Human Research Protection Program
UNIVERSITY OF GEORGIA

External Collaborating Site

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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***. 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. 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 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 which 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 or single 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. 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 clinical trial***: 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 or key personnel. 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. ***Same Research Protocol***: Protocols that address the same research questions, involve the same methodologies, and evaluate the same outcomes. Additionally, sites that are accruing research participants for studies that are identical except for variations due to local context consideration would be considered to be conducting the same research protocol.

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

2.12. ***Relying Institution***: Institution that relies on the reviewing IRB for the regulatory reviews. The relying institution is still responsible for institutional reviews (COI, Radiation, Biosafety, Privacy, and other).

2.13. ***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.

2.14. ***Lead PI***: Responsible for the communication and overall conduct of the study and regulatory compliance. The Lead PI will submit the regulatory IRB submissions on behalf of all sites relying on the reviewing IRB.

2.15. ***Relying PI***: Responsible for providing the Lead PI with necessary information according to the reviewing IRB's policies and procedures so the reviewing IRB can conduct an IRB review. The relying PI must know what is also required from their local relying IRB.

2.16. ***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.

2.17. ***SmartIRB***: A platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the NIH Single IRB Review policy (effective date: January 25, 2018).

2.18. ***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.

2.19. ***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 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 IRB has the responsibility to ensure that the research conducted at an external institution receives appropriate external IRB approval and oversight, regardless of funding and whether the research activities will be conducted within or outside of the USA. Therefore, all research in which UGA is engaged must be submitted in the IRB portal.

3.3. The single IRB (sIRB) policy 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.

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

3.5. 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 UGA's human subjects protection requirements.

3.6. When an external site engaged in UGA research activities does not have a designated IRB and active federal-wide assurance, the UGA IRB will serve as the ***IRB-of-record***.

3.7. 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:

3.7.1. The institution whose IRB will serve as ***IRB-of-record*** has a current federal-wide assurance with OHRP.

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

3.7.3. For ***commercial IRB***s, the ***commercial IRB*** is ***AAHRPP-accredited***

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

3.8. Researchers may have to satisfy additional training requirements as dictated by the ***IRB-of-record***; for FDA-regulated projects, researchers must submit their current CV (curriculum vitae).

3.9. Researchers participating in a NIH-funded ***multi-site clinical trial*** are expected to rely on a ***Single Institutional Review Board (sIRB)*** to carry out the functions that are required for institutional compliance with IRB review set forth in the HHS regulations at 45 CFR 46. Additional information can be found at: http://osp.od.nih.gov/sites/default/files/NIH_sIRB_Policy_Multi_site_Research_UPDATED2016.pdf

3.9.1. For NIH-funded ***multi-site clinical trials***, UGA IRB will not serve as ***IRB-of-record*** but will facilitate submission to collaborating or commercial IRB.

3.9.1.1. Exceptions to this policy will be determined by Office of Research leadership.

3.10. A ***Reliance Agreement*** or ***Memorandum of Understanding*** must be fully executed, or the review arrangement must be documented in ***SmartIRB*** before the research may be initiated at any site.

3.11. The ***Reviewing IRB*** will require researchers to provide documentation related to other regulatory requirements or ancillary review and approvals to the Reviewing IRB if requested, as applicable to the research. Examples include but are not limited: any relevant Financial Conflict of Interest Management Plan, Biosafety review, and documentation of completed Good Clinical Practice (GCP) training for all key personnel.

3.12. The ***Lead PI*** is responsible for following the policies of the ***Reviewing IRB***. This includes using the ***Reviewing IRB*** forms and processes, following the ***Reviewing IRB*** reporting requirements about unanticipated problems and other issues, and complying with stipulations of the Reviewing IRB's approval.

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 single 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 reliance 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 ***Lead PI*** must submit to reviewing IRB and to relying IRB as required by institutional policies of each institution**.**

4.4. If UGA is chosen as the ***Reviewing IRB***, the submission must list all non-UGA sites, sources of funding, and researchers and point of contact for site IRBS.

4.4.1. For non-exempt research involving a collaborator who is affiliated with an institution that does not have an active Federal Wide Assurance or IRB, list the individual as a Non-UGA Collaborator and provide a completed and signed ***Individual Investigator Agreement*** in addition to proof of completion of CITI training or comparable training in human subjects research.

4.4.2. For any ***collaborating site*** that has an active federal-wide assurance and an associated IRB, where prompted in the submission form, indicate that the *collaborating site's* IRB will not review.

4.4.3. The Lead PI must complete the ***PI Checklist*** to acknowledge responsibilities associated with oversight of a multi-site study.

4.5. 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.

4.6. 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: IRB Staff

5.1. The IRB staff will determine if UGA is ***engaged*** in the research.

5.2. The IRB staff 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***.

5.3. 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. *See UGA Reliance Workflow.*

5.3.1. IRB Staff will provide ***local context*** information to the reviewing IRB via *TEMPLATE: UGA Local Context Information* or using the reviewing IRB's preferred format.

5.4. 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 *UGA IRB Reviewing Workflow, Policy and Procedure: Non-Committee Review Preparation and Conduct* and *Policy and Procedure: Pre-Review of IRB Submissions*.

5.5. Using the contact information provided in the submission, the external IRB will be contacted to negotiate responsibility for drafting the ***IRB Authorization Agreement (IAA)*** or ***MOU*** and to provide ***local context*** information (see *Local Context Site Information from Relying Sites*).

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

5.7. In consultation with the *relying IRB*, IRB staff will complete the *Checklist – Division of Responsibilities* to ensure that the executed *IAA* or *MOU* includes or references the information.

5.8. If required by the ***relying IRB***, the IRB office will instruct the UGA PI to enter a request in the ***SmartIRB*** platform. The collaborative review information will be communicated between the IRBs using this platform.

5.9. The signatory official on IAAs for studies with federal funding or support and MOUs will be the ***Institutional Official***. The signatory official on IAAs for studies without any federal funding or support will be the HSO Director or IRB Chair.

5.10. 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.

5.10.1. 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.

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

6. MATERIALS

6.1. TEMPLATE: IRB Authorization Agreement
6.2. TEMPLATE: Individual Investigator Agreement
6.3. Checklist: Division of Responsibilities
6.4. Local Context Information Sheet (UGA)
6.5. Local Context Site Information from Relying Sites
6.6. TEMPLATE: Announcing Policy Changes to External IRBs
6.7. UGA IRB Reliance Workflow
6.8. UGA IRB Reliance Workflow
6.9. TEMPLATE: UGA Local Context Information
6.10. Tracking Log: IRB Authorization Agreements
6.11. PI Checklist

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

Revision History:
6/15/2018: REV0 New Document
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