

# Policies and Procedures for the Protection of Human Research Subjects

115: Collaborative Research	
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## Nonexempt Collaborative Research

Collaborative research takes place when researchers from different institutions are "engaged in the research" as defined by <u>federal guidance</u>. "Engaged in the research" generally means that employees or agents of the institution (including students conducting research to satisfy degree requirements) obtain for the purposes of the research:

- (1) data about the subjects of the research through intervention or interaction with them;
- (2) identifiable private information about the subjects of the research; or
- (3) the informed consent of human subjects for the research.

The engaged institutions must either enter into a joint review of the research, rely upon the review of another institution via an Institutional Authorization Agreement (IAA) or make some other similar arrangement. Such agreements must be in writing and executed by authorized personnel. The institution providing direct oversight is referred to as the "IRB of Record."

<u>Research activities should not begin until all approvals are obtained</u>. Since individual IRBs typically have different requirements, entering into an IAA is encouraged although either institution reserves the right to insist on review by its own IRB for a given protocol.

For research conducted at ISU, the ISU IRB would typically be the IRB of Record. An ISU IRB protocol should be submitted for approval. Researchers affiliated with the collaborating institution would then check the requirements at their institution to determine what approvals are necessary.

For research approved at another institution, a copy of the approved protocol, the approval letter and the IAA Reliance Determination Form should be forwarded by the researchers to Research Ethics and Compliance at <u>irb@ilstu.edu</u> via email with the subject line as "IAA". After verifying that the other institution's IRB is appropriately registered with OHRP and holds a Federalwide Assurance (FWA), REC will administratively review the protocol to determine whether the ISU IRB is satisfied with the other institution's review. REC will prepare an IAA to cede authority for review and forward it to the other institution for signature for those that are satisfactory. The project may begin once the IAA is signed by both institutions. Approved IAA will be sent to the PI and Co-PIs once executed.



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Research that has been approved at another institution would still require an ISU IRB protocol when:

- The other institution is not willing to sign an IAA.
- The ISU IRB is not satisfied with the review at the other institution.
- The approving institution does not have an FWA and a registered IRB.

## Exemptable Research

For research deemed exempt by another institution, the ISU researchers must submit the IAA Reliance Determination Form along with the protocol and approval letter from the other institution in order for the ISU IRB to evaluate the other institution's determination. If the ISU IRB is satisfied with the determination by the other institution, a collaborative research agreement would not be required and the PI will be notified that the research may begin. In some cases, the ISU IRB may require an ISU exempt determination. The research may begin once the PI receives notification from REC that the project has been determined to be exempt. In rare cases, an ISU IRB protocol may be required. As always, researchers are still expected to conduct their research in accordance with established ethical principles.

## **Courtesy Approvals**

Researchers from outside of ISU seeking to access ISU students, staff, and faculty for participation in research should send their request along with a copy of their approved IRB protocol and approval letter from their institution to REC at irb@ilstu.edu. If REC is satisfied with the protocol, a "courtesy approval" can be issued. Please note that the ISU IRB does not have the authority to grant access to potential participants. The courtesy approval will be shared with the individual responsible for the population being sought for approval to access the potential participants (typically a dean, department head, or other administrator). Please note that courtesy approvals are only appropriate when ISU personnel are not "engaged in the research" as described above.

ISU personnel receiving a request from non-ISU researchers should:

- 1. Determine whether courtesy approval has been obtained by contacting REC.
- 2. If not, seek confirmation from the appropriate administrator that they would be supportive of the project; and
- 3. Forward the request to REC at <u>irb@ilstu.edu</u> for follow-up prior to fulfilling the request.