SOP 602J: USE OF SINGLE IRB (SIRB) IN MULTICENTER RESEARCH

1. POLICY

This policy establishes the requirements governing when OU investigators collaborate with non-OU institutions and/or non-OU investigators in multicenter human research.

The OU HRPP retains oversight of human subjects research conducted by OU faculty, staff, and students. As part of the OU HRPP, the OU IRB provides IRB review and oversight unless an alternate IRB has been designated via a formal IRB Reliance Agreement between OU and the alternate IRB.

The OU IRB will consider serving as the IRB of record for non-OU sites and/or non-OU researchers when an OU researcher will serve as the Lead Investigator. When the OU researcher is not the Lead Investigator, the University will consider deferring IRB oversight to a collaborating institution’s IRB or external IRB.

Under certain circumstances, the University may be required to either rely on an outside IRB or serve as an outside IRB in order to participate in multicenter research. Examples include:

1. Use of the Central Institutional Review Board for National Cancer Institute studies (NCI CIRB);
2. Studies that fall under the NIH Policy on the Use of Single IRB for Multi-Site Research;
3. Revised Common Rule mandate that requires single IRB oversight for cooperative research (effective January 19, 2020);
4. A research consortium’s mandate to use a single IRB.

There may be other circumstances when the University may decide to defer to an outside IRB for a study led by an OU investigator; i.e., when the University has an institutional conflict of interest; when an outside IRB may have a particular expertise of the proposed research, or when OU IRB oversight of a particular study or group of studies is not feasible. The IRB will make a determination regarding which IRB shall serve as the relying IRB on a case-by-case basis.

The University shall not approve research subject to a Reliance Agreement if it has not been approved by the designated Reviewing IRB.

Specific Policies

1.1 WHEN OU IRB SERVES AS THE REVIEWING IRB

The OU IRB may serve as the reviewing IRB for multicenter studies in which the Lead Investigator of the research is faculty, staff, or student of OU or an OU affiliate and has direct responsibility for the conduct of the research or of the human subjects.

The OU investigator must provide the OU IRB with a communication and oversight plan for the collaborating sites. The plan shall outline what research activities will occur at each site, the communication plan with the sites, and the plan for ensuring study and regulatory compliance of each site, and local site policy updates. The OU investigator must also provide information about the local context of the relying sites, including the relying site’s PI.

An approved Reliance Agreement must be fully executed between the University and the relying site prior to the site’s participation in the IRB-approved research.
1.2 WHEN OU IS THE RELYING INSTITUTION
The University may rely on a non-OU IRB under the conditions below. OU will take into consideration the Accreditation status of the outside IRB when making a determination of whether to rely on the outside IRB.

1. OU is “engaged” in the proposed research as defined by OHRP.
2. The outside IRB must have an approved and active FWA with OHRP.
3. All non-IRB local context issues must be addressed by the OU investigator, including University ancillary committee reviews (IBC, RSO, SRC, etc.), COI, University HRPP training requirements, and ORA/ORS contract/grant negotiations.
4. The OU investigator must submit an External IRB application into the IRB electronic submission system prior to participating in the multicenter research.
5. A Reliance Agreement must be fully approved and executed between the University and the reviewing IRB prior to the OU investigator’s participation in the multicenter research.

1.3 WHEN OU EXTENDS ITS FWA TO COLLABORATING, NON-OU INVESTIGATORS
The OU investigator may be collaborating on a research project with an individual who is not affiliated with any FWA covered institution. If the OU investigator plans to include a non-OU researcher who is unaffiliated with an FWA-covered institution and that non-OU researcher will be engaged in OU research as defined by OHRP, the University will consider extending its FWA to cover that non-OU researcher.

The following information/actions are required:

1. The OU investigator must provide documentation describing the research activities in which the non-OU collaborating investigator will engage. Examples: The statement of work from a funding arrangement, detailed description in the research protocol, and/or OU IRB application.
2. Copy of the non-OU collaborator’s credentials (i.e., curriculum vitae) to determine if the non-OU collaborator is qualified to conduct assigned research activities.
3. The non-OU collaborator must complete OU IRB education requirements, or equivalent, as deemed appropriate by the OU HRPP.
4. The OU investigator must directly and appropriately supervise all of the collaborative research activities to be performed by the non-OU collaborating investigator.

The University will negotiate an Individual Investigator Agreement (IIA) with the non-OU collaborator. The signed agreement will be added to the IRB study file.

The University retain 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 HRPP staff, IRB members, OU staff, researchers, and non-OU researchers who are involved in human participant research that engages the University.
3. RESPONSIBILITY

3.1 The HRPP Director, after consulting with the OU IRB Chair and the Institutional Official (at NC) or the Vice-President for Research (at OUHSC), is responsible for determining whether the OU IRB will be the relying IRB or will rely on an outside IRB, and for communicating that decision to the OU investigator and University officials.

3.2 The OU investigator is responsible for contacting the HRPP to request (1) OU IRB to be the Reviewing IRB for multicenter research or (2) OU to rely on a non-OU IRB as the IRB of record.

