U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES

IMPLEMENTING **GOLD STANDARD** SCIENCE

Report to the White House Office of Science and Technology Policy

Report to OSTP:
Implementing Gold Standard Science at HHS

August 22, 2025

Executive Summary

Reliable and accurate scientific information is a cornerstone of effective policy- and decision-making. The U.S. Department of Health and Human Services (HHS or the Department) takes seriously the responsibility to conduct and support scientific activities to the highest standard and to foster public trust in federally funded science. In alignment with the May 23, 2025, Executive Order *Restoring Gold Standard Science* (EO) and related guidance from the White House Office of Science and Technology Policy (OSTP), HHS and its Divisions are implementing the nine tenets of Gold Standard Science – reproducibility, transparency, communication of error and uncertainty, collaboration and interdisciplinary science, constructive skepticism of findings and assumptions, use of falsifiable hypotheses, use of unbiased peer review, acceptance of negative results as positive outcomes, and minimizing conflicts of interest.

This report highlights key examples of the policies, programs, and activities being implemented at HHS in support of each of the nine tenets of Gold Standard Science. HHS uses a variety of strategies to promote the nine tenets; for instance, data management policies promote reproducibility, innovative program designs promote constructive skepticism, and robust research practices promote the use of falsifiable hypotheses. HHS and its Divisions provide staff training on scientific integrity, Responsible Conduct of Research, ethics, and other relevant topics. As the Department continues to build robust practices and policies to implement Gold Standard Science, HHS will assess adherence to the nine tenets, incorporate advanced technology where appropriate, and work to address challenges. HHS will also review and, as needed, update its policies, practices, and trainings to enhance implementation of Gold Standard Science.

List of Acronyms

ACF	Administration for Children and Families
AHRQ	Agency for Healthcare Research and Quality
AI	Artificial Intelligence
ARPA-H	Advanced Research Projects Agency for Health
ASPE	Assistant Secretary for Planning and Evaluation
ASPR	Administration for Strategic Preparedness and Response
ASTP	Assistant Secretary for Technology Policy
CDC	Centers for Disease Control and Prevention[1]
CMS	Centers for Medicare & Medicaid Services
EO	Executive Order on *Restoring Gold Standard Science*
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IQA	Information Quality Act
NIH	National Institutes of Health
OASH	Office of the Assistant Secretary for Health
ORI	Office of Research Integrity
OSTP	Office of Science and Technology Policy
SAMHSA	Substance Abuse and Mental Health Services Administration
SMG	Staff Manual Guides at FDA

[1] References in this document to "CDC" refer to both CDC and the Agency for Toxic Substances and Disease Registry (ATSDR).

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Introduction

Science plays a vital role in achieving the mission of the U.S. Department of Health and Human Services (HHS or the Department) and is critical to the ways HHS communicates with the public, evaluates the safety and efficacy of medical products, leads the response to public health threats, and helps families thrive. It is of the utmost importance to HHS that the scientific information considered in our decision-making is the result of rigorous scientific processes and is robust, of the highest quality, and trustworthy. It is equally important that HHS continues to improve its scientific processes, ensuring that HHS science keeps pace with the latest advancements.

The May 23, 2025, Executive Order *Restoring Gold Standard Science* (EO) and subsequent guidance from the Office of Science and Technology Policy (OSTP) directs agencies to advance science that is: (i) reproducible; (ii) transparent; (iii) communicative of error and uncertainty; (iv) collaborative and interdisciplinary; (v) skeptical of its findings and assumptions; (vi) structured for falsifiability of hypotheses; (vii) subject to unbiased peer review; (viii) accepting of negative results as positive outcomes; and (ix) without conflicts of interest. HHS is committed to upholding the nine tenets of Gold Standard Science. This report details key examples of ongoing and planned efforts for the implementation of Gold Standard Science at HHS.

HHS and its Divisions are implementing regulations, policies, and processes, such as the Scientific Integrity Policy, Public Health Service Policies on Research Misconduct, Evaluation Policy, and Peer Review Agenda, that bolster the rigor and robustness of the science conducted and supported by the Department. HHS also promotes transparent communication of scientific information through compliance with the Freedom of Information Act, the Information Quality Act, and the Evidence Act, that support the generation, dissemination, and use of strong science. Additionally, offices like the Office of Research Integrity and the Office for Human Research Protections work to continually improve the science conducted and supported by HHS.

