Using UF as a single IRB (sIRB) for Multi-Institutional Research

Modified: January 2019

**Background:** Single IRB (sIRB) review occurs when research is being conducted at multiple universities/institutions but only a single IRB (IRB of Record) provides regulatory/ethical review of the proposed research. Other institutions (relying or ceding institutions) provide only institutional and local context review. sIRB review is only required for NIH-funded multisite studies submitted after January 25, 2018 where each site will conduct the same protocol involving non-exempt human subjects research.

Effective 1/2020, the revised (2018) Common Rule requires the use of a sIRB for U.S. based institutions engaged in cooperative research.

**Q Are there any exceptions to the NIH Policy?**

Yes. Studies funded to foreign awardees and/or conducted at foreign sites, career development, research training or fellowship awards, or where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy. Further, collaborative projects in which multiple sites are involved but different sites may complete different parts of the study are exceptions to the policy.

**Q: Can sponsors/researchers request UF to be a sIRB for domestic non-federally funded multi-site research?**

Yes. The same considerations will be applied as when assessing proposals that are required to use an sIRB.

**Q: What are the criteria for determining whether UF will serve as sIRB?**

Some of the criteria include but are not limited to: the number of sites, PI’s and research team’s experience/size and IRB compliance history, and a substantive communication plan with the relying institutions.

**Q: When to Contact UF IRBs to Request sIRB service?**

It is an imperative to contact the IRB as early in the process as possible, ideally, at the grant writing stage. If you intend to use UF IRBs as a single IRB, you must discuss this with UF’s sIRB Reliance Team (Committee Chair, Vice Chair, OHRPP Director, and Asst. Director of the IRBs). A written approval from the UF IRB to serve as the sIRB must be obtained before committing to this arrangement with other institutions or in any grants.
Q: How is request for UF to serve as the sIRB made?
Submit an e-mail to sirb@research.ufl.edu to arrange a meeting with the sIRB Team to discuss the study protocol, number of sites, and the communication plan with sites. PI is required to attend at the meeting.

Q: How to obtain an IRB letter of support to a granting agency stating that UF IRB will consider serving as sIRB?
Submit an e-mail to sirb@research.ufl.edu to request a letter of support. If you have already met with UF’s sIRB Reliance Team and if the decision has been made that UF will serve as the sIRB for the study, the IRB can provide a study specific letter to this effect. If the meeting with the sIRB Reliance Team did not occur prior to the request for IRB support letter, the, IRB can issue a generic letter to the effect that we are willing to consider serving in the sIRB capacity.

Q What written agreements does UF need in order to serve as sIRB?
Generally, a reliance agreement (such as IRB Authorization Agreement (IAA), Memorandum of Understanding (MOU) or Reciprocity Agreement) is required when collaborating with other institutions. Such contracts between institutions specify responsibilities of each institution and terms of collaboration. The Institution Official executes reliance agreements.

UF encourages investigators/institutions to use SMART Master Agreement as it cuts on the time needed to negotiate IAAs between institutions, which is often a lengthy process involving General Counsel.

Q: What is the submission/approval process?
Requests for UF to serve as sIRB can be done as part of an initial submission or modification of an existing project in myIRB. This is also a way to put an IAA through the system if it needs to be negotiated and tracked until executed by an Institutional Official.

SmartForms guide investigators to indicate that an sIRB review request is made. Much of the myIRB submission process will follow the regular expedited/Full Board path with familiar SmartForms, except for the addition of the Single IRB Participating Site SmartForm and affiliated detail page.
The IRB will first approve the study at UF without any sites. Once the study is approved at local sites, revisions will be submitted in myIRB to add sites to the main study.

Q: Are revisions to add sites reviewed by Full Board if the study’s review type is Full Board.
No. Revisions to add sites are approved via the executive review.

Q: What is needed from relying sites in order to add them to the approved sIRB study?
Written correspondence evidencing local context review at the relying site.

**Signed Exhibit C/Smart Acknowledgment Agreement** -- a UF study specific document used when UF is the IRB of record, describing the local context at the participating site, signed by the local PI, and local Institutional Official/Representative.

**Exhibit B/SMART Joinder** – a document the signing of which documents acceptance of the terms of the SMART/UF Master IAA agreement.

**Q: What are the PI responsibilities regarding communication with the sIRB and local PIs and their IRBs?**

UF PI (or designated point of contact from the study team) serves as the communication hub between UF IRB and site PIs. The communication responsibilities include:

- Communicating all approvals and approved study documents to all site investigators.
- Submitting all revisions, adverse events, continuing reviews and other items for all sites to UF IRB.
- Ensuring all necessary information needed from sites is obtained in a timely manner to secure approval for the continuing review. If re-approval is not obtained prior to study expiration, research activities must discontinue at ALL sites.

**Q: How Do I close an sIRB Study?**

UF PI will submit a closure. As part of the submission, signed statement by relaying PIs to the effect that all sites are closed.