

Office for Human Research Protections (OHRP)  
Department of Health and Human Services (HHS)

**Considerations in Transferring a  
Previously-Approved Research Project to a  
New IRB or Research Institution**

This guidance, when finalized, will represent OHRP's current thinking on this topic and should be viewed as recommendations unless specific regulatory requirements are cited. The use of the word *must* in OHRP guidance means that something is required under HHS regulations at 45 CFR part 46. The use of the word *should* in OHRP guidance means that something is recommended or suggested, but not required. An institution may use an alternative approach if the approach satisfies the requirements of the HHS regulations at 45 CFR part 46. OHRP is available to discuss alternative approaches at 240-453-6900 or 866-447-4777.

**Date:** May 23, 2012 (DRAFT)

**Scope:** This guidance presents common scenarios for transfer of a previously-approved research project to another institutional review board (IRB) or to a new engaged research institution, and outlines the administrative actions to be considered by IRBs, engaged institution(s), and investigators. This document applies to non-exempt human subjects research conducted or supported by HHS.

The guidance addresses the following questions:

1. What is the regulatory background for research project transfer?
2. What actions may apply when the research project remains at the same institution, but responsibility for IRB review is transferred either from an *internal* to an *external* IRB, or from an *external* IRB to *another external* IRB ?
3. What actions may apply when the research project remains at the same institution, but responsibility for IRB review is transferred from one *internal* to another *internal* IRB?
4. What actions may apply when the research project is transferred to a *new engaged institution*?

To enhance human subject protections and reduce regulatory burden, OHRP and Food and Drug Administration (FDA) have been actively working to harmonize the agencies' regulatory requirements and guidance for human subjects research. This draft guidance document was developed as a part of these efforts. FDA has also issued draft guidance entitled, "Considerations When Transferring Clinical Investigation Oversight to Another IRB." See <http://www.fda.gov/RegulatoryInformation/Guidances/ucm307757.htm>

FDA and OHRP recognize that the two documents may appear somewhat different as there are minor variations in formatting and some necessary variations due to differences in the regulated entities under FDA's and OHRP's jurisdiction. The agencies wish to stress, however, that our intent was to provide harmonized guidance to IRBs, sponsors,

institutions, investigators, and other entities involved in the study oversight transfer process. FDA and OHRP will continue to work closely in the development of final guidance and appreciate comments from interested parties.

**Target Audience:** IRBs, institutions, and investigators that are responsible for the review, oversight, or conduct of human subjects research conducted or supported by HHS.

**Regulatory Background:**

The following represents key regulatory information that is pertinent to this guidance:

- (1) An institution must designate on its Federalwide Assurance (FWA) one or more IRBs to review and approve human subjects research (45 CFR 46.103(b)(2)), and must certify to HHS that non-exempt human subjects research has been reviewed and approved by its designated IRB (45 CFR 46.103(b)).
- (2) Institutions must have written procedures which the IRB will follow for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the human subjects (45 CFR 46.103(b)(4), 46.108(a), and 46.115(a)(6)).
- (3) The IRB must review proposed protocol changes at a convened meeting (45 CFR 46.108(b)), except where expedited review is appropriate under HHS regulations at 45 CFR 46.110(b)(2).
- (4) An IRB must conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year (45 CFR 46.109(e)).
- (5) An institution must have and follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head (or designee) of (i) any unanticipated problem involving risks to subjects or others or any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval (45 CFR 46.103(b)(5) and 46.113). Such reports also must be submitted to OHRP (45 CFR 46.103(a)).
- (6) An institution, or when appropriate an IRB, must prepare and maintain adequate documentation of IRB activities, including the following (45 CFR 46.115):
  - Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects;
  - Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis

for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution;

- Records of continuing review activities;
- Copies of all correspondence between the IRB and the investigators;
- Written procedures for the IRB in the same detail as required in 45 CFR 46.103(b)(4) and (5); and
- Statements of significant new findings provided to subjects, as required by 45 CFR 46.116(b)(5) (45 CFR 46.115(a)).

(7) Documentation of IRB activities, and records relating to research which is conducted, must be retained for at least 3 years after completion of the research. (45 CFR 46.115(b)).

