

## Tip Sheet 24: Single IRB or EC Review

**Related Accreditation Standard I-9: The organization has written policies and procedures to ensure that, when sharing oversight of research with another organization, the rights and welfare of research participants are protected.**

Organizations should define the roles and responsibilities of each collaborating organization when working with other organizations for oversight of research. Although Standard I-9, to which this relates, touches upon overarching HRPP responsibilities, this Tip Sheet focuses on responsibilities when collaborating on IRB or EC review. Policies and procedures, IRB or EC applications, IRB or EC member and staff worksheets, written agreements between organizations, and HRPP workflows should be reviewed carefully to ensure that they comprehensively include the breadth of responsibilities and activities required in these roles.

This Tip Sheet provides suggestions on how to implement Standard I.9, including what information could be included in policies and procedures; agreements between organizations; and checklists, templates, and other materials. This Tip Sheet follows the same structure as Standard I.9 in terms of responsibilities of the organization relying upon an external IRB or EC, and the responsibilities of the reviewing IRB or EC, and responsibilities that may be shared.

### Part A: General Considerations

Organizations should define responsibilities, roles, and workflows related to Standard I.9.

Suggested information for policies and procedures may include a description of:

1. Required written agreement(s) (such as a memorandum of understanding, attestation or reliance agreement) that document the roles of the reviewing IRB and the relying organization(s). Policies and procedures should identify which agreement terms are required, those that are negotiable, and the process for adding participating sites or additional research to existing agreements.
2. The process to ensure the organization maintains a record of all research conducted by the organization regardless of whether the research is under a local review or review by an external IRB or EC.
3. The process for ensuring organizational compliance with the requirements of other parts of the HRPP. For example, if the relying organization typically requires approval by other internal review committees prior to IRB or EC approval (e.g. Institutional Biosafety, Radiation Safety), describe the process for ensuring these required approvals are secured and for communicating the approvals to the reviewing IRB or EC.
4. How researchers are provided information on the process to use a reviewing IRB or EC and to rely on another IRB or EC.

5. The process for how the organization and researchers will identify and maintain compliance with each IRB's or EC's policies and procedures under which their research is conducted. Organizations may consider publishing information on websites, developing tip sheets, adding information to researcher manuals, and sending mass emails to raise awareness or other approaches that fit the needs of the organization.

Examples of Additional Materials that may be created to assist organizations in meeting requirements in Standard I.9.

1. The organization may develop decision trees, matrices, or other tools based on types of research, funding sources, or other pertinent criteria to guide decision-makers and researchers in the reliance determination.
2. Template reliance agreements and checklists of items to negotiate may be developed to identify required terms and points for negotiation.
3. Guidance documents and website information that are readily available to sponsors and researchers may be used to inform the research community when the organization will rely on an external IRB or EC or serve as a reviewing IRB or EC, and to provide a contact for questions.
4. The organization may develop checklists, databases, or other tools to aid researchers in tracking their responsibilities when relying upon other IRBs or ECs, and to help manage compliance with a variety of IRB or EC policies and procedures.

### **Part B: Role of the Reviewing IRB or EC**

When providing IRB or EC review services to other organizations, written materials must describe the responsibilities of the relying organizations, such as expectations for relying organizations to follow the reporting policies of the reviewing IRB or EC. The IRB or EC must be able to access sufficient information to conduct an analysis of the criteria for approval for each relying organization for all applicable studies. However, organizations have considerable flexibility about how they can implement these requirements. The information may be obtained through a variety of ways including standard site questionnaires, study-specific IRB or EC applications, established databases of relying site information, or other appropriate means. The information obtained may be applicable to all studies at the relying organization, or specific to an individual study. The reviewing IRB or EC should define the additional information it needs when providing review services to other organizations.

Suggested information for policies and procedures may include a description of:

1. How general information about other organizations or research sites is collected and made accessible to the reviewing IRB or EC. Information should include:
  - a. Whether the site has a Federalwide Assurance (FWA), including the FWA number, and whether the organization uses different but equivalent protections for research not covered by DHHS regulations, or uses the same policies and procedures for all research.
  - b. Contact information for the Organizational Official or designee and IRB or EC contacts
  - c. Whether the organization is AAHRPP-accredited.
  - d. Whether ancillary reviews must be completed prior to IRB or EC review in order for the IRB or EC to determine the criteria for approval are met.