Efforts are underway to assess and, as necessary, update existing policies and programs to strengthen HHS implementation of Gold Standard Science. FDA, for example, has issued a new Gold Standard Science Staff Manual Guide (SMG), which lays out FDA's approach to each of the core tenets, discusses programs that advance Gold Standard Science at FDA, and provides avenues for reporting related concerns. NIH is similarly developing a Division-specific response to the EO and is reporting directly to OSTP with further details of their efforts.

The Tenets of Gold Standard Science at HHS

HHS aims to produce, support, and use science that follows the nine tenets of Gold Standard Science described in the EO and the OSTP guidance. This section describes key examples of current and planned HHS efforts to implement each tenet of Gold Standard Science.

Reproducibility. To produce generalizable and robust scientific findings, it is essential that HHS conducts and uses science that is reproducible and replicable. Fundamental strategies to promote

reproducibility include the use of rigorous and justifiable methodological approaches, comprehensive documentation and sharing of study materials (e.g., data and analysis code), and independent verification of findings. Current and planned efforts to support reproducibility of HHS science exist across HHS Divisions. For example:

- NIH has updated its grant application and review processes to enhance the reproducibility of research findings through increased scientific rigor and transparency. Several NIH Institutes have published guidelines for reporting elements of rigor in experimental design as part of funding applications.
- FDA promotes reproducibility through independent review by typically requiring that clinical results offered to support new drug application approval be replicated (see, e.g., 21 CFR 314.126 requiring "adequate and well-controlled studies," plural, in the context of new drug application approval). Given that transparent documentation of methods and processes supports reproducibility, FDA's Division-level policies on *Public Access Requirements for Intramural Researchers and FDA Authors of Scholarly Publications Based on FDA-Funded Scientific Research* (SMG 2126.5) and *Public Access Requirements for Extramural Research* (SMG 2126.6) grant public access to peer-reviewed articles and data generated from FDA-funded research, whether conducted by FDA staff or outside organizations with funding from FDA.
- CDC's Data Management and Access policies require that public health data collected or generated using CDC funds are made freely available unless there is an appropriate reason for restricting or disallowing access. Appropriate reasoning is determined through the submission and subsequent review of a data management plan. By making CDC-funded public health data freely available, these policies allow other researchers to access the same datasets, independently repeat analyses, and verify results. This transparency strengthens confidence in findings and ensures they can be reliably reproduced over time. CDC plans to update these policies to further strengthen documentation and therefore support reproducibility.
- ACF makes research and administrative data (and often code, data dictionaries, and codebooks) available for secondary analysis through broad data archives. ACF's Office of Planning, Research, and Evaluation (OPRE) released a *Guide to Publishing Data for Secondary Analysis* in 2023 to support federal agencies in sharing their data for reuse and reproducibility.
- ARPA-H partners with Federal Funded Research and Development Centers (FFRDC), members of its Investor Catalyst (IC) Network, and other organizations for independent verification and validation (IV&V) to ensure that the transformative solutions are reproducible, credible, and ready for transition into impactful solutions.
- At SAMHSA, the Center for Behavioral Health Statistics and Quality (CBHSQ) – a Recognized Federal Statistical Unit (RFSU) – examines research protocols, verifies appropriate application of analyses based on consideration of sample sizes and other methodological concerns, and repeats analyses before public release.

Additional efforts are planned to improve the reproducibility of science conducted or supported by HHS. For example, NIH is exploring approaches to better coordinate research reproducibility efforts

across the Division through targeted funding mechanisms, technological innovation, and institutional culture change. Given challenges with reproducing the results of animal models in human clinical trials, NIH also intends to prioritize and fund human-based research technologies and expand the efforts of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), which has connected 18 federal agencies since 2021 to develop, validate, and implement novel methods that can reduce reliance on animal models.

