to be considered for funding, it must be for a project that is not within the scope of any open/pending or a recently closed NOFO or acquisition solicitation or one that is planned in the next 3 years by, or on behalf of, the awarding agency.

The following steps will take place upon receipt of an unsolicited request for funding:

• The request will be forwarded to a designated awarding agency official (generally the CGMO, the Head of Contracting Activity (HCA), or their designee).

- The request will be reviewed by the CGMO or designee (in consultation with the HCA or designee, if necessary) to:
- determine if the request warrants further review by the awarding agency (e.g., does it fall within the awarding agency mission and statutory authorities); and
- make a preliminary assessment that it does not appear to fall within the scope of a current, pending, or planned NOFO, or acquisition solicitation.
- If the request passes this preliminary screening and the CGMO or designee determines that an award or cooperative agreement is the appropriate award instrument, it will be forwarded to the identified appropriate program office(s).). The email or memo to the program office(s) must:
- describe why the identified program office might consider the unsolicited request for funding;
- identify the appropriate award instrument;
- specify the basis for the determination that the request would result in an award;
- ask the program office to review the request for relevance to that office's mission and program priorities;
- ask for an indication of interest in funding, and if interested, an ability to fund the request; and
- indicate the due date for the program office's response (usually 30 calendar days).
- A program office that is interested in funding the request must respond to the CGMO (or designee) with the following information in the transmittal memorandum, to:
- certify that the request is truly unsolicited;
- indicate that the program office could not fund the proposed project under any current, pending, or planned NOFO;
- confirm the statutory authority under which it could be funded; and
- indicate agreement or disagreement with the award instrument indicated in the transmittal memorandum and provide a rationale for an alternate instrument in cases of disagreement.
- It is the responsibility of the CGMO or designee to advise the unsolicited applicant that the awarding agency will not consider the request if the CGMO does not receive a timely response to his or her memorandum, there is no program office expression of interest, or the program office cannot make the required certification.

The determination of award instrument remains an inherent responsibility of the awarding agency, even if the entity submitting an unsolicited request seeks a particular award

instrument. The awarding agency must determine the correct instrument in accordance with 45 CFR 75.201 and the Federal Grant and Cooperative Agreement Act of 1977 (31 U.S.C. 6301-08).

11.4.9: Exceptions to Award Restrictions for Excluded Parties

The HHS Suspension and Debarment Official has the authority to grant an exception permitting a suspended or debarred organization or individual to participate in HHS-covered transactions, per 2 CFR 180.135.

11.4.10: Exceptions to Prior Approval Limitations

<u>45 CFR 75.308</u> limits agency prior approvals. Any additional prior approval requests must be submitted through a deviation request by the awarding agency to the HHS Office of Grants. No other prior approval requirements for budget revisions may be imposed unless an exception has been approved by OMB.

11.5: Documentation of Exceptions

11.5.1: Required Documentation for All Exception Requests

An exception request must have a written justification. The justification must include the following required information and any additional items as noted in the exception-specific guidance in this section:

- Program title and Assistance Listing (AL) number;
- Detailed exception from the UAR and/or policy provision(s) and the proper citation to the specific regulation and/or policy;
- Statement as to whether a similar exception has been previously requested, when it was last requested, why the previous request was made, and the outcome;
- Statutory authority for the program;
- Detailed description of the reason for the request;
- Whether applicants will need to submit any special documentation to establish eligibility;
- Intended award instrument(s) and purpose (e.g., research or services);
- Proposed period of performance and anticipated award amount (total and average per award budget year);
- Whether the activity to be funded is a new activity, relates to an ongoing activity (supplement), or is a follow-on to a prior activity (renewal);
- Basis for the program office's judgment that the exception should be limited to the named entity/entities;
- Current program challenges and impact if the exception is not approved; and
- Additional terms and conditions, if applicable.

For exceptions where the approving level is DPOE, the DPOE desk officer will provide a response (approval/denial) to the CGMO after review by a level no lower than the Director of DPOE. The official response from DPOE will:

- Provide the rationale for the decision; and
- Indicate whether the approving official has approved or disapproved the request.

If approved, the response will:

- Provide any conditions that an awarding agency must meet when implementing the exception; and
- Specify any approved language to be included in the award terms and conditions of the affected awards or other documents.

Appendix A: Roles and Responsibilities

A.1: Introduction

This chapter provides an overview of key offices and staff, both internal and external to HHS, which impact the administration of HHS awards. This chapter also includes the responsibilities associated with the different functional areas involved in the planning, award, administration, and closeout of HHS awards.

A.2: External Organizations Roles and Responsibilities

The following is general information concerning the external organizations that impact the administration of HHS grants.

A.2.1: Office of Management and Budget (OMB)

OMB develops government-wide policies to ensure grants are managed properly and federal dollars are spent in accordance with applicable laws and regulations. OMB works cooperatively with the awarding agencies and the recipient community to create and maintain regulations and guidance.

A.2.2: Department of the Treasury (Treasury)

Treasury establishes government-wide cash management policies and operates the system for processing Fedwire payments, check payments, and certain transactions with states. Treasury's Bureau of Fiscal Service manages the <u>Usaspending.gov</u> web portal and the <u>Do Not Pay</u> (DNP) Business Center to support federal agencies.

A.2.3: Government Accountability Office (GAO)

The GAO examines the use of federal funds; evaluates federal programs and activities; and provides information, analyses, options, recommendations, and other assistance to help Congress make effective policy, funding, and oversight decisions.

A.2.4: The U.S. General Services Administration (GSA)

GSA maintains government-wide databases for identifying and tracking awards through the following systems:

- Assistance Listings (ALs) ALs are detailed public descriptions of federal programs that provide grants and cooperative agreements, loans, scholarships, insurance, and other types of federal financial assistance. To search for <u>HHS Assistance Listings</u>, set the Federal Organization to Health and Human Services (075).
- The System for Award Management (<u>SAM</u>) SAM is the official U.S. government system where non-federal entities are required to register to do business with the federal government. Awarding agencies provide information on the registration process, deadlines, and application guides for prospective applicants through this portal.

A.3: HHS Awarding Agency Roles

Awarding agencies operate under distinct legal authorities and may have different approaches to award management. Therefore, the roles of the offices and the associated staff vary according to organizational design, resources, and programmatic needs. Awarding agencies have a great deal of flexibility in the assignment of responsibilities; however, staff assignments and the provision of authorities must be made consistently and in accordance with their implementing guidance or standard operating procedures (SOPs).

A.3.1: Chief Grants Management Officer (CGMO)

The CGMO is responsible for the implementation and oversight of HHS grants policy requirements. CGMO must be appointed by the head of the awarding agency, or their designee, and is responsible for the following:

- Serving as the awarding agency point of contact for HHS grants policy matters;
- Ensuring the awarding agency's adherence to the requirements of the HHS UAR;
- Implementing and overseeing HHS grants policy requirements;
- Signing and issuing Notices of Award (NoA) or providing grants staff with the authority to sign and issue the NoA;
- Establishing awarding agency policy that outlines the responsibilities and level of authority associated with grants management staff roles;
- Participating in the Executive Committee for Grants Administration Policy (ECGAP); and
- Ensuring that written guidance and training materials prepared by the awarding agency complies with HHS grants administration regulations and grants policy.

The responsibilities of the CGMO may not be re-delegated.

A.3.2: Grants Management Officer (GMO)

CGMOs may designate a grants management officer to conduct pre-award, post-award, and closeout activities to ensure the integrity of award programs from a business, financial, and administrative perspective. The GMO is responsible for the following:

- Ensuring that assigned grant activities conform to HHS grants policy and regulatory requirements; and
- Providing input to the CGMO on the HHS grants administration regulations, and issues arising during administrative and financial monitoring activities that may impact the recipient's ability to achieve performance goals.

The GMO may have additional roles including those related to collaboration with program officials and others in development, implementation, and evaluation of program plans, strategies, regulations, announcements, guidelines, and procedures.

A.3.3: Program Official (PO)

The PO serves as the primary interface between the GMO and recipients for programmatic issues. The PO consults with the GMO concerning the written or oral interpretation of grants policy guidance and seeks their review of recipient-facing documents related to the management of awards.

POs have pre-award, post award, and closeout responsibilities and are principally responsible for:

- Setting program goals and objectives;
- Developing program regulations and Notices of Funding Opportunity (NOFO);
- Providing advice on the scientific, technical, and programmatic suitability of applications for funding; and
- Providing technical expertise in the post-award administration of awards.

A.3.4: Merit Review Staff

Awarding agencies are responsible for the documentation and maintenance of a merit review process for discretionary awards. The appointed merit review staff is responsible for the management of the merit review process including:

- Establishing guidance for the management of award review activities;
- Developing standards for the maintenance of merit review-related information;
- Working with the program office and CGMO to respond to Freedom of Information Act (FOIA) and Privacy Act requests for information related to merit review; and
- Ensuring all policies and procedures associated with identifying and addressing conflicts of interest are appropriately addressed.

A.4: Internal HHS Organization Responsibilities

The following is general information concerning the internal organizations that impact the administration of HHS awards.

A.4.1: Immediate Office of the Secretary (IOS)

IOS serves as the chief policy officer and general manager administering and overseeing the organization and activities of HHS.

A.4.2: Office of the Assistant Secretary for Financial Resources (ASFR)

The ASFR is the lead official for awards and provides guidance to the Secretary on all aspects of budget, financial management, awards, and acquisition management. The ASFR is responsible for informing awarding agencies of applicable public policy requirements, including annual updates to appropriations provisions, and any implementing guidance. ASFR includes Office of Grants, Grants Quality Service Management Office, Office of Acquisitions, Office of Budget, and Office of Finance.

Office of Grants (OG)

The OG provides federal financial assistance management direction in the following areas: grants policy; grants oversight and evaluation; grants systems management and coordination; grants training and development; and grants streamlining. The office provides department-wide leadership in these areas through policy development, oversight, shared service operations and training.

OG is comprised of three divisions: the Division of Grants Policy, Oversight, and Evaluation (DPOE); the Division of Information and Solutions (DIS) and, the Division of Workforce Development (DWD). OG's activities are related to legislation and regulations, addressing award-related matters, the Grants Policy Administration Manual (GPAM), and the HHS Grants Policy Statement (GPS).

Division of Grants Policy, Oversight, and Evaluation (DPOE)

DPOE responsibilities include:

- Coordinating HHS input on proposed legislation affecting awards;
- Developing and interpreting HHS award administration regulations and policy and drafting the coinciding documents;
- Determining awarding agency compliance with HHS award administration regulations and policies and assisting agencies with managing and updating their Compliance Supplement;
- Providing outreach and training to internal and external stakeholders on federal regulations and HHS initiatives;
- Serving as the departmental liaison for cost policy (including cost principles) with OMB and other federal agencies;
- Monitoring HHS-wide performance in closing out awards and, when needed, assisting awarding agencies in closing out award programs;
- Assembling the annual HHS Forecast using input provided by the awarding agencies;
- Working with the awarding agencies to obtain assistance listing numbers and maintain accurate information in their listings;
- Serving as the approving authority for class exceptions and concurring/non-concurring in-class exception requests;
- Reviewing awarding agency NOFOs for compliance with HHS regulations and policies, as applicable;
- Evaluating requests submitted by the awarding agency CGMO to restrict indirect cost reimbursement by consulting with the Division of Cost Allocation Services (CAS), obtaining final decision from the HHS Secretary, and notifying OMB of any approved decisions to restrict the reimbursement of indirect cost; and

• Using program integrity risk assessments to perform reviews on a periodic basis or upon request.

Division of Information and Solutions (DIS)

DIS provides oversight on HHS and government-wide electronic grant activities including:

- HHS Grants Management Line of Business,
- Congressional and Presidential mandated strategic grants-business streamlining activities implementation,
- HHS grant systems assist in the management and oversight of HHS and Governmentwide grant policy for the pre-award, award, and post award process,
- HHS Intra- and Internet grants websites, and
- <u>Grants.gov</u> system management. DIS is responsible for the operation and maintenance of the <u>Grants.gov</u> portal. HHS serves as the federal managing partner for Grants.gov to ensure compliance within the federal guidelines for competition, effective public access, and the publication of Notices of Funding Opportunities (NOFO).

Division of Workforce Development

DWD promotes and develops formal training and innovative strategies to provide career development, training and oversight support to the HHS grants management community. DWD established the Grants Management Training Academy (GMTA) as the premier training source for grants-related training for HHS staff and recipients.

Grants Quality Service Management Office (Grants QSMO)

Grants QSMO includes a marketplace of validated federal shared solutions and services for use by all federal agencies that award grants or cooperative agreements. <u>The Grants QSMO</u> <u>Marketplace</u> provides federal awarding agency customers with information to support and inform decisions regarding adoption of shared solutions and services across the entire grants lifecycle.

Office of Acquisitions (OA)

The OA provides Department-wide leadership for acquisition functions to include the administration, management, and oversight for policies, programs, workforce development, and business systems required to assure the delivery of transparent best value acquisition solutions.

Office of Budget (OB)

The OB provides analytical support and recommendations to the Secretary and the Assistant Secretary for Financial Resources in the areas of budget, performance, and program policy. It also provides guidance and technical assistance to grants management and program staff across HHS operating divisions pertaining to appropriation-related inquiries, policy proposals, program integrity, and management priorities, and leads in the resolution of issues arising from budget execution activities. The OB coordinates awarding agency NOFO review on behalf of HHS.

Office of Finance (OF)

The OF provides support to awarding agency Chief Financial Officers for financial planning and improvement initiatives and serves as the central point of contact for coordinating program integrity, payment accuracy, and audit resolution activities across the Department.

A.4.3: Division of Financial Advisory Services (DFAS), National Institute of Health (NIH)

DFAS is responsible for negotiating indirect cost rates with for-profit organizations on behalf of all HHS awarding agencies when an organization does not have a currently effective indirect cost rate negotiated by HHS or another federal agency.

DFAS posts current negotiation agreements electronically for those rates that they negotiate and notifies awarding agencies of those recipients that are delinquent in submitting timely indirect cost proposals.

A.4.4: Division of Payment Management Services (PMSvc)

The PMSvc is responsible for:

- Receiving annual, interim (quarterly and semi-annual), and final federal financial reports based on the terms and conditions of the award and requirements provided to PMS by the HHS awarding agency;
- Ensuring federal financial reports are available for review by HHS awarding agencies responsible for internal controls preventing the drawdown of HHS funds without recipient certification of drawdowns;
- Restricting cash at the discretion of HHS awarding agencies;
- Consulting with the grants management office in the event of cash management or financial reporting issues;
- As determined by awarding agency requirements, ensure one notification is sent to any recipient delinquent in submitting a federal financial report;
- Reporting expenditure data to provide certified FFR data to Grants Management System and/or HHS awarding agencies, via FFR Web Service.

A.4.5: Program Support Center (PSC)

The PSC is an office within the Assistant Secretary for Administration (ASA) that provides support services. PSC administers the Payment Management System, one of the most widely used grants payment systems in the federal government. PSC is also responsible for collection services on overdrawn awards, disallowed costs, and excess interest.

A.4.6: Division of Cost Allocation Services (CAS)

CAS is a division under the Program Support Center (PSC) within the ASA. For most HHS applicants/recipients, CAS negotiates indirect costs or, as applicable, approves cost allocation plans. CAS is responsible for the following:

- Negotiating indirect cost rates, including special indirect cost rates, and research patient care rates;
- Approving cost allocation plans;
- Providing a liaison between the HHS CGMO and any other agency with indirect cost cognizance for an HHS recipient, as needed;
- Posting current negotiation agreements electronically;
- Notifying the awarding agency of recipients that are delinquent in submitting timely indirect cost proposals; and
- Coordinating with other federal agencies, such as the Department of Labor, the Department of the Interior, or the Office of Naval Research, which may have cognizance for a particular recipient of an HHS award to obtain and make available indirect cost information.

A.4.7: Office of the Chief Information Officer (OCIO)

OCIO is responsible for overall policy, guidance, and general oversight of HHS records management. The OCIO is also responsible for the HHS policies and procedures related to the Paperwork Reduction Act of 1995 (PRA).

A.4.8: Office for Civil Rights (OCR)

OCR ensures that people have an equal opportunity to participate in all HHS programs without facing unlawful discrimination. OCR is responsible for enforcing various statutes and their HHS implementing regulations on behalf of HHS, including:

- Title VI of the Civil Rights Act of 1964;
- The Age Discrimination Act of 1975;
- Section 504 of the Rehabilitation Act of 1973;
- Title IX of the Education Amendments of 1972;
- Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule;
- The Patient Safety and Quality Improvement Act;
- Enforcement of privilege and confidentiality Provisions found at 42 USC 299b-22(f); and
- The basis for the civil money penalty provisions of the regulation regarding Patient Safety Organizations and Patient Safety Work Product found at <u>42 CFR 3.402</u>.

A.4.9: Office of the General Counsel (OGC)

The OGC is responsible for providing advice to the Office of Grants (OG) and awarding agencies on matters, such as the applicability of public policy requirements, reviewing annual appropriations act provisions, and advising OG and the awarding agency on implementation requirements.

A.4.10: Office of Inspector General (OIG)

Within OIG, The Office of Audit Services, the Office of Evaluations and Inspections, and the Office of Investigations are responsible for:

- Providing independent auditing services of HHS programs and operations, and that of its recipients;
- Making independent audits and investigations of HHS programs, operations, activities, and functions;
- Conducting national evaluations to prevent fraud, waste, and abuse and promote the economy, efficiency, and effectiveness of departmental programs;
- Overseeing the work of non-federal auditors performing audits in connection with federal programs;
- Reviewing responses to audit reports and reporting significant disagreements to the audit follow-up official; and
- Processing exclusions based on the Social Security Act and implementing regulations at 42 CFR part 1001.

The Single Audit Division (formerly NEARC) is responsible for:

- Receiving single audit reports on behalf of HHS;
- Reviewing the single audit reports; and
- Transmitting reports to each awarding agency whose recipients' expenditures are included in the report and assigning those reports with findings to the appropriate awarding agency for resolution.

The Office of Recipient Integrity Coordination (ORIC)

The ORIC manages the Suspension and Debarment (S&D) program on behalf of the HHS Suspension and Debarment Official (SDO). ORIC is responsible for entering information in SAM once HHS takes a suspension or debarment action. In addition to being the HHS official with the authority to suspend or debar an organization or individual, the HHS SDO has the authority to grant an exception permitting a suspended or debarred organization or individual to participate in HHS-covered transactions, per <u>2 CFR 180.135</u>.

Departmental Appeals Board (DAB)

DAB reviews and resolves disputes between recipients of HHS funds and HHS awarding agencies under the authority of <u>45 CFR part 16</u>, and conducts additional reviews, adjudication, and mediation services as assigned.

A.5: Research-Related Responsibilities

The following is general information concerning the internal organizations that impact award-funded research programs.

A.5.1: Office of Human Resource Protection (OHRP)

OHRP has HHS-wide responsibilities with respect to human subjects' research conducted or supported by HHS, including research conducted under grants, cooperative agreements, and contracts, as specified at <u>45 CFR part 46</u>. These responsibilities include:

- Establishing criteria for and negotiating Federal-wide Assurance (FWA) with
 organizations engaged in HHS-conducted or supported human subjects' research.
 Overseeing the implementation of human subjects' requirements;
- Evaluating all written substantive allegations or indications of non-compliance with HHS human subjects' research regulations;
- Preparing policies and guidance documents and interpretations of requirements for human subject protections and disseminating this information to the research community;
- Developing and implementing educational programs and resource materials; and
- Maintaining a database of approved assurances on file with OHRP.

A.5.2: Office of Laboratory Animal Welfare (OLAW), NIH

OLAW has HHS-wide responsibilities with respect to animal welfare requirements under research conducted or supported by HHS, including research conducted under financial assistance. These responsibilities include:

- Establishing criteria for approving, restricting, or withdrawing approval of assurances for organizations engaged in HHS-conducted or supported research involving live, vertebrate animals;
- Overseeing the implementation of animal welfare requirements, including providing waivers where applicable, and conducting site visits;
- Evaluating all allegations or indications of noncompliance with HHS animal welfare requirements;
- Monitoring the filing of the annual report required by the Public Health Service Policy on Humane Care and Use of Laboratory Animals and maintaining the submitted reports;
- Maintaining a listing of valid assurances on file with OLAW; and
- Preparing policies, guidance documents, and providing interpretations of requirements for research involving animals and disseminating this information to the research community.

A.5.3: Office of Research Integrity (ORI)

ORI is responsible for addressing research integrity and misconduct issues related to Public Health Service-supported activities and reviewing institutional research misconduct proceedings and facilitating the responsible conduct of research through education, training, and other activities, as specified in <u>42 CFR part 93</u>.

A.6: Roles and Responsibilities of Recipients and Their Principals

HHS awards are generally made to recipient organizations. The organization is legally accountable for the performance of the award and the expenditure of funds. Organizations receiving HHS funds, whether such funds are received directly from an awarding agency, indirectly under a contract, subaward, or as student assistance under a training award, are responsible for and must adhere to all applicable federal statutes, regulations, and policies, including income tax regulations. Questions concerning the applicability of income tax regulations to award funds should be directed to the IRS. Organizations also are expected to comply with applicable state and local laws and ordinances. The roles and responsibilities of designated individuals at recipient organizations, who serve as agents of the recipient, are as follows:

A.6.1: Authorized Organizational Representative (AOR)

The authorized organizational representative is the designated representative of the applicant/recipient organization with authority to act on the organization's behalf in matters related to the award and administration of awards. In signing and submitting a funding application for federal assistance, this individual certifies that the organization will comply with all applicable assurances and certifications referenced in the NOFO and applicatole federal statutes and regulations and other terms and conditions of the award, including any assurances, if awarded. These responsibilities include accountability both for the appropriate use of funds awarded and the performance of the award-supported project or activities as specified in the award. Although HHS requires that the recipient organization designate such an individual, HHS does not specify the organizational location or full set of responsibilities for this individual.

A.6.2: Principal Investigator/Program or Project Director (PI/PD)

The PI/PD is the individual, designated by the recipient, responsible for the scientific, technical, or programmatic aspects of the award and for day-to-day management of the project or program. The PI/PD generally is an employee of the recipient. However, because an award is made to the recipient organization, if the PI/PD is not an employee of that organization, the organization must have a formal written agreement with the PI/PD that specifies an official relationship between the parties even if the relationship does not involve a salary or other form of remuneration. If the PI/PD is not an employee of the applicant organization, the awarding agency will assess whether the arrangement will result in the organization being able to fulfill its responsibilities under any award.

The PI/PD is a member of the recipient team responsible for ensuring compliance with the financial and administrative aspects of the award. This individual works closely with designated officials within the recipient organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge federal support in publications, announcements, news programs, and other media; and ensure compliance with other federal and organizational requirements.

The PI/PD is encouraged to maintain contact with the PO with respect to the scientific, technical, or programmatic aspects of the project or program and, as applicable, the GMO concerning the business and administrative aspects of the award.

