August 2013

Tiffany Danielle Pineda, Education Coordinator, IRBs

IRB-01 OFFICE CLOSED

The IRB-01 Main Office, Broad Building, Room 130, will be CLOSED all day on August 28, 2013 for our Annual Education Retreat. We apologize for any inconvenience this may cause; however, the sign in box will be outside the door for paper submissions and myIRB will be up and running. If you have any questions related to this, please call the IRB-01 Main Office at 352-273-9600.

Upcoming Education

Michael Mahoney, Assistant Director, IRBs will be presenting a repeat of the August Brown Bag on the 23rd of August at 9:00 a.m. in room 104 of the Broad Building. The topic is Continuing Review submissions in myIRB. CME and CEU credits will be offered.

If there is a Brown Bag topic that you would like to see presented, please contact me at tiffany.danielle@ufl.edu.

Things to consider when taking over as Principal Investigator of an existing study:

1. What is the current state of the study?

2. What is the compliance history of the study?

3. Are all of the paper and electronic files readily available? This includes previously signed Consents, Regulatory correspondence/binders, and correspondence with the IRB and/or sponsors.
4. Do you have the staff, time, expertise, and/or funding for the study?

5. How readily available will the exiting PI/study staff be during the transition?

**myIRB Needs Reply Process**

Please note that the link received with the Reviewer's notes requires two steps to reply. First, you must reply to the note with something as simple as “See the revised SmartForm response.” Second and most important, YOU MUST REVISE YOUR SMARTFORM RESPONSE based on the Reviewer's comment(s). It is important to document your changes in the corresponding SmartForm responses for your submission to be accurate. If you do not revise your SmartForm response, your submission will be returned to you for you to do this which will affect the time it takes for your submission to be approved.

**Telephone Scripts**

The IRB-01 is pleased to offer a guide for researchers to use when writing "telephone scripts" for recruiting subjects. This guide provides the structure and information that the IRB needs in order to approve your phone script. The guide can be found at [http://irb.ufl.edu/irb01/irbposition.htm](http://irb.ufl.edu/irb01/irbposition.htm).

**Office of Research announces Guidelines for PI Qualifications & Student Roles**

Vice President for Research, Dr. David Norton, announced new qualifications for (1) Principal Investigators conducting human subjects research and (2) student roles. The memo stated:

Working with the three UF IRB’s (IRB-01, 02, 03), faculty stakeholders, and research deans in affected colleges, the Office of Research has developed guidelines to better define the qualifications needed to be a Principal Investigator (PI) of a human subjects research project. The new guidelines are posted on the UF IRB website and specifically address the role that students can play in overseeing human subject research. The University must ensure that PIs are suitably qualified and accountable for all aspects of research projects, and that other investigators are qualified to fulfill the requested role. The IRBs designate as Principal Investigator the person who either conducts and/or oversees the entire protocol. The PI is also the person held accountable by the University and IRBs to insure all human subjects’ regulations and any financial issues are addressed. A PI often delegates some of the research activities to students, study coordinators or others, the P.I. remains accountable for the protocol. These guidelines were updated to be consistent with peer institutions.

The new guidelines are effective July 15, 2013, and will apply to any new protocol or revision request submitted. The guidelines are available at [http://irb.ufl.edu/docs/studentpolicy.pdf](http://irb.ufl.edu/docs/studentpolicy.pdf).