Transparency. Transparency, in conjunction with appropriate peer review, produces science that is trustworthy and accountable to the scientific community and the public. Technological advances in data-sharing infrastructure are actively being leveraged across HHS, with ongoing initiatives to further improve and expand sharing of data, code, and other research materials through online data repositories and cloud environments. To support transparency and the use of open data, HHS published its Living HHS Open Data Plan in July 2025. The Open Data Plan creates a living mechanism for HHS and public users to collaborate and share ideas, facilitating data sharing, data-driven innovation, and evidence-based decision-making. Related to this launch was the rollout of an updated HealthData.gov website, which serves as the home of HHS Open Data and provides access to thousands of datasets that support public health, scientific research, and innovation. These recent updates enhanced the search tools, Application Programming Interfaces (APIs), and dashboards on the HealthData.gov platform to make HHS data more accessible and actionable for all users.

Public data repositories make certain HHS data available in open, accessible, and machine-readable formats, including data released by CMS (data.cms.gov), HRSA (Data Warehouse), ACF (Child & Family Data Archive), CDC (open.cdc.gov), FDA (Performance Data), and AHRQ (Medical Expenditure Panel Survey, Healthcare Cost and Utilization Project). To support the use of its open data, ACF published a Data Catalog to help people find and access ACF data assets.

HHS Divisions that fund extramural research require or encourage grantees to develop data-sharing plans that describe how federally funded scientific data will be managed and shared. For example:

- ARPA-H encourages its awardees, or "performers," to develop detailed data-sharing plans, including information about general data management processes, management of sensitive data, data types, and data storage. ARPA-H works with awardees to ensure data-sharing and reproducibility plans facilitate reproducibility and secondary data use. Some ARPA-H programs, like the Lymphatic Imaging, Genomic, and pHenotyping Technologies (LIGHT) program, require such data plans to facilitate data sharing among performers.
- The NIH Policy for Data Management and Sharing (DMS Policy) became effective in 2023 to promote the management and sharing of scientific data generated from NIH-funded or conducted research. The DMS Policy emphasizes the importance of good data management practices and establishes the expectation for maximizing the appropriate sharing of scientific data, with justified limitations or expectations. To ensure unrestricted and timely access to scientific results and publications produced by NIH-funded investigators, the NIH accelerated the establishment of its Public Access Policy to be in effect as of July 1, 2025.
- In Fiscal Year 2026, ACF plans to update its Notice of Funding Opportunity (NOFO) template to require all grant recipients conducting research to ensure that all peer-reviewed publications

are open access, develop data sharing plans, and make all research data publicly available in a data repository.
- CDC implemented an updated Public Access policy in April 2024, that requires immediate, open access to all publications funded by the CDC. In addition, the Data Management and Access requirement (AR-25) mandates that all funded awards include comprehensive Data Management Plans.

These initiatives aim to improve data sharing, enhance transparency, and ensure proper archiving of research data.

Communication of error and uncertainty. Many scientific methodologies generate estimates that inherently involve uncertainty and margins of error or that reflect ranges of possible values. Any given scientific approach also has inherent limitations on the scope of conclusions that can be drawn from data or analyses. Measuring and communicating potential sources of statistical error and uncertainty are crucial for scientific integrity and the robust generation of new scientific advancements. Communicating error and uncertainty includes reporting standard quantitative metrics of statistical error and clearly explaining potential sources of uncertainty, as well as the limitations of the scientific approach employed. At HHS, science is applied to a wide range of contexts, from research studies to evidence-based policymaking. In all these applications, science must be interpreted within an appropriate scope, accounting for statistical error, uncertainty, and methodological limitations. For example:

- When communicating implications of evidence for program and policy, ACF frames findings in the context of a broader set of information that can be used to take action, ties any recommendations clearly and directly to the empirical literature or findings from the analysis or research project, and modifies recommendations based on the strength of the findings and clearly discussed limitations. To further assess the quality of existing evidence, ACF sponsors research clearinghouses to assess and provide information on the quality of the empirical evidence available on specific programs and practices to the general public.
- AHRQ fosters communication of error and uncertainty in research and other work conducted by its staff and by investigators who receive research support from AHRQ, including the use of confidence intervals and sensitivity analyses, alongside clear explanations of methodological limitations.
- At SAMHSA, all outputs, such as statistical publications, Public Use Files, and Congressional and other reports, include a comprehensive limitations section that clearly articulates all reasonable potential sources of error or limitations in measurement or interpretation. SAMHSA's internal review process ensures that each product clearly communicates these limitations and any sources of uncertainty that could affect interpretation.

