WHAT NUMBER DO I USE; WHAT IS AN ENROLLED SUBJECT?

To hopefully clarify, when submitting a protocol, the IRB forms asks you to consider not only how many subjects you need to answer your research question, but how many might screen out, withdraw, etc. You then have two numbers, how many subjects you need to complete the study (smaller number), and how many subjects the IRB has approved for you to enroll in your study (larger number).

So first, what is an “enrolled” subject?

- Anyone who signs an informed consent form, or agrees to participate under a waiver of documentation of consent.
- If you are doing a chart review study, each person’s medical record you review is an enrolled subject.
- If you are calling folks on the phone to see if they are interested in your study, they are only considered “enrolled” if you collect and keep information on the called individual. In this case, they have either agreed to participate, or have screened out.

What number do I use?

- The number the IRB is approving is the larger number (includes completed subjects, screen failures, drop outs, etc.)
- On the consent form, you should state in the appropriate section, “Up to <your larger number> will be enrolled in this study.”
- If you think you may exceed your larger number, submit a revision first, because going over that larger number without approval is a reportable protocol violation.
- If you think you may exceed the original number you told us you needed to answer your research question (smaller number), there is no need to obtain pre-approval from the IRB; however, the IRB may ask you to defend the increase as part of the continuing review.

SCIENCE FAIR PROJECTS

It is that time of year again when 8th graders submit their projects for this activity. Over the past several years, the IRB and the UF Shands VA attorneys and Privacy Office have had to address the unapproved use of tissue or information from these facilities.

Based on many discussions with UF Shands VAMC, the Alachua County Schools science teachers and administrators have been told that “No information, data, tissue or body fluid from UF, Shands or the VAMC can be used in any Science Fair project.”

Please remember that none of these items belong to any parents or friend of any student, and thus they have no authority to use them.
For IRB-02 Researchers

As of July 1, 2016, all researchers are required to complete the Group 1, IRB-01 Mandatory CITI Training or the NIH Extramural Training modules. Selecting Group 1, applies campus-wide and IRB-02 Researchers will not be able to “Agree to Participate” if the Group 3: Social/Behavioral Research modules are completed. Please refer to The IRB-02 Mandatory Training “Cheat Sheet” at http://irb.ufl.edu/wp-content/uploads/cs-CITItraining_IRB-02.pdf for more information.

myIRB
CONVERSION STUDY REMINDERS

1. Please remember to update all documents as clean, unstamped MS Word documents (ICFs, flyers, non-sponsored protocols).

2. Please attach all behavioral measures and/or provide detailed responses to questions in the myIRB conversion study rather than inserting, “As previously approved by the IRB”.

October Brown Bag Series

Broad Building, Room 104
Noon – 1:30 PM
October 12, 2016

“Central IRBS”
Sherri Mizrahy
Assistant Director of the UF IRBs
University of Florida

Objectives: TBA

RSVP: Ivana Simic, IRB Educator
isimic@ufl.edu

SOME FALL FUN