## **Guidance:**

### **Introduction**

Research projects that were previously approved by an IRB sometimes are transferred to another IRB or to another institution. These transfers occur for a variety of reasons, and give rise to a number of regulatory, administrative, and logistical questions.

Transfer of review responsibility for a research project from one IRB to another should be accomplished in a way that assures continuous IRB oversight with no lapse in either IRB approval or the protection of human subjects, and with minimal disruption of research activities. Therefore, we recommend that the original IRB work closely with the investigator, the sponsor, if any, and the receiving IRB, as appropriate, throughout the transfer process to ensure an orderly transition and continued protection of human subjects. Effective communication among the IRBs, investigators, and others (e.g. institutional representatives, Data Safety Monitoring Board, Clinical Research Organization) throughout the process is critical to ensuring a smooth transition to another IRB. In some situations, a transfer may disrupt study enrollment or other aspects of a research project, whether because of unforeseen difficulties in the transfer process or because of concerns arising from the study. OHRP believes that serious disruptions will be rare and hopes that providing this guidance will minimize disruptions.

This document reviews the possible actions to consider when responsibility for IRB review of an ongoing IRB-approved research project is transferred from one IRB to another, or when a research project that was previously approved by an IRB is transferred to another engaged institution. Institutional officials and IRB administrators will want to take into account not only the regulatory requirements, but also a variety of legal, administrative, and logistical considerations in establishing their own policies for such transfers. Of note, the HHS regulations at 45 CFR part 46 do not explicitly address the issue of research project transfer.

The IRB transfer process is expected to vary, depending on the reasons for the transfer, the parties involved, and the number and risk of the studies being transferred. OHRP recognizes that some transfers may be relatively simple and quick to achieve, whereas others may be more complicated and involve additional legal, regulatory, administrative, and logistical considerations. For example, transfer of IRB oversight due to purely administrative reasons such as consolidating IRB workload may be straight-forward, whereas a transfer of oversight due to the original IRB's non-compliance would be anticipated to be more lengthy and involved. In general, the type of IRBs involved (e.g., academic, hospital-based, independent) would not affect the actions to consider when transferring oversight.

The key entities involved in a research project transfer are:

- (1) The *transferring* IRB (also referred to in this document as the *original* IRB);
- (2) The *receiving* IRB (also referred to in this document as the *new* IRB);
- (3) The institution(s) engaged in the research; and
- (4) The investigator.

When transferring IRB review and oversight of research projects from one IRB to another IRB, OHRP recommends that the transfer process be documented in a written agreement between the original and receiving IRBs, if appropriate. [Note: OHRP recognizes that for transfers of oversight between IRBs at the same institution, a written agreement may not be necessary as the process may be addressed by the institution's established procedures (assuming all appropriate steps as identified below are covered).]

The agreement should address the following eight actions, as appropriate. We describe each of these actions in more detail below. [Note: The following list is not meant to be exhaustive. Additional actions may be necessary and/or appropriate.]

- (1) Identifying those studies for which IRB oversight is being transferred;
- (2) Ensuring the availability and retention of pertinent records;
- (3) Establishing an effective date for transfer of oversight, including records, for the research project(s);
- (4) Conducting a review of the study(ies) by the receiving IRB, where appropriate, before it accepts responsibility for the study(ies);
- (5) Confirming or establishing the date for the next continuing review;
- (6) Determining whether the consent form needs to be revised;
- (7) Notifying the key parties; and
- (8) Addressing IRB regulatory issues.

### *Common Transfer Scenarios*

Transfer of responsibility for IRB review can occur under a number of possible scenarios. These are the most common:

Scenario 1: Conduct of the research project remains at the same engaged institution: Transfer from an *internal* IRB to an *external* IRB, or transfer from an *external* IRB to

*another external IRB.* An “internal IRB” refers to an IRB that is operated by the institution; an “external IRB” refers to an IRB operated by another institution, or to a commercial or independent IRB.

Scenario 2: Conduct of the research project remains at the same engaged institution: Transfer from one *internal* IRB to another *internal* IRB.

Scenario 3: Research project is transferred to a new engaged institution:

- (a) Transfer to a new *internal* or *external* IRB designated by the new institution; or
- (b) Continued reliance on the original IRB.

