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**Transferring a Previously Approved Research Project to a New IRB**

**Introduction**

 Research projects that were previously approved by an IRB sometimes are transferred to another IRB or to another institution.

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.  The original IRB should 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.  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.

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.

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, the transfer process be documented in a written agreement between the original and receiving IRBs.

The agreement should address the following eight actions, as 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.

Two scenarios and the possible actions to consider.

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: 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 two 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.**

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.  The original and receiving IRBs must 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.

1. 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.

1. 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 to 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. 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 2, the new institution that becomes engaged in the research project can select one of two options for the continued responsibility of IRB review:

Scenario 2a: Transfer of review responsibility to another IRB; or

Scenario 2b: 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 2, 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 2a), 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 2b), 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)).

**Transfer of IRB Responsibilities**

**When a Research Project Moves from One Engaged Institution to Another**

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| **Actions for Consideration** | **Scenario 2a: Transfer of Review Responsibility to another IRB** | **Scenario 2b: Continuation of Review Responsibility by the Original IRB** |
| *1*  *Identifying those studies for which IRB oversight is being transferred*   | The institutions and IRBs need to clarify responsibilities and logistics. | The institutions need to clarify responsibilities and logistics, even though the IRB remains unchanged. |
| *2.  Ensuring the availability and retention of pertinent records*  | OHRP recommends the transferring IRB or institution make the pertinent records available to the receiving IRB.    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.  | Since the IRB remains the same, there is no need to make the records available to a 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. |
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| *3.*  *Establishing an effective date for transfer of oversight, including records, for the research projects.*  | 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. |
| *4.*  *Conducting a review of the study(ies) by the receiving IRB, where appropriate, before it accepts responsibility for the study(ies)* | 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. |
|  *5. Confirming or establishing the date for the next continuing review*  |  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. |
|  *6.*  *Determining whether the consent form needs to be revised* |  The IRB may require changes to the consent form.  |  The IRB may require changes to the consent form.  |
|  *7. Notifying the key parties*  |  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. |
|  *8. Addressing IRB regulatory issues* |  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. |