WIRB and Ceding to Commercial IRBs
UF’s position on ceding studies to commercial IRBs, other than WIRB:

As you might know, our relationship with WIRB is such that we do not cede studies to WIRB; rather, WIRB is one of UF’s IRBs. The benefit of this relationship is that we have a reliable system of notifications and protocol tracking, and WIRB also serves as a gatekeeper by knowing our local rules.

As ceding to other IRBs is becoming popular, we often hear that “the sponsor requires us to use “XYZ IRB” (Advarra, etc.). If there is a sponsor requirement to go through a specific IRB, we need to get something in writing from the sponsor to this effect.

Absent this requirement, the studies required to go to WIRB will continue to go to WIRB or get an exemption to go through IRB01/03 (if the sponsor does not require any particular IRB to review the study but does not want to pay for WIRB).

To summarize, only studies eligible for ceding and not required to go to WIRB can be ceded to a commercial IRB. Lastly, the benefit of the UF-WIRB arrangement for the PIs is significant too. When ceding, PIs need to submit a CED project through myIRB for a local context review. When going through WIRB, the submission goes directly to WIRB.

Updated WIRB Forms

This update only pertains to investigators/study teams who use WIRB.

Effective immediately, please make a note of two changes to the forms that are submitted to WIRB.

I. To facilitate WIRB’s review and compliance with Florida law/local rules, WIRB Cover Sheet has been updated to add the following two important local context items:

- Pregnancy testing for research in minors, to ensure compliance with FL law
- Emergency research studies that could use exception from informed consent (EFIC)

If any of the listed items could be a part of a study submitted to WIRB, a written approval from the Assistant Director of the IRBs is needed.

II. For studies that include pregnant partners, where pregnant partners only fill out questionnaires or provide a blood sample, we are introducing a brief UF template for WIRB studies. Please note that the brief consent can be used only for this population. The UF template for WIRB must continue to be used for all other populations.
### Authorization v. Informed Consent

A HIPAA Authorization is not the same thing as a research informed consent, although the requirements of each are often included in the same form. The difference is that an Authorization is an individual’s permission for a covered entity to use or share PHI for a research study. An informed consent is the individual’s actual permission to participate in the research.

For more HIPAA and research information, please refer to: [http://privacy.ufl.edu/uf-health-privacy/uf-research-hipaa-regulations/](http://privacy.ufl.edu/uf-health-privacy/uf-research-hipaa-regulations/).

### New IRB-01 Staff

The IRB-01 office is excited to announce that *Amanda Fiantaco*, who worked as an IRB Coordinator for the UF Health Jacksonville Department of Neonatology, started working as a Research Analyst II/Editor on 3/8/2019. Please join us in welcoming her to IRB-01!

### Reminders

#### Data Safety Monitoring Board/Committee Changes

To help prevent a delay in approval of continuing reviews for Full Board/GMR research, please submit a revision to update the safety and monitoring SmartForm pages accordingly if there have been changes to the frequency of the Data Safety Monitoring Board (DSMB)/Committee (DSMC) meetings and/or the generation of a written report.

#### Current ICF Versions

To prevent a new study from being returned to you, please refer to the most recent IRB approved versions of the IRB-01, IRB-02, and IRB-03 consent forms.

#### IRB Specific Forms

If an IRB-02 reviewer asks you to submit to IRB-01 (or vice-versa), please ensure that you update your forms (i.e., protocol and ICF) to the appropriate IRB committee templates. The IRB pre-review team will return your study to you if the ICF has another IRB committee telephone number, does not include the appropriate HIPAA sections, etc.