These three scenarios and the possible actions to consider for each are discussed in the following sections.

### **Scenario 1. Same Engaged Institution: Transfer from an Internal IRB to an External IRB, or Transfer from an External IRB to Another External IRB**

Research projects can be transferred from an internal IRB to an external IRB that is independent or operated by another research institution, or transferred from an external IRB to another external IRB. Such transfers occur for a number of reasons, such as:

- A medical school decides to transfer a category of its studies (e.g., drug clinical trials) to an external IRB that possesses relevant expertise.
- A hospital’s IRB realizes it has an excessive workload, but the institution does not want to establish an additional internal IRB.
- A small college has an insufficient number of studies to justify maintaining its own internal IRB.
- A group of independent institutions establish a new central IRB to review research projects conducted jointly by these institutions.
- A fire, flood, or other disaster temporarily precludes an institution’s internal IRB from fulfilling its review responsibilities.
- An institution decides to transfer its studies to another external IRB because the external IRB that it has been relying upon will be closing.

Such a transfer from an internal IRB to an external IRB, or an external IRB to another external IRB, may involve the following eight actions for consideration:

#### *(1) Identifying those studies for which IRB oversight is being transferred*

One of the first actions in the transfer process is determining for which studies IRB oversight is being transferred. OHRP recommends that the original and receiving IRBs have a clear understanding of this as it will help to bring certainty and continuity to the process and to allow for effective planning. The number of research projects, the risk posed by them, and the circumstances leading to the transfer as discussed below, will influence subsequent actions in the transfer process, e.g., whether records are obtained from the original IRB or the investigator, how the transfer date is established, and

whether the receiving IRB decides to conduct a review before accepting responsibility for the research.

*(2) Ensuring the availability and retention of pertinent records.*

Before the receiving IRB accepts oversight of the transferred research project, it should obtain copies of pertinent records (e.g., research protocol, grant proposal, sample consent form, investigator's brochure, minutes of IRB meetings at which the research was reviewed, etc.) to allow it to meet its ongoing review and oversight responsibilities for the research once transferred.

(a) Availability of pertinent records.

With concurrence of the research institution or sponsor, if relevant, the original IRB should make pertinent records available to the receiving IRB. [Note: In some cases, institutions or sponsors may not agree to the transfer of records to a proposed IRB. If that is the case, the transfer of study oversight to that IRB should not take place. The institution, sponsor, and/or investigator should work expeditiously to arrange for oversight by another IRB.] This can be accomplished by providing the receiving IRB with paper or electronic copies of the pertinent records. Alternatively, the receiving IRB may decide to obtain the records directly from the investigator. If records are obtained in this manner, the receiving IRB should also obtain meeting minutes from the original IRB as this information may be critical to the receiving IRB's assessment of the adequacy of the previous review (e.g., discussion of controverted issues, quorum, etc). The receiving IRB may choose to obtain records directly from the investigator, for example, when a transfer occurs as a result of non-compliance actions of the original IRB.

Both the original IRB and the receiving IRB should maintain adequate records regarding the research projects affected by the transfer. Such records should include any written agreement between the original and receiving IRBs, the title of the protocols being transferred, the research sites affected, the names of the associated investigators, the identities of the original IRB and the receiving IRB, and the date(s) on which the receiving IRB accepts responsibility for oversight of the research projects. In addition, the original and receiving IRBs should keep adequate records of all communications to all affected investigators.

Under some circumstances, e.g., if the original and transferring IRBs are located at the same institution, OHRP recognizes that the records regarding the research projects affected by the transfer may be stored in a mutually accessible location. Duplication of research project records would not be necessary.

(b) Retention of IRB records.

An engaged institution must be able to access documentation of IRB activities and records relating to the research project for at least 3 years after completion of the research at the engaged institution (45 CFR 46.115(b)). In addition, the records must be accessible for inspection and copying by OHRP at reasonable times and in a reasonable manner. The storage of the records (whether in paper or electronic form) can be accomplished by the internal IRB, by the external IRB, by a separate office of the institution (e.g., the vice president for research), by an external organization, or by a combination of these.

