WAYNE STATE UNIVERSITY

Policy/ Procedure

Wayne State University Human Investigation Committee	
SUBJECT:	Collaborative Research
Section:	
Form Date:	August 28, 2006
Approvals	General Counsel 11/20/06, Steering Committee12/07/06, Administrative Review 02/28/07

Background

In the conduct of cooperative research projects in which Wayne State University (WSU) is one of the collaborating institutions, each institution involved is responsible for safeguarding the rights and welfare of human participants (subjects) and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified Institutional Review Board (IRB), or make similar arrangements for avoiding duplication of effort (45 CFR 46.114, 38 CFR 16.114).

When an investigator at Wayne State University (WSU) proposes to do research with an individual or institution that is not authorized to cite the WSU Federal Wide Assurance (FWA), additional administrative arrangements must be made depending on the type of collaboration. Collectively these institutions and/or individuals are known as "Collaborating Entities". The WSU Principal Investigator (PI) and the Human Investigation Committee (HIC) are responsible for assuring that human research participants are protected and federal guidelines are followed during collaboration with other entities including the determination of any Conflict of Interest [42 CFR 50.602].

Scope

Cooperative (Collaborative) research projects which involve more than one institution and Wayne State University and any of its affiliate institutions are covered under this policy. Cooperative research involving the Veterans Administration cannot be conducted with an Institution that does not have a Federalwide Assurance [VA 1200.5 3,5].

Definitions

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

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

Principal Investigator (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 principal investigator.

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.

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

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

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

Coordinating Center – an organization that agrees to accept additional responsibilities for the conduct of a research project. Its employees or agents must maintain an operations center to provide for the scientific oversight and human participant (subject) protection for all of the sites involved in the project. Their functions include, but are not necessarily limited to, data safety and monitoring, data analysis, protocol development, adverse event reporting and assurance verification.

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 activities of engagement

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.

The complete list of activities that determine if an institution is "engaged" or "not engaged" can be found at http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm

HIC Policy

There are five types of collaboration when working with a Collaborating Entity:

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 an FWA without an IRB,
3. The Collaborating Entity does not have an FWA or an IRB,
4. The Collaborating International Entity has an FWA and an IRB, or
5. The Collaborating International Entity has an FWA without an IRB

1. Collaborating Entity has an FWA and an IRB registered with the OHRP

There are two options that may be used to protect human participants (subjects) when the collaborating entity has a FWA and an IRB:

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

A. Individual Review

Each site is responsible for individual IRB review and approval. The responsibility for compliance resides with both parties.

The Lead Institution has overall primary compliance responsibilities and may conduct compliance audits at both institutions, when appropriate. Compliance oversight of the PI and his/her key personnel is the responsibility of the individual IRB that performed the review.

The Lead Institution has the authority to suspend and/or terminate the research protocol at both sites and to take other action as appropriate to protect human participants (subjects). The collaborating institution has the authority to suspend and/or terminate the research protocol at it's site. Normally, the Lead Institution has the responsibility for notifying the sponsor, FDA and/or OHRP when appropriate.

When the PI of the grant proposal is from WSU, the following must be submitted to the WSU HIC:

1. Medical/Behavioral Protocol Summary Form with appropriate Appendices and all other required submission documents (i.e., Informed Consent, HIPAA Summary and HIPAA Consent and advertisement),
2. A copy of the grant proposal,
3. Coordinating Center Application, and
4. IRB approval letter from the collaborating entity.

When the investigator at WSU will be the co-investigator of the grant, the following should be submitted to the HIC:

1. Medical/Behavior Protocol Summary Form with appropriate Appendices and all other required submission documents (i.e., Informed Consent, HIPAA and advertisement), and
2. A copy of the grant.

B. Lead Institution agrees to be the IRB of record for the Collaborating Entity

IRB Review and/or Approval - Under 45 CFR 46.114 it may be permissible for an institution to rely on another IRB to review and approve a research protocol. However, "IRBs should be sufficiently qualified through…. the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel and to able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice."

