Oakland University
Institutional Review

Human Subjects Cooperative Research

Department:	**The Office Research Administration/IRB**
Effective Date:	**10/12/2011**
Version	1.5

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I. Overview and Purpose

Institutions participating in cooperative projects or multi-site studies may use joint review arrangements, rely upon the review of another qualified Institutional Review Board (IRB), or make similar arrangements for avoiding duplication of effort (45 CFR 46.114 and 21 CFR 56.114).
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.114
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.114

The Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) permit institutions involved in cooperative or multi-site studies to use reasonable methods of joint or cooperative review. While the IRB of record assumes responsibility for oversight and continuing review, the principle investigator (PI) and each institution is responsible for safeguarding the rights and welfare of human subjects as specified in 45 CFR 46 and/or 21 CFR 56.

In general, there are five types of collaborations that may exist when working with a Collaborating Entity. These various collaborations are as follows:

1. The Collaborating Entity has a Federal Wide Assurance (FWA) and an IRB registered with the Office for Human Research Protections (OHRP);
2. The Collaborating Entity has a FWA without an IRB;
3. The Collaborating Entity does not have a FWA or an IRB;
4. The Collaborating International Entity has a FWA and an IRB; or
5. The Collaborating International Entity has a FWA without an IRB.

The purpose of these guidelines is to describe procedures and provide guidance for conducting Cooperative Research at Oakland University (OU) with a Collaborating Entity that has a FWA and an IRB registered with the OHRP (Collaboration Type 1 above).

II. Definitions

Co-Investigator of the Grant: Any individual from the Collaborating Entity who is listed as a co-investigator on the grant.

Collaborating Entity: An institution, practice plan, clinic, or individual that is participating in a cooperative research activity with the lead institution.

Cooperative Research Projects: Those human subjects research projects covered by the DHHS and the FDA which involve more than one institution.

Engaged in Research: A Collaborating Entity becomes "engaged" in human subjects (participants) research when its employees or agents: (1) intervene or interact with living individuals for research purposes or (2) obtain individually identifiable private information (that may be used) for research purposes [45 CFR 46.102(d),(f)].

Examples of research engagement activities:

A Collaborating Entity is "engaged" in research when the entity or its employees or agents:

1. Interact with individuals to draw blood, collect biological samples, administer treatments, dispense drugs, employ medical technologies, etc.,
2. Conduct interviews, engage in protocol related communications, obtain informed consent,
3. Maintain statistical, operational or coordinating centers for multi-site collaborative research, or
4. Obtain, receive or possess private information about individuals such as names, information from medical records, etc.

A Collaborating Entity is "not engaged" in research, when the entity or it's employees or agents:

1. Act as consultants on research but at no time obtain, receive, or possess identifiable private information,
2. Perform commercial services meriting neither professional recognition nor publication privileges,
3. Permit use of their facilities for intervention or interaction by research investigators, or
4. Provide prospective participants (subjects) information about the availability of the research either verbally or in writing.

For Guidance on Engagement of Institutions in Human Subjects Research
http://www.hhs.gov/ohrp/policy/engage08.html

IRB Authorization Agreement: A formal, written agreement in which the reviewing IRB agrees to serve as the IRB of Record for another relying institution.

IRB of Record: A reviewing IRB that assumes IRB responsibilities for another organization and is designated to do so through an OHRP approved FWA.

Lead Institution: The institution that is awarded the grant/contract or is leading the research project if unfunded.

PI at Lead Institution: The one individual who is responsible for the conduct of the research protocol and the research project at the Lead Institution. A research protocol or project may have multiple collaborating institutional relationships but there is only one PI.

PI of the Grant: The one individual who is responsible for the grant.

PI of the Sub-Award: The one individual from the collaborating entity or facility who is responsible for the grant received from the Lead Institution.

Site Principal Investigator: The one individual at the collaborating entity who is responsible for the conduct of the research protocol and the research project at that site.

III. Procedures (Collaborating Entity has a FWA and an IRB registered with the OHRP)

When the collaborating entity operates under a FWA through an IRB registered with the OHRP, there are two options that may be used to protect human subjects:

A. Individual IRB Review and Approval (Dual Review by both institutions); or
B. The Lead Institution agrees to be the IRB of record for the Collaborating Entity.

A. Dual Review by Both Institutions

This applies to a cooperative research project when the recruitment of and the direct interaction with human participants are conducted at both institutions. In this case, each entity is responsible for individual IRB review and approval. The responsibility of compliance resides with both parties, although the Lead Institution has the overall compliance responsibility. When appropriate, the Lead Institution may conduct compliance audits at both institutions. However, compliance oversight of each institution's PI and his/her key personnel is the responsibility of each IRB that performed the review.

