**IRB-01 Updates**

- **PI Proxy:** A PI Proxy is chosen by the PI of a study for the purpose of submitting items via myIRB when the PI is out of town or otherwise unavailable. As of 8/7/2015, the PI will no longer be able to assign a PI Proxy without IRB approval.

**Some things to remember:**

1. A PI Proxy must be a current co-investigator on the protocol.
2. The PI must choose the study function of “PI Proxy” for the co-investigator chosen to have this role.
3. The PI Proxy is given all electronic authority with that study, including being able to close the study, all without the PI’s electronic approval.
4. You can only have one co-investigator with the role of PI Proxy per study.
5. The approved PI Proxy remains in that role until the study is closed, or the PI submits a revision to change the PI Proxy.
6. It is strongly recommended that the PI identifies a co-investigator to have the function of PI Proxy at the time of new study submission.
7. If a PI determines that a PI Proxy is needed after approval of a new study, a revision will need to be submitted to designate the PI Proxy function to a co-investigator.

Bottom line, please think ahead about identifying someone to be a PI Proxy to avoid a crisis situation and choose wisely when you request someone as your PI Proxy.

- **New Staff:** The IRB-01 office is excited to announce that Erin Spurlock and Rebecca Wichman joined our staff in July 2015. Erin is replacing Joan Wysocki as an IRB Editor, and Rebecca is replacing Ashley Anderson as a Program Coordinator. Joan and Ashley left the IRB in June 2015 to expand their professional endeavors as research study coordinators at UF. Both Erin and Rebecca have previous human research experience and will benefit the UF research community. Please join us in welcoming them to the IRB!

**HELP!!! Which UF IRB Do I Submit My Research To?**

1. **True or False:** Dr. Floyd Ian Schlep proposes to administer surveys on the effects of standardized testing to parents and students ages 12-17 years. The surveys will be administered at the beginning and the end of the 2015 school year. The 20 questions don’t pose any risk, other than the child subjects may get distracted. Dr. Schlep will ask parents if the child subject has been diagnosed with developmental delay. He will also request review of the child’s medical record. Dr. Schlep should submit his study to IRB-02 (UF Campus/Non-Medical) because his research is behavioral and educational.

2. **True or False:** Mary White, a social worker employed at the UF Jacksonville Health Science Center (UFJHSC), proposes to collect information about health status, stress, and medication compliance from patients 3 months after being discharged from UFJHSC and UF Health in Gainesville. Since she works at UFJHSC and will be collecting PHI, her research must only be reviewed by IRB-03 (UF HSC, Jacksonville).

3. **True or False:** UFJHSC faculty, staff, or students must submit all behavioral and social research to IRB-03.
4. Dr. Carl Beta, a UF endocrinologist, has been conducting research on type 1 diabetes in retired veterans at the Malcom Randal VA Center (VAMC) for the last 12 years. He and his research team were recently added as a site for a multi-center randomized trial sponsored by Merck to compare multiple daily insulin injections to a novel insulin patch. He already submitted his proposal to the VA Research & Development (R&D) Committees. Which of the following are true?

A. He must submit his research to IRB-04 (WIRB) because he is faculty within the College of Medicine, and this is an industry sponsored trial involving FDA regulated drugs.

B. He doesn’t need to submit his research to any of the UF IRBs since his research has already been submitted and approved by the VA R&D committees.

C. He should submit his research to IRB-01 because IRB-01 is the IRB of record for the North Florida/South Georgia Veteran’s Health System (NF/SG VHS or VAMC).

*Quiz answers are listed on the next page.*

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*Retrospective Chart Review Reminder*

Any record that you look at and record information from/about is considered an enrolled subject. The number of records you request to review when submitting a Retrospective Data/Chart Review should account for *every* record, even if you just record that they (enrolled subjects) don’t fit your inclusion criteria. You should request the number of records you wish to have reported from the Integrated Data Repository (IDR). IRB approval for a retrospective chart review does not mean infinite access to medical records. IDR will *only* release the number of records requested and approved by the IRB.

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**IRB Full Board Meeting Deadlines**

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**IRB Education Opportunities**

~ **August Brown Bag Series** ~

Broad Building, Room 104
Noon - 1:30 PM
August 12, 2015

“Privacy Law and IT Security for Research”

By
Cheryl Granto
Information Security Manager
University of Florida

The objective is:

- For participants to understand what data is subject to protections under law, regulations, and contracts

RSVP: Tiffany Danielle Pineda
tiffany.danielle@ufl.edu
**Quiz Answers and Discussion**

1. **False**  
   **Why:** Although Dr. Floyd Ian Schlep is administering surveys that are behavioral and educational, he must submit to IRB-01 since he is accessing/collecting PHI by asking about the child’s diagnosis and reviewing medical records.

2. **False**  
   **Why:** Ms. White will need to have joint IRB-03 and IRB-01 review because her research involves UFJHSC and UF Health in Gainesville. She will only need to formally submit her proposal to IRB-03 (Jacksonville is the primary IRB since the PI is affiliated with the UFJHSC). IRB-03 staff will send copies of the submitted materials to IRB-01 for secondary review. Reviews from each IRB will be discussed in-house and official approval will be generated by IRB-03. (The joint review process will be detailed in a future newsletter).

3. **False**  
   **Why:** UFJHSC faculty, staff, or students may submit social and behavioral research to IRB-02 provided the research does **not** involve PHI as defined by HIPAA.

4. **C**  
   **Why:** Dr. Beta must submit his trial to IRB-01 because (1) WIRB will not accept research that involves the utilization of VA employees, facilities, resources or patients, and (2) IRB-01 is the IRB of record for the VAMC.