In an era of rapid technological advancements, novel scientific methods are being implemented at HHS at an unprecedented rate. A critical next step for HHS is to develop comprehensive mechanisms to continuously assess and develop solutions to new sources of statistical error and uncertainty that may emerge when using these novel approaches. For example, ARPA-H guidance

to performers discourages combining novel experimental conditions with novel tests in a way that might compound or obscure sources of statistical error and uncertainty and aims to foster a culture of accepting and documenting failure and unexpected results.

Collaboration and interdisciplinary science. HHS possesses a rich scientific culture, characterized by a broad spectrum of expertise, methodologies, and perspectives across diverse disciplines. This is a core strength of HHS that supports the Department's ability to overcome complex scientific challenges and uncover impactful discoveries that improve health and wellbeing. HHS strives to continuously enhance and expand collaborative and interdisciplinary approaches to support innovation and public benefit.

Many HHS efforts to integrate collaborative and interdisciplinary scientific approaches center around fostering partnerships within and across agencies, disciplines, institutions, and sectors. For example:

- ARPA-H cultivates networks of interagency partnerships where there is potential for complementary efforts and where subject matter expertise can be shared readily. As one example, ARPA-H managed, in partnership with DARPA, the Artificial Intelligence Cyber Challenge (AIxCC), bringing together experts in AI and cybersecurity to address pressing cybersecurity risks present in public health and health care systems. In addition, many ARPA-H efforts encourage collaboration across external performer teams working on a single effort. Teams are, by nature, multidisciplinary and collaborate to achieve the ambitious milestones set by ARPA-H programs, and often involve a mixture of academia, industry, and non-government organizations. Going forward, ARPA-H will continue to explore synergies among its interagency partners and encourage performers to form teams across networks both in the U.S. and globally to enhance the ability to address the latest challenges in biomedicine and health care.
- SAMHSA convenes technical expert panels, listening sessions, and ad hoc consultations with the public, individuals with lived and living experience, and other key stakeholders to gain feedback and input on various programmatic and policy issues. In addition, SAMHSA regularly collaborates with Federal partners such as the National Institute of Mental Health (NIMH) and National Institute on Drug Abuse (NIDA) at the NIH, CDC, FDA, and the Office of National Drug Control Policy (ONDCP) on data, science, research, evaluation, and programmatic activities. Expanding and exploring new partnerships will be pivotal in the development of new data collection instruments, systems, and program evaluations to best address the behavioral health challenges of the nation.
- ASPR's Center for the Biomedical Advanced Research and Development Authority (BARDA) works closely with interagency partners through ASPR's Public Health Emergency Medical Countermeasures Enterprise to ensure a coordinated, whole-of-government approach to medical countermeasure (MCM) preparedness and response. The BARDA model has proven successful in leveraging public-private partnerships to accelerate development of MCMs that are vital to national security. BARDA has a network of performers and capabilities that support advanced research and development, which can rapidly pivot to address new threats.

- In 2024, CDC launched the Domains of Excellence (DoE) framework to enhance the quality and impact of public health science publications. A key domain, Collaboration, emphasizes early engagement across disciplines and perspectives—vital in the inherently multidisciplinary field of public health. CDC authors must now confirm DoE compliance when submitting work for scientific review.

As interdisciplinary efforts continue to expand, it is essential to document both internal and external collaborations at HHS, not only to promote transparency but also to identify promising opportunities to further build and leverage these partnerships. NIH reports annually on all collaborations with other HHS Divisions, including the nature and frequency of collaborations carried out with specific agencies or Divisions. These ongoing and future efforts across HHS will not only accelerate the pace of research discoveries but will do so while fostering a culture of scientific integrity and trustworthy science practices.