The Lead Institution also has the authority to suspend and/or terminate the research protocol and its approval of the research project, including all approved performance sites operating through the Authorization Agreement or other agreements. The

Collaborating Entity has the authority to suspend and/or terminate the research protocol at its institution/entity. The Lead Institution is responsible for filing all required reports, and notifying sponsors, OHRP and/or FDA, as appropriate

When the PI or Co-PI of the study is from OU, he/she needs to, first, submit IRB applications (original application, amendments, continuing review, etc.) to the lead institution to obtain approval obtain approval from the Lead Institution. If OU is not the Lead Institution, the OU PI or Co-PI must submit to OU IRB the following:

- IRB research protocol application with all appropriate appendices and other required submissions (e.g., Informed Consent or Waiver of Consent, HIPPA Authorization or Waiver, questionnaires, advertisements, permission letters from research site, etc.);
- A copy of the grant proposal if applicable;
- A copy of the IRB application and supporting materials submitted to the collaborating entity; and
- Copies of IRB approval letter(s) issued by the Collaborating Entity.

B. Lead Institution Agrees to be the IRB of Record

1. Using a Non-OU IRB as the IRB of Record

Pursuant to 45 CFR 46.116 and 21 CFR 56.114 it is permissible for an institution to rely on another IRB to review and approve research protocols. Whenever OU relies upon an IRB operated by another institution or organization for review of research to which the other institution's FWA applies, the IRB of record needs to be registered with OHRP and the collaborating entity must operate under a FWA. This applies to a cooperative research project when the recruitment of and the direct interaction with human participants are conducted at the collaborating entity and/or offsite under the supervision of the collaborating entity.

The OU PI must provide the OU IRB with the following:

- A copy of the IRB application and all supporting materials (e.g., Informed Consent or Waiver of Consent, HIPAA Authorization or Waiver, questionnaires, advertisements, permission letters from research site, etc.) submitted to the Lead Institution, including a grant proposal if applicable;

- A copies of IRB approval letters issued by the IRB of Record at the Lead Institution;

- Copies of IRB continuing approval letters or memos from the lead institution.

OU will review the submitted documents and determine if IRB oversight may be deferred to the collaborating entity. A determination letter will be issued to the OU PI regarding the outcome of the review. OU must ensure that this arrangement is documented by a written IRB Authorization Agreement between OU and the lead institution or organization operating the IRB. The IRB Authorization Agreement must outline the relationship between the two entities and must include a commitment that the IRB of Record will adhere to the requirements of the Institution's FWA. OHRP's sample IRB Authorization Agreement will be used for such purpose, or the parties involved may develop their own agreement. This agreement must be signed by the Institutional Officials (IO) of both collaborating institutions, kept on file at both institutions/organizations, and made available upon request to OHRP or any U.S. federal department or agency conducting or supporting research to which the FWA applies.

The responsibility for compliance resides with both parties; however, the IRB of record has primary compliance responsibilities to protect human subjects at both sites. The IRB of Record has the authority to approve, suspend and/or terminate its approval of the research project, including all approved performance sites operating through Authorization Agreement or other agreement and to conduct periodic reviews as deemed necessary. The IRB of Record will have the responsibility to file all required reports, and notify sponsors, OHRP and/or FDA, as appropriate.

Once approval is granted to use another institution as the IRB of Record and the IRB Authorization agreement is signed by the Institutional Official (IO) at each institution, the PI shall send a copy of the IRB Authorization Agreement to the IRB of Record. All amendments and correspondence are to be sent to the IRB of Record unless instructed by them to send the materials to OU IRB. A copy of the IRB of Record continuation approval letter or memo shall be sent to OU IRB when obtained.

2. **Using OU as the IRB of Record**

Currently, OU agrees to serve as the IRB of Record only when the collaborative research projects are conducted by an OU PI or Co-PI and the research activities a) occur at OU sites, and/or b) uses OU students, staff or faculty as research subjects (participants).

When using OU as the IRB of Record, the PI must provide the OU IRB with the following:

- IRB research protocol application with all appropriate appendices and other required submissions (e.g., Informed Consent or Waiver of Consent, HIPPA Authorization or Waiver, questionnaires, advertisements, permission letters from research site, etc.);
- A copy of the grant proposal if applicable;
- Certification of Human Subject Training (CITI or equivalent) for non- OU PI;
- An IRB Authorization Agreement to use the OU IRB as the IRB of Record signed by collaborating entity IO, non OU PI and OU PI.

In this case, the OU IRB, as the IRB of Record, has primary compliance responsibilities and has the authority to approve, suspend and/or terminate its approval of the research project and to conduct periodic reviews as deemed necessary. The OU IRB will have the responsibility to file all required reports, and notify sponsors, OHRP and/or FDA as appropriate.

Section IV. Federal Regulations and Guidance References

45CFR 46.114
21 CFR 56.114
FDA Information Sheet "Guidance for Institutional Review Boards and Clinical Investigators 1998 Update"