Policies and Procedures for the Protection of Human Research Subjects

103: Collaborative Human Subjects Research	
Version: 2	**Effective Date: 06/02/2023**

Collaborative research takes place when researchers from different institutions are "engaged in the research" as defined by federal guidance. "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.

Exemptable Research

For research deemed exempt by another institution covered by an approved Federalwide Assurance (FWA) with Office of Human Research Protection (OHRP) and the other institution's protocol includes the ISU researcher, a collaborative research agreement would not be required by ISU. ISU researchers must create a new submission in the electronic IRB submission system to document the arrangement. If the other institution does not hold an FWA or the ISU researcher is not covered by their protocol, an ISU protocol is required.

Nonexempt Collaborative Research

For Expedited Review and Full Board Review protocols, 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."

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

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 irb@ilstu.edu 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.

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 Institutional Official (or designee) it is not satisfied with the review at the other institution.
- The approving institution does not have an FWA and a registered IRB.

For research conducted at ISU, the ISU IRB would typically be the IRB of Record. An ISU IRB protocol should be submitted for approval. The protocol will require information on the collaboration similar to what is found in the IAA Reliance Determination Form. Researchers affiliated with the collaborating institution would then check the requirements at their institution to determine what approvals are necessary. REC will work with the other institution to complete an appropriate agreement. The collaborative activities under the protocol may not begin until the agreement is signed by both institutions.