UF sIRB Process Ceding Review to External IRBs
UF Serving as the IRB of Record

Ivana Simic, Ph.D.
UF IRBs, Assistant Director
isimic@ufl.edu
Conceptual Apparatus

- **Ceding** of a study – a process the outcome of which is that UF relies on another, external IRB to review the study. UF is reviewing issues pertinent to the local context only. (State laws, OCR, CT.gov, HURRC, HSP, etc.)
  - 87 approved Ceded studies, 160 in all states

- **Reviewing** IRB/IRB of Record/single IRB – an IRB for the entire multicenter study upon which other institutions are relying for study review. Other institutions are ceding review to the single IRB.
  - 3 approved studies, over 100 sites altogether, a half dozen studies in the works

- **IRB Authorization Agreement (IAA)** is a legal document (a contract) between institutions that have a FWA
  - specifies the terms of collaboration (who is sIRB, who is ceding, what are the responsibilities etc.)
  - IAA can be a Master agreement or study specific (the latter kind is falling out of fashion)
  - Joinder – a document the signing of which documents acceptance of a master IAA agreement (e.g. UF’s exhibit B)

- **Exhibit C/Smart Acknowledgement** – a UF document that is study specific and which describes the local context at a participating site.
NIH Mandate

- NIH-funded, multi-site, domestic studies, involving non-exempt human subjects research are expected to use a single IRB
  - All Human Subjects; not just Clinical Trials
  - Effective **January 25, 2018**

Policy does not apply to:
- Foreign sites
- Career development (K), institutional training (T), and fellowship awards (F)
- Current awards
IRB Models that Would Meet the Policy

IRB models that would meet the policy:
1. Existing IRB can agree to serve as sIRB (UF, Vanderbilt, Johns Hopkins, etc.)
   • Awardee or participating site
2. Independent/Unaffiliated IRB (Advarra)*
3. Central IRB organized to review specific projects (NCI)

*UF does not cede reviews to WIRB as WIRB is one of UF’s IRBs by virtue of having a contract with them.
Exceptions to NIH Policy

- Possible
  - Time limited (ancillary studies that are part of ongoing studies or parent studies)
  - Policy based: When Federal, State, Tribal, local laws/regulations/policies require local review
  - Compelling justification for local review
Benefits and Challenges of sIRB

- **Expected benefit:**
  - streamlining IRB Review and avoiding redundancies and administrative burden of individual IRB reviews

**Challenges**

- **Negotiation of IAA’s**
  - Willingness to use a Master Agreement, SMART IRB etc
  - Ability to clearly define roles and responsibilities of sIRB and local IRBs
  - Capacity to facilitate tracking and sharing of sIRB related documents across multiple sites
SMARTTools

- SMARTIRB - a platform for institutions that accept a common non-negotiable master agreement.
  - SMARTJoinder - a document the signing of which by an Institutional Official evidences that the institution accepts the terms specified in the Master Agreement
  - Flexibility Agreements/Indemnification Statements (needs to go through the Legal)
    - SMARTIRB Agreement Implementation Checklist and Documentation Tool

- UF plays on SMARTIRB, along with circa 470 other institutions, but we are not using the SMARTTracking system. We use myIRB for this purpose.

- Advantages of using SMARTIAA Master agreement lie in that significant time is saved in negotiating IAAs between two Universities’ Legals.
How to Cede Study to an External single/central IRB?

UF process
UF Process - Overview

- Preconditions: Main study approved by the IRB of record.
- Create New Ceded Study Review
- IAA ancillary is triggered upon submitting the study
  - IAA is either ready
  - If the IAA is not signed by the institutions, submitting a study is a way to initiate the process
- Different nomenclature CED00000xx
- SmartForms (SF) have rudimentary branching