Adequacy of Research - When determining the adequacy of research at another location, there must be a statement about the research environment and resources at the Collaborating Entity. This can be fulfilled by a signed agreement with the Collaborating Entity stating compliance with 45 CFR 46. Qualifications of the PI and any key personnel at the Collaborating Entity and documentation of completion of Human Participant (subject) Training such as that offered by the National Institutes of Health (NIH) or the equivalent must be provided. WSU on-line training may be mandated.

Community Information - An assurance that the protocol has community input and support must be provided. If the Lead Institution does not have a person on their IRB that has personal knowledge of the local research context of the Collaborating Entity, the Collaborating Entity, through written materials or through discussions, should provide information with appropriate consultants.

Compliance - Responsibility for compliance resides with both parties. The IRB of record has primary compliance responsibilities and has the authority to conduct compliance audits when appropriate and may suspend and/or terminate the research protocol as appropriate to protect the human participants (subjects) at both sites. The IRB of record will have the responsibility for reporting to the sponsor, FDA, and/or OHRP.

Suspension/Termination - The IRB at the Collaborating Entity has the authority to suspend and/or terminate the research protocol at it's' institution. Disciplinary action against the site principal investigator and his/her key personnel at the collaborating site are the responsibilities of the local IRB and the Collaborating Entity.

Using a non-WSU IRB

When a WSU PI chooses to collaborate with a Collaborating Entity and will not be doing any patient recruitment at WSU, he/she may request to use the Lead Institution as the IRB of record. For example, when the PI is developing a data collection tool, conducting lab analysis, performing data analysis, or serving as a consultant, etc., the WSU PI may request that the IRB at the lead institution be the IRB of record for the protocol conducted at WSU.

The WSU PI must submit to the WSU IRB:

1. IRB approval letter from Lead Institution,
2. Authorization to Use Another IRB form signed by Lead Institutional Official and Lead Institution Principal Investigator, and
3. A completed Administrative Application.

Once approval is granted to use another IRB, the PI should send a signed copy of the "Authorization to Use Another IRB" to the Lead Institution. All amendments and correspondence are sent to the Lead Institution's IRB unless instructed by them to send the material to WSU HIC Administrative office. A copy of the Lead Institution's Continuation Approval Memo should be sent with an Administrative Application form with the box checked for continuation within 2 weeks of the expiration date of approval to the HIC Administrative office. In this case, the Lead Institution will be added to the WSU FWA.

WSU as the IRB of Record

In determining if WSU will be the IRB of record for the Collaborating Entity, WSU must determine that there are adequate provisions and resources to conduct research at the site. The Collaborating Entity's institutional official signing the IRB authorization form indicating that the site meets the requirements of 45 CFR 46 provides that assurance. When the Collaborating Entity is located within another state or country, WSU may refuse to serve as the IRB of record because it may not be familiar with the laws of that state that apply. A request under unique circumstances can be made.

The Site PI of the Collaborating Entity must submit the following documents to the WSU PI who will serve as the sponsor for the submission to the WSU IRB:

1. Authorization to Use WSU IRB signed by Collaborating Entity Institutional Official, Site PI, and WSU PI,
2. Either take the WSU online Human Participant Training or provide documentation of equivalent, to be determined by the HIC Chair in consultation with the Assistant Vice President for Research.
3. Medical/Behavioral Protocol Summary Form and consent forms for Collaborating Entity, and
4. Written documentation of community input as appropriate.

In addition, the WSU PI must submit the following documents to the WSU IRB:

1. Coordinating Center Application, and
2. Medical/Behavioral Protocol Summary Form for WSU, if not previously submitted.

Once approval is granted, it is the responsibility of the Site PI of the Collaborating Entity to send a copy of the Agreement to Use another IRB and approval to the Collaborating Entity

2. Collaborating Entity with an FWA and without an IRB

It is possible for an organization to have an FWA but not have an established IRB. For example, a WSU investigator requests approval to collaborate with an investigator from a local hospital that does not normally conduct research and does not have an IRB. In this case, the Collaborating Entity would utilize WSU as the IRB of record.

