A Note From Your IRB Educator

Happy 2020 Gators! I’d like to introduce myself as Tanya, the IRB Education Coordinator. The goal of the IRB Education Program is to facilitate acquiring knowledge about regulations and to provide training in following the UF IRB process from initial submission to study completion.

Upcoming Educational Opportunities:

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Event Description</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/29/2020</td>
<td>12:00PM</td>
<td>IRB Bootcamp: This training is for those new to research and the IRB process at the University of Florida</td>
<td>Shepard Broad Building Room 104</td>
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<tr>
<td>02/12/2020</td>
<td>12:00PM</td>
<td>IRB Brown Bag: Use of Single IRB (sIRB)</td>
<td>Shepard Broad Building Room 104</td>
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The IRB Education Program wants to hear from you. Please send in any requests you have for an upcoming Brown Bag topic to arancat08@ufl.edu.

Common Rule sIRB Mandate

- The revised Common Rule’s sIRB mandate is effective January 20, 2020.
- Studies that will be subject to the sIRB mandate:
  - Not exempt;
  - Federally funded (i.e., National Science Foundation (NSF), Department of Defense (DOD), CDC, etc.);
  - Multisite, defined as two or more sites engaged in non-exempt human subjects research within the United States; and
  - Not otherwise legally prohibited from using a single IRB.
- The Common Rule sIRB mandate does not apply to federally funded non-exempt multisite studies already approved by the UF IRB; it only applies to eligible studies approved on or after January 20, 2020.
- If you are ceding review to an external IRB, a ceded project must be submitted in myIRB in order to complete institutional context review.
- If you would like to request UF to serve as the reviewing IRB, you must contact the IRB at irb@ufl.edu and submit the sIRB request form to set up a meeting with the UF Reliance Team. The reliance meetings are held on Tuesdays from 8:30 AM – 11:00 AM. The PI and lead coordinator must receive confirmation from the UF IRB that UF will serve as the sIRB before you submit a sIRB application in myIRB.

NOTE: The revised Common Rule sIRB mandate is separate from the NIH single IRB policy, which went into effect on January 25, 2018.

To learn more about how to submit a sIRB study or to cede to an external IRB, please refer to http://irb.ufl.edu/sirb-2.html and http://irb.ufl.edu/wp-content/uploads/Researcher-Manual_FINAL.pdf.
Forms to Submit for a Continuing Review for a sIRB Study Where UF is the IRB of Record

The following sIRB specific forms must be submitted at continuing review for sIRB studies where UF is the IRB of Record: Adverse Event Summary Table, Deviation Tracking Log, and Subject Enrollment. These forms are available on the Alphabetical Listing of IRB-01 Forms found on the IRB website.

Updated WIRB Cover Letter

The Submission of UF Research to WIRB ® cover letter has been updated. As always, please remember to go the WIRB section of the IRB website to download current IRB/WIRB forms.

Reminders

What are the various definition for study subjects?

- Active subjects – consented subjects who met enrollment criteria and are currently receiving study-related procedures/interventions/activities.
- Subjects in follow-up – consented subjects who completed study procedures/interventions/activities, and all that remains is protocol-specific data collection and/or follow-up as described in the protocol.
- Subject Withdrawals – consented subjects who met eligibility but participation has ended prior to meeting a study endpoint (ended prematurely). This will include:
  - A subject who dies before completing the study is considered a withdrawal if survival is not a study endpoint. (Note that if death was related to the study, it must be reported as a reportable event to the IRB within 5 days.)
  - A subject who is no longer eligible (no longer meets inclusion or now meets exclusion criteria)
  - A subject whose participation is ended by the PI, or
  - A subject who no longer wants to participate for any reason.
- Subject Screen Failures – consented subjects found to be ineligible (do not meet protocol-specific inclusion criteria or meet protocol-specific exclusion criteria) as a result of study specific eligibility/screening procedures, prior to beginning study-related procedures/interventions/activities.
- Completed subject – consented subjects that have completed all procedures required by the protocol (e.g., interventions, tests, monitoring, visits, phone calls, and collection of data from medical or other records, including any protocol-specific follow-up) or have met a study endpoint.

For additional information please refer to the Study Subject Definitions, Enrolling and Over Enrolling Study Subjects Guideline.

NIH-Funded Clinical Trial Mandated GCP Training

All study staff listed on NIH-funded clinical trials must complete the GCP training and submit a copy of the completion certificate along with their UFID to our Contact Us form so that it can be manually entered into myTraining. Once entered, it will update in myIRB within 2-3 business days. If the training does not update in individual myIRB profiles after 3 days, please call the IRB front office at (352) 273-9600.

Please note that staff added as part of a new study submission or revision, will not be able to ‘agree to participate’ until the GCP training is done. Existing staff members with incomplete training will hold up the submissions, and they will be returned to the PI by IRB staff. Additionally, please be advised that any training that was taken more than 1 month ago, may not automatically update in the system.