Appendix B: Acronyms and Definitions

B.1: Acronyms

The following are acronyms that are used within the Grants Policy Administration Manual (GPAM).

ACA	Affordable Care Act
ACF	Administration for Children and Families
ACL	Administration for Community Living
ADR	Alternative Dispute Resolution
AHRQ	Agency for Healthcare Research and Quality
AL	Assistance Listing
AOR	Authorized Organizational Representative
ARD	Audit Resolution Division
ASFR	Assistant Secretary for Financial Resources
ASL	Assistant Secretary for Legislation
AT	Action Transmittal
CAAC	Civilian Agency Acquisition Council
CAN	Common Accounting Number
CAS	Program Support Center's Cost Allocation Services (formerly Division of Cost Allocation (DCA))
СВО	Community-based Organization
CCR	Central Contractor Registration
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CGMO	Chief Grants Management Officer
CMIA	Cash Management Improvement Act
CMS	Centers for Medicare & Medicaid Services
COR	Contracting Officer's Representative
CPARS	Contractor Performance Assessment Reporting System
CR	Continuing Resolution
CRADA	Cooperative Research and Development Agreements
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DAB	Departmental Appeals Board
DCIA	Debt Collection Improvement Act
DNP	Do Not Pay
DQDA	Data Quality Database Application
EIN	Employer Identification Number
eRA	Electronic Research Administration
FAC	Federal Audit Clearinghouse
FACA	Federal Advisory Committee Act (5 U.S.C. Appendix 2)
FAIN	Federal Award Identification Number
FAPIIS	Federal Awardee Performance and Integrity Information System (now SAM.gov Responsibility and Qualification)
FAR	Federal Acquisition Regulations
FDA	Food and Drug Administration
FFATA	Federal Funding Accountability and Transparency Act, also referred to as "The Transparency Act"
FFR	Federal Financial Report
FGCA	Federal Grant and Cooperative Agreement Act
FMR	Federal Management Regulation
FOIA	Freedom of Information Act
FTCA	Federal Tort Claims Act
FY	Fiscal Year
GAGAS	Generally Accepted Government Accounting Standards
GAO	Government Accountability Office
GMO	Grants Management Officer
GMS	Grants Management Specialist
GPAM	Grants Policy Administration Manual
GPS	Grants Policy Statement
GRS	General Records Schedule
GS	GrantsSolutions
GSA	General Services Administration
HCA 150	Head of Contracting Activity

ł	HHS	U.S. Department of Health and Human Services
ł	HRSA	Health Resources and Services Administration
I	IACUC	Institutional Animal Care and Use Committee
I	IHS	Indian Health Service
I	IMPAC II	Information for Management, Planning, Analysis, and Coordination
I	IRB	Institutional Review Board
ł	KMSAL	Key Management Single Audit Liaison
l	LOI	Letter of Intent
I	MTDC	Modified Total Direct Cost
I	MOE	Maintenance of Effort
1	NFI	Notice of Federal Interest
1	NIH	National Institutes of Health
1	NHPA	National Historic Preservation Act
I	NoA	Notice of Award
I	NOFO	Notice of Funding Opportunity
(OA	Office of Acquisitions
(OASH	Office of the Assistant Secretary for Health
(OG	Office of Grants
(OGC	Office of the General Counsel
[DPOE	HHS Office of Grants Division of Policy, Oversight, and Evaluation
(OHRP	Office for Human Research Protections
(OIG	Office of the Inspector General
(OLAW	Office of Laboratory Animal Welfare
(омв	Office of Management and Budget
(ORIC	Office of Research Integrity Coordination
I	PHS	Public Health Service
I	PI/PD	Principal Investigator/Project Director
I	PMS	Payment Management System
I	PMSvc	Payment Management Services (formerly Division of Payment Management (DPM))

РО	Project Officer or Program Official
PRA	Paperwork Reduction Act
PSC	Program Support Center
R/Q	Responsibility and Qualifications (SAM.gov)
SAAO	Single Audit Accountable Official
SAM	System of Award Management
SAMHSA	Substance Abuse and Mental Health Services Administration
SDO	Suspension and Debarment Official
SF	Standard Form
SII	Successor in Interest
SAT	Simplified Acquisition Threshold
TAGGS	Tracking Accountability in Government Grants System
UEI	Unique Entity Identifier

B.2: Definitions and Working Terms

This GPAM chapter is not intended to be an all-inclusive listing but provides a single reference source for many of the definitions and abbreviations applicable to grants management used in the GPAM. See relevant HHS regulations in the Code of Federal Regulations (CFR), for instance, <u>Title 45</u>, <u>Subtitle A</u> – Department of Health and Human Services, for additional definitions.

- *Definitions (d)* are terms with a citation, typically from statutes, regulations (especially <u>45 CFR 75.2</u>) policies, or guidance.
- Working terms (wt) do not have a citation but are words and phrases that are used frequently. Many working terms were adapted from previous policy documents with the source unknown.

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Acquisition (d) – the process of acquiring by contract with appropriated funds of supplies or services (including construction) by and for the use of the federal government through purchase or lease, whether the supplies or services are already in existence or must be created, developed, demonstrated, and evaluated (also termed "procurement") (Source: Federal Acquisition Regulation (FAR) 2.101).

Addition Alternative (d) – with prior approval of the HHS awarding agency, program income may be added to the federal award by the federal agency and the non-federal entity. The program income must be used for the purposes and under the conditions of the federal award (Source: 45 CFR 75.307(e)(2)).

Ad hoc committee (wt) – a temporary committee established for a single, specific short-term effort, e.g., review of applications resulting from a single Notice of Funding Opportunity (NOFO), after which the committee disbands.

Administrative offset (wt) – withholding funds payable by the United States to, or held by the United States for, a recipient to satisfy a debt.

Administrative requirements (wt) – those matters common to awards in general, such as financial management, kinds and frequency of reports, and retention of records. These are distinguished from programmatic requirements.

Advance payment (d) – a payment that a federal awarding agency or pass-through entity makes by any appropriate payment mechanism, including a predetermined payment schedule, before the recipient disburses the funds for program purposes (Source: 45 CFR 75.2).

Allocation (d) – the process of assigning a cost, or a group of costs, to one or more cost objective(s), in reasonable proportion to the benefit provided or other equitable relationship. The process may entail assigning a cost(s) directly to a final cost objective or through one or more intermediate cost objectives (Source: <u>45 CFR 75.2</u>).

Allowable cost (wt) – a cost incurred by a recipient that is:

- necessary;
- reasonable for the performance of the award;
- allocable;
- in conformance with, or incorporated by reference, any limitations or exclusions set forth in the federal cost principles applicable to the organization incurring the cost or in the Notice of Award (NoA) as to type or amount;
- consistent with regulations, policies and procedures of the recipient that apply uniformly to both federally supported and other activities of the organization;
- accorded consistent treatment as a direct or indirect cost;
- determined in accordance with generally accepted accounting principles; and
- not included as a cost in any other federally supported award (unless specifically authorized by statute).

Animal (d) – any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes (Source: <u>Public Health Service</u> <u>Policy on Humane Care and Use of Laboratory Animals</u>, Revised 2015; Chapter III. Definitions, A. Animal).

Appointing official (wt) – the individual who has been assigned the responsibility to select merit reviewers for an awarding agency, under a given program(s), under a specified NOFO, or on another basis.

Approved but unfunded (wt) – an application recommended for approval in the merit review process but not selected for funding. Applications that are approved but unfunded may receive funding if additional funds become available or may compete for funding during the next review cycle (even if that occurs in the next fiscal year).

Approving official (wt) – the individual with delegated authority to make funding decisions for a given program.

Assistance listing (d) – the publicly available listing of federal assistance programs managed and administered by the General Services Administration, formerly known as the Catalog of Federal Domestic Assistance (CFDA). (Source: <u>2 CFR 200.1</u>)

Audited financial statement (wt) – a financial statement issued by an independent public auditor.

Authorized organizational representative (wt) – the individual(s), named by the applicant/recipient organization, who is authorized to act for the applicant/recipient and to assume the obligations imposed by the federal laws, regulations, requirements, and conditions that apply to applications or awards.

Authorizing statute (wt) – the statute that provides the authority to establish a federal financial assistance program or make a particular award, e.g., an earmark, and either in general or specific terms, provides programmatic requirements, such as eligibility and allowable activities.

Awarding agency (wt) -

- with respect to an award, federal agency (see federal awarding agency), and
- with respect to a subaward, the party that awarded the subaward.

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Block grant (d) – *block* grants are given primarily to general purpose governmental units in accordance with a statutory formula. Such grants can be used for a variety of activities within a broad functional area (Source: <u>GAO Red Book</u>, *Principles of Federal Appropriations Law*).

Budget (d) – the financial plan for the project or program that the federal awarding agency or pass-through entity approves during the federal award process or in subsequent amendments to the federal award. It may include the federal and non-federal share or only the federal share, as determined by the federal awarding agency or pass-through entity (Source: 45 CFR 75.2).

Budget period (d) – the time interval from the start date of a funded portion of an award to the end date of that funded portion during which recipients are authorized to [obligate] the funds awarded, including any funds carried forward or other revisions pursuant to $\frac{§ 200.308}{2 \text{ CFR } 200.1}$

Budget review (wt) – the process of reviewing the categorical budget, including federal funds requested and any required matching or cost sharing, and accompanying budget

justification/narrative submitted as part of an application, to ensure proper categorization of costs, identify unallowable costs, verify rates, and check arithmetic accuracy.

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Categorical budget (wt) – a budget that requests, and is reviewed and approved based on, amounts in individual categories for direct costs, e. g, personnel, travel, equipment, supplies.

Change in scope (wt) – an activity whereby the objectives or specific aims identified in the approved application are significantly changed by the recipient after award. GMO prior approval is required for a change in scope to be allowable under an award.

Change of recipient (wt) – a transfer of the legal and administrative responsibility for an awardsupported project or program from one legal entity to another before the ending date of the approved period of performance. A change in recipient may be the result of a:

- "Change in the principal investigator's/project director's organization,"
- "change in sponsoring organization" for a fellowship,
- "change in a designated entity," under a program where a state or other eligible recipient can designate another organization to receive the award on its behalf, or
- a "replacement award."

Claim (*d*) – depending on the context, either:

- A written demand or written assertion by one of the parties to a federal award seeking as a matter of right:
- The payment of money in a sum certain;
- The adjustment or interpretation of the terms and conditions of the federal award; or
- Other relief arising under or relating to a federal award.
- A request for payment that is not in dispute when submitted. (Source: <u>45 CFR 75.2</u>)

Class exception or deviation (wt) – a change from an HHS grants administration regulation or grants policy requirement that would otherwise apply that affects more than a single application or award. The "class" may be all awards under a program or a subset of all awards sharing common characteristics. If a competitive Notice of Funding Opportunity (NOFO) includes an exception or deviation, this is considered class exception or deviation because it potentially affects multiple applicants/recipients.

Closeout (d) – the process by which the federal awarding agency or pass-through entity determines that all applicable administrative actions and all required work of the federal award have been completed and takes actions described in <u>45 CFR 75.381</u> (Source: <u>45 CFR 75.2</u>).

Cognizant agency for indirect costs (d) – the federal agency responsible for reviewing, negotiating, and approving cost allocation plans or indirect cost proposals on behalf of all

federal agencies. The cognizant agency for indirect cost is not necessarily the same as the cognizant agency for audit. For assignments of cognizant agencies see the following:

- For Institutes of Higher Education: <u>45 CFR part 75, appendix III, C.11</u>.
- For nonprofit organizations: <u>45 CFR part 75, appendix IV, C.1</u>.
- For state and local governments and Indian Tribes: <u>45 CFR part 75, appendix V, F.1</u>.

(Source: <u>45 CFR 75.2</u>)

Competition, full and open (d) – when used with respect to an award action, means that all responsible [eligible] sources are permitted to compete (Source: <u>Federal Acquisition Regulation</u> <u>Subpart 2.1</u>). For discretionary grant-making, a process whereby applications undergo merit review, and are evaluated against established review criteria, scored, and ranked.

Completion date (wt) – the date on which all work under an award is completed or the date on the award document, or any supplement or amendment thereto, on which awarding agency sponsorship ends. This also may be referred to as the period of performance end date.

Conference (d) – a meeting, retreat, seminar, symposium, or event that involves attendee travel. The term 'conference' also applies to training activities that are considered to be conferences under 5 CFR 410.404 (Source: 41 CFR 300-3.1).

Conference award (wt) – an award whose purpose is to support activities related to the conduct of a conference(s) or defined ser of conference-related activities. A conference award may involve a single conference in one location, a series of separate but related conferences, or one conference that is conducted in multiple forums.

Congressional Directive (wt) – designation of any portion of a lump-sum amount for particular purposes by means of legislative language. Sometimes, "earmark" is colloquially used to characterize directives included in Congressional committee reports. The Office of Management and Budget (OMB) has refined congressional directives to mean funds provided by the Congress for projects, programs, or awards where the purported Congressional direction (whether in statutory text, report language, or other communication) circumvents otherwise applicable merit-based or competitive allocation processes, or specifies the location or recipient, or otherwise curtails the ability of the Executive branch to manage its statutory and constitutional responsibilities pertaining to the funds allocation process (Source: Executive Order 13457, January 29, 2008). A congressional directive may be characterized as "statutory" or "non-statutory."

Construction (d) – the erection of a building, structure, or facility, including the installation of equipment, site preparation, landscaping, associated roads, parking, environmental mitigation and utilities, which provides space not previously available. It includes freestanding structures, additional wings or floors, enclosed courtyards or entryways, and any other means to provide usable space that did not previously exist (excluding temporary facilities) (Source<u>: HHS Program</u> Facilities Manual, Vol. I, Section 1-2-00).

Construction award (d) – funds awarded for the erection of a building, structure, or facility, including the installation of equipment, site preparation, landscaping, environmental mitigation, and utilities, which provides space not previously available. It includes freestanding structures, additional wings or floors, enclosed courtyards or entryways, and any other means to provide usable space that did not previously exist (excluding temporary facilities) (Source: modified from <u>HHS Program Facilities Manual</u>, Vol. I, Section 1-2-00).

Contract (d) – a legal instrument by which a recipient purchases property or services needed to carry out the project or program under a federal award. The term as used in this policy does not include a legal instrument, even if the recipient considers it a contract, when the substance of the transaction meets the definition of a federal award or subaward (see subaward) (Source: $45 \ CFR 75.2$).

Contractor (d) – an entity that receives a contract as defined in Contract (Source: 45 CFR 75.2).

Cooperative agreement (d) – means a legal instrument of financial assistance between a federal awarding agency or pass-through entity and a recipient that, consistent with 31 U.S.C. 6302-<u>6305</u>:

- Is used to enter into a relationship the principal purpose of which is to transfer anything
 of value from the federal awarding agency or pass-through entity to the recipient to
 carry out a public purpose authorized by a law of the United States (see <u>31 U.S.C.</u>
 <u>6101(3)</u>); and not to acquire property or services for the federal government or passthrough entity's direct benefit or use.
- Is distinguished from a grant in that it provides for substantial involvement between the federal awarding agency or pass-through entity and the recipient in carrying out the activity contemplated by the federal award.
- The term does not include:
- A cooperative research and development agreement (CRADA) as defined in <u>15 U.S.C. §</u> <u>3710a</u>; or
- An agreement that provides only direct United States Government cash assistance to an individual, a subsidy, a loan, a loan guarantee, or insurance.

(Source: <u>45 CFR 75.2</u>)

Copyright Protection (d) -

- Copyright protection subsists, in accordance with <u>U.S.C. Title 17</u>, in original works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device. Works of authorship include the following categories:
- literary works;
- musical works, including any accompanying words;

- dramatic works, including any accompanying music;
- pantomimes and choreographic works;
- pictorial, graphic, and sculptural works;
- motion pictures and other audiovisual works;
- sound recordings; and
- architectural works.
- In no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work (Source: <u>17 U.S.C. § 102</u>).

Cost sharing or matching (d) – the portion of project costs not paid by federal funds or federal contributions (unless otherwise authorized by federal statute). This may include the value of allowable third party in- kind contributions, as well as expenditures by the recipient. See also <u>45</u> <u>CFR 75.306</u> (Source: <u>45 CFR 75.2</u>).

Note: Although additional terms sometimes are used when characterizing matching or cost sharing, e.g., hard match, soft match, involuntary cost sharing, or overmatch, these terms are not used in HHS grants policy and are not defined in the GPAM.

Cost-sharing or matching alternative (d) – with prior approval of the awarding agency, program income may be used to meet the cost sharing or matching requirement of the federal award. The amount of the federal award remains the same (Source: $\frac{45 \text{ CFR } 75.307(e)(3)}{10}$).

Cost-type contract (wt) – a contract or subcontract under an award, which the contractor or subcontractor is paid on the basis of the allowable costs it incurs, with or without a fee.

Covered transaction (d) – a non-procurement or procurement transaction at the primary tier, i.e., between a federal agency and a person, or a lower tier, i.e., between a participant in a covered transaction and another person. For HHS, covered transactions include (a) all subawards and (b) contracts under covered non-procurement activities at any tier expected to equal or exceed \$25,000 (Source: <u>2 CFR 180.200</u>, <u>Appendix to part 180</u> – Covered Transactions, and <u>2 CFR 376.220</u>).

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Data (d) – recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information (Source: <u>48 CFR 27.401</u>). The term also includes copyrightable work (including those works for which recipient asserts copyright or purchases copyright ownership), as well as data that may be ineligible for copyright protection (e.g., purely factual information or uncreative work). An example is computer software and 158 documentation thereof, developed under an award in which the recipient asserts copyright or purchases copyright ownership, qualify as "data," as defined in the HHS and NIH Grants Policy Statements.

Debarment (d) – an action taken (by a Suspension and Debarment Official) to exclude a person from participating in covered transactions and transactions covered under the Federal Acquisition Regulation. A person so excluded is debarred and may be referred to as an excluded party (Source: <u>2 CFR 180.925</u>).

Deduction alternative (d) – Ordinarily program income must be deducted from total allowable

costs to determine the net allowable costs. Program income must be used for current costs unless the HHS awarding agency authorizes otherwise. Program income that the non-federal entity did not anticipate at the time of the federal award must be used to reduce the federal award and nonfederal entity contributions rather than to increase the funds committed to the project (Source: 45 CFR 75.307(e)(1)).

Deferred (wt) – postponed funding action on a discretionary application pending another action, such as receipt of additional information.

Delinquent debt (d) – a debt which the debtor does not pay or otherwise resolve by the date specified in the initial demand for payment, or in an applicable written repayment agreement or other instrument, including a post-delinquency repayment agreement (Source: 45 CFR 30.2).

Departmental Appeals Board (d) – the independent office established in the Office of the Secretary with delegated authority from the Secretary to review and decide certain disputes between recipients of HHS funds and awarding agencies under <u>45 CFR part 16</u> and to perform other review, adjudication and mediation services as assigned (Source: <u>45 CFR 75.2</u>).

Direct assistance (wt) – a financial assistance support mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. Direct assistance generally involves the assignment of federal personnel or the provision of equipment or supplies such as vaccines.

Direct cost base (d) – the accumulated direct costs (normally either total direct salaries and wages, or total direct costs exclusive of any extraordinary or distorting expenditures) used to distribute indirect costs to individual federal awards. The direct cost base selected should result in each federal award bearing a fair share of the indirect costs in reasonable relation to the benefits received from the costs (Source: <u>45 CFR part 75, appendix VII</u>, B.1.).

Direct costs (d) – those costs that can be identified specifically with a particular final cost objective, such as a federal award, or other internally or externally funded activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy. Costs incurred for the same purpose in like circumstances must be treated consistently as either direct or indirect (F&A) costs. See also <u>45 CFR 75.405</u> (Source: <u>45 CFR 75.413</u>).

Disallowed costs (d) – those charges to a federal award that the federal awarding agency or pass- through entity determines to be unallowable, in accordance with the applicable federal 159

statutes, regulations, cost principles, or the terms and conditions of the federal award (Source: <u>45 CFR 75.2</u>).

Disbursement (wt) – Amounts paid for goods and services by the recipient.

Discretionary award (wt) – an award made by an awarding agency in keeping with specific statutory authority which enables the agency to exercise judgment ("discretion") in selecting the applicant/recipient organization through a competitive award process.

Disposition (wt) – actions taken regarding records, property, and equipment no longer needed for the conduct of the work on the federal award.

Disqualified (d) – a status that prohibits a person from participating in specified federal procurement and non-procurement transactions as required under a statute, Executive order (EO) (other than EOs 12549 and 12689), or other authority. Examples of disqualifications include persons excluded under the Davis-Bacon Act; equal employment opportunity acts and EOs; and the Clean Air Act, Clean Water Act, and EO 11738 (Source: <u>2 CFR 180.935</u>).

Disqualifying financial interests (d) – for purposes of 18 U.S.C. 208(a), the term financial interest means the potential for gain or loss to the employee, or other person specified in section 208, as a result of governmental action on the particular matter. The disqualifying financial interest might arise from ownership of certain financial instruments or investments such as stock, bonds, mutual funds, or real estate. Additionally, a disqualifying financial interest might derive from a salary, indebtedness, job offer, or any similar interest that may be affected by the matter (<u>Source: 5 CFR 2640.103(b)</u>).

Domestic organization (wt) – a public (including a state or other governmental agency) or private non-profit or commercial organization that is located in the United States or its territories and is subject to U.S. laws.

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Emergency application/award (wt) – an application(s) submitted, or an award(s) made, based on a presidentially declared disaster under the Stafford Act, a public health emergency declared by the Secretary, HHS, or other local, regional or national disaster. The term includes, but is not limited to, an application/award for a replacement award for continuation of health services in a community or to a specified population because of termination of an existing award (See also urgent applications/awards).

Employer Identification Number (EIN) (d) – a nine-digit number assigned by the IRS to identify the tax accounts of employers and certain others. The number is used to identify taxpayers that are required to file various business tax returns (Source: <u>www.irs.gov/pub/irs-pdf/p1635.pdf</u>).

Entity (d) – all of the following as it is used in the Transparency Act award term as defined at $\frac{2}{CFR part 25, subpart C:}$

• A Governmental organization, which is a state, local government, or Indian Tribe;

- A foreign public entity;
- A domestic or foreign nonprofit organization;
- A domestic or foreign for-profit organization; and
- A federal agency.

(Source: <u>2 CFR 25, Appendix A.I.C.3</u>.).

For purposes of the Transparency Act and GPAM policies regarding implementation of the Transparency Act, the term "entity" refers to nonprofit organizations including colleges and universities; hospitals; and tribal organizations, other than those included in the definition of Indian Tribe. The term "entity" does not include these organizations as nonprofit organizations outside the context of the Transparency Act.

Entity Identification Number (wt) – a three-part coding scheme of 12 characters used in the Payment Management System (PMS). The first character identifies the recipient as an organization or an individual. The next nine characters are the federal Taxpayer Identification Number (Employer Identification Number or Social Security Number) assigned by the Internal Revenue Service. The last two characters are a suffix to distinguish different organizational components within a recipient organization.