As a general matter, the original and receiving IRBs have the flexibility to work out any suitable arrangement for handling the transfer and maintenance of the records as long as the records remain accessible for inspection and copying by authorized representatives of OHRP at reasonable times and in a reasonable manner. For example, the original IRB could transfer to the receiving IRB the records related to the research projects that are still active and retain the records for “closed” research projects.

There may be circumstances where the original IRB reaches an agreement with the receiving IRB to retain some of the documentation for the transferred research projects, yet may not be able to commit to retaining the documents for at least 3 years after the completion of the research. This situation may arise, for example, where an IRB ceases operations yet retains responsibility for some records for projects that are still ongoing, either by physically maintaining these records or by reaching a storage arrangement with a responsible third party. Factors to consider in selecting an appropriate record retention arrangement may include the reasons for the transfer, as well as the nature of the research projects and the records.

*(3) Establishing an effective date for transfer of oversight, including records, for the research project(s)*

Human subjects research that is not exempt must have ongoing oversight by an IRB in order to meet several regulatory requirements, including requesting proposed changes in research, reporting unanticipated problems involving risks to subjects or others, and exercising the authority to suspend or terminate research at any time (45 CFR 46.103 and 45 CFR 46.113). Therefore, to avoid any interruption in the conduct of human subjects research when IRB oversight is being transferred to another IRB, OHRP recommends establishing a transfer date for each research project, including records, for which oversight is being transferred. Although there is no regulatory requirement to establish a transfer date, such an action promotes continuity, helps prevent a lapse in IRB coverage, and minimizes confusion regarding which IRB is responsible for review and action if, for example, an unanticipated problem should arise or research needs to be quickly suspended or terminated. If oversight is being transferred because of the closure of an IRB, the original IRB should inform all investigators and institutions, as appropriate, of the pending closure date. If oversight by a new IRB cannot be obtained by the closure date, the non-exempt human subjects research that had been overseen by the now closed IRB must stop (45 CFR 46.103).

Depending on the circumstances of the transfer, the transfer date may be established using one of a variety of methods, such as the following:

- In the written agreement, the exact date is specified in advance between the original IRB and the receiving IRB; or
- In the written agreement, the date is made contingent upon the review and acceptance of the research project by the receiving IRB. For example, if the receiving IRB decides to perform an initial review of the research project, the transfer may take effect on the date the receiving IRB makes its decision to approve, require modification in (to secure approval), or disapprove the research project. In this situation, the receiving IRB should notify the original IRB and other involved parties of the date of its approval and acceptance of oversight responsibilities

Note that if both the original and receiving IRBs are located within the same institution or IRB organization, the transfer date may be determined according to the established procedures of that institution or IRB organization.

When a large number of research projects are being transferred, it may be preferable to phase-in the transfer over a period of weeks or months to facilitate a smooth transition.

If oversight is being transferred because of the closure of an IRB, the original IRB should inform all investigators and/institutions, as appropriate, of the pending closure date.

*(4) Conducting a review of the study(s) by the receiving IRB, where appropriate, before it accepts responsibility for the study(ies)*

When the research project is transferred from an internal to external IRB, or an external IRB to another external IRB, and the research institution remains the same, 45 CFR part 46 does not require the receiving IRB to review the project prior to the next continuing review date established by the original IRB.

In practice, however, such a review is often done. Depending on the circumstances of the transfer and characteristics of the specific research project, the receiving IRB may decide to undertake an *initial* review or a *continuing* review (either by the convened IRB or under an expedited review procedure, if appropriate). For additional information on continuing review, see OHRP's "Guidance on IRB Continuing Review of Research", at <http://www.hhs.gov/ohrp/policy/continuingreview2010.html>).

Alternatively, the receiving IRB may decide to *not* conduct any review prior to the next continuing review date established by the original IRB, especially if such a review is not deemed to substantively add to human subject protections. In such a circumstance, some receiving IRBs nonetheless may request the IRB chairperson, another IRB member, an IRB administrator, or another qualified administrative staff member to perform an informal assessment of the research project.