- e. Whether the relying organization requires any site-specific language in approved consent documents such as local contacts for research participants' questions or compensation for injuries.
  - f. If the study site is located in another state or country, information about whether there are any laws, regulations or policies relevant to the site. Examples may include the age of majority; circumstances that affect the age of consent; who can be a legally authorized representative. See AAHRPP Tip Sheet 19: State and Local Law.
  - g. Describe which organization is responsible for maintaining and updating the general information.
2. Describe how study-specific information is collected. It is not necessary for each researcher on a study to provide duplicate copies of study-wide information, such as the study protocol or investigator brochure. Instead, researchers at each local site may complete a short, abbreviated, application limited to the site-specific information. Examples of information the organization may consider collecting include:
- a. Information about what laws and regulations related to human participant protections are directly relevant to the study (for example, DHHS, DoD, FDA) and whether the sponsor is requiring compliance with ICH-GCP (E6) for the study.
  - b. Information about the qualifications and expertise of researchers and research staff, including research workload, which may be provided in any number of ways. It need not necessarily include specific information about each member of the research team.
  - c. Information about resources at the local research site, including space, equipment, and personnel, which may be provided in any number of ways. For example, if the research organization has an existing process for verifying resources, the reviewing IRB can accept that, and does not need to conduct additional review.
  - d. Information about the process of recruitment and consent at the local site, including any local recruitment materials; who will obtain consent at the local site; the location of the consent discussion; the language spoken by participants; and the language spoken by the person obtaining consent.
  - e. When relevant to the specific study, information about the local population. Information about the local population may include information about race/ethnicity, languages, religious affiliations; and whether the research involves discrete and insular communities and sensitive areas of inquiry.
  - f. Plans to protect the confidentiality of information, such as the method for secure storage of records.
  - g. If not managed centrally by a pharmacy at the organization, study-specific information about plans for storage, handling and dispensing of drugs and medical devices. If managed centrally by the organization, no additional information is needed for each study.
  - h. Whether researchers or research staffs have financial or other interests in the research, information about the financial interest, and the management plan, if the conflict is managed by the researcher's organization.
3. Describe the process for adding study sites. IRBs or ECs may consider reviewing requests to add study sites using the expedited procedure as a minor change to the study if the site will be following the same protocol that has already been reviewed and approved.
4. Describe the process for review of amendments, unanticipated problems involving risks to subjects or other, or noncompliance and for conducting continuing review. Policies and

procedures should identify who is responsible for submitting information related to each of these reviews and whether the relying organizations may submit changes directly to the IRB or EC or through a PI or coordinating center.

5. Describe how the IRB or EC communicates its decisions to relying organizations. The IRB or EC may communicate directly with each relying organization and its researchers, communicate via a lead or overall study PI or via a Coordinating Center.
6. The process for a relying organization to communicate directly with the IRB or EC (IRB or EC Chair) when necessary to discuss questions, concerns or obtain interpretation of determinations.

Examples of Additional Materials that may be created to assist organizations in meeting requirements in Standard I.9.

Reviewing IRBs or ECs may make use of templates and checklists to guide researchers, administrative staff and outside organizations involved in IRB review of collaborative research, which can include:

1. Research initiation checklists to document decisions and procedures that may vary depending on terms of reliance agreements, types of research, or relying organizations, or other study-specific factors.
2. Consent and assent templates that allow for insertion of study-site required language.
3. Checklists for reviewing continuing review, reports of potential unanticipated problems involving risks to subjects or others, and reports of noncompliance or deviations from relying sites.
4. Reporting templates for approval documentation, regulatory reporting, and routine communication with relying sites such as continuing review reminders or notices of approval lapses.

Information Collection and Communication Tools:

Organizations may consider collecting and tracking information through IRB or EC application forms or other information collection and communication tools, which may include:

1. A single IRB or EC application form that collects study-wide information such as a protocol and template consent common to all relying sites. This application may be reviewed separately from a site-specific application.
2. Site-specific application forms for submission from each site or through a central PI or Coordinating Center. If collected separately from each site, the site-specific information may be reviewed either as stand-alone submission or as an amendment to the common protocol.
3. Tracking and documentation tools such as spreadsheets, matrices, databases, or other tools to manage administrative information.
4. Mechanisms to track reliance agreement terms applicable to each research study reviewed such that appropriate review and reporting activities occur for each study.
5. If local context information is collected separately from IRB or EC application forms, checklists or worksheets or other methods to provide this information to the IRB or EC for review as needed.

