Ceding Review to an External IRB

Modified: January 2019

**Background:** Single IRB (sIRB) review occurs when research is 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 January 2020, the revised (2018) Common Rule requires the use of a sIRB for U.S. based institutions engaged in cooperative research.

1. **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.

2. **Q: Can sponsors/researchers request UF to cede non-federally funded multi-site research?**

   Yes. The same considerations will be applied to all requests to cede regardless of funding. However, the Institution will consider the practicality and administrative burden of ceding a study that does not require single IRB review.

3. **Q: Will UF IRBs cede studies to commercial IRBs?**

   Only studies that are eligible for ceding and not required to go to WIRB could be ceded to a commercial IRB. Please note that the relationship with WIRB is not that of Ceding, but rather WIRB is one of UF’s IRBs.

4. **Q: What are the criteria for determining whether UF will cede review to an external IRB?**

   UF will cede review to another Institution or commercial IRB provided that the institution has sufficient standards of review. UF will consider all AAHRPP accredited institutions as sufficiently qualified. If an institution is not AAHRPP accredited, UF IRB Chair/Vice Chair will determine and document as part of UF’s local context review if the review standards of the IRB of record are equivalent to UF’s.

   UF will also consider the nature of the study.

   UF will not cede research on UF’s Student Athletes, research involving the Alachua County School System, research involving fetal tissue, and embryonic stem cells.

   UF will not cede studies **required to go to WIRB** to other commercial IRBs.
5. **Q: Will UF IRBs review studies that are to be ceded to an external IRB?**

Yes. However, UF is will only perform an institutional review regarding state/local and institutional regulatory requirements.

6. **Q: What is required at UF to cede study to an external IRB?**

A reliance agreement is required when you are collaborating with researchers external to UF who are engaged in research. However, the agreement is constrained by the requirements of the local context (local state laws and institutional policies).

UF participates in the SMART IRB Initiative. SMART IRB members are listed at [SMART IRB Participating Institutions](#). All other IAA agreements must be submitted through the myIRB system by creating a new Ceded Project. Please note for these IAAs General Counsel must be involved.

7. **Q: How to request ceding review to an external IRB?**

Create and submit new a Ceded Project in myIRB. The ceded submission path does not have regular myIRB branching due to ceding. For detailed instructions how to submit a ceded study please look at the [Researcher Manual](#), pp. 57-71.

8. **Q: Who will review Ceded Studies at UF?**

IRB Chairs/Vice-Chairs review ceded submissions looking for the locally relevant elements of the submission. A decision to cede is documented in myIRB. If the determination to cede is permitted, an acknowledgement letter is issued to the UF PI who can then submit the study to the external IRB. Note: this is not approval to commence the study. Please see below.

9. **Q: When can I start the study at UF?**

Once UF is added as a site at the IRB of record, the UF study team will submit the approval letter in myIRB with the other relevant approved documents. UF will Approve ceding of the study to that external IRB. Upon approval of ceding, study activities may commence at UF.

10. **Q: What is the requested review type of a ceded study?**

The requested review type should correspond to the review type at the IRB of record. For instance, if a study had a full board review at the IRB of record, the requested review type at UF will be Full Board. However, the IRB office will assign such studies to an expedited reviewer and they will be approved under an expedited review.
11. **Q: How often are CRs?**

CRs will be submitted per the IRB of record’s schedule of CRs. If there is a CR, the UF PI will submit the approval letter for CR, updated protocol, and ICF(s). If the study is reviewed as expedited at the IRB of record, the UF PI will submit a CR activity every 3 years indicating that the study is still ongoing or closing the study.

12. **Q: Do I need to submit all revisions to the IRB?**

No. Only revisions that affect personnel/PI changes, changes in funding, changes requiring an Institutional ancillaries’ review, or changes for which there is a specific institutional policy/state law requirement must be submitted.

13. **Q: What Events do I need to report?**

Serious or continuing noncompliance (either local or non-local), local adverse events that are serious, unexpected and more likely than not related to the study participation, and non-local events only if UF would have a duty to report an unanticipated problem to the Federal Agencies.

14. **Q: How do I obtain an IRB letter of support to a granting agency stating that UF IRB will consider ceding a study to an external IRB?**

Submit an e-mail to IRB-01 Questions <UFIRB-L@LISTS.UFL.EDU> to request a letter of support.

15. **Q: What is needed from the IRB of record?**

Written correspondence evidencing the main study approval at the IRB of record.

Documentation evidencing executed (SMART) IAA with UF.

16. **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 overall PI and his/her IRB. The communication responsibilities include:

- Staying up-to-date with the IRB of record’s determinations/communications.
- Communicating UF IRBs’ determinations to the overall PI.

Being knowledgeable about the IRB of record’s policies and procedures (especially regarding event reporting).