OHRP reminds receiving IRBs that they have the authority to suspend or terminate approval of research in circumstances, for example, where the research project is not being conducted in accordance with the receiving IRB's requirements or has been associated with unexpected serious harm to subjects (45 CFR 46.113). The receiving IRB must promptly report any suspension or termination of IRB approval, including the reasons for the action, to the investigator, appropriate institutional officials, and OHRP (45 CFR 46.103(b)(5)).

*(5) Confirming or establishing the date for the next continuing review*

If the receiving IRB performs a review at the time of research project transfer (whether an initial or a continuing review), it may choose to maintain the anniversary date established by the original IRB or establish a new date of approval. If it is decided that a new anniversary date will be established, the new date must be within one year of the receiving IRB's approval.

If the receiving IRB does not conduct an initial or continuing review at the time of transfer, the date of research project approval by the original IRB is presumed to remain in effect for the full approval period established at the time of the most recent review by the original IRB. For example, if the original IRB initially approved the research project for one year effective July 1, 2011, and the project is transferred to another IRB effective October 1, 2011, the expiration date of IRB approval would continue to be July 1, 2012, unless or until the receiving IRB establishes a new expiration date.

*(6) Determining whether the consent form needs to be revised.*

Under 45 CFR 46.116(a)(7), the informed consent document is required to contain “[a]n explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject.” Therefore, when a change in IRB oversight results in changes in the contact information regarding subject rights and/or whom to contact in the event of research-related injury, the new contact information must be provided to subjects (45 CFR 46.116(a)(7)). For subjects who were previously enrolled, this may be accomplished in a number of ways, for example, with a postcard providing the relevant contact information. For new subjects, the informed consent, assent, and/or parental permission form must be revised to reflect the new contact information (45 CFR 46.116(a)(7)).

Other changes to the consent form may also be necessary, for example, if the receiving IRB requires modifications to the consent form at the site(s) under its jurisdiction as a condition of approval (e.g., changes in template language, changes in risks, etc.) (45 CFR 46.109(a) and (b)). Depending upon the types of changes needed, they may be conveyed to the investigator as required modifications to secure IRB approval for the research at that site or sites (See, e.g., 45 CFR 46.109(a)).

*(7) Notifying the key parties.*

At the beginning of the process, it is important to notify pertinent groups (e.g., investigator, Data Safety Monitoring Board, etc.) of the transfer of responsibility of IRB review, and to provide contact information of the receiving IRB.

*(8) Addressing IRB regulatory issues.*

Both the internal and external IRBs must have an active registration with OHRP before reviewing human subjects research conducted or supported by HHS. When an institution holding an OHRP-approved FWA relies upon an external IRB to review HHS-conducted or -supported research, the institution holding the FWA must execute an IRB Authorization Agreement (see <http://www.hhs.gov/ohrp/assurances/forms/iprotsup.rtf>) with the institution or organization operating the IRB (45 CFR 46.103(a) and 46.103(b)(2)).

***Temporary Transfers***

Sometimes the transfer to the external IRB is temporary and the responsibility for IRB review eventually will revert back to the original internal or original external IRB. This may be the case when a natural disaster temporarily disrupts the functioning of an IRB.

In such cases, the transfer procedure back to the original IRB may only involve identifying studies for which IRB oversight is being transferred (Action #1), and ensuring availability and retention of pertinent records (Action #2), establishing an effective date for transfer of oversight (Action #3), and notifying the key parties (Action #7). As in all scenarios described in this guidance document, the appropriate actions depend on the specific circumstances of the transfer.

**Scenario 2. Same Engaged Institution: Transfer from One Internal IRB to Another Internal IRB**

A transfer from one internal IRB to another internal IRB is a common type of transfer, especially in large institutions. Such transfers occur in a variety of situations such as the following:

- A large multi-campus university decides to consolidate its human subject protection system by closing one or more of its existing internal IRBs.
- An institution realizes its current IRBs are overburdened and establishes another internal IRB to share the workload.
- An institution establishes a new internal IRB to oversee a category of existing research studies, such as social-behavioral research, being conducted at the institution.
- For the sake of administrative convenience, an institution with several internal IRBs assigns an amendment or a continuing review application to whichever of its IRBs has time available at its upcoming meeting.