6. Mechanisms to document key organizational individuals at each site. This may be a spreadsheet, table, or a database to include roles and contact information, for example, for Organizational Official, IRB or EC administrative contacts, reporting contacts, and quality assurance or monitoring program contacts.

### **Part C: Role of the Relying Organization**

When relying on an external IRB or EC, the relying organization should have policies and procedures that are applicable to and encompass reliance on all IRBs or ECs or types of IRBs or ECs, which will be used for oversight of research conducted at the organization. In addition to the information in Part A, the following may be useful in the role of a relying organization.

Suggested information for policies and procedures may include a description of:

1. The workflow, including any approvals by the researcher's own organization that is relying on an external IRB or EC, the point of contact at the relying organization, and the timeframe for submitting this information in relation to submission to the external IRB or EC.
2. The types of circumstances when the organization may decide to rely on an outside IRB or EC, and the process for making these determinations.
  - a. Organizations may be required to allow review by an external IRB or EC if the organization wants to participate in particular multi-site research. Policies and procedures should include the criteria, if any, that will be considered in deciding whether a required IRB or EC is acceptable to the organization and if necessary, when the organization will not participate in research due to concerns with the identified IRB or EC or their IRB or EC review. Examples of when the use of a specific external IRBs or ECs may be required include:
    - i. Use of the Central Institutional Review Board for the National Cancer Institute (NCI CIRB)
    - ii. The funding entity requires use of an external IRB or EC when the organization is a participating site in a multi-site research. For example, the Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research requires all multi-site research to use a single IRB or EC with a few exceptions.
    - iii. Federal regulations, state laws, or local policies require use of a specific IRB or EC. For example, the HHS 2108 Common Rule requires review by a single IRB or EC for any cooperative research as of January 20, 2020.
    - iv. The principal investigator(s) (PI), or a research consortium is mandating use of a single IRB or EC.
  - b. Organizations may voluntarily decide to rely on external IRBs or ECs in a variety of situations. Policies and procedures should include the criteria, if any, that will be considered in deciding whether to voluntarily rely on an external IRB or EC. Examples of voluntary reliance may include:
    - i. Using another IRB or EC because it has particular expertise for reviewing the research;
    - ii. Identifying areas of research where external IRBs or ECs are already commonly used (e.g use of independent IRBs or ECs for industry-sponsored research.)

- iii. Identifying external IRBs or ECs to act as the IRB or EC on behalf of the organization when the organization has determined due to resources, legal, organizational conflicts of interest, or other concerns that conducting its own review or serving as the IRB or EC for a multi-site project is not feasible.
    - iv. Relying upon external IRBs or ECs to facilitate collaborations among researchers and organizations.
  - c. Organizations should rely upon AAHRPP-accredited IRBs or ECs, except when this is not possible. (See the section below on relying upon a non-accredited IRB or EC.)
- 3. A description of who in the organization will determine when the organization will rely on external IRB or EC, and who is responsible for determinations. This may be the responsibility of the Organizational Official, the HRPP director, or another appropriate individual may be responsible for determinations.
- 4. The information that the organization may want to obtain from researchers when relying on an external IRB or EC. This may include confirmation of IRB or EC approval at the point of study initiation, and as appropriate, any amendments, unanticipated problems involving risks to subjects or others, noncompliance, or continuing reviews conducted by the external IRB or EC.
- 5. When, how, and to whom reports of suspensions, terminations, or study closures should be made for research under an external IRB or EC. Reporting may be the responsibility of the external IRB or EC, or site PI, and may depend on the type of reporting.
- 6. How to provide to the reviewing IRB or EC any site-specific language in approved consent documents such as local contacts for research participants' questions or compensation for injuries, where applicable.
- 7. How to provide to the reviewing IRB information about whether there are laws, regulations or policies relevant to protection of human participants that are relevant to the study, where applicable. Examples may include laws governing the age of majority; circumstances that affect the age of consent; who can be a legally authorized representative. See AAHRPP Tip Sheet 19: State and Local Law.

In addition, note that organizations may be asked by the reviewing IRB or EC to provide additional information. (See Part B, Item 2 a-h above).