Equipment (d) – tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the recipient for financial statement purposes, or \$5,000. See also capital assets, computing devices, general purpose equipment, information technology systems, special purpose equipment, and supplies (Source: <u>45 CFR 75.2</u>).

Exception (wt) – a change, whether more restrictive or less restrictive, to a requirement in the HHS grants administration regulations (and any requirements incorporated by reference therein) that is not based on statute. An awarding agency's use of any flexibility provided in the HHS grants administration regulations is not considered an exception.

Exempt federally owned property (d) – property acquired under a federal award where the federal awarding agency has chosen to vest title to the property to the recipient without further obligation to the federal government, based upon the explicit terms and conditions of the award. The federal awarding agency may exercise this option when statutory authority exists. Absent statutory authority and specific terms and conditions of the federal award, title to exempt federally owned property acquired under the federal award remains with the federal government (Source: <u>45 CFR 75.319(c)</u>).

Expanded authorities (wt) – operating authorities provided to recipients that waive the requirement for prior approval for specified actions. Expanded authorities generally are available under research awards to institutions of higher education, for-profit entities, and non-profit entities that perform research. These authorities apply automatically to the above recipients/activities unless overridden by the awarding agency in the NoA. Expanded authorities do not automatically apply to other types of recipients/activities, but the awarding 161

agency has the discretion to afford expanded authority to other classes of recipients, except construction awards.

Expenditure report (d) -

- For non-construction awards, the SF-425 Federal Financial Report (FFR) (or other OMBapproved equivalent report)
- for construction awards, the SF-271 "Outlay Report and Request for Reimbursement" (or other OMB-approved equivalent report)

(Source: 45 CFR 75.2)

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Facilities and administrative (F&A costs) – See indirect costs.

Federal Awardee Performance and Integrity Information System (FAPIIS) (wt) – the Federal Awardee Performance and Integrity Information System (FAPIIS) is the integrity and performance system established by OMB and GSA that includes government-wide data with specific information related to the integrity and performance of non-federal entities. The FAPIIS.gov integrity records are now called Responsibility and Qualification information in SAM.gov which is located within Entity Information.

Federal Audit Clearinghouse (FAC) (d) – the clearinghouse designated by OMB as the repository of record where non-federal entities are required to transmit the reporting packages required regulation. The webpage for the FAC is <u>https://facweb.census.gov/uploadpdf.aspx</u>. (Source: <u>45</u> <u>CFR 75.2</u>).

Federal award (d) -

- Has one of the following meanings, depending on the context:
- The federal financial assistance that a recipient receives directly from a federal awarding agency or indirectly from a pass-through entity, as described in <u>45 CFR 75.101</u>; or the cost-reimbursement contract under the Federal Acquisition Regulations that a recipient receives directly from a federal awarding agency or indirectly from a pass- through entity, as described in <u>45 CFR 75.101</u>; or
- The instrument setting forth the terms and conditions. The instrument is the award agreement, cooperative agreement, other agreement for assistance covered in paragraph (2) of *federal* financial *assistance at* <u>45 CFR 75.2</u>, or the cost-reimbursement contract awarded under the Federal Acquisition Regulations.
- Federal award does not include other contracts that a federal agency uses to buy goods or services from a contractor or a contract to operate federal government owned, contractor operated facilities (GOCOs).

• See also definitions of federal financial assistance, grant agreement, and cooperative agreement.

(Source: <u>45 CFR 75.2</u>)

Federal awarding agency (d) – the federal agency that provides a federal award directly to a recipient (Source: <u>45 CFR 75.2</u>)

Federal Award Identification Number (FAIN) (d) - a number, unique within the Federal

Agency, assigned to each award for financial assistance (Source: <u>OMB Memorandum title:</u> <u>"Improving Data Quality for USAspending.gov", date: June 12, 2013</u>).

Federal financial assistance (d) – assistance that non-federal entities receive or administer in the form of grants, cooperative agreements, non-cash contributions or donations of property (including donated surplus property), direct appropriations, food commodities; and other financial assistance (except assistance listed in <u>45 CFR 75.2</u>, *federal financial assistance* paragraph (2).

For the requirement to provide public notice of federal financial assistance programs at <u>45 CFR</u> <u>75.202</u> and audit requirements at <u>45 CFR part 75, subpart F</u>, *federal financial assistance* also includes assistance that non-federal entities receive or administer in the form of loans, loan guarantees, interest subsidies, and insurance.

Federal financial assistance does not include amounts received as reimbursement for services rendered to individuals as described in $\frac{45 \text{ CFR } 75.502(h)}{45 \text{ CFR } 75.502(h)}$ and <u>(i)</u>.

(Source: <u>45 CFR 75.2</u>)

Federal interest (d) – for purposes of reporting on real property at 45 CFR 75.343 or when used in connection with the acquisition or improvement of real property, equipment, or supplies under a federal award, the dollar amount that is the product of the:

- Federal share of total project costs; and
- Current fair market value of the property, improvements, or both, to the extent the costs of acquiring or improving the property were included as project costs.

(Source: <u>45 CFR 75.2</u>)

Federal institution (wt) – a Cabinet-level department or independent agency of the executive branch of the federal government or any component organization of such a department or agency.

Fee (wt) – an amount, in addition to actual, allowable costs, paid to an organization providing goods or services consistent with normal commercial practice. Fees are only allowable under limited circumstances. A fee may be referred to as a "profit" for Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) programs.

Financial conflict of interest (FCOI) (wt) – a significant financial interest that could directly compromise or bias professional judgment and objectivity.

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First-tier subaward (wt) – an award made by a pass-through entity to another non-federal entity, where the subrecipient is accountable to the pass-through entity for the use of the federal funds provided by the subaward.

Financial reconciliation (wt) – the process of ensuring that reported federal cash status and expenditure information are equal, including making (or requiring the recipient to make) any necessary adjustments, e.g., for an overpayment.

Fixed amount awards (d) – a type of award agreement under which the federal awarding agency or pass-through entity provides a specific level of support without regard to actual costs incurred under the federal award. This type of federal award reduces some of the administrative burden and record-keeping requirements for both the recipient and federal awarding agency or pass-through entity. Accountability is based primarily on performance and results. See <u>45 CFR 75.201(b)</u> and <u>75.353</u> (Source: <u>45 CFR 75.2</u>).

Flow down/flow through requirements (wt) – terms and conditions of the federal award that are required to be applied to subrecipients and their subawards, that is, "flowed down" by the recipient. In most cases, these requirements are the same requirements that apply to the recipient/award.

Foreign organization (d) – an entity that is:

- A public or private organization located in a country other than the United States and its territories that are subject to the laws of the country in which it is located, irrespective of the citizenship of the project staff or place of performance;
- A private nongovernmental organization located in a country other than the United States that solicits and receives cash contributions from the general public;
- A charitable organization located in a country other than the United States that is nonprofit and tax exempt under the laws of its country of domicile and operation, and is not a university, college, accredited degree-granting institution of education, private foundation, hospital, organization engaged exclusively in research or scientific activities, church, synagogue, mosque or other similar entities organized primarily for religious purposes; or
- An organization located in a country other than the United States not recognized as a *foreign public entity*.

(Source: 45 CFR 75.2)

Foreign public entity (d) -

- a foreign government or foreign governmental entity;
- public international organization, which is an organization entitled to enjoy privileges, exemptions, and immunities as an international organization under the International Organizations Immunities Act (Source: 22 U.S.C. 288-288(f));
- an entity owned (in whole or in part) or controlled by a foreign government; and

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• any other entity consisting wholly or partially of one or more foreign governments or foreign governmental entities

(Source: <u>45 CFR 75.2</u>)

Freedom of Information Act (d) – provides individuals with the statutory right of access to certain federal agency records. The Freedom of Information Act (FOIA) requires agencies to disclose requested records unless they are protected from public disclosure by the FOIA. Congress included in the FOIA nine exemptions and three law enforcement exclusions to protect important interests such as national security, personal privacy, privileged communications, and law enforcement. In brief, the nine exemptions are as follows:

- Exemption 1 Information that is classified to protect national security;
- Exemption 2 Information related solely to the internal personnel rules and practices of an agency;
- Exemption 3 Information that is prohibited from disclosure by another federal law;
- Exemption 4 Information that concerns business trade secrets or other confidential commercial or financial information;
- Exemption 5 Information that concerns communications within or between agencies which are protected by legal privileges;
- Exemption 6 Information that, if disclosed, would invade another individual's personal privacy;
- Exemption 7 Information compiled for law enforcement purposes;
- Exemption 8 Information that concerns the supervision of financial institutions; and
- Exemption 9 Geological information on wells.

(Source: <u>5 U.S.C. 552</u>)

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GAGAS (d) – generally accepted government auditing standards issued by the Comptroller General of the United States, which are applicable to financial audits (Source: <u>45 CFR 75.2</u>).

Government employee (d) –an officer and an individual who meets the definition of employee at 5 U.S.C. \$ 2105.

Grant or grant agreement (d) – means a legal instrument of financial assistance between a federal awarding agency or pass-through entity and a non-federal entity that, consistent with <u>31 U.S.C. 6302</u>, <u>6304</u>:

• Is used to enter into a relationship the principal purpose of which is to transfer anything of value from the federal awarding agency or pass-through entity to the non-federal entity to carry out a public purpose authorized by a law of the United States (see <u>31</u>

<u>U.S.C. 6101(3)</u>); and not to acquire property or services for the federal awarding agency or pass-through entity's direct benefit or use;

- Is distinguished from a cooperative agreement in that it does not provide for substantial involvement between the federal awarding agency or pass-through entity and the non-federal entity in carrying out the activity contemplated by the federal award.
- Does not include an agreement that provides only direct United States Government cash assistance to an individual, a subsidy, a loan, a loan guarantee, or insurance.

(Source: <u>45 CFR 75.2</u>)

Grants management (wt) – the totality of processes and activities for the award, administration, and closeout of grants that are required to be performed by HHS staff (e.g., grants management officers) in grants management offices, program offices, or other offices.

Grants management system owners (wt) – the two shared service providers (eRA Commons/IMPAC II and GATES/Grant Solutions, operated by the National Institutes of Health [NIH] and the Administration for Children and Families [ACF]), respectively, that HHS has authorized for use by all awarding agencies to support the grants management operations lifecycle.

Grant official (wt) – a designated employee of the awarding agency or one to whom, through a servicing intra-agency agreement, the awarding agency has provided authority to sign awards under one or more programs on its behalf.

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The HHS Grants Forecast (Forecast) (wt)) – an HHS-wide database in Grants.gov of planned competitive award opportunities developed for each fiscal year. The forecast contains actual or estimated dates and funding levels for competing funding opportunities that each awarding agency intends to issue during the upcoming fiscal year, subject to change based on enactment of Congressional appropriations.

Human subject (d) – a living individual about whom an investigator (whether professional or student) conducting research: (a) obtains data through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (b) obtains, uses, studies, analyzes, or generates identifiable private information or biospecimens. (Source: 45 <u>CFR 46.102(e)</u>. See also the <u>Guidance on Engagement of Institutions in Human Subjects</u> <u>Research</u>, October 16, 2008; Section I. Background)

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Improper payment (d) –

- any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and
- includes any payment to an ineligible party, any payment for an ineligible good or service, any duplicate payment, any payment for a good or service not received (except for such payments where authorized by law), any payment that does not account for credit for applicable discounts, and any payment where insufficient or lack of documentation prevents a reviewer from discerning whether a payment was proper (Source: <u>45 CFR 75.2</u>).

Indian tribe (d) – any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to Alaska Native Claims Settlement Act (43 U.S.C. Chapter 33), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians (25 U.S.C. 450b(e)). See annually published <u>Bureau of Indian Affairs list</u> of Indian Entities Recognized and Eligible to Receive Services (Source: <u>45 CFR 75.2</u>).

Indirect (Facilities and Administration or F&A) costs (d) – necessary costs incurred by a recipient for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved. To facilitate equitable distribution of indirect expenses to the cost objectives served, it may be necessary to establish a number of pools of indirect (F&A) costs. Indirect (F&A) cost pools should be distributed to benefitted cost objectives on bases that will produce an equitable result in consideration of relative benefits derived (Source: <u>45 CFR 75.2</u>).

Indirect cost rate proposal (d) – the documentation prepared by a recipient to substantiate its request for the establishment of an indirect cost rate as described in Appendix III through Appendix VII, and Appendix IX of 45 CFR 75 (Source: <u>45 CFR 75.2</u>).

Indirect cost rate agreement (wt) – a formal rate agreement signed by the agency negotiating the indirect cost rate, i.e., the HHS Program Support Center's Cost Allocation Services (CAS) office, the National Institutes of Health's Division of Financial Advisory Services (DFAS), or other cognizant federal agency office, and an authorized organizational representative of the recipient.

Individual (d) – for the purposes of the Freedom of Information and/or Privacy Acts, a living person who is a citizen of the United States or an alien lawfully admitted for permanent residence. It does not include persons such as sole proprietorships, partnerships, or corporations. A business firm which is identified by the name of one or more persons is not an individual within the meaning of this part (Source: <u>45 CFR 5b.1(e)</u>).

Information (d) – any statement or estimate of fact or opinion, regardless of form or format, whether in numerical, graphic, or narrative form, and whether oral or maintained on paper, electronic or other media. "Information" does not generally include items in the following categories; however, OMB may determine that any specific item constitutes "information":

- Affidavits, oaths, affirmations, certifications, receipts, changes of address, consents, or acknowledgments; provided that they entail no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument (by contrast, a certification would likely involve the collection of "information" if an agency conducted or sponsored it as a substitute for a collection of information to collect evidence of, or to monitor, compliance with regulatory standards, because such a certification would generally entail burden in addition to that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument);
- Samples of products or of any other physical objects;
- Facts or opinions obtained through direct observation by an employee or agent of the sponsoring agency or through non standardized oral communication in connection with such direct observations;
- Facts or opinions submitted in response to general solicitations of comments from the public, published in the *Federal Register* or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration of the comment;
- Facts or opinions obtained initially or in follow-on requests, from individuals (including
 individuals in control groups) under treatment or clinical examination in connection with
 research on or prophylaxis to prevent a clinical disorder, direct treatment of that
 disorder, or the interpretation of biological analyses of body fluids, tissues, or other
 specimens, or the identification or classification of such specimens;
- A request for facts or opinions addressed to a single person;
- Examinations designed to test the aptitude, abilities, or knowledge of the persons tested and the collection of information for identification or classification in connection with such examinations;
- Facts or opinions obtained or solicited at or in connection with public hearings or meetings;
- Facts or opinions obtained or solicited through non standardized follow-up questions designed to clarify responses to approved collections of information; and
- Like items so designated by OMB.

(Source: 5 CFR 1320.3(h))

In-Kind Contribution (wt) – see definition for third-party in-kind contributions.

Institutional allowance (wt) – an amount paid to and administered by the sponsor institution to defray expenses for an individual fellow, such as supplies, equipment, travel to scientific

meetings, and health insurance; and to otherwise offset, insofar as possible, appropriate administrative costs of training.

Intangible property (d) – property having no physical existence, such as trademarks, copyrights, patents and patent applications and property, such as loans, notes and other debt instruments, lease agreements, stock and other instruments of property ownership (whether the property is tangible or intangible) (Source: 45 CFR 75.2).

Intellectual property (d) – the separate and distinct types of intangible property that are referred to collectively as "intellectual property," including but not limited to: Patents, trademarks, copyrights, trade secrets, SBIR technical data (as defined in this section), ideas, designs, know- how, business, technical and research methods, other types of intangible business assets, and all types of intangible assets either proposed or generated by a small business concern as a result of its participation in the SBIR Program (Source: <u>7 CFR 3403.2</u>).

Interim report (wt) – any financial or performance/progress report required to be submitted by a recipient on a periodic basis during a period of performance. This can be any report other than the final report.

International Organization (d) – a public international organization in which the United States participates pursuant to any treaty or under the authority of any Act of Congress authorizing such participation or making an appropriation for such participation, and which shall have been designated by the President through appropriate Executive order as being entitled to enjoy the privileges, exemptions, and immunities herein provided (Source: International Organizations Immunities Act, <u>22 U.S.C. 288, Section I</u>).

Invention (d) – any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.) (<u>Source: 37 CFR 401.2(c)</u>).

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Key personnel (wt) – individuals, in addition to the principal investigator/program director (PI/PD), identified by the awarding agency in the Notice of Award (NoA) that are considered critical to the project, i.e., their removal or absence from the project would have a significant impact on the approved project. The PI/PD is always considered both a "key person" and a "principal," as defined below. Other key personnel generally are not considered "principals" for purposes of suspension and debarment.

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Letter of intent (wt) – a preliminary, non-binding indication of an organization's intent to submit an application.

License (d) – includes the whole or a part of an agency permit, certificate, approval, registration, charter, membership, statutory exemption or other form of permission (Source: 5 <u>U.S.C. §551(8)</u>).

Limited competition (wt) – an administrative restriction of competition to a particular class of applicants, which prohibits otherwise eligible applicants from submitting proposals. The limitations may be based on Congressional directives or on shared attributes of the applicants, such as geographic area, technological or research specialization, status as current recipient, or other requirements as identified in authorizing statute or by the awarding office.

Local government (d) – any unit of government within a state, including a county; borough; municipality; city; town; township; parish; local public authority, including any public housing agency under the United States Housing Act of 1937; special district; school district; intrastate district; council of governments, whether or not incorporated as a nonprofit corporation under state law; and any other agency or instrumentality of a multi-, regional, or intra-state or local government. (Source: <u>45 CFR 75.2</u>)

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Maintenance of Effort (wt) - – a statutory requirement where the recipient is required, as a condition of eligibility for federal funding, to maintain its financial contribution to the program at not less than a stated percentage (which may be 100 percent or less) of its contribution for a prior time period, usually the previous fiscal year.

Management decision (*d*) – the evaluation by the federal awarding agency or pass-through entity of the audit findings and corrective action plan and the issuance of a written decision to the auditee as to what corrective action is necessary (Source: 45 CFR 75.2).

Management systems (wt) – the accounting, budgeting, human resources, property management, and procurement management systems and associated policies, procedures, and internal controls maintained by an organization.

Merger (wt) – legal action resulting in the unification of two or more legal entities, which may invoke the need for a successor-in-interest if an HHS award is affected.

Modernization (d) – the alteration, repair, remodeling and/or renovation of a building (including the initial equipment thereof and improvements to the building's site) which, when completed, will render the building suitable for use by the project for which the grant is made (Source: 42 CFR 51c.502c). Construction is specifically excluded. Modernization may be comprised of:

i. Major Alteration and Renovation (Major A&R) – a structural change (e.g., to the foundation, roof, floor, or exterior or load-bearing walls of a facility, or extension of an existing facility) to achieve the following: Increase the floor area; and/or, change function and purpose of the facility. Agencies may adopt a dollar amount as a specific indicator of major A&R. Dollar amounts may be dictated by specific statutes.

ii. Minor Alteration and Renovation (Minor A&R) – improvements to a facility which do not meet the definition of major A&R. Agencies may assign a maximum dollar value to distinguish minor A&R from major A&R.

Modified Total Direct Cost (MTDC) (d) – all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subawards and subcontracts up to the first \$25,000 of each subaward or subcontract (regardless of the period of performance of the subawards and subcontracts under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward and subcontract in excess of \$25,000. Other items may only be excluded when necessary to avoid a serious inequity in the distribution of indirect costs, and with the approval of the cognizant agency for indirect costs (Source: $45 \text{ CFR} \frac{75.2}{100}$).

Monitoring (wt) – a process whereby the programmatic and business management performance aspects of an award are reviewed after award by collecting and assessing information from reports, audits, desk reviews, site visits, government repositories (SAM.gov, FAC, etc.), and other sources.

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Name change (wt) – an action that changes the legal name of an organization without otherwise affecting the rights and obligations of the organization as a recipient of an awarding agency award.

No-cost extension (wt) – a non-competitive extension of time to the final budget period of a period of performance, without additional federal funds, to complete the work under an award or avoid a hiatus while a non-competing continuation application is under consideration.

Non-competing continuation application/award (wt) – an application and resulting an award made for additional funding/budget period within a previously approved period of performance, through a non- competing process.

Non-discretionary award (wt) – an award made by an awarding agency in keeping with specific statutory authority under which the agency has no ability to exercise judgment ("discretion"), due to "mandatory" award requirements, in selecting the applicant/recipient organization through a competitive process. Non-discretionary awards can be both formula and non-formula based.

Non-federal entity (d) – a state, local government, Indian tribe, institution of higher education (IHE), or nonprofit organization that carries out a federal award as a recipient or subrecipient (Source: 45 CFR 75.2).

Nonprofit organization (d) – any corporation, trust, association, cooperative, or other organization, not including IHEs, that:

- Is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest;
- Is not organized primarily for profit; and
- Uses net proceeds to maintain, improve, or expand the operations of the organization.

(Source: <u>45 CFR 75.2</u>)

Notice of Award (NA) (wt) – the official legally binding award document that:

- notifies the recipient of the issuance of an award;
- contains or references all the terms and conditions of the award and federal funding limits; and
- provides the documentary basis for recording the obligation of federal funds in the agencies' accounting systems.

Notice of Funding Opportunity (NOFO) (wt) – a publicly available document by which a federal agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. NOFOs may be known as program announcements, notices of funding availability, requests for applications, solicitations, or other names depending on the agency and type of program.

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Obligations (d) – when used in connection with a non-Federal entity's utilization of funds under a federal award, obligations are orders placed for property and services, contracts and subawards made, and similar transactions during a given period that require payment by the recipient during the same or a future period (Source: <u>45 CFR 75.2</u>).

Other forms of federal financial assistance (wt) – loans, loan guarantees, scholarships, fellowships, mortgage loans, prize challenges, insurance or donation of federal facilities, goods, services, property, technical assistance, advisory services and counseling, statistical and other expert information, and service activities of regulatory agencies.

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Participant (d) – any person who submits a proposal for, or enters into, a covered transaction, including an agent, or representative of a participant (Source: 2 CFR 180.980).

Pass-through entity (d) – a non-federal entity that provides a subaward to a subrecipient to carry out part of a federal program. (Source: 45 CFR 75.2)

Pass-through program (wt) – a program where the recipient's role is to select subrecipients that are expected to carry out provide the objectives of the award, coordinating and overseeing their activities, and providing the administrative support needed to meet awarding agency requirements.

Patent (wt) – an intellectual property right granted by the Government of the United States of America to an inventor "to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States" for a limited time in exchange for public disclosure of the invention when the patent is granted.

Patient care (d) – those departments or cost centers which render routine or ancillary services to in-patients and/or out-patients. As used [for research awards], it means the cost of these services applicable to patients involved in research programs (Source: <u>45 CFR part 75, Appendix</u> IX, B.2., and I.2.w).

Payment (d) – any transfer or commitment for future transfer of federal funds, such as cash, securities, loans, loan guarantees, and insurance subsidies to any non-federal person or entity that is made by a federal agency, a federal contractor, a federal recipient, or a governmental or other organization administering a federal program or activity (Source: P.L. 111-204, Section 2(f)(3)). The term includes federal awards subject to the Single Audit Act Amendments of 1996 that are expended by recipients and subrecipients.