3. Collaborating Entity without an FWA and without an IRB

In the research community it is possible for a PI to develop a working relationship with an individual or clinic that is acting as the collaborating entity that does not have a FWA or an IRB. In this case, the Collaborating Entity (individual or clinic) must obtain a FWA and then could utilize WSU as the IRB of record. Cooperative research involving the Veterans Administration cannot be conducted with an Institution that does not have a Federal Wide Assurance [VA 1200.5 3,5].

4. Collaborating International Entity with a FWA and an IRB

International research is reviewed by the HIC chair prior to IRB review. Currently research is being encouraged between international sites to facilitate growth, knowledge, and resources. International sites are being encouraged to obtain FWA's to facilitate collaborative research. While the U.S. cites the Belmont Report as the ethical standard for the protection of human participants, international sites may choose other ethical standards such as the Declarations of Helsinki, World Health Organization (WHO), or federal law. When research is being carried out with an international entity, special attention must be given in order to be sensitive to local community standards. When USA researchers are conducting research in a foreign country (Collaborating International Entity), US regulations require that the research protocol must adhere to the standards of both countries.

International Individual Review

The criteria and guidelines are the same for Individual International Review as it is for local review.

International Collaborating Entity to use the IRB of Record

If an international entity has an IRB, WSU will generally refuse to be the IRB of record because the IRB in that country is more familiar with the local mores and culture. However, under certain circumstances, the WSU HIC may consider being the IRB of Record. This determination is done by the HIC Chair in consultation with the Assistant Vice President of Research (AVPR).

When the WSU HIC has agreed to be the IRB of Record, the Site PI of the International Collaborating Entity must submit the following documents to the WSU PI:

1. Authorization to Use WSU IRB signed by Collaborating Entity Institutional Official, Site PI, and WSU PI,
2. Either take the WSU online Human Participant Training or provide documentation of equivalent as determined by the HIC chair in consultation with the AVPR.
3. Medical/Behavioral Protocol Summary Form for Collaborating Entity, and
4. All consent forms, advertisements and any written language in the original English language and then a certified translated version in the language spoken by the participants,[1] and
5. Written documentation of community input as appropriate.

[1] When the translation is not certified, submit a back-translated version of the native language consent completed by someone not associated with the original translation. For studies approved under Category 1 (no more than minimal risk) a back translation is not required.

In addition, the WSU PI must submit the following documents to the WSU IRB:

1. Coordinating Center Application, and
2. Medical/Behavioral Protocol Summary Form for WSU, if not previously submitted.

5. Collaborating International Entity with a FWA and without an IRB

It is possible to collaborate with an International Entity that has a FWA but does not have an IRB. Critical to the determination of the designation as the WSU IRB as the IRB of record is that proper community input has been incorporated into the IRB review of the protocol. The IRB review process is exactly equivalent to the previous discussion about conducting research at a Collaborating Entity that wishes to use the WSU HIC as the IRB of Record, including the pre-review by the HIC Chair. Therefore, investigators should refer back to that section for how to conduct research at these Collaborating International Entities.

The type and extent of local community involvement is usually dependent on the level of risk associated with the research protocol. The protocol must include a description of a profile of the community.

A community profile should discuss the following:

1. The demographics, unique populations, and any unique concerns of the community,
2. A description of how the community problems are identified and addressed,
3. The potential benefit to the research participant, and
4. When appropriate a discussion of why multiple locations are being proposed.

During the review process, the WSU IRB must determine if the community beliefs in the country of the Collaborating Entity are equivalent or if they are substantially different from the community in which the Lead Institution and its affiliated health care institutions normally provide educational, research, and health care services.

When the research presented involves no more than minimal risk to the research participant in the local context, this must be presented to the IRB in written materials. The IRB should demonstrate necessary discussion and obtain appropriate consultant(s), if needed, to verify risk to local context.