Common Rule sIRB Mandate

The revised Common Rule, which went into effect on January 21, 2019, includes a requirement for all federally funded, multisite studies that are not exempt to use a single IRB review model. This means that those studies subject to the sIRB mandate must use a single IRB of record to provide IRB oversight for their study.

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

- 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.

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.
IRB. Clinical trial websites that include more than basic descriptive information, however, must be reviewed and approved by the IRB before posting. Please refer to the Advertising for Research Subjects Guideline for additional information.

NIH-Funded Clinical Trial Mandated GCP Training
Similar to the NIH training from not-so-long-ago, 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 http://irb.ufl.edu/contact-us.html 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.

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.

UF IRB Office Closure
UF IRB offices will be closed from 12/25/2019 – 1/01/2020. Normal business hours will resume on Thursday, January 2nd.