Cooperative Research and IRB Review

Katherine Bright, IRB Compliance Officer for Reliance and Cooperative Research

RESEARCH MATTERS LIVE

UNIVERSITY OF GEORGIA
Office of Research

The Single IRB (sIRB) Mandate

- 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."

- *Cooperative research* projects are those projects that involve more than one institution.

Does this apply to my project?

- Applies only to federally-funded research involving human subjects
- Applies only to sites within the U.S.
- Does NOT apply if the project qualifies as exempt research under the regulations
- Does NOT apply to UGA if the scope of work for UGA is limited to non-human research activities

Does this apply to my project?

What research is exempt?

Low-risk:

- Surveys, interviews, focus groups
- Educational research
- Chart review or secondary use of data

Decision chart at:
https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c2

Does this apply to my project?

If you think the project may be exempt, call the IRB to discuss before proceeding with reliance discussions!

The UGA IRB will not enter into reliance agreements for exempt research.

Does this apply to my project?

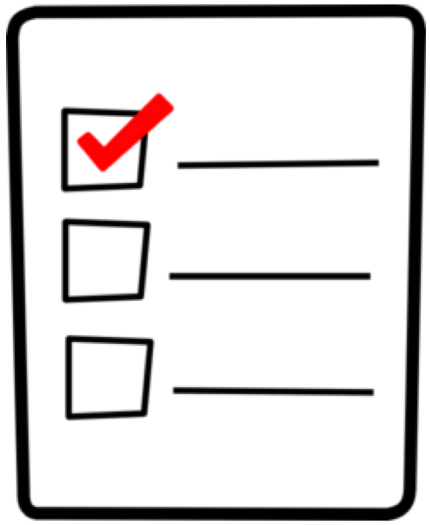
The specific activities to be performed by each collaborator matter!

- The sIRB mandate could apply to the larger project, but not to UGA.

Beginning the conversation with the IRB

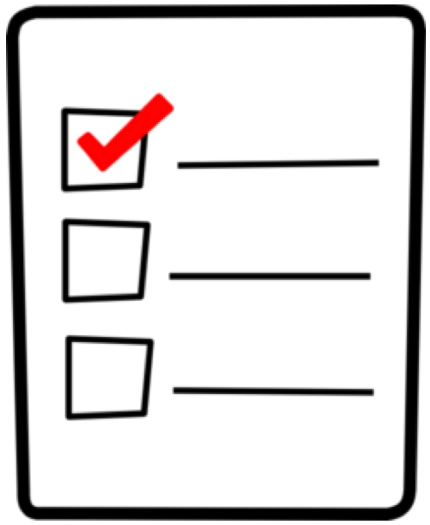
Complete and submit the *Reliance Intake Form*:

- ✓ Principal Investigator Name
- ✓ Funding information
- ✓ Project summary
- ✓ Scope of work for UGA
- ✓ Proposed role of UGA IRB – serving as the sIRB or relying on an external IRB?



What is a scope of work?

A succinct description or list of the activities involving human subjects or their data that will be performed by investigators at a particular site.



- Obtain consent
- Deliver research intervention or other in-person interactions with participants
- Maintain or access identifiable human data from the research
- Specimen collection/ analysis

Beginning the conversation with the IRB

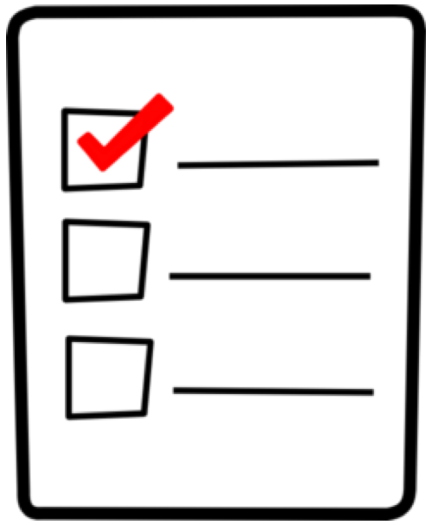
- Each collaborator must communicate with the IRB at their respective institution about local requirements. Collaborating investigators can propose a plan, but it is ultimately an IRB decision which IRB can serve as the sIRB, and which IRB(s) will rely.

- **Do not plan for or promise sIRB services unless the sIRB has reviewed the project specifics and agreed to serve this role.**

Relying on an External IRB

Complete *External IRB Review* submission in the UGA IRB portal:

- ✓ Approval documentation from reviewing IRB
- ✓ Approved consent form(s)
- ✓ Funding information
- ✓ Relevant contact information
- ✓ Scope of work for UGA
- ✓ Reliance Intake Form



Serving as the Reviewing IRB (sIRB)

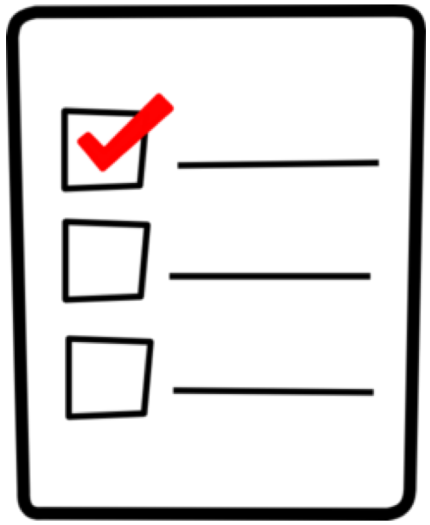
IRB Considerations:

- Which site is doing the bulk of the work?
- How many sites are participating?
- Which IRB has the most expertise in this subject matter?
- Is there a site IRB that has a more robust sIRB program or more frequent meetings?

Serving as the Reviewing IRB (sIRB)

Standard UGA IRB portal study submission process:

- ✓ Complete information about external sites in smartforms
- ✓ Relevant contact information for collaborating site IRBs
- ✓ Funding information
- ✓ Scope of work for UGA and relying sites
- ✓ Reliance Intake Form



Reliance Process

- IRB staff will negotiate and complete reliance agreements with collaborating IRBs after a complete submission has been received.
- The reliance agreement will be complete before IRB approval will be issued unless the IRB has agreed that relying sites will be onboarded via modification after initial approval of the main study.

Reliance Process

Communicate, communicate, communicate!!

The single IRB requirement is new to investigators and IRBs nationwide, and best practices are still being developed. Frequent communication between investigators and IRBs is essential.

Questions?

Katherine Bright
kathdunc@uga.edu

(706) 542-6685