SOP 602G: IRB OF RECORD

1. POLICY
Investigators at the University often engage in research projects involving participants or testing procedures that may fall under the purview of multiple IRBs. The Human Research Participant Protection (HRPP) Director evaluates the role of the OU researchers and determines the appropriate IRB of record. Where possible, the IRB will collaborate with other OU and non-OU IRBs to reduce the number of IRB reviews that a research project may undergo.

Research Involving Multiple University IRBs: Human research projects involving IRBs from both the Health Sciences (HSC) and Norman (NC) campuses may include research projects that recruit participants from both campuses, involve investigators from both campuses, or utilize resources from both campuses. Research projects that target a specific patient population or that utilize research procedures that may result in elevated physical risk may require HSC IRB approval, as determined by the HSC IRB Chair or IRB designee.

Research Involving Other Non-University IRBs: The University encourages collaborative research with investigators who are not OU faculty, staff, or students. To facilitate the timely review of research that involves collaborators at multiple institutions and to minimize the amount of administrative work when multiple IRBs from different institutions require the review and approval of a research project, the University will consider serving as the IRB of record for non-OU researchers when the OU researcher is the lead investigator. When the OU researcher is not the lead investigator, the University will consider deferring IRB approval to the collaborating institution of the lead investigator.

Policies regarding collaborative research and the acceptance of another institution’s IRB approval vary widely and some institutions will NOT enter into collaborative research agreements. For example, some IRBs do not defer to any other institution’s IRB, they do not review Exempt research, or they do not recognize social behavioral research. In addition, federal agency or externally-funded research may have specific expectations about the IRB of record. In these situations, the University IRB will work with the investigator to determine the appropriate course of action.

Specific Policies

1.1 Determination of Reviewing Campus
To determine the IRB of record, the investigator will submit the original application materials to the University IRB on the campus of his or her academic program. The initial determination of the IRB of record will be made according to the following guidelines:

1.1.1 All medical, clinical, FDA-regulated, and VA studies involving human participants will be reviewed by the OU-HSC IRB unless another IRB with medical and clinical expertise is reviewing the research protocol. For example, if OU-NC faculty, staff, or students conduct research in a
hospital setting and the IRB from that facility will conduct an independent
IRB review, an OU-HSC IRB review is not required.

1.1.2 Studies that include a research procedure that may result in greater than
a minimal level of physical risk or that target research participants with a
specific medical diagnosis or clinical intervention, may be evaluated by
the IRB Chairs at both the HSC and NC campuses to determine why such
participants are at increased physical risk from participation compared to
a healthy population.

1.1.3 Any University IRB can require review of a research submission by an
investigator for whom they oversee their academic program.

1.1.4 When the University investigator’s campus of record will not serve as the
IRB of record, the IRB from the originating campus shall cooperate in
response to requests for additional information and reporting
requirements, adequately support the designated IRB in its function, and
abide by the designated IRB decisions. No IRB shall administratively
overrule disapprovals by another University IRB of proposed projects.

1.3 RECIPROCAL CAMPUS IRB REVIEW POLICY

The University of Oklahoma Norman Campus and the University of Oklahoma
Health Sciences Center shall sign and maintain a Cooperative Memorandum of
Understanding (MOU) that specifies which IRB is designated with sole IRB
oversight when a research project involves both campuses or when research
proposed by OU-NC faculty, staff or students requires medical oversight.

1.3.1 Unless otherwise stipulated in Section 1.1, when participants of a
research project will be recruited primarily at one University campus, that
campus shall be assigned IRB oversight for the research project.

1.3.2 When participants of a research project will be recruited from both
University campuses, IRB Chairs at both campuses will confer to
determine which IRB should retain sole oversight.

1.3.3 If the originating University IRB determines it does not possess the
necessary expertise to review a particular research project, it shall
transfer the IRB review process to an IRB on the other campus.

1.4 Collaborating Non-OU Institutional Investigators

The investigator must be a full-time faculty member at the University. The
University IRB will consider the following factors when investigators request that
an IRB Authorization Agreement (IAA) to govern the collaborative research be
signed by the Institutional Officials for each participating institution.

1.4.1 Deferral of OU IRB review to Other Research Institutions
Deferral by OU IRB to another research institution’s IRB may occur
subject to the following:
A. The institution to which deferral by the OU IRB is proposed must have a current Federal Wide Assurance (FWA) on file with the Office of Human Research Protections (OHRP).

B. The lead investigator for the research is not an OU faculty, staff, or student and has more direct responsibility for the conduct of the research and human subjects protections (often because of federal agency or external funding arrangements.)

C. The investigator shall describe the role and responsibility of the OU researcher in the research project to the IRB (for example, their interaction with participants or access to identifiable data).

D. The investigator shall describe the level of risk involved in the research project to the IRB.

E. The accreditation status of the other institution shall be considered.

Requests for OU IRB deferral will be considered on a case-by-case basis by evaluating the above factors and any others deemed necessary by the IRB to ensure the other IRB meets relevant accreditation standards.

1.4.2 Other Research Institution’s Deferral to OU IRB
Deferral by another research institution for OU to be the IRB of record may occur subject to the following:
A. The institution from which the deferral to OU IRB is proposed must have a current Federal Wide Assurance (FWA) on file with the Office of Human Research Protections (OHRP).

B. The lead investigator for the research is an OU employee and has more direct responsibility for the conduct of the research and human subjects protections (often because of federal agency or external funding arrangements.)

C. Request a copy of the non-OU collaborators credentials (such as a curriculum vitae) to determine if the non-OU collaborator is qualified to conduct research.