Peer review (wt) – a form of objective review. It is an assessment of scientific or technical merit of applications by individuals with knowledge and expertise equivalent (peer) to that of the individuals whose applications they are reviewing, i.e., professional equals of the principal investigator or program/project director for the proposed project and who often are engaged or were previously engaged in comparable activities. If qualified, federal and non-federal representatives can participate in peer reviews, unless otherwise specified.

Performance goal (d) – a target level of performance expressed as a tangible, measurable objective, against which actual achievement can be compared, including a goal expressed as a quantitative standard, value, or rate. In some instances (e.g., discretionary research awards), this may be limited to the requirement to submit technical performance reports (to be evaluated in accordance with agency policy) (Source: <u>45 CFR 75.2</u>).

Period of performance (d) – the time during which the non-Federal entity may incur new obligations to carry out the work authorized under the federal award. The federal awarding agency or pass-through entity must include start and end dates of the period of performance in the federal award (see <u>45 CFR 75.210(a)(5)</u> and <u>75.352(a)(1)(v)</u>) (Source: <u>45 CFR 75.2</u>).

Person (d) – any individual, corporation, partnership, association, unit of government, or legal entity, however organized (Source: <u>2 CFR 180.985</u>).

Personal property (d) – property of any kind except real property. It may be tangible, having physical existence, or intangible, such as copyrights, patents, or securities (Source: <u>45 CFR</u> <u>75.2</u>).

Personally Identifiable Information (PII) (d) - information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. Some information that is PII is available in public sources such as telephone books, public Web sites, and university listings. This type of information is public PII and includes, for example, first and last name, address, 173 work telephone number, email address, home telephone number, and general educational credentials. The definition of PII is not anchored to any single category of information or technology. Rather, it requires a case-by-case assessment of the specific risk that an individual can be identified. Non-PII can become PII whenever additional information is made publicly available, in any medium and from any source, that, when combined with other available information, could be used to identify an individual. (Source: <u>45 CFR 74.2</u>)

Pre-application (wt) – a preliminary submission, providing summary-level information, concerning an organization's intent to submit an application for federal funds under a NOFO. It differs from a letter of intent in that it includes information that an awarding agency is required to evaluate and on which feedback must be provided.

Principal (d) – (a) an officer, director, owner, partner, principal investigator (PI), or other person within a participant with management or supervisory responsibilities related to a covered transaction, or (b) a consultant or other person, whether or not employed by the participant or paid with federal funds, who is in a position to handle federal funds; is in a position to influence or control the use of those funds; or occupies a technical or professional position capable of substantially influencing the development or outcome of an activity required to perform the covered transaction, or (c) for HHS, an individual who provides federally required audit services or a researcher (Source: 2 CFR 180.995, as supplemented by 2 CFR 376.995).

Principal Investigator/Program Director/ (PI/PD) (d) – the individual (s) designated by the recipient to direct the project or program being supported by the award. The PI/PD is responsible and accountable to officials of the recipient organization for the proper conduct of the project, program, or activity (Source: <u>45 CFR 75.2</u>).

Prior approval (d) – written approval by an authorized HHS official evidencing prior consent before a recipient undertakes certain activities or incurs specific costs (Source: <u>45 CFR 75.2</u>).

Privacy Act of 1974 (d) – a statute that regulates the collection, maintenance, use, and dissemination of personal information by federal executive branch agencies. Generally, the Act prohibits the disclosure of records contained in a system of records without the written request or consent of the individual to whom the records pertain, unless a condition of disclosure is met or the release is covered by a routine use of the System of Records Notice (SORN) for the system (Source: <u>5 U.S.C. 552a</u>).

Procurement activities (d) – all acquisition programs and activities of the federal government, as defined in the FAR, including subcontracts at any tier, other than subcontracts for commercially available off-the-shelf items (as defined in section 35(c) of the Office of Federal Procurement Policy Act, 41 U.S.C. 104), except that in the case of a contract for commercial items, such term includes only first-tier subcontracts (Source: <u>P. L. 103-355, section 2455(c)(1)</u>).

Program income (d) – gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the federal award during the period of performance except as provided in $\frac{575.307(f)}{10}$. (See period of performance.) Program income includes but is not limited to income from fees for services performed, the use or rental or for real or personal

property acquired under federal awards, the sale of commodities or items fabricated under a federal award, license fees and royalties on patents and copyrights, and principal and interest on loans made with federal award funds. Interest earned on advances of federal funds is not program income. Except as otherwise provided in federal statutes, regulations, or the terms and conditions of the federal award, program income does not include rebates, credits, discounts, and interest earned on any of them. See also <u>45 CFR 75.307</u>, <u>75.407</u> and <u>35 U.S.C.</u> <u>200-212</u> (applies to inventions made under federal awards) (Source: <u>45 CFR 75.2</u>).

Program management (wt) – management of the technical, scientific, or other programmatic purpose of an award program or award by program officials (POs), and other program staff.

Program office (wt) – the organization reporting directly to the approving official responsible for programmatic administration of a particular award, if awarded.

Programmatic requirements (wt) –concern matters that can be treated only on a program-byprogram or award-by-award basis, such as kinds of activities that can be supported by awards under a particular program. They are distinguished from administrative requirements.

Project costs (d) – total allowable costs incurred under a federal award and all required cost sharing and voluntary committed cost sharing, including third-party contributions (Source: <u>45</u> <u>CFR 75.2</u>).

Property (d) – real property or personal property (Source: <u>45 CFR 75.2</u>).

Protected Personally Identifiable Information (Protected PII) (d) –an individual's first name or first initial and last name in combination with any one or more of types of information, including, but not limited to, social security number, passport number, credit card numbers, clearances, bank numbers, biometrics, date and place of birth, mother's maiden name, criminal, medical and financial records, educational transcripts. This does not include PII that is required by law to be disclosed. (See also Personally Identifiable Information (PII)) (Source: <u>45 CFR 75.2</u>).

Public Health Service (PHS) (d) – Includes the Office of the Assistant Secretary for Health (formerly the Office of Public Health and Science) and the following OPDIVs:

- Agency for Healthcare Research and Quality (AHRQ);
- Agency for Toxic Substances and Disease Registry (ATSDR);
- Centers for Disease Control and Prevention (CDC);
- Food and Drug Administration (FDA);
- Health Resources and Services Administration (HRSA);
- Indian Health Service (IHS);
- National Institutes of Health (NIH);
- Substance Abuse and Mental Health Services Administration (SAMSHA); and
- Offices of the Regional Health Administrators.

(Source: <u>42 CFR 93.220</u>)

Public policy requirement (wt) – a non-financial compliance requirement, based in statute (including appropriations statutes), Federal Regulation, Executive Order (EO), or Presidential memorandum, which (a) serves a national purpose, and which (b) federal agencies must apply to applicants.

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Questioned cost (d) – a cost that is questioned by the auditor because of an audit finding:

- Which resulted from a violation or possible violation of a statute, regulation, or the terms and conditions of a federal award, including for funds used to match federal funds;
- Where the costs, at the time of the audit, are not supported by adequate documentation; or
- Where the costs incurred appear unreasonable and do not reflect the actions a prudent person would take in the circumstances.

(Source: <u>45 CFR 75.2</u>)

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Ranking list (wt) – a list submitted by the designated official in the program office to the appropriate grants official identifying the rank of all applications, according to the (normalized) scores assigned by the merit reviewers.

Real property (d) – land, including land improvements, structures, and appurtenances thereto, but excludes moveable machinery and equipment (Source: 45 CFR 75.2).

Recipient (d) – an entity, usually but not limited to non-federal entities, which receives a federal award directly from a federal awarding agency to carry out an activity under a federal program. The term recipient does not include subrecipients. See also non-federal entity. (Source: <u>45 CFR</u> <u>75.2</u>).

Records or Federal Records (d) – all books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the government or because of the informational value of data in them (Source: 44 U.S.C. 3301). An OPDIV record is an information resource, in any format (for example, electronic or hard copy), that is: (a) created in the course of official business; (b) received for action; or (c) needed to document departmental activities. See also 45 CFR 5.5 for FOIA regulations, and 45 CFR 5b.1(h) for Privacy Act regulations.

Reimbursement payment (wt) – a payment made to a recipient, upon its request, after cash disbursements are made by the recipient.

Replacement award (wt) – award to a new recipient for the same project in instances where the original award has been ended by the awarding agency or the original recipient is unwilling to continue and there is a continuing awarding agency need for the project, e.g., provision of health services.

Research (d) – a systematic study directed toward fully scientific knowledge or understanding of the subject studied. "Development" is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes (Source: <u>45 CFR</u> <u>75.2</u>).

Research and Development (R&D) (d) – all research activities, both basic and applied, and all development activities that are performed by HHS award recipients. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function (Source: <u>45 CFR 75.2</u>).

Research data (d) – the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples). Research data also do not include:

- Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and
- Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of privacy, such as information that could be used to identify a particular person in a research study.

(Source: 45 CFR 75.322(e)(3))

Research award (wt) – a type of discretionary award that involves systematic, intensive study intended to increase knowledge or understanding of the subject studied, a systematic study specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements. "Research" also may be characterized as "research and development."

Research-related (wt) – activities that are integrally related to the performance of research, which may include activities involving the training of individuals in research techniques (also

known as research training), and as applicable, alteration, renovation, modernization, or construction of research facilities.

Retention Period (d) – the length of time that records must be kept (Source: <u>36 CFR 1220.18</u>).

Royalties (wt) – payments for the privilege of using another entity's patents, copyrights, secret processes and formulas, trademarks, and similar intellectual property.

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Service-level agreement (wt) – an agreement entered into by a service provider and users that establishes a common understanding about services and responsibilities, including, as applicable, the levels of availability, serviceability, performance, operation, or other attributes of the service, such as billing.

Significant rebudgeting (wt) – a threshold that is reached when expenditures in a single direct cost budget category deviate from the approved budget amount for that budget category and budget period by 10 percent of the total budget last approved by the HHS awarding agency, and the federal share exceeds the simplified acquisition threshold. Significant rebudgeting is an indicator of a potential change of scope. A threshold that is reached when the cumulative changes between direct cost categories reaches an established percentage of total award amount.

Single-source application/award (wt) – an administrative restriction of competition resulting in an awarding agency:

- seeking an application from only one otherwise eligible source, including an earmark, with the intent of providing funding if the application receives a favorable merit review, or
- accepting an unsolicited request for funding.

The award made through this process is called a single source award.

Site visit (wt) – a monitoring technique conducted by a representative of the awarding agency grants management office and/or program office at the project location, awarding agency, or virtually.

Simplified Acquisition Threshold (d) - the dollar amount below which a non-Federal entity may purchase property or services using small purchase methods. Non-Federal entities adopt small purchase procedures in order to expedite the purchase of items at or below the simplified acquisition threshold. The simplified acquisition threshold for procurement activities administered under Federal awards is set by the FAR at <u>48 CFR part 2, subpart 2.1</u>. (Source: <u>2</u> <u>CFR 200.1</u>)

Small awards (wt) – a grant or cooperative agreement not exceeding the simplified acquisition threshold.

State (d) – any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any agency or instrumentality thereof exclusive of local governments (Source: <u>45 CFR 75.2</u>).

Stipend (d) – a payment to an individual to help meet that individual's subsistence expenses during the training period (Source: 42 CFR 63a.2). Stipends are not salary and should not be provided as a condition of employment with either the federal Government or the recipient/sub- recipient organization.

Subaward (d) – an award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a federal award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract (Source: <u>45 CFR 75.2</u>).

Subject inventions (d) – any invention of a recipient conceived or first actually reduced to practice in the performance of work under a funding agreement; provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of performance (Source: <u>37</u> <u>CFR 401.2(d)</u>).

Subrecipient (d) – a non-federal entity that receives a subaward from a pass-through entity to carry out part of a federal program and is accountable to the recipient for the use of the funds provided; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other federal awards directly from a federal awarding agency (Source: 45 CFR 75.2).

Subrecipient monitoring (wt) – a process whereby a recipient ensures that:

- subawards are made and reported consistent with federal requirements; and
- subrecipients carry out the programmatic and administrative/financial management aspects of performance in accordance with requirements set forth by the recipient.

Substantial involvement (d) – Federal programmatic collaboration or participation in carrying out the effort under the award. Substantial involvement during performance does not include:

- agency approval of recipient plans prior to award;
- normal exercise of federal stewardship responsibilities during the period of performance, such as site visits, performance reporting, financial reporting, and audit to ensure that the objectives, performance goals, terms, and conditions of the award are accomplished;
- unanticipated agency involvement to correct deficiencies in project or financial performance from the terms of the assistance instrument;

- general statutory requirements understood in advance of the award, such as civil rights, environmental protection, and provision for the handicapped;
- agency review of performance after completion; and/or
- general administrative requirements.

Substantial involvement may include, but is not limited to the following:

- agency power to immediately halt an activity if detailed performance specifications (e.g., construction specifications) are not met. These would be provisions that go beyond the suspension remedies of the federal government for nonperformance;
- agency review and approval of one stage before work can begin on a subsequent stage during the period covered by the assistance instrument;
- agency review and approval of substantive provisions of proposed subawards or contracts. These would be provisions that go beyond existing policies of federal review of recipient procurement standards and sole source procurement;
- agency involvement in the selection of key relevant personnel (This does not include assistance provisions for the participation of a named principal investigator for research projects.);
- agency and recipient collaboration or joint participation;
- agency monitoring to permit specified kinds of direction or redirection of the work because of interrelationships with other projects;
- substantial, direct agency operational involvement and participation during the assisted activity is anticipated prior to award to ensure compliance with such statutory requirements as civil rights, environmental protection, and provision for the handicapped. This would exceed the normally anticipated general statutory requirements; and/or
- highly prescriptive agency requirements prior to award limiting recipient discretion with respect to scope of services offered, organizational structure, staffing, mode of operation, and other management processes, coupled with close agency monitoring or operational involvement during performance over and above the normal exercise of federal stewardship responsibilities to ensure compliance with these requirements.

(Source: Implementation of Federal Grant and Cooperative Agreement Act of 1977, Final Office of Management and Budget (OMB) Guidance, August 18, 1978).

Successor in interest (SII) (wt) – a process whereby the rights to, and obligations of, an awarding agency award (and possibly other federal awards) are acquired incidental to the transfer of all or part of the assets of the recipient involved in the performance of the award. Such transfer may result from legislative (usually state or local) action or other legal action such as a merger (i.e., the unification of two or more legal entities), divestiture, or other corporate change.

Summary statement (wt) – term is used for two separate documents with two unique uses:

- a written review of each application, which identifies the strengths and weaknesses by criterion, scores, and ranking. The summary statement is prepared by the merit review chairperson or individual responsible for coordinating field reviewers, with assistance by the program official/project officer. This summary statement is part of the award file for successful applicants and may be included as part of the merit review file.
- a written overview of the merit review for each application, with sufficient information for an applicant to understand why the application will not be funded. The summary statement reflects the tone of the comments from the reviewers and may actually include written comments submitted by the reviewers and discussion notes from the review session.

Supplement (wt) – a request for or the award of additional funds during a current budget period to:

- support new or additional activities which are not identified in the current award representing a change in scope;
- support an expansion of the award-approved activities; or
- provide for an increase in costs due to unforeseen circumstances.

Supplement, not supplant (wt) – a form of Maintenance of Effort requirement that specifies that federal funds received may not be used to replace existing state, local, or agency funds with federal funds. Existing State, local, or agency funds for a project, may not be replaced by federal funds and reallocated for other organizational expenses. The baseline for a supplement-not-supplant requirement may be the recipient's previous fiscal year or another baseline year or period.

Supplies (d) – all tangible personal property other than those described in *Equipment*. A computing device is a supply if the acquisition cost is less than the lesser of the capitalization level established by the recipient for financial statement purposes or \$5,000, regardless of the length of its useful life. See also Computing devices and equipment (Source: <u>45 CFR 75.2</u>).

Suspending and Debarring Official (d) – the individual in an agency with discretionary authority to impose debarment or suspension (Source: <u>2 CFR 180.930</u> and <u>180.1010</u>). HHS uses the phrases "Suspension and Debarment" and "Suspending and Debarring" interchangeably. For HHS, the Suspension and Debarment Official (SDO) is the Deputy Assistant Secretary for Grants and Acquisition Policy and Accountability.

Suspension (d) – an action that immediately prohibits a person from participating in covered non- procurement and procurement transactions for a temporary period, pending completion of an agency investigation and any judicial or administrative proceedings that may ensue (Source: <u>2 CFR 180.1015</u>). This usage of the term 'suspension' differs from 'suspension of award activities' which is an enforcement action that may be followed by termination.

Suspension of award activities (d) – an action by the awarding agency requiring the recipient to cease all activities on the award pending corrective action by the recipient. It is a separate action from suspension under HHS regulations (<u>2 CFR part 376</u>) implementing Executive Orders <u>12549</u> and 12689 (Source: <u>45 CFR 75.2</u>).

Synopsis (of Funding Opportunity) (d) – summary information extracted from or based on the NOFO that is electronically posted at the government-wide website known as Grants.gov/Find. The posting at Grants.gov/FIND includes a direct link to the NOFO or includes an uploaded copy of the NOFO (Source: <u>Grants.gov Grants Terminology</u>.)

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Taxpayer Identification Number (TIN) (wt) – an identification number used by the Internal Revenue Service (IRS) in the administration of tax laws. It is issued either by the Social Security Administration (SSA) or by the IRS. A Social Security number (SSN) is issued by the SSA whereas all other TINs are issued by the IRS.

Termination (d) – the ending of a federal award, in whole or in part at any time prior to the planned end of the period of performance (Source: 45 CFR 75.2).

Terms and conditions (wt) – all requirements of the award or subaward, whether in statute, regulations or the award document. The terms and conditions are legally enforceable and may be referenced or specified in the full text of the NoA and/or the Grants Policy Statement (GPS).

Third-party in-kind contributions (d) – the value of non-cash contributions (i.e., property or services) that:

- Benefit a federally assisted project or program; and
- Are contributed by non-federal third parties, without charge, to a non-federal entity under a federal award.

(Source: <u>45 CFR 75.2</u>).

Types of applications and awards (wt) – crosswalk of terminology related to types of applications and awards under a period of performance system.

Table 1: Types of applications and awards: SF 424 application cover sheet definitions

Type of Application	SF 424: General, Discretionary Applications	SF 424: Research & Related (R&R) Multi-Project R&R	SF 424: Non- Discretionary (Mandatory) Awards
New	An application that is being submitted to an agency for the first time.	An application that is being submitted to an agency for the first time.	An initial submission by the applicant or entity.

Resubmission	N/A	An application that has been previously submitted, but was not funded, and is being resubmitted for new consideration.	A resubmission of the initial submission which is being resubmitted without change. The resubmission is due to problems with the initial submission.
Renewal	See continuation, below.	An application requesting additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be developed as fully as though the applicant is applying for the first time.	N/A
Continuation	A submission (application) that is an extension for a new period of performance. This can include renewals.	A non-competing application for an additional budget period within a previously approved period of performance.	N/A
Revision See also <u>Table</u> <u>2: Types of</u> <u>Revisions</u>	A submission that is a change in the federal government's financial obligation or contingent liability from an existing obligation.	An application that proposes a change in: 1) the federal government's financial obligations or contingent liability from an existing obligation; or	A change to a submission that has not yet been accepted or approved by the agency.
Y		2) any other change in the terms and conditions of the existing award.	

Update	N/A	N/A	A change to an accepted
			or approved
			submission.

(Source: <u>Grants.gov Forms</u>)

Table 2: Types of Revisions

	SF 424	SF 424
	General Form,	R&R and Multi-
	Discretionary Awards	Project R&R
A. Increase Award	Х	X
B. Decrease Award	Х	X
C. Increase Duration	x	X
D. Decrease Duration	X	х
E. Other (specify)	X	Х
AC. Increase Award,	Х	
Increase Duration		
AD. Increase Award,	Х	
Decrease Duration		
BC. Decrease Award,	Х	
Increase Duration		
BD. Decrease Award,	Х	
Decrease Duration		

--U--

Undertaking (d) – a project, activity, or program funded in whole or in part under the direct or indirect jurisdiction of a federal agency, including those carried out by or on behalf of a federal agency; those carried out with federal financial assistance; and those requiring a federal permit, license, or approval (Source: <u>36 CFR 800.16(y)</u>).

Unilateral closeout (wt) – the process by which an awarding agency closes out an award without receipt of all final reports required by the terms and conditions of an award, after making reasonable efforts to obtain them.

Unique Entity Identifier (d) – the federal government's method to identify organizations. Replaced DUNS number. (Source: <u>48 CFR 2.101</u>)

Unliquidated obligations (d) – for financial reports prepared on a cash or accrual basis, obligations incurred by the recipient that have not been paid (liquidated). For reports prepared on an accrual expenditure basis, these are obligations incurred by the recipient for which an expenditure has not been recorded (Source: 45 CFR 75.2).

Unobligated balance (d) – the amount of funds authorized under a federal award that the nonfederal entity has not obligated. The amount is computed by subtracting the cumulative amount of the recipient's unliquidated obligations and expenditures of funds under the federal award from the cumulative amount of the funds that the federal awarding agency or passthrough entity authorized the recipient to obligate (Source: <u>45 CFR 75.2</u>).

Unrecovered indirect cost (d) – the difference between the amount charged to the federal award and the amount which could have been charged to the federal award under the recipient's approved negotiated indirect cost rate (Source: 45 CFR 75.306(c)).

Unsolicited request for funding (wt) – a written proposal generated solely on an organization's own initiative and not in response to any formal solicitation or Notice of Funding Opportunity (NOFO) issued by an awarding agency or any informal solicitation by an awarding agency official. Investigator-initiated applications submitted to Center for Scientific Review (CSR), National Institutes of Health (NIH), although termed "unsolicited," however are considered competitive applications.

Urgent application/award (wt) – an application or award resulting from a competitive process for which the award must be expedited so that the project's potential for success is not jeopardized. With this policy manual, emergency applications/awards are distinguished from urgent application/awards (see definition of emergency applications/awards).

Unsuccessful application (wt) – an application that:

- has received an unfavorable merit review;
- is not approved for funding by the approving official; or
- is recommended for approval but unfunded (see definition of approved but unfunded).

--V--

Vendor (wt) – see contractor.

--W--

Working capital advance (d) – a procedure whereby the awarding agency or passthrough entity must advance cash payments to the recipient to cover its estimated disbursement needs for an initial period generally geared to the recipient's disbursing cycle. Thereafter, the awarding agency or pass-through entity must reimburse the recipient for its actual cash disbursements (Source: <u>45 CFR 75.305(b)(4)</u>).

Appendix C: Systems, Services and Unique Identifiers

This appendix provides an overview of internal and external systems, identifiers, and services HHS uses in financial assistance administration and oversight. While not exhaustive, this section outlines the systems, identifiers, and services used to announce and facilitate the financial assistance application process and manage awards from pre-award through closeout. Responsibilities associated with the systems are highlighted in this appendix.