If a determination is made for OU to serve as the Reviewing IRB with the OU investigator serving as the lead PI, the OU investigator is responsible for complying with the requirements as described in the applicable Reliance Agreement.

The OU investigator is responsible for complying with SOP 801: Investigator Qualifications and Responsibilities, providing adequate oversight of the collaborating sites, communicating this plan to the Reviewing IRB, and ensuring that all items requiring IRB review are submitted to the Reviewing IRB.

If the OU investigator serves as a relying site investigator, the OU Investigator is responsible for submitting the External IRB application into iRIS for HRPP tracking and complying with local context requirements. The OU investigator is responsible for complying with the Reviewing IRB’s protocol determinations and lead study site’s requirements, as described in the applicable Reliance Agreement.

3.3 The Reviewing IRB is responsible for the review and approval of human participant research, including initial, continuing review, modifications, and unanticipated problems involving risks to participants or others, in accordance with applicable laws and SOPs. Additional responsibilities may include, but are not limited to:

- Reviewing additional study sites to previously approved studies, considering the local context of the research;
  - NOTE: Such changes may be considered minor modifications reviewed in accordance with the expedited review process documented in SOP 402: Expedited Review. See SOP 405: Modifications for a definition and examples of minor modifications.
- Notifying relying institutions of the Reviewing IRB’s determinations;
- Making available relevant IRB minutes, SOPs, and other documents to the relying institution upon request;
- Conducting scientific review;
- Reviewing potential non-compliance, including complaints, deviations, and results of audits
  - Deciding whether allegations of non-compliance are based in fact;
  - Determining whether an incident of non-compliance is serious or continuing;
  - Reporting serious or continuing non-compliance, unanticipated problems, and suspensions or terminations of IRB approval;

Note: This responsibility may necessitate negotiation between the two sites, as the Relying Site may require their own non-compliance responsibility.
• Obtaining additional approvals from DHHS when then research involves pregnant women, fetuses, and neonates; or children; or prisoners;
• Managing organizational conflicts of interest for research of the Reviewing site;
• Meeting other requirements as defined by the applicable Reliance Agreement.

3.4 The Relying Institution is responsible for conducting the research as approved by the Reviewing IRB and complying with requirements, as defined by the applicable Reliance Agreement. The Relying site is also responsible for notifying the Reviewing IRB when local policies that impact IRB review are updated. Additionally, the Relying site is responsible for managing organizational conflicts of interest of research of the Reviewing site.

3.5 In the event that termination of a reliance agreement occurs, the Reviewing and Relying sites will work together to ensure that one party is clearly responsible for continued oversight of active studies until closure or a mutually agreed upon transfer of studies.

3.6 Non-OU Collaborating Researcher is responsible for complying with the standards and requirements 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.

4. APPLICABLE REGULATIONS AND GUIDELINES
   OHRP Policy and Guidance
   NIH Policy on the Use of Single IRB Policy for Multi-Site Research

5. REFERENCES TO OTHER APPLICABLE SOPS
   SOP 402: Expedited Review
   SOP 405: Modifications
   SOP 801: Investigator Qualifications and Responsibilities

6. ATTACHMENTS
   602J-A Non-OU Employee Collaborator Assurance Form (NC)
   602J-B Local Context Form for Relying Sites
   602J-C Communication Plan Template
   602J-D Relying Institution Checklist Template
   602J-E OUHSC Reliance Agreement Template
   602J-F OUHSC Individual Investigator Agreement Template

7. PROCESS OVERVIEW
   When the OU IRB is to be the Reviewing IRB:
7.1 The OU PI should consult with the HRPP for guidance upon becoming aware that a multicenter study proposal may require single IRB oversight by OU IRB.

7.2 The OU PI must submit the proposed study to the OU IRB via iRIS and indicate the study will involve multiple non-OU sites.

7.3 The HRPP will consult with the IRB Chair and appropriate University officials to obtain concurrence for OU IRB to serve as IRB of record.

7.4 If concurrence is reached, the HRPP will work with the OU PI and relying sites to begin the reliance agreement process.

7.5 The OU PI may begin the study when (1) all OU requirements have been met, (2) the Reliance Agreement is fully executed, and (3) the Reviewing IRB has approved the protocol and the OU site to participate in the study.

When OU relies on a non-OU IRB

7.6 The OU PI should consult with the HRPP for guidance upon becoming aware that a proposal may require non-OU IRB oversight.

7.7 The OU PI must submit a request to rely on an External IRB form to the HRPP (available on the HRPP website), along with the protocol.

7.8 The HRPP Office will review the request and identify the status of the non-OU IRB, including its accreditation status and registration with OHRP.

7.9 The HRPP will consult with an OU IRB Chair and University officials to obtain concurrence to rely on the non-OU IRB.

7.10 If concurrence is reached, the HRPP will work with the OU PI and the non-OU IRB to begin the reliance agreement process, and provide a HRPP Acceptance letter.

7.11 The OU PI will submit an External IRB Application into iRIS.

7.12 The OU PI may begin the study when (1) all OU requirements have been met, (2) the Reliance Agreement is fully executed, and (3) the Reviewing IRB has approved the protocol and the OU site to participate in the study.