Human Research Protection Program
UNIVERSITY OF GEORGIA

Reliance and Cooperative Research – UGA relying on an external IRB

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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. Two recent federal mandates have altered the way IRBs are required to review multi-site and ***cooperative research***.

- The Federal Policy for the Protection of Human Subjects (the Common Rule) was revised effective July 19, 2018. The Revised Common Rule includes a requirement that, "Any institution located in the United States that is engaged in ***cooperative research*** must rely upon approval by a ***single IRB*** for that portion of the research that is conducted in the United States. The ***reviewing IRB*** will be identified by the Federal department or agency supporting or conducting the research or proposed by the ***lead institution*** subject to the acceptance of the Federal department or agency supporting the research" (45 CFR 46.114). The policy applies to research initially approved by an IRB on or after January 20, 2020. Federal departments and agencies that have signed onto the Revised Common Rule are listed at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html
- The ***Single IRB (sIRB)*** Policy for Multi-site Research is a NIH policy that applies to most grants and contracts submitted to NIH on or after January 25, 2018 that involve multi-site non-exempt human subjects research. The policy requires the use of a ***single IRB*** to accomplish IRB review and approval for all domestic sites. The requirement for ***single IRB*** review does not apply to awardees or research sites outside the United States.
    - Awardee institutions are responsible for ensuring ***reliance agreements*** are complete and documented.
    - Participating sites are expected to rely on the ***single IRB*** unless an exception is granted by NIH in accordance with NIH policy on exceptions from single IRB review.

1.2. For research not subject to these requirements, 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 another IRB (the "***IRB of record***" or "***sIRB***") for review and continuing oversight of the research in order to comply with the new federal requirement, or to avoid duplication of review and facilitate the review process. The purpose of this policy is to provide guidance on the requirements and procedures that the UGA IRB follows when relying on an ***external IRB***.

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2. DEFINITIONS

2.1. ***IRB Authorization Agreement (IAA):*** a written agreement between two institutions collaborating in non-exempt research that describes each institution's authority, roles, and responsibilities for review and oversight of the research and communication between the reviewing and the relying IRBs. The IAA is usually for a single project. Also known as: ***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 investigator or collaborating organization is affiliated.

2.4. ***Cooperative research:*** is human subjects research that involves more than one institution. Also known as: ***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 multisite or collaborative research projects. Also referred to as a ***central IRB***, ***single IRB or sIRB***.

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. It also may describe each institution's authority, roles, and responsibilities for review and oversight of the research and communication between the reviewing and the relying IRBs. An MOU generally covers multiple studies.

2.9. ***Multi-Site study***: means that the same research procedures (i.e., protocol) are being conducted at one or more domestic sites and that each site is under the control of a local participating investigator. This typically involves a lead site that receives the grant or contract directly and that then establishes a sub-award or subcontract to each participating site. The research could be a clinical trial, an observational study, or a basic clinical research study.

2.10. ***Single IRB (sIRB***): One ***IRB of record*** selected on a study-by-study basis, providing the regulatory review for all sites participating in a specific multisite study.

2.11. ***Relying Site***: Institution that relies on the ***reviewing IRB*** for regulatory oversight.

2.12. ***Reviewing IRB***: The selected ***IRB of record*** that conducts the regulatory review for participating sites of the ***multi-site study***, including initial reviews, modifications, continuing reviews, and reportable events.

2.13. ***Lead PI:*** PI at the Lead Institution.

2.14. ***Relying PI***: PI at the Relying Site.

2.15. ***Commercial IRB***: Commercial or Independent IRBs are contracted agencies that are not affiliated with specific institutions and are paid to conduct reviews of research with human subjects. Fees for IRB review will be charged.

2.16. ***SMART IRB***: A platform that offers a master IRB ***reliance agreement*** (the SMART IRB Agreement) and a web-based system (SMART IRB's Online Reliance System) that provides a central process for participating institutions and their investigators to request, track, and document study-specific reliance arrangements.

2.17. ***Local context***: Refers to the acceptability of proposed research in terms of institutional commitments and policy, applicable law, and standards of professional conduct and practice in the locale where research will be conducted.