Constructive skepticism of findings and assumptions. Science is trustworthy precisely because it is skeptical of itself, and HHS strives to uphold this ideal in the science it conducts and supports. Throughout the Department, scientific findings are subject to review, such as external peer review to assess methodology, data interpretation, and experimental design. Meetings that bring in members of the public help scientists to maintain outside perspectives. HHS has several specific initiatives designed to foster constructive skepticism. For example:

- The ARPA-H Model, designed to address high-risk, high-reward research that cannot be readily accomplished through traditional research or commercial activity, incorporates milestones in each of its efforts during which subject matter experts scrutinize the quality of work, identify potential errors and assumptions, ensure that risk or failure does not compound from one phase to another, and continuously adjust as necessary.
- FDA has a longstanding Scientific Dispute Resolution process that ensures that open debate, skepticism, and the ability to challenge assumptions are built into FDA's scientific decision-making process. FDA scientists are encouraged to voice scientific disagreements, document the dispute, and elevate scientific disagreements if necessary.
- Looking to the future, NIH is launching the Replication to Enhance Research Impact Initiative, which will support partnerships between independent contract research organizations and researchers to replicate important lines of research and validate novel technologies. This initiative will not only support reproducibility but also push scientists to maintain ongoing skepticism of their results and findings by subjecting them to rigorous replication studies. NIH has also announced a new, comprehensive review of all policies and practices within its intramural research program to establish academic freedom as a rule, and not the exception. Academic freedom allows scientists to freely express skepticism of findings and propose alternate views and methods.

Use of falsifiable hypotheses. Strong science makes precise claims that can be tested and then rejected if the tests produce evidence that is inconsistent with those claims. Structuring studies around falsifiable hypotheses is one way of promoting rigor in the research process. In addition to the efforts described under the other tenets, which support the generation and critical evaluation of

robust scientific approaches, several HHS policies specifically support the use of falsifiable hypotheses. For example:

- The ACF Evaluation Policy specifically encourages advance publication of study plans (e.g., pre-registration), where researchers publicly share their research and analysis plans prior to starting a study, which can in turn encourage researchers to develop falsifiable hypotheses.
- NIH and FDA recently launched Modernizing Research and Evidence (MoRE) Consensus Definitions for more than 40 clinical research terms used to describe design, methods, analysis, and interpretation of innovative clinical study designs, including studies using real-world data for FDA-regulated medical products (i.e., drug, device, or biologic). This collaboration supports rigorous research by facilitating efficient, well-designed clinical studies.

Use of unbiased peer review. Rigorous science requires that plans for conducting research, as well as the analyses and conclusions drawn from that research, be evaluated by independent experts for validity before being approved or subsequently disseminated. HHS makes extensive use of peer review across its intramural research activities, implements world-class peer review in the process of awarding extramural research funding, and strongly encourages all HHS-supported scientists to publish in peer-reviewed journals. HHS complies with the Information Quality Act (IQA) and offers guidelines and staff training on its requirements. The IQA requires that information disseminated by the agency meet quality, utility, objectivity, and integrity standards, and that influential scientific information, including highly influential scientific assessments, be peer reviewed by qualified specialists before it is disseminated. HHS adheres to the Office of Management and Budget Final Information Quality Bulletin for Peer Review, which is designed to improve the quality, objectivity, utility, and integrity of information disseminated by the Federal Government to the public. There are many approaches to peer review at HHS. For example:

- Peer review may take the form of traditional publications, such as Public Health Reports, the official peer-reviewed journal of the office of the U.S. Surgeon General and the U.S. Public Health Service, which is managed by OASH.
- ARPA-H leverages a network of reviewers from U.S. Government partners with appropriate expertise and independence to analyze merits and feasibility, share additional perspectives, flag potential oversights, and probe the validity of prospective performers and their proposals.
- ASPR TRACIE (Technical Resources, Assistance Center, and Information Exchange) serves as a virtual force multiplier for public health and health care professionals by providing a centralized source of peer-reviewed emergency preparedness resources and enhanced technical assistance.

HHS is dedicated to continually improving the quality and integrity of Departmental research through peer review. In March 2025, NIH announced a new plan to centralize the initial peer review process for all applications for grants, cooperative agreements, and research and development contracts solely within the NIH Center for Scientific Review (CSR). By centralizing peer review, NIH review can be more efficient and maximize competition of similar science across the Division.

Acceptance of negative results as positive outcomes. The "publish or perish" mindset prevalent in research, and the lack of journals that publish negative results, can lead researchers to publish

only results that confirm a given hypothesis and may lead to research being unnecessarily duplicated. HHS recognizes that negative or null results can provide valuable contributions to scientific knowledge and programmatic and policy decision-making and strives to advance a research culture that values negative results as a positive outcome when appropriate.

