



Reliance and Cooperative Research – UGA as the Single IRB of Record

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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 serve as a **single 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 serving as the **single 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.



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- 2.13. **Lead PI:** PI at the Lead Institution.
- 2.14. **Relying PI:** PI at a 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. The IRB at UGA will consider serving as the **sIRB** for a **multi-site study** when the UGA PI is the **lead PI** or when UGA is the prime awardee of a grant. Specific circumstances under which UGA will consider serving as the **sIRB** will be reviewed on a case by case basis. IRB resources and expertise in relation to the subject matter of study and number of **collaborating sites** must be considered when identifying the **sIRB**. **Relying sites** must:
 - have an active federal-wide assurance (FWA)
 - have the ability to perform post approval monitoring
 - be part of the United States
- 3.2. When another site requests to rely on UGA 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.



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4. PROCEDURES and RESPONSIBILITIES: UGA Lead 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 during the grant proposal process about requests to have UGA serve as the **sIRB** 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 UGA is designated as the **sIRB**, the submission to the UGA IRB must include:
 - A list of all non-UGA sites, sources of funding, **relying PIs**, and point of contact for IRBs at relying institutions.
 - Protocol, consent form for UGA, consent template for relying institutions.
 - The **PI Checklist** to acknowledge responsibilities associated with oversight of a **multi-site study**.
 - Documentation of additional ancillary review and approvals, as applicable to the research. Examples include but are not limited to: any relevant conflict of interest management plans, radiation or biosafety review, and documentation of completed Good Clinical Practice (GCP) training for all key personnel.
- 4.4. The UGA PI will work with the UGA IRB to disseminate **reliance agreements** to the **collaborating sites** to facilitate completion.
- 4.5. The UGA PI is responsible for the communication and overall conduct of the study and regulatory compliance. The UGA PI will submit the regulatory IRB submissions on behalf of all sites relying on the UGA IRB and be responsible for communicating with **Relying PIs** regarding UGA IRB approvals and requirements.
- 4.6. The UGA PI is responsible for following the policies of the UGA IRB. This includes using UGA IRB forms and processes, following UGA IRB reporting requirements for all reports of new information, and complying with stipulations of the UGA IRB's approval.
- 4.7. The UGA PI is responsible for meeting the additional requirements of the NIH Genomic Data Sharing Policy, when applicable.
- 4.8. After approval, the UGA PI is responsible for the submission of:



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- Modifications to add **relying sites** or make other changes to the study.
- Continuing review information from each **relying site**.
- Reports of new information (adverse events, subject complaints, unanticipated problems, non-compliance, etc.) from all study sites.

5. PROCEDURES and RESPONSIBILITIES: UGA IRB

- 5.1. The IRB staff will review the submission to determine if UGA is **engaged** in human subjects research and if UGA has been requested to be the **sIRB** for **cooperative research**.
- 5.2. If UGA is to be the **sIRB**, review of research will be conducted according to applicable regulations, codes, guidance, and laws including initial review, continuing review, and review of modifications to previously approved research. Onboarding of **relying sites** will include review of items from section 4.3 and may be reviewed as modifications using expedited procedures. (See *UGA IRB Reviewing Workflow, Policy and Procedure: Non-Committee Review Preparation and Conduct, Policy and Procedure: Pre-Review of IRB Submissions* and *Policy and Procedure: Review of Modifications to Previously Approved Research*.)
- 5.3. Collect **local context** information (see Local Context Site Information from Relying Sites) from **relying sites**.
- 5.4. Negotiate with relying IRBs 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 the fully executed **reliance agreement**, online confirmation of agreement in the **SMART IRB** Online Reliance System, or **SMART IRB** Letter of Acknowledgement.
- 5.5. Collect and review local institutional determinations from **relying sites** such as conflict of interest management plans. When serving as the **sIRB**, the UGA IRB has the final authority to review conflict of interest management plans.
- 5.6. Communicate IRB determinations in writing to contact person(s) at the **relying site(s)**.
- 5.7. Provide IRB meeting minutes to **relying site** IRBs upon request.
- 5.8. Request post approval monitoring or audit by the **relying site** when deemed necessary.



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5.9. 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.

5.10. Suspend or terminate IRB approval when deemed necessary.

5.11. UGA Human Research Protection Program (HRPP) Policies and Procedures are publicly available on the UGA HRPP website. When UGA IRB is the **sIRB**, local policy changes will be communicated to the Relying IRB via email (see TEMPLATE: Announcing Policy Changes to External IRBs).

6. PROCEDURES and RESPONSIBILITIES: Relying Site and PI

6.1. Provide the UGA IRB with all **local context** information relevant for the conduct of the IRB review, in accordance with UGA IRB policies.

6.2. The **relying PI** must adhere to any additional requirements from the local relying IRB.

6.3. The **relying site** is responsible for local institutional reviews (COI, Radiation, Biosafety, Privacy, etc.) and for communication of this information to the UGA IRB during the review process.

6.4. Monitor determinations and management plans related to disclosed conflicts of interest and communicate to the UGA IRB prior to the completion of their review.

6.5. Education and training of **relying site** research staff. Researchers at the **relying site** may have to satisfy additional training requirements as dictated by the UGA IRB; if the relying institution does not have a protection of human subjects educational requirement, research staff at **relying sites** must complete applicable CITI Course or equivalent training.

6.6. The **relying PI** is responsible for following the approved protocol and ensuring compliance with the UGA IRB requirements at the research site.

6.7. The **relying PI** is responsible for reporting timely and accurate continuing review information to the **lead PI**.

6.8. The **relying PI** is responsible for prompt reporting to the **lead PI** reports of new information (adverse events, subject complaints, unanticipated problems, non-compliance, etc.).

6.9. The **relying site** must have the capacity to conduct post approval monitoring or audit of the study when deemed necessary by the UGA IRB.

7. MATERIALS

7.1. TEMPLATE: IRB Authorization Agreement



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- 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: REV3 minor procedural clarifications to meet AAHRPP Standards