2.18. ***AAHRPP-accredited:*** An institution that has earned accreditation from the Association for the Accreditation of Human Research Protection Programs, Inc.

3. POLICY

3.1. IRB approval for research conducted by UGA employees or agents may be obtained from another IRB designated to perform the review when the IRBs and PIs from both institutions agree on the arrangement. UGA IRB has the responsibility to ensure that research conducted by employees or agents of UGA receives appropriate IRB approval and oversight, regardless of whether the UGA IRB performs the review.

3.2. When UGA relies on another IRB for the review of non-exempt research, per OHRP guidance, UGA IRB requires a formal ***reliance agreement*** between the collaborating IRBs to document the reliance relationship. The ***reliance agreement*** must be fully executed, or the review arrangement must be documented in ***SMART IRB*** before the research may be initiated at any site.

3.3. The UGA IRB does not enter into ***reliance agreements*** for exempt research. For projects that qualify for exempt review, an exempt application should be submitted to the UGA IRB for determination.

3.4. The UGA IRB will consider relying on the review of an ***external IRB*** if the following criteria are met:

- The institution's IRB that will serve as ***reviewing IRB*** has a current federal-wide assurance with OHRP.
- The ***external IRB*** is currently registered with OHRP and is in good standing with OHRP (no recent warning letters, no open investigations).
- For ***commercial IRB***s, the ***commercial IRB*** is ***AAHRPP-accredited***

3.5. The UGA IRB may limit reliance on institutions that are not ***AAHRPP-accredited***.

4. PROCEDURES and Responsibilities: UGA PI (*Relying PI*)

4.1. UGA researchers engaged in ***cooperative research*** must plan with collaborators prior to submission to determine if the multi-site design could or must be overseen by a ***single IRB***. This will involve conversations with all sites' IRBs to obtain initial assessments of institutional engagement or other factors used by IRBs to gauge the appropriateness of a ***reliance agreement***. The time needed for negotiating ***reliance agreements*** and/or site authorizations should be considered when planning the project timeline.

4.2. The UGA PI must consult the UGA IRB about requests to have UGA rely on an ***external IRB*** for multi-site and ***cooperative research***. The UGA PI should complete the Reliance Intake Form for Cooperative Research in order to begin this dialogue with the IRB office.

4.3. If a ***reliance agreement*** is required or 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.

4.4. If UGA will be requested to rely on the review of another IRB, the UGA PI must submit the application in the IRB portal as an External IRB Review application.

- UGA research personnel must be listed on this application.
- The specific human subjects research activities to be performed by UGA employees or agents must be made clear in this application by providing a separate attachment describing the scope of work for UGA.
- The UGA PI must provide all required information about the external ***reviewing IRB*** and any materials that were reviewed and approved by the ***reviewing IRB*** such as the protocol or grant application, consent forms, as well as a copy of the approval letter.

4.5. Education and training of UGA research staff, and maintenance of a current list of research personnel with UGA IRB.

4.6. Obtaining required local institutional reviews and approvals such as conflict of interest, radiation or biosafety, privacy, etc., and communication of this information to the external ***reviewing IRB*** during the review process.

- Compliance with any conflict of interest management plans that may result.

4.7. Cooperation with review requirements and policies of the ***reviewing IRB***. This includes providing any information requested by the ***reviewing IRB*** in a timely manner, using the r***eviewing IRB*** forms and processes, following the ***reviewing IRB*** reporting and record keeping requirements, and complying with stipulations of the ***reviewing IRB's*** approval for initial and continuing review.

4.8. The ***relying PI*** must not enroll participants in research prior to review and approval by the ***reviewing IRB*** as well as receipt of a completed ***reliance agreement***.

4.9. Obtain, document and maintain records of informed consent for each participant or each participant's legally authorized representative, when consent is being obtained by UGA personnel.

4.10. Prompt reporting to the external ***reviewing IRB*** and ***lead PI*** reports of new information (adverse events, subject complaints, unanticipated problems involving risks to subjects or others, non-compliance, data safety monitoring reports, proposed changes to the research, etc.).