Similar to Scenario 1, such a transfer may involve eight actions for consideration:

*(1) Identifying those studies for which IRB oversight is being transferred*

This scenario may involve some or all of the same responsibilities and actions outlined in Scenario 1 (described previously in this guidance document).

*(2) Ensuring the availability and retention of pertinent records*

The pertinent IRB records maintained by the original IRB should be made available to the receiving IRB. Under Scenario 2, this can be accomplished by providing the receiving IRB with physical access to, or paper or electronic copies of, the pertinent records of the original IRB.

An engaged institution must be able to access documentation of IRB activities and records relating to the research for at least 3 years after completion of the research at the engaged institution (45 CFR 46.115(b)).

*(3) Establishing an effective date for transfer of oversight, including records, for the research project.*

Human subjects research that is not exempt must have ongoing oversight by an IRB in order to meet several regulatory requirements, including requesting proposed changes in research, reporting unanticipated problems involving risks to subjects or others, and exercising the authority to suspend or terminate research at any time (45 CFR 46.103 and 45 CFR 46.113). Therefore, while there is no regulatory requirement to establish a formal transfer date, depending on the specifics of the situation, establishing an effective date to transfer the research project from one internal IRB to another internal IRB will sometimes be appropriate.

For example, if a hospital is establishing a new IRB to oversee ongoing research being conducted at a remote ambulatory care center, establishing a formal transfer date can foster continuity and minimize confusion regarding which IRB is responsible for review and action if an unanticipated problem should arise. In contrast, if a university has identified one of its IRBs to conduct all of its continuing reviews, then a formal transfer date may be unnecessary.

*(4) Conducting a review of the study(ies) by the receiving IRB, where appropriate, before it accepts responsibility for the study(ies)*

When a research project remains at the same engaged institution, 45 CFR part 46 does not require the receiving IRB to review the project prior to the next continuing review date established by the original IRB. So the decision of whether the receiving IRB reviews the research project at the time of the transfer depends on administrative, scientific, and other non-regulatory considerations.

In some cases, such a review will be deemed unnecessary by the IRB or institution. In other cases, the IRB or institution may determine it is appropriate for the IRB chairperson, another IRB member, an IRB administrator, or another qualified administrative staff member to perform an informal assessment of the research project. And compelling reasons may occasionally exist to justify that the receiving IRB perform a full initial review.

*(5) Confirming or establishing the date for the next continuing review*

The receiving IRB may choose to conduct initial or continuing review at the time of transfer and may either maintain the date of anniversary approval date established by the original IRB or establish a new approval date.

If the receiving IRB does not conduct a formal review of the research project at the time of the transfer, research project approval by the original IRB is presumed to remain in effect for the full approval period established at the time of the most recent review by the transferring IRB.

*(6) Determining whether the consent form needs to be revised*

Revision of consent forms generally does not apply under Scenario 2 involving the transfer of a project from one internal IRB to another internal IRB, because the receiving IRB typically allows use of the previously-approved consent form.

*(7) Notifying the key parties.*

Depending on local administrative and logistical considerations, it may or may not be appropriate to notify the investigator or other pertinent entities (e.g., Data Safety Monitoring Board) of the transfer of responsibility of IRB review. For example, if the institution is establishing a new internal IRB that specializes in research involving children, then it would be appropriate to advise investigators affected by the change. Conversely, if an institution has established a separate IRB to conduct continuing review and this is reflected in the established procedures of the institution, no additional notification may be necessary.

*(8) Addressing IRB regulatory issues.*

Both the IRBs (the transferring/original and receiving IRBs) must have active registrations with OHRP before reviewing human subjects research conducted or supported by HHS. Since both IRBs are internal to the institution, no IRB Authorization Agreement is necessary.

### **Scenario 3. Transfer of the Research Project to a New Engaged Institution**

Sometimes an investigator moves to a new research institution, and the ongoing human subjects research project accompanies the investigator. In such cases, sponsors and

funding agencies often have policies and procedures for research project transfer that need to be followed.

Under Scenario 3, the new institution that becomes engaged in the research project can select one of two options for the continued responsibility of IRB review:

Scenario 3a: Transfer of review responsibility to another IRB; or  
Scenario 3b: With approval of appropriate officials at both the original and the new institutions, continuation of the review responsibility by the original IRB -- in this case there is no “receiving” IRB.