The following federal statutes, executive orders and regulations provide the framework for fiscal management and oversight:

- <u>45 CFR 75.211</u>, USAspending.gov (USAS);
- Digital Accountability and Transparency Act of 2014 (DATA Act) (Public Law 113-101);
- Federal Funding Accountability and Transparency Act (FFATA) (<u>Public Law 110-252</u> as amended); and
- <u>Executive Order 13576</u>, Delivering an Efficient, Effective, and Accountable Government.

C.1: Grants Management Systems

Awarding agencies must use a Quality Service Management Office (QSMO) approved grants management system and the Payment Management System (PMS) to manage awards throughout the lifecycle.

HHS uses two financial assistant management systems solutions outlined below to foster efficiency, reduce duplication of associated cost, facilitate data sharing, and reduce awarding agency administrative burden.

C.1.1: eRA Commons

eRA is NIH's online system where applicants, recipients, federal staff at NIH, and other awarding agencies can access and share administrative information relating to research awards. eRA supports two main subsystems "eRA Internal Applications" (also known as IMPAC II (Information for Management, Planning, Analysis, and Coordination), used by NIH staff, and "eRA External Applications" (Commons, iEdison), accessed virtually by the awardee community.

C.1.2: GrantSolutions

GrantSolutions is a comprehensive financial assistance management system housed in the Office of Grants and available to all federal awarding agencies. It is a single system where applicants, recipients, and federal staff can perform and monitor the status of their respective grants management activities. It provides the following:

- Business solutions for processing of applications from receipt (including those submitted through Grants.gov) through award; and
- Assistance with portfolio management, including post-award reporting and closeout.

C.2: Planning and Pre-Award Phases

C.2.1: Grants.gov

Grants.gov is an e-government initiative managed by the Department of Health and Human Services, operating under the governance of the Office of Management and Budget (OMB). Using the Grants.gov system makes it faster, easier, and more cost effective for grant applicants to electronically interact with federal awarding agencies.

The HHS Office of Grants requires awarding agencies to use the Grants.gov system to:

- Publicize proposed and/or upcoming competitive funding opportunities for HHS; and
- Identify potential upcoming funding opportunities proposed by HHS agencies by providing forecasts.

Forecasts generally provide:

- Early information on Notices of Funding Opportunity (NOFOs) by posting advance forecasts on a public website (currently Grants.gov).
- Public notice of up to 12 months of planned proposed and/or upcoming opportunities for the fiscal year.
- An opportunity to post unanticipated NOFOs arising throughout the fiscal year as early as possible to maximize public notification.

Awarding agencies are required to provide essential information for each forecasted NOFO, which includes:

- Funding Opportunity Number and Title
- Agency Code and Name
- Estimated Funding
- Expected Number of Awards
- Awarding Agency Contact
- Agency Contact Phone and Email
- Estimated Post Date and Estimated Application Due Date

Awarding agencies should immediately update a forecast on the forecasting module when a decision is made not to fund a Notice of Funding Opportunity (NOFO).

Agencies can find additional information and instructions for posting forecasts to Grants.gov on their help page at <u>Create/Add a Forecast</u>.

All awarding agencies must post the full text of the NOFO for competitive grants or cooperative agreements to Grants.gov (as an attachment in the "Full Announcement" folder on the "Related Documents tab), in addition to completing the synopsis. The notices will be listed at Grants.gov.

C.2.2: Unique Entity Identifier (UEI)

The UEI became the official identifier for doing business with the U.S. Government as of April 4, 2022. The UEI is generated and assigned by System Award Management at <u>SAM.gov</u>.

Any entity which desires to apply for a federal funding must register with SAM. This includes for-profit businesses, nonprofits, government contractors or subcontractors, as well as state and local governments.

All government awarding agencies use the Entity Management section of SAM for their contracting and financial assistance awarding and processes. SAM.gov allows entities to register for a UEI and update required data to keep the UEI current.

Awarding agencies must:

- Include SAM registration requirements for applicants in NOFOs;
- Verify that applicants' SAM registrations are current as part of the pre-award process and at the time of any award amendment that adds funds to an existing award; and
- Include the award term at <u>2 CFR part 25, appendix A</u>, which requires the recipient to maintain current information, through at least an annual review, until it submits the final required financial report or receives the final payment, whichever is later.

C.2.3: Sam.gov

SAM is the system awarding agencies must use to determine whether an organization or individual recommended for an award is suspended, debarred, disqualified, or voluntarily excluded from receiving federal contracts, certain subcontracts, and certain types of federal financial and non-financial assistance and benefits. It is maintained by the HHS Office of Inspector General (OIG) based on their exclusion authority.

SAM contains an up-to-date "<u>List of Excluded Individuals/Entities</u>" which includes organizations and individuals disqualified by awarding agencies. SAM's list includes the name of the suspending/debarring agency; the basis for the exclusion; the start (action date) and end dates (termination date) of the exclusion; and current status.

C.2.4: Do Not Pay (DNP)

The <u>DNP Business Center</u>, managed by the Department of Treasury's Bureau of the Fiscal Service, established a centralized system that federal agencies can use to detect improper payments. DNP helps to reduce the number of improper payments by providing streamlined access to relevant data during the pre-award process and anytime during the payment lifecycle. DNP provides a robust source of multiple data points to help determine eligibility of applicants to receive federal funds. Data sources include the credit alert system, the death master file, list of excluded individuals and entities, foreign assets control, UEI records, SAM exclusion records, and the Treasury Offset Program's Debt Check.

C.2.5: SAM.gov Responsibility and Qualification

Formerly known as the Federal Awardee Performance and Integrity Information System (FAPIIS), <u>Responsibility and Qualification</u> is the integrity and performance system established by 189

OMB and GSA that includes government-wide data with specific information related to the integrity and performance of non-federal entities. It is comprised of information from various sources on the eligibility of non-federal entities to receive award funds from the federal government. Federal agencies must report information to SAM.gov Responsibility and Qualification and also review it prior to making all federal awards.

C.3: Award Phase

C.3.1: Payment Management System (PMS)

PMS (<u>Payment Management System (psc.gov</u>) is a centralized automated award payment and cash management system. PMS provides awarding agencies and recipients the tools to manage award payment requests, drawdowns, and disbursement reporting activities. PMS manages award payment-related activities from the time of award through award closeout.

The HHS Program Support Center's Payment Management Services (PMSvc) operates and provides daily oversight for PMS. In that capacity, PMSvc serves as a fiscal intermediary between awarding agencies and recipients.

C.3.2: Award Management (FBO, FPDS-NG, eSRS/FSRS)

The <u>Federal Funding Accountability and Transparency Act Subaward Reporting System (FSRS)</u> is the reporting tool that federal recipients use to capture and report subaward and executive compensation data regarding their first-tier subawards in accordance with FFATA reporting requirements. The FSRS is a component of the Integrated Award Environment (IAE). Recipients are responsible for entering information in FSRS to report applicable subaward obligations; however, they are not required to report obligations resulting from vendor relationships. The subaward information entered in FSRS is available on <u>USAspending.gov</u>.

C.4: Post-Award Phase

C.4.1: Payment Management System (PMS)

See information in Award Phase above.

C.4.2: SAM.gov Responsibility and Qualification

See information in the Planning and Pre-Award Phases above.

C.4.3: Federal Audit Clearinghouse (FAC)

OMB designated the General Services Administration (GSA) to operate the FAC, which is responsible for receiving, processing and distributing Single Audit packages. Federal agencies and the public can access FAC's database of completed audits at the <u>FAC website</u>. FAC is also used pre-award to assess recipient risk.

C.4.4: Tracking Accountability in Government Grants System (TAGGS)

- TAGGS (<u>http://taggs.hhs.gov</u>) is a publicly accessible database that serves as the central repository for awards awarded by HHS.
- TAGGS is an integral tool in HHS' Open Government Financial Spending Initiative and helps HHS meet its statutory requirements for transparency under FFATA.

- The DG Office of Grants Systems Management (OGSM) is responsible for the operation and maintenance of TAGGS. Awarding agencies are required to upload data into TAGGS.
- TAGGS currently provides HHS financial assistance award data to the <u>USAspending.gov</u> website.

TAGGS, which is the only HHS system approved for submitting federal financial assistance data to USAspending.gov, provides all required information for financial assistance, which includes awards, in accordance with OMB guidance.

C.4.5: USAspending.gov

<u>USAspending.gov</u> was established by the Office of Management and Budget (OMB) and is a publicly accessible website that fulfills the requirements of FFATA and subsequent amendments to provide information about federal financial assistance awards to the public.

USAspending.gov is operated and maintained by the Department of Treasury. Federal agencies must report to USAspending.gov on federal grants, cooperative agreements, contracts, loans, and other financial assistance awards of more than \$30,000.

C.4.6: Data Quality Database Application (DQDA)

- DQDA is a business support tool that monitors and tracks awarding agency's awards' submission statuses to their respective grant awarding systems per OMB Circular A-123 and the Open Government Initiative.
- As a part of HHS's ongoing efforts to enhance transparency, accountability, and data quality, DQDA is used for measuring the timeliness, completeness, and accuracy of submissions to TAGGS and USASpending.gov.
- The Office of Grants Systems Management (OGSM) is responsible for the operation and maintenance of DQDA, which interfaces with TAGGS to retrieve award data.
- Awarding agencies can use DQDA as a tool to quickly identify and measure data quality in terms of a performance standard.

Appendix D: Administrative and National Policy Requirements

The awards process is governed by laws and policies – both federal government-wide and HHS-specific. Below are common general administrative and national policy requirements.

D.1: Sources of Laws and Policies

There are four general sources of laws and policies that may apply to awards. This Appendix focuses on federal government-wide and HHS-wide sources.

The first two sources are more fully explained in this Appendix:

• Federal Government-Wide Sources. The U.S. Constitution, statutes, regulations, executive orders, and statements of policy.

• **HHS-Wide Sources.** Statutes, regulations, statements of policy, and award terms and conditions.

You will find information about the next two sources in the terms and conditions of award, some of which may be mentioned in the NOFO:

- Agency-Wide Sources. Awarding agencies may set policies for their awards through regulations, award terms and conditions, and other means.
- **Program-Wide Sources**. Individual funding programs may have their own specific policies. You may find these in the NOFO or the award terms and conditions. They may be based on the authorizing statute, implementing program regulations, or program guidance.

D.2: Locations of Laws and Policies

You can find laws and policies in a variety of places. This Appendix compiles many of the laws and policies that may apply to awards, but it is not intended to be an exhaustive list or to reproduce the full text. Readers are encouraged to review the original sources for more information.

Your award terms and conditions may incorporate specific statutes, regulations, or policies by reference. However, the following three are part of the terms and conditions of every award. This Appendix will address them more fully below.

- The HHS Grants Policy Statement.
- The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (<u>45 CFR part 75</u>).
- In SAM.gov you agree to the Financial Assistance General Certifications and Representations. These require you to follow all federal laws, executive orders, regulations, and public policies governing financial assistance awards. A few of them are specifically mentioned. This Appendix addresses those in the tables below. They are marked with "see the Financial Assistance General Certifications and Representations."

D.3: Applicability of Laws and Policies

Many laws and policies apply to all HHS awards. But some apply only to awards with certain types of activities or to certain types of recipients. For example, some may apply only to construction awards, conference awards, or research awards. Additionally, most apply to subrecipients. Some of the exceptions are noted in the tables below.

D.3.1: General Order of precedence

The general order of precedence determines the order in which laws and policies may apply. The table includes examples of the types of laws and policies at each level; it is not an exhaustive list.

Level of Policy	Examples (Note: This list is not exhaustive.)
1. US Constitution	The foundation of all laws, rules, and policies.
2. Statutes	Program Authorizations and Appropriations Federal Grant and Cooperative Agreement Act of 1977 Federal Funding Accountability and Transparency Act (FFATA) of 2006 Digital Accountability and Transparency Act (DATA) of 2014 Grant Reporting Efficiency and Agreements Transparency (GREAT) Act of 2019
3. Regulations	Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards: <u>2 CFR 200</u> (government-wide) & <u>45 CFR 75</u> (HHS) Program-specific regulations
4. Policies, Program Guidance, and Award-Specific Requirements	Executive Orders OMB Memos HHS Grants Policy Statement (GPS) HHS Grants Policy Administration Manual (GPAM) Agency-Specific Grants Policies Agency- and program-specific guidance related to one or more award programs such as Notices of Funding Opportunity (NOFO), FAQs, and other program announcements, e.g., agency guidance, manuals, "Dear Colleague" letters. For non-discretionary awards these might include state or Tribal plans, public assistance or statewide cost allocation plans. Requirements specific to an individual award or class of awards, such as a requirement to perform activities described in the recipient's application.

D.4: HHS Grants Policy Statement

The GPS applies to all HHS awards. The awarding agency may list any exceptions to the GPS in the Notice of Award.

D.5: Uniform Requirements

The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (<u>45 CFR part 75</u>) apply to all HHS awards, unless specifically exempted by <u>45 CFR</u> <u>75.101(d) or (e)</u>.

While all of 45 CFR part 75 applies to grants and cooperative agreements, following are some key requirements:

D.5.1: Subrecipients

The uniform requirements also address subrecipient responsibilities. See <u>45 CFR 75.101(b)(1)</u>, <u>45 CFR 75.351-353</u>.

Recipients and subrecipients must follow the award terms and conditions.

In general, the primary recipient must:

- Apply terms and conditions to their subawards.
- Evaluate the risk of subawards and use specific conditions, if needed.
- Monitor subaward compliance.
- Verify that the subrecipient meets audit requirements.
- Remedy noncompliance.
- Ensure that their subrecipients have a Unique Entity Identifier and maintain a SAM.gov registration.

D.5.2: Termination

HHS may terminate awards under certain circumstances. See <u>45 CFR 75.372.</u>

D.6: Financial Assistance General Certifications and Representations

When you registered in SAM.gov, your authorized organization representative agreed to the Financial Assistance General Certifications and Representations. These are binding on every award.

You can review these certifications and representations in Appendix I of the SAM.gov Entity Registration Checklist. You can find the checklist on SAM.gov <u>Get Started with Registration and</u> the Unique Entity ID page.

While the Financial Assistance General Certifications and Representations expressly identify certain requirements, they also require compliance with all applicable laws and policies. Those expressly identified are marked with "See General Certifications and Representations."

D.7: Laws and Policies

This section outlines various laws and policies that may apply to HHS awards (including recipients and subrecipients), but it is not intended to be an exhaustive list.

The following laws and policies apply to all recipients and subrecipients, with any exceptions noted within the guidance or notes.

D.7.1: Administrative and Activities

Laws and Policies	Source	Notes
Abortions Related to limitations on use of federal funds for abortions.	Statute: <u>Consolidated Appropriations Act</u> <u>2023</u> , Division H, Title V, Sections 506 and 507	Agreed to in general certifications.
Debt Collection Related to how the federal government collects debt.	Statute: <u>31 USC 3701</u> Regulation: <u>31 CFR part 285</u>	
Needle Exchange Related to prohibition on using award funds to give out sterile needles to inject illegal drugs, with some exceptions.	Statute: <u>Consolidated Appropriations Act</u> 2023, Division H, Title V, Section 526	See General Certifications and Representations
Publications and Acknowledgement of Support Related to recipients acknowledging HHS funding in public documents related to the awarded project.	Statute: <u>Consolidated Appropriations Act</u> 2023, Division H, Title V, Section 505	See <u>Supplemental</u> Information for requirements and example.
Reporting Subaward and Executive Compensation Information Related to requirements to report certain information on subawards and executive salaries.	Statute: Federal Funding Accountability and Transparency Act of 2006 (FFATA), <u>31 USC</u> <u>6101</u> note. Regulation: <u>2 CFR part 170</u>	See General Certifications and Representations
Salary Rate Limitation – Federal Executive Level II. Related to restrictions to not use award funds to pay a salary over the <u>Federal</u> <u>Executive Level II</u> rate for that year.	Statute: <u>Consolidated Appropriations Act</u> 2023, Division H, Title II, Section 202	For 2023, the amount is \$212,100. See General Certifications and Representations
SAM.gov and Universal Entity Identifier (UEI) Related to the requirement to register and maintain registration, including gaining a UEI.	Regulation: <u>2 CFR part 25</u>	See the award term at 2 2 CFR part 25, <u>Appendi</u> <u>A.</u> See General Certifications and Representations
Use of Logos Related to prior approval for using an HHS or awarding agency logo.	Statute: <u>42 USC 1320b-10</u> .	See <u>Supplemental</u> <u>Information</u> for more.

D.7.2: Civil Rights Protections

Find more detail on civil rights protections at HHS Office for Civil Rights, <u>Laws and Regulations</u> <u>Enforced by OCR.</u>

Laws and Policies	Source	Notes
Civil Rights Assurance of Compliance	Required by: Condition of Award; 45 CFR	<u>See HHS Form 690,</u>
Related to requirements to certify	<u>80.4; 84.5; 86.4; 91.33; 92.4</u>	Assurance of
compliance with civil rights laws.		Compliance.
Copeland Anti-Kickback Act	Statutes: <u>18 USC 874</u> and <u>40 USC 3145</u>	Applies to awards with
Related to requiring contractors to follow 29	Regulation: <u>48 CFR 22.403-2</u>	construction or
CFR part 3 under awards that include		alterations.
construction, alteration, and renovation and	,	
weekly compliance statements on the wages		
paid to each employee.		
Davis-Bacon Wage Protections	Statute: <u>40 USC 3141, et seq.</u>	Applies to awards with
Related to using contractors that pay		construction or
prevailing wages and benefits under awards		alterations.
funding construction, alteration, or repair.		
Discrimination Based on Age	Statutes: Age Discrimination Act of 1975, <u>42</u>	See General
Related to protecting people from	USC 6101, et seq.; Section 1557 of the	Certifications and
discrimination based on age.	Affordable Care Act, <u>42 USC 18116</u>	Representations
$\langle \rangle$	Regulations: <u>45 CFR part 91</u>	
Discrimination Based on Disabilities	Statutes: Section 504 of the Rehabilitation Act,	See General
Related to protecting people from	29 USC 794; (for state and local government	Certifications and
discrimination based on a disability.	recipients; Section 1557 of the Affordable	Representations
	Care Act; <u>42 USC 18116</u>	
	Regulations: <u>45 CFR part 84; 45 CFR part 92</u>	
Discrimination Based on Race, Color, and	Statutes: Title VI of the Civil Rights Act, <u>42</u>	See General
National Origin	USC 2000d; Section 1557 of the Affordable	Certifications and
Related to protecting people from	Care Act; <u>42 USC 18116</u>	Representations
discrimination on the basis of race, color, or national origin.	Regulations: <u>45 CFR part 80; 45 CFR part 92</u>	

Discrimination Based on Religion and	Statutes: Church Amendments, <u>42 USC 300a-</u>	See General
Religious Conscience	<u>7</u> ; Coates-Snowe Amendment, <u>42 USC 238n</u> ;	Certifications and
Related to protecting people from	and the Weldon Amendment, Consolidated	Representations
discrimination based on their religious	Appropriations Act, 2022, P.L 117-103, div.	
beliefs.	H, title V General Provisions, § 507(d)(1)	
	(Mar.15, 2022).	
	Guidance: HHS Office for Civil Rights,	
	Conscience and Religious Freedom for	
	situations where this protection applies.	
Discrimination Based on Sex	Statutes: Title IX of the Education	See General
Related to protecting people from	Amendments of 1972, as amended; 20 USC	Certifications and
discrimination based on sex.	1681 et seq.; Section 1557 of the Affordable	Representations (Title
	Care Act, <u>42 USC 18116</u>	
	Regulations: <u>45 CFR part 86; 45 CFR part 92</u>	
	See other sex discrimination guidance and	
	requirements at HHS Office for Civil Rights,	
	Laws and Regulations Enforced by OCR.	
	See also <u>Sex-Based Harassment</u> .	
Drug-Free Workplace	Statute: Drug-Free Workplace Act, <u>41 USC</u>	See the award term a
Related to maintaining a drug-free	8101-8106	<u>CFR 382.400</u> .
workplace and notifying the awarding	Regulation: 2 CFR part 182, subpart B	See General
agency if an employee is convicted of		Certifications and
violating a criminal drug law. Failure to	<i>Y</i>	Representations
follow these requirements may be cause for		
debarment.		
Earthquake Hazards Reduction	Statute: <u>42 USC 7701, et seq.</u>	Applies to new
Related to requirements to use earthquake-	Directive: Executive Order 13717	construction.
resistant design when constructing new		
buildings.		
Fair Housing	Statute: Title VIII of the Civil Rights Act of	See General
Related to protecting people from	1968, <u>42 USC 3601,</u> et seq.	Certifications and
discrimination in housing.		Representations

Faith-Based Organizations	Statute: <u>42 USC 2000bb, et seq.</u>	
Related to protections for faith-based organizations to apply and receive federal funds without discrimination or interference with their mission. Describes limitations on the use of federal funds.	Directives: Executive Orders <u>13279</u> , <u>13559</u> , and <u>13831</u> . Regulation: <u>28 CFR part 38, appendix A</u> and <u>45 CFR part 87, appendix A</u>	
Hotel and Motel Fire Safety Related to fire safety activities for hotels and motels used for venues.	Statute: <u>15 USC 2201, et seq</u>	Applies to awards using hotels or motels as venues.
Limited English Proficiency Related to steps to improve access to persons with limited English proficiency.	Required by: <u>Title VI of the Civil Rights Act, 42</u> USC 2000d; Section 1557 of the Affordable Acre Act, 42 USC 18116 Regulations: <u>45 CFR part 80</u> ; 45 CFR part 92 Guidance: <u>Guidance to Federal Financial</u> Assistance Recipients Regarding Title VI <u>Prohibition Against National Origin</u> Discrimination Affecting Limited English <u>Proficient Persons</u>	See also <u>LEP.gov</u> Does not apply to subcontractors.
Military Recruiting and Higher Education Related to limitations on funding institutions of higher education that do not allow Reserve Officer Training Corps (ROTC) on campus and allow military recruiting on campus.	Statute: <u>10 USC 983</u>	Applies to subrecipients where HHS must approv them. Does not apply to subcontractors.
Pro-Children Act – Non-Smoking Related to prohibiting smoking in indoor facilities where award-funded projects serve children. Not following this law can bring civil monetary penalties.	Statute: Pro-Children Act of 2001, <u>20 USC</u> <u>7181 through 7184</u>	
Privacy Act Related to protecting information about a person, unless the person gives permission or under the exceptions at <u>5 USC 552a(b)</u> .	Statute: <u>5 USC 552a</u>	
Seat Belts Related to encouragement to adopt and enforce seat belt policies.	Directive: <u>Executive Order 13043</u>	Does not apply to subrecipients or subcontractors.