4.11. Reporting timely and accurate continuing review information to the external ***reviewing IRB*** or ***lead PI*** and supplying the UGA IRB with all current approval letters from the ***reviewing IRB***.

5. PROCEDURES and Responsibilities: UGA IRB

5.1. Review the submission to determine if UGA is engaged in human subjects research and if reliance on an ***external IRB*** has been requested.

5.2. Provide ***local context*** information to the ***reviewing IRB*** via *TEMPLATE: UGA Local Context Information* or using the ***reviewing IRB's*** preferred format.

5.3. When relying on an IRB that is not AAHRPP-accredited:

- For minimal risk research, UGA will obtain an assurance of compliance with applicable regulations.
- For greater than minimal risk research, IRB staff will perform a review of relevant policies and procedures of the potential ***reviewing IRB*** and log documentation of this review in the study record in the IRB portal.

5.4. Negotiate with the ***reviewing IRB*** the responsibility for drafting the ***reliance agreement*** or to arrange use of the ***SMART IRB*** platform.

- IRB staff will track the status of pending ***reliance agreements*** using *Tracking Log: IRB Authorization Agreements.*

- The signatory official on ***reliance agreements*** for studies with federal funding or support will be the ***institutional official***. The signatory official on ***reliance agreements*** for studies without any federal funding or support will be the HSO Director.
- Each institution shall receive a copy of fully executed ***reliance agreements***.

5.5. Monitor determinations and management plans related to disclosed conflicts of interest and communicate to the ***reviewing IRB*** prior to the completion of their review.

5.6. Review of qualifications of UGA personnel who will be engaged in human subjects research to ensure that research personnel are appropriately trained and qualified to conduct the proposed research.

5.7. Ensure that the ***reviewing IRB*** has approved the research and the ***reliance agreement*** is complete prior to issuing local approval.

5.8. Conduct post approval monitoring or audit of the study when deemed necessary by the ***reviewing IRB***.

5.9. Notify the ***reviewing IRB*** of policy changes that would impact the IRB review.

6. PROCEDURES and RESPONSIBILITIES: External Reviewing IRB (IRB of Record)

6.1. Negotiate with relying IRBs the responsibility for drafting the ***reliance agreement*** or to arrange use of the ***SMART IRB*** platform.

6.2. Conduct complete review of the research according to applicable regulations and laws as determined by the IRB including initial review, continuing review, and review of modifications to previously approved research.

6.3. Communicate IRB determinations in writing to PI and UGA IRB.

6.4. Provide IRB meeting minutes to the UGA IRB upon request.

6.5. Request post approval monitoring or audit by the UGA IRB when deemed necessary.

6.6. Review results of audits and reports of new information (adverse events, subject complaints, unanticipated problems, non-compliance, etc.) and report related determinations to UGA IRB, regulatory agencies, and sponsors as applicable.

- Determine whether each allegation of non-compliance is serious or continuing and whether each allegation of noncompliance has a basis in fact.

6.7. Suspend or terminate IRB approval when deemed necessary.

7. MATERIALS

7.1. TEMPLATE: IRB Authorization Agreement

7.2. Local Context Information Sheet (UGA)
7.3. Local Context Site Information from Relying Sites
7.4. TEMPLATE: Announcing Policy Changes to External IRBs
7.5. UGA IRB Reliance Workflow
7.6. Tracking Log: IRB Authorization Agreements
7.7. PI Checklist
7.8. Reliance Intake Form for Cooperative Research

8. REFERENCES

8.1. OHRP Correspondence: Use of a Centralized Institutional Review Board (IRB) http://www.hhs.gov/ohrp/policy/Correspondence/mcdeavitt20100430letter.html
8.2. Policy and Procedure: Engagement Determination
8.3. Policy and Procedure: Non-Committee Review Preparation and Conduct
8.4. Policy and Procedure: Pre-Review of IRB Submissions

Revision History:
6/15/2018: REV1 New Document
3/12/2021: REV2 Split into 10a (reviewing) and 10b (relying); update for 2018 Common Rule requirements
5/24/2021: REEV3 minor procedural clarifications to meet AAHRPP Standards