Several policies across the Department support the disclosure of negative results. For example:

- The IHS Program Evaluation Policy states, "Evaluation reports will present all results, including favorable, unfavorable, and null findings."
- The ACF Evaluation Policy requires ACF to post all findings, irrespective of whether they are positive, null, or negative as contributions to the field.
- FDA's ClinicalTrials.gov Civil Money Penalty Program helps ensure that results from clinical trials conducted to support most product approvals, including negative results, are made public.
- As part of its "fail-fast" program model, ARPA-H encourages performers to share negative results among fellow performers and with the scientific community as opportunities to learn and refine understanding of the issue, anticipating that documented negative results will inform decisions and directions of future investments and efforts.
- Divisions that typically do not conduct evidence generating activities may rely on negative results, making their disclosure particularly important. For instance, CMS and its contractors have made coverage decisions that rely heavily on negative results, including warfarin responsiveness (NCD 90.1) and certain urine drug testing scenarios (LCD L36707).

While some policies exist that encourage disclosure of negative results, HHS is committed to exploring new avenues for improving implementation of this aspect of Gold Standard Science. In 2024, NIH released a Request for Information on Potential Solutions for Reducing Publication Bias Against Null Studies to solicit public input on the barriers and solutions to reducing publication bias (i.e., the preferential dissemination of statistically significant or otherwise exciting studies) in biomedical research. After reviewing the responses received, NIH plans to launch initiatives that will help to address this multi-faceted issue.

Avoiding conflicts of interest. Freedom from inappropriate conflict of interest is essential for fostering trust in science and scientific results. HHS provides ethics training to all staff on how to avoid conflicts of interest and complies with all relevant conflict of interest statutes. Divisions also have specific conflict of interest policies, for example, governing evaluation at ACF or extramural peer review at NIH. HHS and many of its Divisions retain ethics and integrity experts who can advise on matters relating to conflicts of interest. Examples of other efforts to eliminate problematic conflicts of interest include:

- ASPR's requirements process ensures sound, trustworthy, and defensible interagency-validated requirements for the development of MCMs and acquisitions for the Strategic National Stockpile.
- NIH is developing a conflict-of-interest tool that synthesizes information on investigators, key personnel, and reviewers that goes beyond what is currently available in NIH systems. This tool will allow NIH staff to more thoroughly vet reviewers for potential conflicts of interest before creating reviewer assignments.

HHS will continue to innovate and find new ways to minimize conflicts of interest to the greatest degree possible.

Evaluating Adherence to Gold Standard Science

To inform the ongoing mission to improve scientific processes, HHS plans to develop strategies to understand and improve the state of Gold Standard Science at the Department. This effort will include developing metrics and evaluation mechanisms to assess Departmental adherence to the nine tenets of Gold Standard Science and determine how technology might best be used to support the generation and use of high-quality scientific information. The results of these efforts will inform improvements to policies and practices related to Gold Standard Science. Additionally, HHS is reviewing its existing policies related to Gold Standard Science to ensure alignment with the EO, including the HHS Scientific Integrity Policy and policies related to peer review, research integrity, and communications.

Training

HHS provides several trainings related to Gold Standard Science. All HHS employees have access to training on scientific integrity, which includes guidance on supporting science that is reproducible, transparent, communicative of error and uncertainty, collaborative and interdisciplinary, subject to unbiased peer review, and without conflicts of interest. This training discusses the use of well accepted scientific practices and unbiased peer review as a means of protecting scientific processes. It also educates employees about the free flow of scientific information, openness and transparency, and correcting the scientific record when necessary. Employees are encouraged to collaborate with others by sharing scientific findings and participating in professional societies and other professional activities. ARPA-H, SAMHSA, and IHS require or plan to require the HHS Scientific Integrity Training as part of onboarding for new staff or as part of ongoing staff training activities.