Under Scenario 3, the new institution that becomes engaged in this research project must have or obtain an OHRP-approved Federalwide Assurance.

When the research project moves to a new institution and responsibility for review is transferred to another IRB (Scenario 3a), the receiving IRB must conduct an initial or continuing review of the research project before the new institution becomes engaged in the human subjects research project (45 CFR 46.103(b)).

However, if appropriate officials at the original and new institutions have executed an Authorization Agreement for the *new* institution to rely on the *original* IRB at the *original* institution (Scenario 3b), a new initial or continuing review is not necessary.

Instead, since the transfer involves changes to the research (i.e., conducting the research in a new location, consent form revisions, possible changes of key staff, etc.), a protocol amendment must be submitted to the original IRB (45 CFR 46.103(b)(4)). In many cases this amendment represents a “minor change” to the research that the original IRB may review under an expedited review procedure (45 CFR 46.110(b)(2)).

The original IRB must review and approve these changes to the research project before the new institution becomes engaged in the human subjects research activities, unless these changes are necessary to eliminate apparent immediate hazards to the research subjects (45 CFR 46.103(b)(4)).

The eight possible actions for consideration under Scenario 3 are summarized below:

<b>Transfer of IRB Responsibilities</b>		
<b>When a Research Project Moves from One Engaged Institution to Another</b>		
<b>Actions for Consideration</b>	<b>Scenario 3a: Transfer of Review Responsibility to another IRB</b>	<b>Scenario 3b: Continuation of Review Responsibility by the Original IRB</b>
<i>1. Identifying those studies for which IRB oversight is being transferred</i>	The institutions and IRBs need to clarify responsibilities and logistics.	The institutions need to clarify responsibilities and logistics, even though the IRB remains unchanged.
<i>2. Ensuring the availability and retention of pertinent records</i>	OHRP recommends the transferring IRB or institution make the	Since the IRB remains the same, there is no need to make the records available to a

	pertinent records available to the receiving IRB.	receiving IRB. The receiving institution, however, may request copies of certain records held by the IRB or transferring institution.
	The engaged institution needs to have access to IRB records for at least three years after project closure at that institution. Record retention requirements can be met through a variety of arrangements.	The engaged institution needs to have access to IRB records for at least three years after project closure at that institution. Record retention requirements can be met through a variety of arrangements.
<i>3. Establishing an effective date for transfer of oversight, including records, for the research projects.</i>	Usually the transferring and receiving institutions establish the effective date for project transfer and advise their respective IRBs.	Usually the transferring and receiving institutions establish the effective date for project transfer and advise the IRB.
<i>4. Conducting a review of the study(ies) by the receiving IRB, where appropriate, before it accepts responsibility for the study(ies)</i>	The receiving IRB needs to conduct an initial or continuing review of the project.	The IRB needs to review and approve an amendment to the research project.
<i>5. Confirming or establishing the date for the next continuing review</i>	The receiving IRB establishes a new continuing review date, or confirms the continuing review date set by the original IRB.	Usually the continuing review date remains the same.
<i>6. Determining whether the consent form needs to be revised</i>	The IRB may require changes to the consent form.	The IRB may require changes to the consent form.
<i>7. Notifying the key parties</i>	The key parties are notified by the investigator, transferring institution, receiving institution, or the transferring IRB.	The key parties are notified by the investigator, transferring institution, receiving institution, or the IRB.
<i>8. Addressing IRB regulatory issues</i>	If the new IRB is internal to the newly engaged, FWA-holding institution, no IRB Authorization Agreement is necessary. If the new IRB is external to the newly engaged institution, an IRB Authorization agreement is necessary.	The newly engaged, FWA-holding institution needs to establish an IRB Authorization Agreement with the original IRB.

**Additional Information:**

If you have specific questions about how to apply this guidance, please contact OHRP by phone at (866) 447-4777 (toll-free within the U.S.), (301) 496-7005, or (240) 453-6900, or by e-mail at [ohrp@hhs.gov](mailto:ohrp@hhs.gov).