- New SF sIRB: IRB of Record Site for Ceded Review
  - The name of the Institution, Overall PI and Coordinator, and IRB Contact information.
  - Upload IAA agreement/ Smart Joinder
  - The approval letter for the study at the institution providing regulatory oversight
- The informed consent template will be from the IRB of record.
- Local UF information is captured in the editable portions of the consent (which is usually highlighted or tracked) or there is a consent addendum, or there is a check list with the local language that the IRB of record used to produce final consent.
  - Local information includes subject cost/injury language, HURRC, HSP, etc., any applicable state laws.
  - Depending who the privacy board is, HIPAA language is either UF’s or the IRB of records
    - This is usually specified in an IAA agreement or in SMART Flexibility Agreement.
- The study team will work with all the ancillaries (which get myIRB notifications prompting them to review), and insert all necessary language in the consent form.
  - Unlike our regular practice, we’ll not be entering the ancillary language into the consent for you as we are not finalizing documents.
- The study team must also attach any additional documentation that the IRB of record may require (local context check list, worksheet, etc.)
When office review is done and all ancillaries are in place, the study is acknowledged and in the state of Awaiting Site Materials.

- PI submits Acknowledgement Letter to the overall PI who initiates a revision at the IRB of record to add UF as a site.

- Once the revision is approved, a coordinator/PI submits the letter of approval with the approved documents to UF IRB via ‘Submit IRB of Record Correspondence’. The UF IRB approves ceding of the study.
  - OR if the IRB of record has concerns about local context issues, they might request changes which are also submitted by using ‘Submit IRB of Record Correspondence’.
  - The study team addresses issues and the study is acknowledged again, after which UF PI sends the acknowledgment letter to the overall PI who follows up on the submitted revision to the IRB of record.
Post Approval

- Revisions
  - Only changes in the local context: PI/study staff, ancillaries, items related to state laws (testing in pregnant minors, for example)
- CRs: (Current Protocol, ICF, and Approval letter from the IRB of record)
- Reportable Events:
  - Serious or continuing local non-compliance
  - Local AEs that are serious, unexpected, and related/more likely than not caused by study participation
UF serving as a sIRB

UF process
The Initial Process

- PI and staff meet with the IRB reliance team in the study planning phase
- IAA status (SMART, UF Master Agreement)
- Upon PI’s explanation of the project, a decision is made if UF can serve as sIRB; the reliance team sets parameters.
  - Study team is the link between the IRB and all the sites. The team must be highly organized and have systems in place for reporting events and ensuring that CR is submitted in time. Implications of study expiring affect all sites.
Approval

- Study is approved as sIRB but without any sites; sites are added with revisions (this is done via exec review)
  - Study Title and Staff SF declares that the submission is sIRB (UF serves as IRB of Record label is on Study Workspace)
  - Nomenclature the same as other IRB studies (IRBYEARNUMBER)
  - UF core consent is used with site addenda.
    - Each site addendum has the local institution’s logo and captures the local context items.
- New SmartForm: Single IRB Participating Site
  - Site information (PI, Coordinator, local IRB Contact Info)
  - Attach IAAs/Joinders
  - Attach Exhibit Cs/Smart Acknowledgments
  - Participating Site Approval
- If there are any sites that are obtaining their own IRB approval, they are added on the Multi-Centered Project: Information and Approval SF
Revisions to Add Sites

- Revisions to add sites, review goes via exec route
  - The IAA ancillary is pinged each time when a new revision that adds a site is submitted in order to document the IAA status (signed SMART J oinder or UF Exhibit B, and exhibit C/SMART Acknowledgment).
  - If SMART IAA is used, the revision is submitted once the site is active on smart and the PI has the exhibit C signed by the local PI. The document is then routed for signature by the IO’s designee. When ready, the IAA ancillary is submitted and if everything else is in order, the revision is approved.
Revisions CRs, AEs

- As Revisions and Continuing Reviews are approved by the UF IRB, the main PI is responsible for providing a copy of the UF IRB approval letter and any applicable documents (i.e. stamped consent, protocol, etc.) to the local PI(s) at the relying site(s).
  - A tip about revisions: Group revisions so that nothing holds up approval (IAA, Exhibit C, trainings). Add first quick revisions while working on the more complicated ones.
  - Plan CRs so they do not interfere with Revisions and vice versa (revisions and CRs can’t be in the system at the same time)
- The main PI, submits reportable events received by the relying site(s) to the UF IRB per UF reporting policy.
- Acknowledged AEs have to be communicated to the local sites by the main PI.
Resources

- http://irb.ufl.edu/sirb.html