Examples of Additional Materials that may be created to assist organizations in meeting requirements in Standard I.9.

The relying organization may want to develop tools to assist its HRPP components in completing their research reviews and oversight functions, and to support their researchers in the conduct of the research in collaboration and compliance with external reviewing IRBs or ECs. These may include:

- 1. Listing or checklists of terms required in reliance agreements and those terms that may be negotiated on a case-by-case basis
- 2. Checklists or other tools used to document case-by-case reliance determinations and documentation of the research overseen by each external IRB or EC.

3. Local consent language required by the organization that may be provided to reviewing IRBs or ECs.
4. Checklist of local regulations, laws or policies that may be applicable based on the research under review and provided to reviewing IRBs or ECs for consideration of local context issues.
5. Checklists or other methods to document approvals of other organizations reviews such as radiation committee, scientific reviews, institutional biosafety, pharmacy, etc.
6. A description of the local organizational structure that describes the relationship between various legal components where human subjects research is conducted and FWA coverage.

#### Information Collection and Communication Tools:

The relying organization remains responsible for oversight of the conduct of research. Examples of materials and tools that relying organizations may want to develop to aid in this responsibility, regardless of whether the IRB or EC is local or external, may include:

1. An administrative application or study file for each research study undergoing review by an external IRB or EC. The relying organization should identify the minimum key information necessary to maintain oversight of the conduct of the research.
2. Reporting tools for communicating results of any HRPP reviews such as monitoring reports and conflict of interest management plans to the reviewing IRB or EC.

Organizations may consider developing or using tracking and documentation tools such as spreadsheets, matrices, databases, or other tools to manage administrative information. Organizations may find it helpful to use such tools to:

1. Document reliance agreement terms applicable to each research study reviewed such that appropriate reporting activities occur for each study.
2. Develop methods to document key administrative and IRB or EC officials at each reviewing IRB. This may be collected in a spreadsheet, table, or a database to include roles and contact information, for example for Organizational Official, IRB or EC administrative contacts, IRB or EC Chair(s), reporting contacts, and quality assurance or monitoring contacts.

#### **Part D: Relying on an IRB or EC that is not AAHRPP-accredited**

Organizations may rely upon non-accredited IRBs or ECs for a portion of research, but must take reasonable steps, based on the risks posed by the research, to ensure participants in the research are adequately protected. For minimal risk research, this may simply involve obtaining an assurance that the reviewing IRB or EC will comply with applicable ethical standards and regulations. For greater than minimal risk research, or if the relying organization is required to rely on an organization with significant regulatory issues or other problems, the relying organization may wish to consider more extensive oversight. When more extensive review is considered, it should be reasonable and flexible, and organizations should work together to develop innovative approaches to work collaboratively to

ensure human participants are protected. For example, depending on the level of risk posed by the research:

1. For minimal risk research, the relying organization may simply:
  - a. Obtain an assurance from the non-accredited IRB or EC that it will conduct its review consistent with the applicable ethical standards and regulations, and that it will report any regulatory violations or investigations of the reviewing IRB or EC by regulatory agencies, such as OHRP, the FDA, or regulatory agencies in other countries.
  - b. Request the reviewing IRB or EC to attest that it has completed its own internal quality review process, such as use of AAHRPP's Evaluation Instrument for Accreditation to conduct a self-assessment, completion of the US FDA's self-evaluation checklist for IRBs or ECs, or another process satisfactory to the relying organization.
  
2. For greater than minimal risk research, the relying organization may consider additional oversight. To provide additional oversight, organizations could consider, when appropriate:
  - a. Reviewing relevant portions of the minutes of the IRB or EC meeting where the particular study is reviewed.
  - b. Reviewing IRB or EC records of the particular study being reviewed. For example, the relying organization might request access to an electronic system to review IRB or EC records for the specific study.
  - c. Evaluating relevant policies and procedures of the reviewing IRB or EC.
  - d. Confirm that IRBs or ECs in countries outside the US have completed relevant certifications, when other credentialing is required by those countries.
  - e. Observing a portion of an IRB or EC meeting where the particular study is reviewed.
  - f. Having someone from the relying organization serve as a consultant to the non-accredited IRB or EC for review of a particular study.
  - g. Conducting not-for-cause monitoring of the IRB or EC.