1. PURPOSE

1.1. It is common for University of Georgia (UGA) researchers to be involved in multi-site studies or collaborative work with researchers from other institutions. Department of Health and Human Services (DHHS) regulations allow institutions conducting cooperative research projects to “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). UGA IRB may rely on a single IRB (the “IRB-of-record”) for review and continuing oversight of the research in order to avoid duplication of review and facilitate the review process. However, current regulations and Office for Human Research Protections (OHRP) guidance also place the responsibility for safeguarding the rights and welfare of human subjects and for compliance with the regulations on each institution involved in the research, regardless of reliance on another IRB. The purpose of this policy is to provide guidance on the requirements and procedures that the UGA IRB follows when entering into cooperative agreements with other IRBs.

2. DEFINITIONS

2.1. IRB Authorization Agreement (IAA): a written agreement between two institutions collaborating in non-exempt research that describes each institution’s responsibilities for review and oversight of the research. The IAA is usually for a single project. Also: Reliance Agreement.

2.2. External IRB: is the local IRB at an external site.

2.3. Collaborating site: refers to an institution or organization with which a non-UGA collaborator is affiliated.

2.4. Cooperative research: is human subject research which involves more than one institution. Also: Collaborative research.

2.5. Lead institution: is one that initiates or manages a research study involving multiple sites that conduct research procedures for the study.

2.6. IRB-of-record: refers to the IRB that conducts the review of and provides oversight for multi-site or collaborative research projects. Also referred to as a central IRB.

2.7. Institutional Official: is the individual authorized by the terms of the federal-wide assurance to act for the institution and to assume on behalf of the institution the obligations imposed by the federal regulations for protections of human research subjects.
2.8. **Memorandum of Understanding (MOU)** is a written agreement between two institutions describing terms for determining the IRB-of-record for research projects in which the two institutions are both engaged. An MOU generally covers multiple studies.

3. **POLICY**

3.1. IRB approval is required when UGA is engaged in human subjects research. Approval for the research may be obtained from the UGA IRB or another IRB designated to perform the review.

3.2. UGA may be engaged whenever a UGA faculty/staff/student receives federal funding for research involving human subjects. UGA IRB must review and approve the research, unless another IRB is designated to perform the review, even if there will be no human research activities performed at any UGA site.

3.3. UGA IRB has the responsibility to ensure that the research conducted at an external institution receives appropriate approval and oversight, regardless of funding and whether the research activities will be conducted within or outside of the USA.

3.4. When UGA relies on another IRB for the review of non-exempt research, per OHRP guidance, UGA IRB requires a written IRB Authorization Agreement (IAA) or Memorandum of Understanding (MOU) between collaborating IRBs to achieve the required level of institutional oversight and to ensure that the external IRB’s review will meet the human subject protection requirements of the relying IRB.

3.5. When an external site engaged in UGA research activities does not have an active IRB and active FWA, the UGA IRB will serve as the IRB-of-record.

3.6. Review of research conducted by UGA researchers at an external site can be performed by the IRB at the local site if the following criteria are met:

3.6.1. The institution whose IRB will serve as IRB-of-record has a current federal-wide assurance (FWA) with OHRP.

3.6.2. The external IRB is currently registered with OHRP and is in good standing with OHRP (no recent warning letters, no open investigations).

3.6.3. If there is no existing MOU with the IRB-of-record’s institution, a formal IRB Authorization Agreement is required for non-Exempt research

3.6.4. For commercial IRBs, the commercial IRB is AAHRPP-accredited

3.6.5. All researchers must satisfy the IRB training requirements;

3.6.6. All researchers must be identified as study team members on the submission to the IRB-of-record.

3.7. UGA retains the right to revoke a reliance agreement at any time in order to conduct its own review.
4. **PROCEDURES: Researchers**

4.1. Researchers engaged in cooperative research must plan with collaborators prior to submission to determine if the multi-site design could be overseen by a central IRB. This may involve conversations with non-UGA IRBs to obtain initial assessments of institutional engagement or other factors used by IRBs to gauge the appropriateness of a cooperative agreement.

4.2. If a reliance agreement is desirable, the lead institution must be identified and the local IRB for that institution should be approached first to determine willingness to serve as the reviewing IRB for the collaborating institutions.

4.3. The researcher (any study team member) must complete the submission through the IRB’s electronic application system.

4.4. For any collaborating site that has an active federal wide assurance (FWA) and an associated IRB, where prompted in the submission form, the researcher should indicate if that IRB will conduct a separate IRB review to provide oversight and approval for the site.

4.4.1. If the collaborating site’s IRB will review the research, the researcher should indicate, where prompted in the submission, that the research will be reviewed by an External IRB. When applicable, the researcher must provide all required information about the collaborating site and any materials that were or will be reviewed by the External IRB as well as a copy of the External IRB determination or approval, if available.

4.4.2. If the collaborating site’s IRB determines that the institution is engaged but does not wish to conduct an IRB review (if UGA is identified as the lead institution), where prompted in the submission, the researcher should indicate that the collaborating site IRB will rely on the UGA IRB. The UGA researcher should prompt the non-UGA collaborator to contact his/her IRB to determine if there is a preference for drafting the IRB Authorization Agreement.

4.5. For any external site that does not have an FWA and/or an associated IRB and whose individuals are engaged in non-exempt research, the individual must complete IRB-required training and sign an *Individual Investigator Agreement* with UGA so that UGA IRB may extend oversight for that individual.

4.6. The researcher is responsible for factoring extra time needed for external IRB reviews or agreements and/or site authorizations when planning the research study timeline.
5. PROCEDURES: Institutional Review Board

5.1. The IRB will review the submission to determine if reliance on an external IRB has been requested or if UGA has been requested to be the IRB-of-record for cooperative research.

5.2. If review by an external IRB is requested and UGA is engaged (see Policy and Procedure: Engagement Determination), the IRB will evaluate the materials reviewed by the other IRB to assess the following: activities that UGA is engaged in, the source of funding and sponsor protocol, the site where activities will be conducted, and the targeted population.

5.3. If UGA is to be the IRB-of-record, review will be conducted according to the route and assignment determined by the IRB staff. See Policy and Procedure: Non-Committee Review Preparation and Conduct and Policy and Procedure: Pre-Review of IRB Submissions.

5.4. Using the contact information provided in the submission, the external IRB will be contacted to negotiate responsibility for drafting the IRB Authorization Agreement.

5.5. The signatory official on agreements (IAAs) for studies with federal funding or support will be the Institutional Official. The signatory official on agreements for studies without any federal funding or support will be the HSO Director or IRB Chair.

5.6. Final drafts of the IAA will be provided to the signatory official of each identified institution for signature. Each institution shall receive a copy of the fully executed agreement.

5.6.1. For non-committee reviews, the IRB will offer the researcher the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence, if needed.

5.6.2. For committee reviews, descriptions of missing information or required modifications will be documented in the meeting minutes and in post-meeting correspondence.

6. MATERIALS


6.2. TEMPLATE: Individual Investigator Agreement

7. REFERENCES

7.1. OHRP Correspondence: Use of a Centralized Institutional Review Board (IRB)
   http://www.hhs.gov/ohrp/policy/Correspondence/mcdeavitt20100430letter.html

7.2. Policy and Procedure: Engagement Determination

7.3. Policy and Procedure: Non-Committee Review Preparation and Conduct

7.4. Policy and Procedure: Pre-Review of IRB Submissions