

## Tip Sheet 24: Relying on An External IRB

### Related Accreditation Standard: I.2.

Relying on an external IRB, whether it is for a single protocol or a portion of the organization's research portfolio can be efficient and cost-effective. It is important to develop a formal written agreement which clearly delineates the roles and responsibilities of each party. In addition, there should be a working and communicative relationship between the two parties. Below are roles for the reviewing IRB and relying organizations that should be included in written agreements.

### Recommended Content:

#### *Roles of the Reviewing IRB:*

1. Conduct review of research according to all applicable regulations and laws, including initial review, continuing review, and review of modification to previously approved research.
2. Suspend or terminate IRB approval.
3. Reviews unanticipated problems involving risks to participants or others.
4. Review incidents of serious or continuing non-compliance.
5. Notify the researchers and organizations in writing of its decisions.
6. Make available relevant IRB minutes to the relying organization upon request.
7. When appropriate, conduct on-site or remote post-approval monitoring or audits, unless delegated to the relying organization.
8. Specify the contact person and provide contact information for the reviewing IRB.

*Roles of the Relying Organization and Researchers:*

1. Researchers must comply with the determinations and requirements of the IRB and the organization is responsible for ensuring compliance with the IRB's requirements at the research site.
2. Prior to IRB review, provide the IRB with any local context issues relevant to the research protocol.
3. Research may be further reviewed and approved or disapproved by officials of the relying organization, but they may not approve the research if it has not been approved by the reviewing IRB.
4. The organization and the researchers acknowledge and agree to cooperate in the IRB's responsibly for initial and continuing review, record keeping and reporting. All information requested by the IRB will be provided in a timely manner.
5. Researchers and research staff agree to disclose financial conflicts of interest according to the agreed upon process and comply with any conflict management plans that may result.
6. The organization or researchers will report promptly to the IRB any proposed changes in the research. The investigator will not initiate changes in the research (including changes in the consent document) without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
7. Researchers will not enroll individuals in research prior to review and approval by the IRB.
8. The researchers, when responsible for enrolling participants, will obtain, document, and maintain records of consent for each participant or each participants legally authorized representative as stipulated by the IRB.
9. Researchers will report to the IRB any unanticipated problems involving risks to participants or others according to the IRB's reporting policy.
10. Researchers will provide to the IRB any data safety monitoring reports they receive, either at continuing review, upon request by the reviewing IRB, or on an emergent basis if appropriate.
11. Researchers will report to the IRB any non-compliance or protocol deviations according to the IRB's reporting policy.
12. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.
13. The organization and researchers acknowledge that they are primarily responsible for safeguarding the rights and welfare of each research participant, and that the participant's rights and welfare must take precedence over the goals and requirements of the research.
14. The relying organization may conduct post-approval monitoring in addition to, or in cooperation with, the reviewing IRB.
15. The written agreement does not preclude the organization or researchers from taking part in research not covered by the agreement.
16. Specify the contact person and provide contact information for the relying organization.

*Roles that may be delegated to either the Reviewing IRB or Relying Organization:*

1. The agreement should stipulate whether the relying organization or reviewing IRB performs these responsibilities:
  - a. Reporting to organizational officials, regulatory agencies, and sponsors of serious or continuing non-compliance, unanticipated problems involving risks to participants or others, suspensions or terminations of IRB approval.
  - b. Education and continuing education of researchers and research staff. The educational requirements followed should be specified in the agreement.
  - c. Obtaining disclosure and management of financial conflict of interest, although if the relying organization maintains responsibility for this issue, any disclosure or management plan will be proved to the IRB in timely manner prior to the decision by the IRB.
  - d. Management of organizational conflict of interest related to the research.

**Other Suggestions:**

*Relying on a non-accredited IRB:*

When an organization relies upon an accredited organization's IRB, they can be assured that the reviewing IRB complies with high performance standards and regulatory and legal requirements. Conversely, when a reviewing IRB is not accredited, the quality of the review or compliance with regulations and laws is unknown. Relying on accredited organizations is most desirable. If reliance on a non-accredited organization is considered, there must be a process to ensure that the research is being reviewed appropriately. The extent of the oversight process may be based on the number of research protocols involved, the type of research and the level of risk involved in the research. Reviewing relevant IRB minutes, or having a member serve on the IRB are two examples of ensuring an adequate review. AAHRPP offers an IRB Evaluation Checklist ([https://admin.share.aahrpp.org/Website%20Documents/IRB\\_Evaluation\\_Checklist.DOC](https://admin.share.aahrpp.org/Website%20Documents/IRB_Evaluation_Checklist.DOC)) to aid in the evaluation of a non-accredited IRB.