Many research staff across the Department are required to take training on Responsible Conduct of Research, as appropriate to their roles. Additionally, extramural research training programs funded by NIH, AHRQ, and HRSA are required to consider including instruction on Responsible Conduct of Research as part of their support for trainees' professional development. Other relevant trainings available to HHS staff include Human Subjects Collaborative Institutional Training Initiative Training, Monitoring and Evaluation training for ACF staff, and Scientific Integrity Quality Training (SIQT) and Grading of Recommendations Assessment, Development and Evaluation (GRADE) Training for CDC staff.

HHS will assess and, as appropriate, revise existing trainings or develop new trainings to educate staff on Gold Standard Science. Additionally, some Divisions are planning new or revised Division-specific training. As part of its new Gold Standard Science SMG, FDA has directed each of its Centers, Offices, and Programs to develop specific policies, procedures, and training relevant to their staff, as appropriate. CDC is updating its SIQT and GRADE trainings to ensure that principles of Gold Standard Science are explicitly highlighted.

Using Technology to Drive Gold Standard Science

HHS is considering how technology, particularly AI-driven technologies, can be leveraged to enhance Gold Standard Science at the Department. Many HHS Divisions already utilize artificial intelligence and other advanced technologies or are developing plans to do so. HHS intends to consult with technology leaders across the Department, as needed, to assess use of these technologies and promote their responsible application to Gold Standard Science. ASTP maintains a list of AI use cases that may be helpful in assessing AI capabilities in various areas of HHS. Examples of AI and other cutting-edge technologies being used and developed across HHS include:

- CDC uses several AI tools, including the CDC chatbot, which helps increase staff efficiency at proof reading, summarizing research, and assisting with coding,
- Among NIH's AI capabilities are the Bridge2AI program, which brings technological and biomedical experts together with social scientists to tackle complex biomedical challenges beyond human intuition.
- FDA also embraces the use of AI-driven tools across the board and in particular uses AI to streamline the review process and improve productivity.
- ARPA-H has developed an internal AI assistant that can provide technical support, landscape analysis, literature reviews, and data synthesis and analysis.
- AHRQ evidence-based practice centers (EPCs) use AI extensively in performing systematic reviews.

HHS Divisions are continually expanding their technology use and plan on applying technological solutions to Gold Standard Science. For example:

- FDA's Advanced Manufacturing Program aims to boost the use of new or innovatively applied medical product manufacturing technologies in a variety of public health contexts.
- ARPA-H has developed an internal data management and analytics platform that, among other uses, facilitates transparency across the agency about ARPA-H's funding.
- ACF, through the ACF Chief Artificial Intelligence Officer, is rolling out a Generative AI platform with the ability to create AI agents for specific tasks.
- SAMHSA is developing an AI platform with a governance framework.

Potential Challenges

HHS is a large agency with a broad scope and wide-ranging program activities, and implementing Gold Standard Science will require coordination among Divisions with diverse missions, from primarily research-oriented Divisions to those that primarily deliver services. Some Divisions may implement measures to promote Gold Standard Science that are relevant to their own staff. Similarly, the size and range of Division functions and scientific activities may create challenges in evaluating the implementation and impact of Gold Standard Science. Such an evaluation will require commensurate resources.

Gold Standard Science urges open access to underlying research data. However, transparency must be balanced with privacy and adherence to federal privacy laws (e.g., HIPAA, the 2018 Common Rule, Section 301(d) of the Public Health Service Act, and the Privacy Act), which set limits on the uses and disclosures of protected health information and data. Further data releases

will need thorough review to ensure compliance with legal and ethical obligations to protect privacy. Patients and clinicians trust HHS to secure their private health data, and HHS must honor that trust by managing, analyzing, and interpreting their data with care.

Organizational challenges may arise in ensuring that there are appropriate policies in place to implement Gold Standard Science and that all staff receive relevant training. However, there are also opportunities to align similar work. For example, ASPE leads the HHS Scientific Integrity Council and will identify further opportunities to collaborate on Gold Standard Science implementation.

Conclusions

The efforts highlighted in this report reflect dedication to the principles of Gold Standard Science and serve as a foundation for improving Gold Standard Science at HHS. Many areas of the Department have already begun implementing new activities to enhance Gold Standard Science in response to the EO, and HHS will continue to coordinate implementation of EO requirements. HHS commits to continuing to improve its standards and implementing the tenets of Gold Standard Science Department-wide.