Texting While Driving Related to limitations on texting while driving when federal funds pay for vehicles or cell phones.	Directive: <u>Executive Order 13513</u>	Does not apply to subcontractors.
Trafficking Victims Protection Related to bans providing funds to organizations involved in human trafficking.	Statute: Trafficking Victims Protection Act (TVPA) of 2000, as amended, <u>22 USC</u> <u>7104(g)</u> . Regulation: <u>2 CFR part 175</u> , Award Term for Trafficking in Persons.	See General Certifications and Representations
Whistleblower Protections Related to protecting employees from reprisal for disclosing information about violations.	Statute: Protection from Reprisal of Disclosure of Certain Information, <u>41 USC</u> <u>4712</u> .	See General Certifications and Representations

D.7.3: Environmental

D.7.3: Environmental		
Laws and Policies	Source	Notes
Clean Air and Water Related to the requirement to follow certain environmental laws.	Statute: Clean Air Act of 1970, <u>42 USC 7401</u> et seq. Statute: Clean Water Act of 1972, <u>33 USC</u> <u>1251 et seq.</u>	See <u>Summary of the</u> <u>Clean Air Act</u> . See <u>Summary of the</u> <u>Clean Water Act</u> .
Earthquake Hazards Reduction Related to using earthquake-resistant design when constructing new buildings.	Statute: <u>42 USC 7701, et seq.</u> Directive: <u>Executive Order 13717</u>	Applies to new construction.
Flood Insurance Related to requirements for flood insurance in areas with special flood hazards.	Statute: <u>42 USC 4001, et seq.</u>	Applies to awards that acquire or construct buildings. Does not apply to subrecipient or subcontractors.

National Environmental Policy Act	Statute: National Environmental Policy Act of	Applies to construction
Related to policies to conduct reviews to	1969, as amended, <u>42 USC 4321 et seq</u> .	or major renovation
assess and mitigate environmental impact.		activities.
	Guidance: <u>HHS General Administration</u>	Doos not apply to
	<u>Manual (GAM), Part 30-50</u> , National Environmental Policy Act Review for the	Does not apply to subcontractors. See more
	NEPA process.	in <u>Supplemental</u>
	NEFA process.	Information.
		See General
		Certifications and
		Representations
National Historic Preservation Act (NHPA)	Statute: National Historic Preservation Act	Applies to awards buying
Related to requirements to consider the	(NHPA) of 1996, as amended, <u>54 USC 300101</u>	constructing, or altering
effect of potential awards on historic	<u>et seq.</u>	real property.
properties.	Regulation: <u>36 CFR 800</u>	See resources and a
		summary of the process
		in <u>Supplemental</u>
		Information.
Resource Conservation and Recovery	Statute: <u>42 USC 6962</u>	Applies to state and loca
Relating to requirements to give preference	Regulation: <u>40 CFR part 247</u>	institutions of higher
to the purchase of recycled products.		education, hospitals, and
	(See list of relevant recycled products at <u>40</u>	non-profit organizations
	<u>CFR part 247, subpart B</u> .)	
Safe Drinking Water Act	Statute: <u>42 USC 300f, et seq</u> .	Applies to public water
Related to ensuring that public water	Regulation: <u>40 CFR part 141</u>	systems.
systems provide safe and reliable drinking		
water.		
Halfama Balanatha As 11	Statute: <u>42 USC 4601 et seq.</u>	Does not apply to
Uniform Relocation Assistance		
Uniform Relocation Assistance Related to real estate activities that may	Regulation: 45 CER part 15 and 49 CER	subcontractors.
	Regulation: <u>45 CFR part 15</u> and <u>49 CFR</u>	subcontractors.
Related to real estate activities that may	Regulation: <u>45 CFR part 15</u> and <u>49 CFR</u> part 24	subcontractors.
Related to real estate activities that may		subcontractors.
Related to real estate activities that may		subcontractors.
Related to real estate activities that may displace people.	part 24	subcontractors.

Laws and Policies	Source	Notes
Anti-Lobbying, Publicity, and Propaganda	Statutes: <u>31 USC 1352. Consolidated</u>	
Related to restrictions against lobbying,	Appropriations Act 2023, Division E, Title VII,	
publicity, or propaganda using federal funds.	Sections 715, 718, and 731; Division G, Title	
Applicants must certify their compliance.	IV, Section 401; Division H, Title V, Sections	
	503 and 522.	
	Regulation: 45 CFR 75.450	
Controlled Substances	Statute: Consolidated Appropriations	See General
Related to restrictions on activities that	Act 2023, Division H, Title V, Section 509	Certifications and
promote the legalization of any drug or		Representations
other substance.		1
Gun Control	Statute: Consolidated Appropriations Act	See General
Related to requirements about not using	2023, Division H, Title II, Section 210; Title V,	Certifications and
federal funds to advocate for or promote	Section 503(c).	Representations
gun control.		
Hatch Act	Statute: <u>5 USC 1502</u>	Does not apply to
Related to restrictions on political activity	(For exceptions see <u>5 USC 1501)</u>	subcontractors.
and running for public office.		
	Regulation: <u>5 CFR part 151</u>	
Lobbying Disclosure Act of 1995	Statute: 2 USC 1601 et seq	You can find the
Related to requirements to disclose lobbying		Disclosure of Lobbying
activities.	7	Activities (SF-LLL) at
		Grants.gov/Forms.
		See General
		Certifications and
		Representations

D.7.5: Lobbying, Advocacy, & Political Activity

Laws and Policies	Source	Notes
Anti-Lobbying, Publicity, and Propaganda	Statutes: 31 USC 1352. Consolidated	
Related to restrictions against lobbying,	Appropriations Act 2023, Division E, Title VII,	
publicity, or propaganda using federal funds.	Sections 715, 718, and 731; Division G, Title	
Applicants must certify their compliance.	IV, Section 401; Division H, Title V, Sections	
	503 and 522.	
	Regulation: <u>45 CFR 75.450</u>	

Controlled Substances Related to restrictions on activities that promote the legalization of any drug or other substance.	Statute: <u>Consolidated Appropriations Act</u> <u>2023</u> , Division H, Title V, Section 509	See General Certifications and Representations
Gun Control Related to requirements about not using federal funds to advocate for or promote gun control.	Statute: <u>Consolidated Appropriations Act</u> <u>2023</u> , Division H, Title II, Section 210; Title V, Section 503(c).	See General Certifications and Representations
Hatch Act Related to restrictions on political activity and running for public office.	Statute: <u>5 USC 1502</u> (For exceptions see <u>5 USC 1501)</u> Regulation: <u>5 CFR part 151</u>	Does not apply to subcontractors.
Lobbying Disclosure Act of 1995 Related to requirements to disclose lobbying activities.	Statute: 2 USC 1601 et seq	You can find the Disclosure of Lobbying Activities (SF-LLL) at <u>Grants.gov/Forms</u> . See General Certifications and Representations

D.7.6: Patents, Inventions, and Data

Laws and Policies	Source	Notes
Federal government rights Related to the federal government's rights to use inventions.	Statute: <u>35 USC 202-203</u> Regulation: <u>37 part 401</u>	Applies to research projects with inventions.
Federal Information Security Management Act (FISMA) Related to policies when recipients collect, store, process or send data on behalf of HHS.	<u>44 USC 3551 et seq.</u>	
Retaining Rights Related to the rights to new inventions developed from funded research.	Statute: Bayh-Dole Act of 1980, <u>35 USC 200</u> et seq. and the related <u>EO 12591</u>	Applies to research projects with inventions.

D.7.7: Procurement

Laws and Policies	Source	Notes
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American-Manufactured Goods Related to required preferences for certain products and materials made in the US. Waivers may be possible.	Statute: Buy American Act, <u>41 USC 8301 et</u> <u>seq</u> , Statute: Build America, Buy America Act, <u>Public Law 117–58</u> , Title IX, Subtitle A Regulations: <u>2 CFR 200.322</u> and <u>48 CFR part</u> <u>25</u> Guidance: <u>M-22-11</u>	
Fly America Act Related to requirements for travelers to use certified U.S. airlines for award-funded air travel.	Statute: <u>49 USC 40118</u> Regulation: <u>41 CFR 301-10.131 - 143</u>	
Prohibition on certain telecommunications and video surveillance services or equipment Related to restrictions on using federal funds for telecommunications equipment produced by certain companies.	Statute: <u>41 USC 3901 et seq</u> Regulation: <u>2 CFR 200.216</u>	
U.S. Flag Vessels Related to using U.S. owned and operated vessels to ship goods and supplies bought with award funds.	Statute: <u>46 USC 55305</u> Regulation: <u>46 CFR 381.7</u>	

D.7.8: Professional Integrity

Laws and Policies	Source	Notes
Blocking Access to Pornography Related to requirements for computer systems to not allow people to view, download, or exchange pornography. The only exclusion is for law enforcement functions.	Statute: <u>Consolidated Appropriations Act</u> 2023, Division H, Title V, Section 520	See General Certifications and Representations
Civil Actions for False Claims Act Related to the federal government's ability to take civil actions on violations of the false claims act.	Statute: <u>31 USC 3730</u>	See General Certifications and Representations

Debarment and Suspension	Regulation: 2 CFR part 180	Does not apply to
Related to not providing federal funds to		subcontractors unless th
excluded parties.		contract is over \$25,000.
		See General Certification
		and Representations
False Claims Act	Statutes: <u>31 USC 3729</u> , <u>18 USC 287</u> , and <u>18</u>	See General Certification
Related to liability on persons and	<u>USC 1001</u>	and Representations
companies who defraud government		
programs		
False or Misleading Information	Statute: Consolidated Appropriations Act	See General Certification
Related to requirements to not use federal	2023, Division H, Title V, Section 515(b)	and Representations
funds to share deliberately false or		Y
misleading information.		
Mandatory Disclosure	Statute: <u>41 USC 2313</u>	
Related to requirements to disclose certain	Regulation: <u>45 CFR 75.113</u> and <u>45 CFR part</u>	
violations of federal criminal law.	75, Appendix XII	
Program Fraud and Civil Remedies Act	Statute: <u>31 USC 3801 et seq</u>	See General Certification
Related to administrative hearings for	Statute of OSC Source steel	and Representations
certain false claims actions.		
Recent Felony Convictions	Statute: Consolidated Appropriations Act	See General Certificatior
Related to eligibility for awards for	2023, Division E, Title VII, Section 745	and Representations
corporations with felony criminal		
convictions in the past 24 months.		
Recipient Integrity and Performance	Regulation: <u>45 CFR 75.210(b)(1)(iii)</u> and <u>45</u>	
Related to information reported to SAM.gov	CFR part 75, appendix I, E.3	
Responsibility/Qualification.		
Unpaid Federal Tax Liability	Statute: Consolidated Appropriations Act	See General Certification
Related to eligibility corporations with an	2023, Division E, Title VII, Section 744.	and Representations
unpaid tax liability, with some conditions.		Does not apply to
		subrecipients or
		· · · · · · · · · · · · · · · · · · ·

D.7.9: Research Awards

Laws and Policies	Source	Notes
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Animal Welfare	Statutes: 7 USC 2131-2159 and 42 USC 289d	See Supplemental
Related to requirements when live animals are involved in award-funded programs and	Regulation: <u>9 CFR subchapter A</u>	Information.
	Policy: PHS Policy for the Humane Care and	
	Use of Laboratory Animals	
Certificates of Confidentiality	Statute: <u>42 USC 241(d)</u>	
Related to protecting subjects from		
compelled disclosure of identifying		
information and addressing voluntary		
disclosure.		
Clinical Investigations of FDA-Regulated	Statutes: <u>21 USC 355(i)</u> , <u>360b(j)</u> , and <u>360i(g</u>).	Applies to clinical
Products	Regulations: 21 CFR parts 50, 54, 56, 21 312,	investigations regulated by FDA.
Related to clinical investigations regulated by FDA.	<u>511, and 812.</u>	by FDA.
·	Directive: Classing of Using Deings Dec	
Cloning Related to ban on cloning human beings.	Directive: <u>Cloning of Human</u> <u>Beings Ban</u> (Presidential memorandum, March 4, 1997)	
Confidentiality: Substance Use Disorder	Statute: <u>42 USC 290dd-2</u>	
Patient Records Related to requirements for substance use		
disorder patient confidentiality.		
Federal Technology Transfer	Statuta: 15 USC 2701 at cog	
Related to access to federal government	Statute: <u>15 USC 3701 et seq</u>	
laboratories by non-federal organizations		
Financial Conflicts of Interest	Desulation: 42 CED next EQ. Submert E	Anglias ta yaaaayah
Related to a process to identify and address	Regulation: <u>42 CFR part 50, Subpart F</u>	Applies to research awards.
financial conflicts.		
		Does not apply to
		subcontracts, Phase I of the SBIR/STTR programs
		and federal institutions.
НІРАА	Statuto: Hoalth Incurance Portability and	
Related to the Privacy Rule standards that	Statute: Health Insurance Portability and Accountability Act	Applies to HIPAA covere entities.
address the use and disclosure of individuals'	P.L.104-191	
health information (known as "protected		
health information") by entities subject to		
the Privacy Rule.		

Human Embryos Related to policies for the destruction or creation of human embryos.	Statute: <u>Consolidated Appropriations Act</u> <u>2023, Division H, Title V, Section 508(a)</u>	See General Certifications and Representations
Human Subjects Protection Related to requirements for research involving human subjects.	Statutes: <u>42 US. 289</u> and <u>42 USC 300v-1(b)</u> Regulation: <u>45 CFR part 46</u>	See <u>Supplemental</u> Information.
Recombinant DNA and Human Gene Transfer Related to NIH guidelines for such research.	Guidance: <u>NIH Guidelines</u>	
Research Misconduct Related to Public Health Service Policies on Research Misconduct	Regulation: <u>42 CFR part 93</u>	
Research on Human Fetal Tissue Related to the use of human fetal tissue in research.	Statute: <u>42 USC 289g-1 and g-2</u> Regulation: <u>45 CFR 46.206</u>	

D.7.10: Other

Laws and Policies	Source	Notes
Freedom of Information Act (FOIA) FOIA establishes a 'strong presumption in favor of disclosure of requested information.	Statute: <u>5 USC 552</u>	
Intergovernmental Personnel Act Provides for the temporary assignment of personnel between the federal government and state and local governments, colleges and universities, Indian tribal governments, federally funded research and development centers, and other eligible organizations	Statute: <u>5 USC 3371 et seq</u> Regulation: <u>5 CFR part 334</u>	
Paperwork Reduction Act Minimizes the paperwork burden resulting from the collection of information by or for the federal government	Statute: <u>44 USC 3501, et seq</u>	
Public Health Security and Bioterrorism Requires the biennial review and republication of the HHS list of select agents and toxins.	Statute: <u>42 USC 262a</u>	

Standards of Conduct	Regulation: <u>45 CFR 73</u>	
To assure HHS is conducted effectively,		
objectively, and without improper influence		
or the appearance of improper influence,		
sets standards for employees and special		
Government employees		

D.8: Supplemental Information

D.8.1: Administrative and Activities *D.8.1.1: Use of Logos*

Recipients must have prior written approval from the GMO before using an HHS or awarding agency logo. Using a logo without approval may lead to a financial penalty.

D.8.1.2: Publications and Acknowledgement of Support

Recipients must acknowledge HHS funding in public documents related to the awarded project.

Acknowledgements must include:

- Name of awarding agency and HHS
- Amount of federal funding
- Percentage of federal funding to total costs
- Disclaimer of HHS endorsement or agreement.

Example of statement for public documents:

The [awarding agency], Department of Health and Human Services provided financial support for this [project / publication / website / etc.]. The award provided XX% of total costs and totaled \$XX. The contents are those of the author. They may not reflect the policies of the Department of Health and Human Services or the U.S. government.

Contact the GMO if you need to revise the contents of the acknowledgement statement. Also contact the GMO to coordinate all media releases.

Recipients must include this statement in materials for funded conferences:

"The [Awarding agency] made this conference possible [in part] through [award number]. Views expressed by speakers, moderators, and in writing may not reflect the policies of the Department of Health and Human Services. Mentions of trade names, commercial practices, or organizations do not imply endorsement by the U.S. Government."

D.8.2: Environmental Policies

To comply with NEPA for its award-supported activities, HHS must review the environmental aspects of awards that include construction or major renovation activities before award, unless a specific condition is placed on the award. If, because of a post-award change, an awarding

agency determines NEPA applies to an award, the NEPA process must be satisfactorily completed before drawdown of funds for the activity. Consult the awarding agency's <u>NEPA</u> <u>contact</u> for specific information on what must be addressed.

D.8.2.1: National Historic Preservation Act (NHPA)

If the recipient takes actions on real property that are not in compliance with historic preservation requirements, the awarding agency may have a basis to take an enforcement action and recoup some or all its funding.

Resources:

- EO 13287, "Preserve America"
- For questions on NHPA, contact <u>Real Estate Policy and Strategy</u>, Program Support Center (PSC), Assistant Secretary for Administration (ASA).
- The HHS implementation process is detailed in Section 3-4 of the <u>HHS Facilities Program</u> <u>Manual</u> (Volume II).

The table below summarizes the process used to determine if a proposed activity will have any effects on historic properties. It provides a general outline of the NHPA section 106 process, but not all details. Therefore, this attachment must be used with, not instead of, the NHPA requirements.

Activity	Guidance
 Determine if any portion of the project may include activities that affect an historic property. Such activities typically include acquisition, construction, or alteration of real property. Note: The applicant is primarily responsible for this determination. If the awarding agency has concerns about the applicant's determination, they will address them with the applicant and consult the State Historic Preservation Office (SHPO) or Tribal Historic Preservation Office (THPO), as applicable. 	If the answer is "yes," then continue with the process. If the answer is "no," then the process may stop.
2. Identify the appropriate SHPO or THPO with jurisdiction in the area where the project will be performed.	Find an <u>SHPO</u> . Find a <u>THPO</u> .

 In consultation with the SHPO or THPO, identify whether any National Register historic properties (or those eligible for inclusion) are within the project's Area of Potential Effect (APE). 	If the answer is "yes," then continue with the process. If the answer is "no," and the SHPO or THPO agrees, then the process may stop.
The APE can include areas outside of the project's boundaries. For example, constructing a building may not affect an historic resource on the property itself, but may affect the view or setting of a nearby historic resource.	
4. Determine if the undertaking will result in any adverse effects on an historic property.	If the answer is "yes," then continue with the process. If the answer is "no," and the SHPO or THPO agrees, then the process may stop.
5: Consult with SHPO or THPO and other appropriate parties to develop measures that mitigate adverse effects on historic properties. The consultation may result in a Memorandum of Agreement (MOA), signed by each party, which outlines each party's responsibilities for implementing the mitigation measures.	If the parties sign an MOA, the awarding agency must ensure that the undertaking is carried out in accordance with the MOA. If the parties cannot agree and do not execute an MOA, then proceed to Activity 6.
 6. Any party terminating consultation shall notify the other parties in writing. <u>36 CFR</u> <u>800.7</u> outlines the procedures to follow, depending on which party terminates the consultation. 	If there is a failure to reach resolution, the awarding agency head may decide to approve proceeding with the undertaking after following the applicable requirements of <u>36 CFR part 800</u> .

D.8.3: Research Awards

D.8.3.1: Human Subjects in Research

The regulations for the protection of human subjects in <u>45 CFR part 46</u>, Basic HHS Policy for Protection of Human Subjects (Subpart A of which is also known as the Common Rule) implement Section 491(a) of the Public Health Service (PHS) Act. The regulation applies to all HHS awards involving human subjects research.

The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is the office with HHS-wide responsibility for research involving human subjects under this policy. Foreign applicant organizations applying for awards for research involving human subjects are required to comply with <u>45 CFR part 46</u>. There is a single version of the Federal-

wide Assurance (FWA) form and Terms of Assurance for domestic (U.S.) and international (non-U.S.) institutions.

All NOFOs must clearly state the parameters of human subject use, and indicate the necessary information and assurances required from the applicant prior to the issuance of award.

Recipients, whether domestic or international, must safeguard the rights and welfare of human subjects in HHS-conducted or -supported activities (<u>45 CFR 46.101(a)</u> and <u>45 CFR 46.103(a)</u>).

As a matter of grants policy, recipients must ensure that subrecipients follow these requirements, as applicable. Recipients must facilitate the process for obtaining prior approval for subrecipients if not approved in the award.

Some human subject research is exempt from the requirements of the HHS regulations. The categories of research that qualify for exemption are found at <u>45 CFR 46.104(d)(1)-(8)</u>. OHRP guidance recommends that investigators not be given the authority to make an independent determination that human subjects research is exempt. HHS retains final authority as to whether a particular research study supported by HHS is exempt from the HHS regulations. Contact OHRP for any related questions.

OHRP is the only component of HHS with the delegated authority to interpret and enforce the regulatory requirements in <u>45 CFR 46.101(c)</u> as to whether a particular activity is regulated by <u>45 CFR part 46</u>.

Before engaging in HHS award-supported non-exempt human subjects research, the recipient, including any collaborating organization under a subaward, must:

- Hold or obtain an OHRP-approved FWA (<u>45 CFR 46.103(a)</u>); and
- Certify to the awarding agency, within the time frame specified, that the research has been reviewed and approved by an Institutional Review Board (IRB) designated in the FWA (45 CFR 46.103(d))

The <u>OHRP web site</u> contains a listing of those organizations with OHRP-approved assurances.

The awarding agency must make sure that an applicant and any collaborating organizations have the required assurance and certification in place, before:

- Making an award, unless a specific condition is included in the NoA restricting expenditures for this purpose;
- Non-exempt human subjects research is initiated, if non-exempt research is planned but will not occur until a subsequent phase of the project, by including a specific condition in the NoA that restricts expenditures for this purpose; or
- Approving a post-award change in scope that will result in non-exempt human subjects research.

The award condition must indicate that the recipient may not draw down funds, obligate or expend federal funds, or claim required cost sharing or matching costs for research involving

human subjects at any site engaged in non-exempt research until all requirements for are met. The prohibition on expenditures may extend to the whole project if that activity is not severable. The recipient must be advised that failure to comply within the stated time may result in full or partial termination of the award.

D.8.3.2: Research Involving Animals and Their Welfare

Requirements related to the use of live, vertebrate animals apply to all PHS agencies and to other research-related awards. PHS agencies include AHRQ, CDC, FDA, HRSA, IHS, NIH, and SAMHSA. These requirements apply to recipients, subrecipients, and contractors, whether foreign or domestic.

The requirements:

- Are included in the <u>Public Health Service Policy on Humane Care and Use of Laboratory</u> <u>Animals</u> (PHS Policy),
- Incorporate the <u>U.S. Government Principles for the Utilization and Care of Vertebrate</u> <u>Animals used in Testing, Research, and Training</u>,
- Require the recipient to maintain an animal care and use program based on the <u>Guide for</u> <u>the Care and Use of Laboratory Animals</u>; and
- Require compliance, as applicable, with the <u>Animal Welfare Act</u> and other federal statutes and regulations relating to animals.

Recipients must establish appropriate policies and procedures to ensure the humane care and use of animals and are ultimately responsible for compliance with the PHS Policy. Information about animal welfare topics is available from the <u>Office of Laboratory Animal Welfare</u> (OLAW), Office of Extramural Research, National Institutes of Health.

