Think About Closing Your Protocol:

By Dr. Peter Iafrate, IRB Chair

In a recent review of all currently active protocols in myIRB, we have found that almost 1/3, some 400 plus protocols currently have less than 10% recruitment based on the number of subjects the investigator has told us they need to answer their research question. We have had protocols open for 12 years that have only enrolled 2 subjects.

There are many reasons for this:
- The PI has other priorities, either work related or a shift in research interests
- An over estimate of potential study subjects in our area that meet study criteria
- A grad student, resident, etc. has left, and they really were running the study
- Still waiting on funding

Keeping studies open, when it becomes clear accrual will not meet what is needed to complete the research; consumes a tremendous amount of effort on the part of the study team, and all the regulatory groups that must re-review the protocol each year. More importantly, it could make an ethically sound protocol turn un-ethical since the benefits to science from answering the research question are never met.

Please note that the IRB will be asking investigators to justify continuing studies when it appears that the study will not be completed. Also, it is a federal requirement that any change in the status of a protocol be submitted to the IRB for approval that includes closing your study. It is a simple process; please call the IRB office if you have any questions. Thanks!

- **RESPONDING TO EMAILS IN myIRB:** If you “Reply All” to a notification or email sent from the myIRB system (myIRB@research.ufl.edu), your response will default to the IRB-01 listserv. Please contact the person who sent you the email directly by sending them an email via “Send E-Mail to Study Team” in myIRB or outside of the system.

- **RETROSPECTIVE CHART REVIEWS:** Please note that all data must be existing (or “on the shelf”) when you submit your retrospective chart review. This means that your record review end date must be prior to the study submission date, not the study approval date.
1. **True or False**
   Protected Health Information (PHI) is any information in the medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment.

2. **True or False**
   PHI includes individually identifiable health information in education records covered by the Family Education Rights and Privacy Act (FERPA); in employment records held by a covered entity in its role as an employer; and regarding a person who has been deceased for more than 50 years.

3. **True or False**
   Oliver Socks intends to submit a retrospective chart review. His review will be of patients admitted to the ER with hallucinations between January 1, 2003 and December 31, 2010. He will collect dates, but not names or medical records numbers; whereas, his study will be appropriate for exempt review.

4. **True or False**
   Names, addresses, dates (birth, surgeries, etc.), phone numbers, social security numbers, medical record numbers and license plate numbers are all considered as HIPAA identifiers.

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**Brain Teaser answers:** (1) True; (2) False; (3) False; and (4) True

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**Education Opportunities**

**July Brown Bag Series**

*Broad Building, Room 104*

**Noon - 1:30 PM**

**July 13, 2016**

**“IRB and Sponsored Research”**

*Stephanie Gray*

*Assistant Vice President*

*Division of Sponsored Programs*

*University of Florida*

**Objectives:** The discussion will focus on the University of Florida policies and processes to support activating and managing sponsored programs. Key topics will be:

- At what point in the award cycle does IRB need to be involved? Specifically, at what time does DSP expect PIs to start heading to the IRB for approval?
- How does DSP get information when an IRB is approved?
- How does the University know that the IRB actually covers my sponsored program?
- What unique sponsors require additional attention?

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