D. The non-OU collaborator has completed the OU IRB educational requirements.

E. The OU Investigator provides documentation describing the research activities in which the non-OU collaborating investigator will engage. Examples: The statement of work from a funding arrangement or detailed description in the research protocol.

F. Complete the check-off in the IRB application that confirms the OU investigator will directly and appropriately supervise all of the
collaborative research activities to be performed by the non-OU collaborating investigator.

1.4.3 The executed IAA is kept on file in the electronic information system and copies are provided to OHRP upon request.

1.4.4 When an IRB deferral request cannot be granted, then the University investigator is responsible for submitting evidence of the non-OU IRB initial, modification, or continuing review approval before the research submission can be approved by the OU IRB.

1.4.4 The University retains the right to revoke an IAA at any time. If OU is the IRB of record, it will notify the collaborating institution of this revocation. If OU is not the IRB of record, the investigator must cease all research activities until the research project is approved by the IRB.

1.5 Collaborating Investigators with No FWA Covered Institution Affiliation

A non-OU collaborating independent investigator is:

a. not otherwise an employee or agent of the University;

b. conducting collaborative research activities outside the facilities of the University; and

c. not acting as an employee of any institution with respect to his or her involvement in the research being conducted by the University.

The University investigator may be collaborating on a research project with an individual who is not affiliated with any FWA covered institution. The University IRB will consider the following factors when OU investigators request that an Individual Investigator Agreement (IIA) be signed by the collaborating investigator and the University’s Institutional Official:

1.5.2 Request a copy of the non-OU collaborators credentials (such as a curriculum vitae) to determine if the non-OU collaborator is qualified to conduct research.

1.5.3 The non-OU collaborator has completed the OU IRB educational requirements or equivalent education training.

1.5.4 The OU Investigator provides documentation describing the research activities in which the non-OU collaborating investigator will engage. Examples: The statement of work from a funding arrangement or detailed description in the research protocol.

1.5.5 Complete the check-off in the IRB application that confirms the OU investigator will directly and appropriately supervise all of the collaborative research activities to be performed by the non-OU collaborating investigator.
When the request for the University to cover a collaborating investigator is approved, the University IRB will maintain the IIA on file and provide copies to OHRP upon request.

The University retains the right to revoke an IIA at any time. The collaborating investigator must cease all research activities at the time of revocation of the IIA.

2. SCOPE

This SOP applies to all research that involves investigators or research participants from multiple research institutions.

3. RESPONSIBILITY

3.1 The OU investigator shall provide to the IRB a written justification for the University IRB to be the IRB of record for the research for the collaborating institutional investigator. The HRPP Director may consult with Legal Counsel and present the agreement to Legal Counsel for review prior to signature by the Institutional Official. The IRB shall make the agreement available to OHRP upon request.

3.2 The collaborating researcher shall understand and accept the responsibilities to comply with the standards and requirement found in the Belmont Report; OHRP rules and guidance (or other internationally recognized equivalent institutions), the FWA and applicable terms of the FWA for the assured institution; the relevant institutional policies and procedures for the protection of human subjects of the assured institution; and all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protections for human subjects research.

3.3 The collaborating researcher shall agree not to conduct any research activities until IRB approval has been granted.

3.4 The collaborating researcher shall agree to report promptly any proposed changes in the research, any unanticipated problems involving risks to participants, and instances of serious and/or continuing non-compliance to the IRB of record (SOP 407: Unanticipated Problems/Protocol Deviations: SOP 903: Non Compliance/Scholarly Misconduct).

3.5 The collaborating researcher shall agree to provide all information requested by the IRB in a timely fashion.

3.6 If OU is the IRB of record, in the OU IRB electronic information system, the OU investigator will provide additional information about: 1) the role and responsibilities of the collaborating investigators during recruitment, consent, data collection, and data analysis activities; 2) the protocol for data sharing, storage, security, retention, and disposal; and 3) the contact information for the IRB official at the collaborating institution.

3.7 The OU IRB Director contacts the IRB Director for the collaborating research institution to determine if a deferral by one institution is possible; prepares the
agreement for signature of the University Institutional Official and secures OU Legal Counsel approval, if necessary; works with the investigator to secure signatures from collaborating researchers and/or institutional officials and to upload the executed agreement to the IRB’s electronic information system.

3.8 The IRB Director or the IRB Chair is responsible for providing initial review and recommendation concerning the appropriate IRB to retain oversight.

3.9 For research projects where OU is the IRB of record, the research project cannot be approved by the IRB Chair or IRB designee until an executed IAA or IIA, as appropriate, is uploaded into the IRB’s electronic information system.

4. APPLICABLE REGULATIONS AND GUIDELINES

OHRP Policy and Guidance

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 302: Administrative Review & Distribution of Materials
SOP 407: Unanticipated Problems/Protocol Deviations
SOP 903: Non Compliance/Scholarly Misconduct

6. ATTACHMENTS

602G-A Non OU Employee Collaborator Assurance Form (NC)

7. PROCESS OVERVIEW

7.1 When a research project involves multiple research institutions or University campuses, a reviewing IRB shall be designated as described above in Section 1.1.

7.2 The IRB Administrator reviews submitted documents per SOP 301: Research Submission Requirements.

7.3 The IRB Chairs from both campuses may confer to determine which IRB is responsible for regulatory oversight and appropriate notation is documented in the research project file.

7.4 The IRB Administrator or IRB Chair notifies the investigator regarding determination of IRB oversight.

7.5 On the Norman campus, for research projects where OU is the IRB of record, the IRB Chair or IRB designee approves the research project when the agreement has been fully executed.

APPROVED BY: ___________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016

Version No. 8
Effective Date: 08/31/14
Supersedes Document: 05/31/12
SOP 602G