Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

Collaborations:
Single IRB Review and Reliance

Federal Regulation and Policy

- **January 2018**: All competing NIH grant applications (new, renewal, revision, or resubmission) with receipt dates on or after January 25, 2018, *must include a plan describing the use of an sIRB for the study.*
- **January 2020**: 45 CFR 46.114 (b) (1) 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 the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.*

UGA Policy

- **Version 0** included in 2015 accreditation application and revised (**Version 1**) in 2018 in response to guidance during/after AAHRP site visit (to meet NIH policy requirements)
- **Version 2** was approved in 2021 and split original policy (External Collaborating Site) into two:
  - Reliance and Cooperative Research – UGA as the Single IRB of Record
  - Reliance and Cooperative Research – UGA relying on an external IRB
- Webinar was held on 3/12/2021 to explain policy

UGA Collaborations: Basic Info

- UGA's HRPP manages 152 active collaborations (we are lead for 27)
- HSO has .4 FTE (Jennifer Freeman) dedicated to managing collaborations
- UGA does not rely or provide sIRB for Exempt research (except for chart reviews via 2 MOUs)
- UGA belongs to SmartIRB which standardizes and facilitates reliance terms
- HRPP Website has a page with guidance

SmartIRB

- SmartIRB has a Master Agreement to standardize the terms of the review arrangement and addendums that standardize common negotiable terms as well as templates and guides for PIs
- SmartIRB has a platform to track the agreement/review arrangement, communicate the decisions, etc. Not all institutions who are members use the platform.

PI To-Do List for Collaborations

- Consult the Human Subjects Office early in project planning and begin the conversations with other IRBs (with or through the co-PIs)
  - Consult = Complete and a Reliance Intake Form and submit it to IRB@uga.edu Attention: Reliance Manager
  - Early = during funding proposal
- Draft a Communication Plan
- Get collaborating HRPPs/IRB Offices to provide letters of support OR get one for UGA if UGA is not the lead site
- Either describe activities that must be completed before IRB submission and an associated timeline of six months or more (planning) OR start working on drafting the submission with collaborations as soon as possible
  - Submit for Developmental Determination if you chose the former
  - Submit for external reliance OR for UGA IRB review of protocol and templates as soon as you have a fully developed application if you chose the latter

HSO To-Do List for Collaborations

- Participate in consultations
- Provide Letters of Support, track and maintain records related to preliminary conversations
- Provide Developmental Determinations
- Negotiate and execute Reliance agreements, MOUs, or SmartIRB tasks
- Provide local context information to reviewing IRB for all sites
- Pre-review study submission and all follow-on submissions for performance sites as they are onboarded
  - Onboard – adding performance site materials, local context, and documentation of reliance to IRB portal + IRB review
- Manage and Approve External Reliance submissions
- Track all reliance arrangements

IRB To-Do List for Collaborations

- None for Reliance
- For Review (as lead IRB)
  - Review and approve study submission
  - Review and approve all performance sites via modifications
  - Consider local context for each site
  - Review all adverse events, noncompliance, and UPIRSOs for project

Important Things
(What can possibly go wrong?)

- UGA must limit reliance on non-accredited IRBs so sometimes we will not agree to rely
  - Reliance on NA IRBs requires extra review by HSO (and legal counsel in some cases)
- Developmental determinations require documentation that the preliminary activities are necessary and will take significant time/resources. If not provided, HSO may not agree to provide the determination so you might need alternate funding
- Collaborating PIs might tell you they talked with their IRB office (but they may not have). Documentation is the best way to avoid issues.

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Questions?