Before engaging in any HHS award-supported research using animals, applicants must:

- Have a current Animal Welfare Assurance approved by OLAW (the list of organizations with approved assurances is available at the OLAW website for both <u>domestic institutions</u> and <u>foreign institutions</u>;
- Provide, as part of the application or just-in-time, verification of current Institutional Animal Care and Use Committee (IACUC) approval of the animal activities. (PHS Policy requires that IACUC approval must have occurred within three years of the period of performance start date for new or renewal awards and at least every three years after that); and
- Comply with the awarding agency's internal IACUC requirements if a cooperative agreement.

Reporting requirements under the PHS Policy include an annual report to OLAW describing any change in the institution's program for animal care and use as described in the Assurance, changes in IACUC membership, and the dates the IACUC conducted its semiannual evaluations of the institution's program and facilities.

Foreign applicant organizations applying for awards for activities involving animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met. This includes providing OLAW with an Animal Welfare Assurance for Foreign Institutions, which constitutes institutional assurance and certification of compliance with the applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted, and a commitment to follow the International Guiding Principles for Biomedical Research Involving Animals.

No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy.

If the applicant does not have a current Animal Welfare Assurance (or made alternative arrangements, e.g., an inter-institutional assurance acceptable to OLAW) or has not provided the required verification by the time an award will be made, the awarding agency will notify the PO and the applicant and the awarding agency may:

- Delay the award until the recipient and all performance sites are operating in accordance with approved Animal Welfare Assurances and the organization has provided verification of IACUC approval of those sections of the application that involve use of animals; or
- Include a specific condition in the NoA restricting expenditures.

The award condition must prohibit drawdown or expenditure of funds under the award (whether federal funds or any required matching or cost sharing) until the requirements have been met. The prohibition on expenditures may extend to the whole project if that activity is not severable. The recipient must be advised that failure to comply within the stated time may result in full or partial termination of the award.

An awarding agency may not approve a post-award change that will result in research involving animals unless the awarding agency determines that an appropriate Animal Welfare Assurance has been negotiated with OLAW and the required IACUC verification has been received.

Reporting requirements under the PHS Policy include an annual report to OLAW describing any change in the institution's program for animal care and use as described in the Assurance, changes in IACUC membership, and the dates the IACUC conducted its semiannual evaluations of the institution's program and facilities. The IACUC, through the institutional official signing the Assurance, must promptly report any serious or continuing noncompliance with the PHS Policy, serious deviations from the *Guide for the Care and Use of Laboratory Animals*, and any IACUC suspensions.

Appendix E: Types of Award Programs and Associated Program-Specific Policies

E.1: Discretionary versus Nondiscretionary Awards

The distinction between discretionary and non-discretionary programs has a bearing on applicable pre-award requirements and the terms and conditions of award. Discretionary and non-discretionary programs generally are distinguished by statutory language. Authorizing statutes categorize the programs and activities under award programs and awarding agencies must apply any requirements specific to that type of award program, whether based on statute, regulation (programmatic, administrative, or other) or policy.

HHS's regulations at 45 CFR part 75 cover administrative, cost principles and audit requirements for all HHS awards. Specific regulations and policies may additionally be applicable based on discretionary or non-discretionary status.

To the extent feasible, HHS's policy is to use common terminology, systems, and processes for discretionary and non-discretionary programs. Awarding agencies must characterize a program in a consistent manner, e.g., a type of program/award cannot be a training award for one purpose, but characterized as another type of program/award for another purpose.

E.2: Discretionary Awards

E.2.1: Discretionary Research Awards

For research and research-related awards, or awards for other purposes that may involve research activity, awarding agencies must include the following in Notice of Funding Opportunity Announcements (NOFOs) and Notices of Award (NoAs), as applicable:

- Awarding agency or program-specific requirements;
- Whether the statute requires merit review;
- Whether expanded authorities are being overridden for any or all those authorities;
- Human subjects and animal welfare requirements;
- Other public policy requirements specifically applicable to research, or to specific types of research, e.g., clinical research;
- If patient care may be involved, the need for a research patient care rate and, if proposed as a post-award change, the need to obtain awarding agency prior approval (45 CFR 75.308(c)(9));
- Any direct or indirect cost limitations;
- A provision indicating that equipment acquired under the award is considered exempt property (pursuant to 45 CFR 75.319(c)); and
- Intellectual property provisions.

In addition, HHS encourages awarding agencies to use the <u>standard research terms and</u> <u>conditions issued by the HHS/NIH</u> with any modification as appropriate, to reflect HHS awarding agency-specific policy.

E.2.1.1: Research Misconduct

The Public Health Service (PHS) Policies on Research Misconduct in <u>42 CFR part 93</u> specify responsibilities related to research misconduct (Note: This requirement pertains to the following: AHRQ, CDC, FDA, HRSA, NIH, and OASH).

An applicant/recipient must have written policies and procedures for addressing allegations of research misconduct, file an Assurance of Compliance with the Office of Research Integrity (ORI), and take all reasonable and practical steps to foster research integrity. The assurance must state that the recipient has developed and will comply with an administrative process for responding to allegations of research misconduct in PHS supported research.

The recipient must report promptly to ORI any decision to initiate an investigation of research misconduct in connection with projects for which funds have been made available under the PHS Act. Please contact ORI with questions at <u>AskORI@hhs.gov</u>.

E.2.1.2: Conflict of Interest

All recipients must disclose, in writing, any potential conflict of interest to the awarding or passthrough agency in accordance with <u>45 CFR 75,112</u>. Each awarding agency must develop conflict of interest policies which address the following:

- conditions under which outside activities, relationships, or financial interests are proper or improper;
- mechanisms for advance notification of the activities above;
- a process for reviewing and assessing the appropriateness of the activities; and
- an outline how conflicts of interest may be addressed.

If an individual is applying for/receives a research award, the awarding agency must make a case-by-case determination on the steps to be taken, consistent with <u>42 CFR part 50, subpart F</u>, to provide a reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from a financial conflict of interest of the individual.

E.2.1.3: Research Patient Care Costs

Research awards to hospitals (or subawards to hospitals under research awards) may reimburse research patient care costs only when such care is specifically authorized under an award.

The allowability of research patient care costs as charges to awards depends on the type of patient and type of services received. In general:

• If the patient receives service or care that neither differs from usual patient care nor results in expenses greater than those that would have been incurred if the study had not existed, then the patient is considered to be hospitalized for usual care purposes and award funds will generally not support the costs.

- When the research extends the period of hospitalization beyond that ordinarily required for usual care, or imposes procedures, tests or services beyond usual care, whether in an inpatient or outpatient setting, the award funds may pay the additional costs.
- In certain kinds of clinical trials where accepted treatments are compared against new therapies, research patient care costs, generally, may be charged to an award only insofar as they are measurements or services above and beyond those that constitute usual patient care and are specified by the study protocol.

Awarding agencies should note research patient care costs do not include:

- otherwise allowable items of personal expense reimbursement, such as patient travel, consulting physician fees, or any other direct payments related to all classes of individuals
- costs of ancillary tests performed in facilities outside the hospital on a fee-for-service basis (e.g., in an independent, privately owned laboratory) or in an affiliated medical school/university, not associated with a hospital routine or ancillary service, based on an institutional fee schedule; or,
- data management or statistical analysis of clinical research results.

The recipient must retain records supporting reimbursement of research patient care costs as which are subject to review or audit. Reimbursement of research patient care costs and use of negotiated rates includes the general requirements for reimbursement of research patient care costs.

In order to receive reimbursement for research patient care costs, any hospital that, as a direct recipient of HHS funds, expects to incur more than \$100,000 in research patient care costs in any single budget period under a single HHS award must either have in place or take steps to negotiate a research patient care rate agreement(s) with the HHS/PSC Cost Allocation Service (CAS).

Despite a previously established a research patient care rate(s) with CAS, a hospital must submit a new research patient care rate proposal to CAS annually in accordance with CAS's requirements. Failure to negotiate a new research patient care rate(s) with CAS as required will result in the disallowance of all research patient care costs charged to an award.

If the hospital has not previously established a research patient care rate with CAS and an award including more than \$100,000 in research patient care costs in any single budget period is expected to be made, the awarding agency should advise the applicant of the need to negotiate a rate with CAS. The applicant should submit the patient care rate request upon receiving the initial notification of a pending award, but may submit it no later than ninety (90) days after the beginning date of the initial budget period.

If the proposal is submitted timely but the rate cannot be established before the award is awarded, the awarding agency may accept estimated rates (such as the Medicare interim billing

rates) for funding purposes pending negotiation of the rate to support later claims for such costs.

If a recipient does not meet the threshold for negotiation of a research patient care rate agreement with CAS in a given budget period, but has a currently negotiated research patient care rate, that rate will be used in awarding and reimbursing research patient care costs, regardless of the amount that the recipient expects to incur.

In all other cases, the hospital will be reimbursed at a rate not to exceed the lesser of actual research patient care costs or the rate included in the hospital's Medicare cost report.

The research patient care rate(s) contained in the Negotiation Agreement must be shown in all requests and/or claims for reimbursement of research patient care costs. The amount reimbursed will be based on the most current rates available at the end of the budget period.

When provisional rates are used as the basis for award of research patient care costs, the amount awarded shall constitute the maximum amount that the awarding office is obligated to reimburse the recipient for such costs. However, if a provisional rate is used, the research patient care costs paid must be adjusted if the final rate results in a decrease in research patient care costs.

If research patient care services are needed to meet special research protocol requirements, an awarding agency may approve and reimburse these costs other than through use of a research patient care rate if the costs are not otherwise covered by an applicable rate.

If the costs of patient care are funded by an HHS award, in whole or in part, whether such costs are classified as usual patient care or research patient care, the amount recovered from third parties must be credited to the award as an "applicable credit." However, patient charges must be adjusted for both routine services and ancillaries based on the negotiated rate before applying the third-party recoveries. The recipient is obligated to pursue recovery to the fullest extent possible and should be able to document those efforts.

E.2.1.4: Subrecipients Research Patient Care Costs

If a hospital that is a subrecipient or contractor under an award expects to incur more than \$100,000 in research patient care costs in any single budget period of the subaward or contract, the recipient will be responsible for establishing the rate or amount that will be reimbursed for such costs unless:

- The hospital is also a direct recipient of other HHS awards and in that capacity has established a rate with CAS; or,
- The relationship between the recipient and the hospital is considered less-than arm's length; in which case, CAS may negotiate the rate.

If a hospital that is a subrecipient or contractor under an award expects to incur \$100,000 or less in research patient care costs in any single budget period of the subaward or contract, the recipient will use the lesser of actual costs or the rate in the hospital's Medicare cost report as the basis for determining reimbursement.

E.2.1.5: Relationship of Research Patient Care Costs to Indirect Costs

If a hospital is submitting both an indirect cost and a research patient care rate proposal to CAS, both proposals must be based on the same cost report. HHS may not pay indirect costs on any cost component representing the cost of research patient care activities. Research patient care rates (routine and ancillary) include indirect costs related to "hospital-type" employees (nurses, medical technicians, etc.) supported as a direct cost under a award.

If the award or a subaward/contract under the award provide funding exclusively for research patient care activities, indirect costs normally will be unallowable as a separate cost element since all allocable indirect costs will be accounted for in routine or ancillary activity costs contained in research patient care rates.

E.2.2: Training Awards

With respect to training awards, as applicable, fellowships or traineeships, funding opportunity announcements and/or the terms and conditions of the award must address the following:

- Specific eligibility, including citizenship requirements (i.e., individual to be trained must be a citizen or a non-citizen national of the United States);
- Funding basis (i.e., whether certain costs or allowances are based on a published schedule or formula basis;
- Allowable costs or uses of funds, including, as applicable, payment of tuition, fees, stipends, student travel, and student health insurance;
- Required training period and what is considered full-time or part-time training;
- Any "payback" requirements for trainees once they complete the program;
- Documentation and reporting requirements;
- Any special requirements related to training at foreign sites or in federal laboratories;
- Rebudgeting flexibility, including whether any expanded authorities apply;
- Any requirements for awarding agency prior approval;
- Intellectual property rights; and,
- Payment provisions, which may vary based on the type of recipient.

The indirect cost rate for training awards is at a fixed rate of 8% of the Modified Total Direct Cost (MTDC), exclusive of tuition and related fees.

E.2.3: Conference Awards

HHS's agency-wide policy pertaining to allowable activities and costs for conferences is located at <u>https://www.hhs.gov/grants-contracts/contracts/contract-policies-</u> regulations/index.html#spending.

Awarding agencies may award conference awards only if:

- The subject matter of the conference(s) to be supported is clearly within the awarding agency's mission and is an area(s) of programmatic interest; and,
- Statutory authority under which the award will be made permits support of conferences.

E.2.3.1: Application Requirements

At a minimum, applications for conference support must include a narrative, a detailed budget, and supporting budget narrative justification. The application narrative must explain how the conference(s) will serve a public purpose, and include the following information, as applicable, along with any other information required by the awarding agency:

- the country or countries in which the conference will be held or will host a virtual conference;
- expected number of attendees;
- proposed inclusive dates of the conference;
- conference format, e.g., assembly in a defined location or virtual assembly;
- planned agenda, including a list of the principal areas or topics to be addressed and possible speakers;
- physical facilities, if any, required for the conduct of the meeting, such as simultaneous translation facilities;
- whether registration fees will be charged; and
- if the conference will be a virtual conference, the applicant must address relevant details, such as the medium to be used, how invitations will be issued, and whether participation will be controlled in any manner.

The application budget must show:

- the total cost of the conference (and breakdown by conference if support is requested for multiple conferences);
- those costs for which awarding agency support is requested;
- proposed per diem/subsistence rates and transportation costs; and
- other federal or non-federal entities that have been or are being requested to provide support.

Awarding agencies may not award funds for "operating costs," facilities and administrative costs (F&A), or other undesignated purposes.

Registration fees are prohibited in the budget because they are not costs that will be incurred by the recipient.

Awarding agencies may defray costs that will not be offset by the use of program income that would otherwise have been available by increasing federal funding for otherwise allowable direct costs if a registration fee is charged and, will be waived, e.g., for students or trainees.

E.2.3.2: Award Requirements

Funding of conference awards must comply with the requirements of the GPAM as applicable and must be consistent with the following:

- A conference award must be restricted to a single year. A multi-year period of performance may be used if the award will support multiple conferences;
- Awards in support of a conference should be made for a period of performance commensurate with the time involved in planning and conducting the conference and post-conference follow-up, including completion of final reports; and
- The award must be made before the intended beginning date of the conference.

The NoA must clearly address:

- Whether awarding attendees (and the number of such attendees) will be able to attend the conference at no charge to the agency,;
- Use of any awarding agency equipment, supplies, or personnel to plan or carry out the conference;
- The specific language to be used in the conference program or other materials to describe the role of the awarding agency;
- Additional public policy requirements;
- Language advising the recipient that it should notify conference participants that any presentation or discussion constitutes public disclosure of information;
- Whether use of the awarding agency name and identifying logo is allowed; and
- Any restrictions on use of the awarding agency name in recipient fundraising to cover additional conference expenses.

Please note: The NOFO for conference awards, and the terms and conditions of the NoA, must specifically prohibit budgeting funds for food and meals, and must state that the cost of food and meals are an unallowable expense and are not to be charged to federally funded conference awards, in accordance with the HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Food. (<u>http://www.hhs.gov/awards/contracts/contract-policies-regulations/spending-onfood/index.html</u>).

E.2.3.3: Final Performance Report

The final performance report must include the following information:

- award number;
- title, date, and place of conference;

- name of the conference director, program director, or principal investigator;
- name of the organization that conducted the conference;
- a list of the individuals (and their organizational affiliations) who participated as speakers or panelists in the formal, planned sessions of the meeting; and
- a summary of topics discussed and conclusions reached.

E.2.3.4: Publication and Copyright

If the recipient charges for published material which was developed in whole or in part with HHS funds, the proceeds of such sales are considered program income. Unless otherwise provided in the NoA, the recipient/author is free to arrange for copyright of any publication resulting from a conference award, except that any copyright shall exclude presentations by federal employees given as part of their official duties. Any such copyrighted publication, however, shall be subject to the royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use the work for federal government purposes, and to authorize others to do so.

E.2.3.5: Acknowledgment of Support and Disclaimer

Conference award materials, including promotional materials (brochure, program booklet, other), the agenda, any Internet sites that advertise the conference, and any publication resulting from the meeting must acknowledge that the awarding agency provided support for the conference, whether in whole or in part. The acknowledgment must be accompanied by the following disclaimer:

• "Funding for this conference was made possible [in part, if applicable] by [insert award agreement number] from [insert name of awarding agency]. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government."

Responsibility for the contents of any publication resulting from the conference must not be ascribed to the awarding agency.

E.2.3.6: Use of Department of Health and Human Services/Awarding agency Logos

Use of the HHS or awarding agency name or logo, is governed by 42 U.S.C. 1320b-10, which also prohibits misuse of the HHS name and emblem in a written communication. The HHS or awarding agency logo cannot be used on any promotional or other conference-related material regardless of sponsorship without the written prior approval of the awarding agency. Approval will be consistent with any guidance issued by the Assistant Secretary for Public Affairs (ASPA), within HHS.

E.2.3.7: Participation of Federal Employees in Conferences Funded by HHS Award Federal employees can attend, both as speakers and participants, if the following applies:

• The agenda is established and speakers selected by the recipient;

- Their expenses are paid directly by the awarding agency and not paid by the recipient;
- The awarding agency applies the following requirements on food reimbursement:
- The conference meets the criteria for authorized government employee training program under the Government Employees Training Act; and
- The registration fee includes the cost of food, and the cost of food cannot be separated from the registration fee.
- Attendees do not receive any payment, including honoraria, from the award or recipient;
- The number of awarding agency staff in attendance (in relation to the overall attendance) should be consistent with the premise that the conference is not an awarding agency conference; and
- Attendance of federal staff must be handled in compliance with HHS and awarding agency procedures.

E.2.4: Construction and Modernization Awards

Awarding agencies must have specific statutory authority to provide support for construction or modernization activities (except Minor Alteration & Renovation (A&R)). To the extent that specific statutory authority exists, public and private nonprofit organizations located in the United States (U.S.) or in U.S. territories or possessions, generally are eligible for awards whose primary purpose is construction or modernization.

Foreign organizations and federal institutions are not eligible for construction awards other than minor A&R activities under other types of awards (in this case, foreign organizations include domestic awards with a foreign component) unless specifically made eligible for construction or modernization by the governing statute.

Requirements that pertain to construction or modernization of real property, including the recipient's obligation to the awarding agency for use of the property and the duration of the obligation, will be based on the requirements of the governing statute, any implementing program regulations, and requirements of <u>45 CFR 75.318</u>, the terms and conditions of the award, and any related federal laws and executive orders, as applicable.

If the governing statute establishes a requirement that differs from that in 45 CFR part 75, the statute takes precedence.

E.2.4.1: Notice of Funding Opportunity

In addition to the general requirements for NOFOs, the NOFO for a construction or modernization award program or where such activities may be permitted under another type of award, must address the following, as applicable:

• If matching or cost sharing is legislatively required, it must be in the form of such costs or contributions as institutional reserves, donation of cash, third-party donation of land

or services, bonds, or pledges. Sufficient information concerning other sources of matching or cost sharing, for example, bonds or mortgages must be provided by the applicant to allow for awarding agency evaluation;

- The types of insurance that will be required as a condition of award;
- Design requirements, including any special design requirements to allow applicants to include associated costs and descriptions;
- The types of construction or modernization-related documents an applicant is required to submit with the application and those that will be required as a condition of award;
- The types of bonding and/or guarantees that will be required as a condition of award;
- The requirements for site control;
- If the property is owned or leased, and corresponding requirements for proof of title, or lease requirements;
- Any provisions that will be applied to protect the federal interest in the property;
- Any administrative or programmatic requirements applicable to construction or modernization awards or activities, including the following:
 - Allowable costs;
 - A statement that, construction or modernization is not allowable under an award to a federal institution or foreign organization (including domestic awards with a foreign component), unless specifically made eligible by the governing statute;
 - Requirements related to construction contracts under awards, which may be accomplished by reference to the GPS; and
 - A statement that the pre-award construction or modernization costs are unallowable; therefore, if the construction or modernization activity is ineligible for the expanded authority related to pre-award costs
 - A statement that pre-award construction or modernization costs are unallowable; therefore, if the construction or modernization activity is eligible for the expanded authority related to pre-award costs, a statement that the authority applies only to costs for architect's and consultant's fees necessary to the planning and design of the project;
- If the award will result in acquisition or modernization of a facility on an amortized basis, how the federal interest will be computed in the event of disposition pursuant to 45 CFR 75.318; and
- Any required environmental or historic preservation requirements that may be required and must be met prior to award or as a condition of award before any physical work on the facility is initiated.

E.2.4.2: Notice of Award

The NoA for a construction or modernization award or an award that involves such activities must do the following:

- Specify a period of performance that is consistent with any applicable limitation on the availability of appropriations for expenditure;
- Include a condition that the recipient may not advertise for bids or negotiate a contract for any part of the work until drawings and specifications have been approved by the awarding agency;
- Specify the requirement for filing of a NFI and updating it, as appropriate, based on any change in organizational status;
- Specify any NEPA, NHPA, or related requirements that must be met (if any) prior to initiating any work on the project;
- Specify any required usage period, including any post-performance requirements for reporting and the duration of record retention as provided in 45 CFR 75.361;
- Provide details concerning the construction or modernization activity, e.g., prior approval requirements;
- Estimated date of construction completion, how/when funds will be released for expenditure;
- Requirements for bonding, guarantees, title insurance and physical destruction insurance, and any other insurance;
- Payment method;
- Reporting requirements during the period of performance;
- Prior approval or documentation review requirements, e.g., the requirement to obtain awarding agency approval of any changes that materially alter the scope or costs of the project, use of space, or functional layout;
- The method of computing the federal interest in property acquired or modernized on an amortized basis and required documentation;
- Applicable requirements, including required reporting, after the end of award support and an indication that any specific costs of compliance which normally would not be considered indirect costs are not reimbursable and are the recipient's responsibility; and
- If the awarding office requires an appraisal to determine market value or far rental rate for matching or cost-sharing purposes, the award must specify that this requirement also must be imposed on subrecipients and contractors under the award.

E.2.4.3: Notice of Federal Interest

A Notice of Federal Interest (NFI) is required for construction, acquisition, and modernization (except for Minor A&R). The recipient (or owner, if other than the recipient) must file a NFI 223

prior to initiating construction or modernization or when an existing facility or land is acquired with federal funds. The recipient must:

- Record the NFI by the owner in the appropriate public records of the jurisdiction in which the property is located. Associated fees are allowable costs;
- Provide a copy of the NFI to the awarding agency;
- Accurately indicate that the property was constructed, acquired, or modernized with awarding agency funds and, that during its useful life of the facility, as defined in the NFI, the awarding agency's use and disposition requirements apply; and
- Seek review by the awarding agency to ensure its adequacy.

Both the Awards and Program Office must work with the recipient when the NFI is considered deficient to ensure that the necessary changes are made and the NFI is re-filed, at the recipient's expense. The federal interest may not be conveyed, transferred, assigned, mortgaged, leased, or otherwise be encumbered or subordinated by a recipient unless a single-case deviation is approved in writing by the awarding agency.

Concerns regarding ownership or title should be addressed with the Office of the General Counsel.

E.2.4.4: Federal Interest and Federal Assistance for Loans, Mortgages or Other Methods of Financing

If an awarding agency assists in financing the acquisition, construction, or modernization (except for Minor A&R) of real property, the awarding agency must also do the following:

Require in the terms and conditions of award, that any mortgage agreement the recipient enters specifically provide:

- When mortgage costs are allowed, any interest paid in servicing the mortgage agreement must be counted as acquisition costs at the time of disposition of the acquired property;
- The mortgagee must notify the awarding agency at least thirty (30) days before initiating foreclosure action so that the agency can determine the preferred course of action. Any awarding agency assignment of the property and mortgage responsibilities to a third party must receive the concurrence of the mortgage;
- In the event of a default, if the awarding agency chooses not to assume the role of mortgagor, the mortgagee must pay the awarding agency an amount equal to the federal share (percentage) of the sales proceeds otherwise due the recipient (mortgagor), which is calculated by multiplying the federal share in the project to the proceeds from the sale of the property;

- In the event of any default on the mortgage by the recipient, require the recipient to immediately notify the appropriate awards official by telephone and in writing of the default; and
- Consult the General Law Division, OGC, before assuming the role of mortgagor. Amounts owed by the recipient to the awarding agency will be determined and collected pursuant to debt collection requirements.

E.2.4.5: Disposition of Property Involving Loans, Mortgages or Other Methods of Financing

The reimbursement methodology for real property disposition in 45 CFR 75.318(c) assumes that the property will be paid for in full at the time of acquisition or completion of construction or modernization, that is, when the recipient receives constructive title or upon final acceptance of the building or facility (or portion thereof).

When amortization of the principal and payment of interest (i.e., mortgage payments) on a loan for the purpose of acquiring or modernizing real property is allowable, the federal share may vary over time, resulting in the need to make multiple calculations rather than a single calculation of market value at the time of disposition.

Under those conditions, the federal interest at the time of disposition must be computed on a different basis than simply multiplying the percentage of federal participation in the acquisition by the fair market value at disposition. This computation can happen as long as the awarding agency Chief Awards Management Officer (CGMO), consults with the Program Office (PO), OGC, and any other relevant officials to determine whether, based on the authorizing statute, the duration of accountability for use of the property, or other factors, an alternate means of calculating reimbursement to the awarding agency is appropriate.

If an alternate calculation is necessary, then the awarding agency develops the proposed formula, which must achieve an equitable result for the recipient and the awarding agency.

For new awards, the formula must be addressed in the NoA.

For existing awards, if the awarding agency issues disposition instructions (following a request by a recipient) and must communicate to the recipient how the amount of the federal interest will be calculated.

E.2.4.6: Federal Interest Involving Construction and Modernization of Leased Property

The applicant proposing construction or modernization (except for Minor A&R) of leased property must ensure that their lease is long enough for the full value of the award supported improvements to benefit the award activity and to support the expected useful life of the facility for award-supported purposes.

The lease language must be submitted to the CGMO for approval as part of the pre-approval documentation or, if timing is not practical, before the recipient can draw down funds or be reimbursed, as applicable.

When approving the construction or modernization of leased property, the owner of the property must consent to the proposed work being undertaken, acknowledge federal interest in the property, and file a Notice of Federal Interest, if required.

The owner of the property must agree to include in the lease (or agree to amend the lease to include) language providing the equivalent of:

- The recipient's full use of and access to the leased property during the term of the lease;
- The recipient's agreement not to sublease, assign, or otherwise transfer the leased property, or use the property for a non-award-related purpose(s) without the written approval of the CGMO (at any time during the term of the lease, whether or not award support has ended);
- The lessor informing the awarding agency of any default by the recipient under the lease;
- The awarding agency having 60 days from the date of receipt of the lessor's notice of default in which to attempt to eliminate the default, and that the lessor will delay exercising remedies until the end of the 60-day period;
- The awarding agency intervening to ensure that the default is eliminated by the recipient or another recipient named by the awarding agency;
- The lessor accepting payment of money or performance of any other obligation by the awarding agency's designee, for the recipient, as if such payment of money or performance had been made by the recipient;
- In the event that the recipient defaults, the award is terminated, or the recipient
 vacates the leasehold before the end of the lease term, the awarding agency having the
 right to designate a replacement for the recipient for the balance of the lease term,
 subject to approval by the lessor in a separate agreement with HHS, which will not be
 withheld except for good reason; and
- The recordation of a Notice of Federal Interest in the leased property.

E.2.4.7: Insurance and Bonding Builders Risk Insurance

Builder's risk insurance is an allowable cost either for the recipient or the construction contractor. Bonding recipients must follow their own requirements for bid guarantees, performance and payment bonds. Otherwise, recipients are required to ensure that construction contracts over \$150,000 have surety bonds for bid, performance, and payment.

Bonds are to be secured from companies holding certificates of authority from the US Department of Treasury, in conformance with 31 CFR 223 ("Surety Companies Doing Business with the United States"), as amended. The cost of bonding is an allowable award cost.

E.2.4.8: Title and Physical Destruction Insurance

A recipient must, at a minimum, obtain a title insurance policy and an insurance policy insuring against risk from physical destruction immediately upon acquiring real property or equipment, the completion of construction (i.e., the date of the recipient's final acceptance of the building or beneficial occupancy date, whichever occurs first), or modernization.

The title insurance policy must insure the fee interest in the real property in an amount not less than the full-appraised value of the building (as approved by the awarding agency) and any land acquired by the recipient as part of the construction or modernization project.

When the federal participation in the construction, modernization, or acquisition of real property covered only a portion of the cost of the building or land, title insurance must cover the total cost of the facility/land to prevent liens on the unsecured portion from affecting the federal interest in the property.

The physical destruction insurance policy must insure the full-appraised value (as approved by the awarding agency) of the building from risk of partial and total physical destruction, including flood insurance, or other special hazard riders, where appropriate.

The policy must also include a requirement for the insurance company to notify the awarding agency of any changes in the policy or coverage. The title and physical destruction insurance policies must be maintained for the useful life the property, or the statutory limitation on the awarding agency's interest (e.g., twenty (20) years under certain construction award authorities).

E.2.4.9: Insurance Requirements and Waivers

The NoA must require the recipient to provide copies of applicable insurance policies to the awarding agency within five days of completion of construction, modernization, or acquisition to ensure that the property is insured for the full-appraised value. During the period of support, the costs of the insurance may be charged to the award consistent with the applicable cost principles.

After the period of performance is over, the costs of any required insurance are solely the responsibility of the recipient. These requirements do not apply to federally-owned property provided to a recipient for use.

E.2.4.10: Modernization of Real Property

Unless otherwise stated, modernization includes both Major and Minor Alterations and Renovations (A&R). Modernization of any magnitude is not an allowable cost under the following:

- Awards to individuals;
- Training awards; and

• Conference awards

Minor A&R is allowable under all types of awards unless inconsistent with program design and stated as a limitation in the NOFO. Awarding agencies should note in the NOFO or NoA if prior approval is required.

A recipient may not undertake major A&R using award funds and/or required matching or cost sharing unless:

- The funding program has specific statutory authority for such activities; and
- An award explicitly allows such activity/expenditure by the recipient.

The following types of costs are not considered modernization costs:

- Costs associated with routine maintenance, painting, and repair of facilities or equipment, which are considered normal costs of business and generally are charged as indirect costs;
- Certain costs of installing equipment, such as the temporary removal and replacement of wall sections and door frames to place equipment in its permanent location, or the costs of connecting utility lines, replacing finishes and furnishings, and installing any accessory devices required for the equipment's proper and safe utilization, unless the recipient's accounting system considers these modernization costs rather than equipment costs; and
- Costs of furnishings and movable equipment.

Awarding agencies do not require specific statutory authority to allow minor A&R if the proposed changes meet the following criteria:

- The governing statute and/or any implementing program regulations do not specifically exclude minor A&R as an allowable cost/activity;
- The work is incidental to the purpose of the project and is required to use the space more effectively for its designed purpose in order to meet the award-supported programmatic need;
- The building has a useful life consistent with program purposes and is architecturally and structurally suitable for conversion to the type of space required:
 - If the recipient owns the building, the building has a useful life consistent with the purposes of the award-supported project; or
 - If the building is leased, the terms and length of the lease are consistent with the purposes of the award. In either case, the building must be architecturally and structurally suitable for conversion to project needs;
- If the building is suitable for occupancy prior to the minor A&R, work and associated costs to obtain an initial occupancy permit is not an allowable cost;

- The minor A&R costs are for making the space suitable for a purpose other than human occupancy (e.g., storage);
- If the building is under construction, or the minor A&R will take place in an incomplete structure, the costs associated with the minor A&R must be:
 - Cost effective to perform such work while the building is under construction or the structure is being completed; and
 - Limited to the difference between the cost of completing the interior space for general use and the cost of adapting it for the award-supported purpose consistent with the other limitations on minor A&R.
- The space involved will actually be occupied by the project or program;
- If the modernization will affect a site listed in (or eligible for inclusion in) the National Register of Historic Places, the awarding agency has followed all necessary requirements; and
- If the modernization will have a potential environmental impact, the National Environmental Policy Act (NEPA) requirements have been followed by the awarding agency and the recipient.

E.2.4.11: Major Alteration and Renovation of Real Property

The awarding agency must consult with OGC prior to authorizing major A&R (as determined by applying quantitative and qualitative criteria differentiating it from minor A&R), whether before or after award, to determine if there is an appropriate statutory authority.

E.2.4.12: Public Policy Requirements

Please see Attachment D for requirements that apply to construction and modernization. Compliance with other related laws and Executive Orders such as Floodplain Management, Wetlands, NHPA, Endangered Species Act, the Comprehensive Environmental Response and Liability Act, among other federal, state and locally required laws, may still be required.

Please check with OGC to ensure all requirements are included in the NOFO and NoA.

All environmental and historic preservation requirements must be fulfilled before award, or before allowing drawdown of funds.

E.2.4.13: Sustainable Design/Green Building

Sustainable design considerations should be included to the maximum extent feasible in construction or modernization (excluding Minor A&R) awards or activities that will be funded at \$1 million or more. Sustainable design considerations relate to ensuring consistency with, and contributing to, maintaining the economic, social, and ecological environment.

E.2.4.14: Construction Contract Clauses

Labor standards and equal employment opportunity clauses must be included in construction contracts awarded under construction awards, or contracts awarded for purposes of modernization (inclusive of both major and minor A&R), as applicable. These clauses must also be included in the information furnished to bidders on such projects and in the contract documents for all such projects. The contractor must be directed to include this clause in any applicable subcontracts. In addition, recipients and contract requirements for affirmative action specified in <u>41 CFR part 60-4</u> for contracts in named geographical areas that will exceed \$10,000. These requirements are specified in the "Notice of Requirement for Affirmative Action to Ensure Equal Employment Opportunity" and the "Standard Federal Equal Employment Opportunity Construction Contract Specifications" (<u>Source: EO 11246</u>).

The OFCCP regulations also require that the recipient notify the applicable OFCCP regional, area, or field office when it expects to award a contract for construction services that will exceed \$10,000. (116) Pursuant to 41 CFR 60-1.8, for any contract for construction services that will exceed \$10,000, the recipient must require that each prospective contractor:

- does not, and will not, maintain any facilities it provides for its employees in a manner that is segregated on the basis of race, color, religion, sex or national origin;
- does not, and will not, permit its employees to perform their services at any location, under the contractor's control, where segregated facilities are maintained; and
- will ensure that prospective subcontractors under any covered subcontract do not maintain segregated facilities or perform services at segregated facilities.

Each contract or subcontract exceeding \$100,000 for construction services under awardsupported construction or modernization is subject to the requirements of the Contract Work Hours and Safety Standards Act, 40 U.S.C. 3701-3708, concerning the payment of overtime and the maintenance of healthful and safe working conditions.

Please contact OGC to ensure all provisions for construction contractors/subcontractors are applied as directed (i.e., Davis-Bacon Act, Copeland Act)

E.2.4.15: U.S. Design Standards

General design requirements must be used in all award-assisted construction or modernization (both major and minor A&R). Applicants for construction or modernization awards and applicants/recipients proposing modernization under other types of awards must be made aware of awarding agency facility design requirements prior to the preparation of any design documents.

Drawings and specifications must address two sets of design standards:

- Any program-specific standards for the functional performance of the building, i.e., that the facility suitably accommodates the purpose of the award funding; and
- Design requirements include those needed to comply with applicable public policy requirements and appropriate national codes.

E.2.4.16: Accessibility of Facilities

Awarding agencies must ensure construction award recipients follow HHS implementation of Section 504 of the Rehabilitation Act of 1973 [Public Law (P. L.) 93-112, as amended], which is found in <u>45 CFR part 84</u>, Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving Federal Financial Assistance, Subpart C.

E.2.4.17: Earthquake Hazards Reduction Act

The Earthquake Hazards Reduction Act of 1977, as amended (P. L. 95-124), and EO 12699, Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (January 5, 1990) apply to award-assisted construction or modernization (both major and minor A&R) located in applicable geographic locations.

E.2.4.18: Metrics

Consistent with EO 12770 (July 25, 1991), Metric Usage in Federal Government Programs, all construction, modernization (both major and minor A&R) must be designed using the metric system, unless waived by the awarding agency.

E.2.4.19: Draw Down of Award Funds

The drawdown of award funds must not be authorized until all restrictive conditions of the award have been met. This stipulation does not apply under any of the following conditions:

- The authorization to proceed is explicitly withheld by the awarding agency for another stated reason (for example, non-completion of relocation activities);
- When phased construction or modernization methods are employed, the recipient normally will be authorized to proceed with construction or modernization and receive payment prior to approval of a later phase contract award, provided a guaranteed maximum price is obtained by the recipient for completion of the total project within the amount of funds available to meet the cost of the project. The guaranteed maximum price must be obtained before award of the first construction contract; or
- The applicant demonstrates the need for, and the awarding agency authorizes, an amount of funding to cover allowable costs in advance of actual construction or modernization, for example, costs related to project planning.

E.2.4.20: Other Requirements for Modernization

A Notice of Federal Interest is not required for only minor A&R. Provisions in <u>45 CFR 75.318(c)</u> require that when real property improved with award funds is no longer used for the original authorized purpose(s), the awarding agency must take steps to have the property disposed of

in a manner consistent with the federal interest in the property. Those requirements make no distinction between minor and major A&R.

If a recipient has used award funds (or required matching or cost sharing) for modernization, at closeout the awarding agency must require submission of the SF 429, Real Property Status Report, Attachments A and C.

E.2.4.21: Post-award Requirements

An award-supported construction or modernization project is considered complete when the builder turns over to the recipient a facility or portion of a facility that:

- o conforms to the design and specifications approved by the awarding agency; and
- is available for occupancy.

This date is either the final acceptance of the building or portion of a building or the date of beneficial occupancy, whichever comes first.

After construction or modernization is completed, a final inspection is required to ensure that the project was constructed or modernized in accordance with the approved design documents. The awarding agency must compare actual costs against project estimates to determine if the recipient is authorized to claim 100 percent of the award amount. For example, when a project is funded, the costs relating to the project are estimated since ordinarily a construction contract has not been signed and construction or modernization has not begun. Depending on the outcome of the bidding, the cost of the project may be more or less than anticipated.

Therefore, to determine the actual cost of the project, the awarding agency must require the recipient's final report under the award to do the following:

Include a simplified floor plan of the award-supported space or a statement indicating that the agency-approved schematic drawing (whether in included in the application or based on a subsequent submission) has not changed significantly; and

Detail the actual allowable costs of construction or modernization per net square foot/meter and of the entire award-supported project (administrative costs, architectural and engineering costs, surveys, demolition, fixed equipment, filing of the NFI, etc.). As appropriate, these amounts should be prorated for the space actually supported under the award.

E.2.4.21: Prior Approval Requirements for Construction and Modernization

A modification to a construction contract that would materially alter the location, footprint, cost of the project, space utilization, or functional layout from that previously approved by the awarding agency is considered a change in scope. The recipient also must obtain awarding agency prior approval if the proposed modification would increase the budgeted amount of federal funds needed to complete the project.

Under either of these circumstances, a recipient is prohibited from authorizing the corresponding modifications to its construction contract(s) until after receiving approval. Even if prior approval is not required, the recipient must retain copies of all change orders to construction contracts and treat them as award-related records consistent with 45 CFR 75.361.

Depending on the size of the modernization project and aggregate costs, a recipient is required to obtain awarding agency prior approval if:

- costs for a single modernization project exceed \$150,000—or such higher ceiling established by the awarding agency on a class basis in policy;
- rebudgeting for modernization in a single budget period exceeds the lesser of \$150,000 (or higher amount adopted in awarding agency policy) or 25 percent of the total approved budget for the budget period (direct and indirect costs and both the federal and any non-federal share); and
- aggregate costs for modernization projects exceeds the lesser of \$150,000 (or higher amount established in awarding agency policy) or 25 percent of the total direct costs reasonably expected to be awarded for a competitive segment.

The awarding agency review of any prior-approval request to incur modernization costs must consider:

- the necessity and reasonableness of the costs and relation to successful project performance;
- whether the amount requested represents an overrun for a smaller modernization project or other change in assumptions from those stated in the approved application; and
- whether the modernization project is considered minor or, if not, the program has the authority to fund it.

E.2.4.22: Prior Approval Documentation Requirements for Modernization

The appropriate awards management personnel and the awarding agency's servicing facilities management office are responsible for determining the required pre-award or post-award documentation needed for review of proposed modernization projects.

When prior approval is required, documentation for modernization must include the following:

- single-line drawing of the existing space and proposed alterations; and
- a detailed narrative explanation of the need, character, and extent of the functions to be housed in the space proposed for modernization, including, as appropriate, the following:
- description of the functions to be performed in the space;
- space schedule (detailed description of floor space);

- o a list of fixed equipment proposed for the facility;
- detailed project cost estimate;
- identification of any special design problems;
- o description of the existing and proposed utility systems for the modified space;
- o description of plans to provide accessibility for the physically handicapped;
- description of safety criteria incorporated in the existing building and in the facility as modified;
- o if property is leased, a statement, and documentation of, the length of lease;
- \circ time schedule for each major activity in the project; and
- o other information required by program legislation or regulations.

When proposed minor A&R will take place in a building under construction or in an incomplete structure, the appropriate awards official also should request the following documentation:

- a detailed narrative justification of the need to perform the work before the building is completed;
- a cost comparison between doing the work before and after the building is completed; and
- a description of other specific benefits to be gained by doing the work before the building is completed.

E.2.5: Other Types of Award Programs

E.2.5.1: Congressional Directives

Congressional Directives are discretionary awards made on an award-by-award basis consistent with Congressional direction.

HHS awarding agencies must do the following to ensure the effective award and management of grants and cooperative agreements funded by Congressional Directives:

Pre-Award Review. Language in the Congressional Directive appropriates funds to one or more organizations. Therefore, objective or merit review and scoring is not required (see GPAM Part F. Chapter 2). HHS awarding agencies may choose to conduct a review and must conduct a pre-award risk evaluation used for similar discretionary programs in accordance with 45 CFR 75.205. HHS awarding agencies should also ensure applications are of a significant enough completeness and quality to ensure the recipient can be held accountable for achieving the goals of the project.

Recipient of Award/Transfer of Funds. Congressionally Directed funding identifies the awarding agency and a specific award recipient. Other non-specified entities may not receive replacement grants or serve as successors-in-interest after the award is made. In addition, as with other appropriations, if Congress appropriates funds to one agency for a specified

purpose, absent explicit statutory authority, funds may not be transferred to another federal agency.

Length of Award. In general, the award project period is not to exceed one year unless otherwise stated in the Congressional Directive language. HHS awarding agencies may set a lengthier project period for construction awards or other complex projects. Additionally, the project and budget start and ends dates should be the same regardless of length.

Award Description. Awarding agencies must specifically state in the award description that the award is made pursuant to a Congressional and cite the statute.

Assigned Assistance Listing. For tracking and transparency purposes, HHS has assigned one Assistance Listing Number for all Congressionally directed awards. All awards must include Assistance Listing number 93.493. HHS awarding agencies must record and maintain separate data for each project under the consolidated 93.493 Assistance Listing number.

E.2.5.2: Emergency Application/Award

Whether discretionary or non-discretionary, these awards provide funding under specified conditions as indicated in the respective statute and any HHS implementing regulations. Generally, these programs have the word "emergency" in the program title. They are awarded pursuant to a disaster declaration by the President of the United States under the Stafford Act or a public health emergency declared by the Secretary of HHS (in contrast to an entire program authorized to meet an emergency need as evidenced by the use of the term "emergency" in the program title).

For emergency awards the following must be considered:

Discretionary awards may be awarded on an individual award basis under emergency conditions. These emergency awards do not include awards that must be made on an expedited basis due to poor planning;

An awarding agency may exempt an applicant from the required registration in the System for Award Management (SAM) prior to award when the award is an emergency award (however, registration in SAM is required as soon as possible); and

An awarding agency may allow for relief from use of electronic funds transfer for award payments under certain conditions. Agencies must consult with the Program Support Center (PSC) to determine whether this relief is available for a specific emergency award.

E.2.5.3: Formula Awards

These awards may be a type of discretionary or non-discretionary program. The formula basis determines the ceiling amount of the award or component part of an award. In some instances, the formula may also establish a floor. (154) Small awards may be awarded on a program-wide basis. The small award threshold is determined by the AWARDING AGENCY on the basis of anticipated funding for the entire period of performance.

E.3: Non-Discretionary Award Programs

HHS uses various types of non-discretionary award programs to include entitlements (whether open-ended or closed-ended); block awards, and formula awards. HHS-wide regulations for block awards are located at <u>45 CFR part 96</u> and specified nondiscretionary award programs are subject to the requirements of <u>45 CFR part 95</u> (includes cost allocation requirements).

Programmatic requirements established in statute, regulation, or any administrative requirement specifically applicable to non-discretionary awards govern these awards. Additional regulatory provisions regarding applicability are specified in <u>45 CFR 75.101</u>.

Non-discretionary award programs must be specifically authorized by Congress. It is HHS policy to recognize the unique statutory and regulatory requirements that apply to non-discretionary awards while maintaining a systematic approach to their award and administration. Non-discretionary awards require monitoring and may include a variety of compliance requirements, including those related to allowable activities, limits on particular types of costs (such as administrative costs), beneficiary eligibility determinations, matching, collection and reporting of programmatic data, maintenance of effort, and collection and use of program income.

Please consult with OGC to ensure the unique statutory and regulatory requirements are implemented effectively.