**IRB’s Definition of “Subject Enrollment”**

According to IRB standards, there are 3 methods for enrolling an individual into a research project:

1. **Informed Consent**: A person is considered enrolled at the time the consent is signed even if they change their mind about participating or discontinue before completing the study.

2. **Full Waiver of Informed Consent**: Typically used for retrospective chart or record reviews. Each record accessed for research purposes is considered enrolled.

3. **Waiver of Documentation of Consent**: A verbal or written explanation of the study is given to the participant and they agree to let you keep the research information. An example of this is cases of phone screens when you plan to keep the PHI.

   If you realize during an internal self-audit or at continuing review that the number of participants exceeds the number approved (check the protocol, Enrollment Details smart form page, or Introductory Questionnaire for a paper study), this constitutes as a Protocol Deviation as well as Noncompliance. This would need to be reported as both because over enrollment deviates from the protocol and violates IRB policy.

   The PI may request a Revision to increase the number of approved participants at any time during the conduct of the study. This must be done before over-enrollment occurs to allow for the collection and use of additional data for research; the IRB cannot grant retroactive approval of Revisions to increase participant numbers after the fact. The IRB cannot allow PIs to use data collected on over-enrolled subjects for research.

**Are You Smarter Than a UF Researcher?**

A Short IRB Quiz for the Inquisitive…

1. **True or False**: A Full Waiver of Informed Consent is the only waiver or authorization needed for a retrospective chart review.

2. **True or False**: I plan on submitting an anonymous online survey study. I am only asking participants if they have ever suffered complications from an appendectomy. I am not collecting names, and participants will need to log into the survey with their email address. I will not have any direct contact with participants, and I am not collecting their names; therefore, I can submit the study as nonhuman.

3. Dr. Belmont was just awarded a gazillion dollars from The Color Blindness Society of America (CBSA). This is the 1st time he has ever been funded, and he really wants to hit his target enrollment of 76 subjects in the next 2 years. He only sees patients twice a week in his clinic; he would be terribly blue if he doesn’t enroll at least 23 subjects over the next 6 months. Dr. Belmont has probably seen hundreds of patients over the last 25 years, so he has plenty of potential participants to work with.

   Which of the following recruitment methods are acceptable?

   A. He can have his teaching assistant call all patients he has seen in the clinic over the past 3 years.

   B. He can recruit from an IRB approved clinic registry. He can mail them a study recruitment letter and flyer along with his phone number; they will call him if they are interested in the study.
C. He can post an advertisement in his waiting room informing potential participants that their color blindness will be cured and they will be paid $95 for their time.

D. He can review medical records to identify potential participants.

E. He can send an email to his UF departmental listserv and request that other physicians in the clinic send referrals.

F. (B and D).

G. (A, C, D, and E)

H. All of the above.

*Quiz answers will be provided in next month’s newsletter.*

**Informed Consent Form Woes…**

**Problem:** “I can’t get rid of the gray boxes throughout my ICF. I need to insert more information and I can’t edit what I have typed… HELP!”

**Solution #1:** Unprotect your document before you input all of your study information. This is done by the following (once the document is unprotected, the gray boxes will disappear when you start typing):

1. On the Review tab, in the Protect group, click **Restrict Editing**.

   ![Restrict Editing](image)

2. In the **Restrict Formatting and Editing** task pane (on the right side of your screen), click **Stop Protection**.

   ![Stop Protection](image)

**Solution #2:** If you don’t unprotect the document before inserting all of your information, you may get rid of the gray boxes by doing the following:

1. Select the gray areas that you want to cut or copy, and then press **Cut** (CTRL+X) to move the text, or press CTRL+C to **Copy** the text.

2. Click where you want to paste the text (the same spot), and then press **Paste** (CTRL+V).

3. Click **Paste Options**, which appears after you paste the text, and click **Keep Text Only** (farthest paste option on the right).

**IRB Education Opportunities**

~ *April Brown Bag Series ~*

**Broad Building, Room 104**

**Noon - 1:30 PM**

**April 8, 2015**

**“Give Me A Call……Or Not”**

By Sara Jo Nixon, Ph.D.

Faculty, Psychiatry Department

University of Florida

**The objectives for participants are:**

- To clarify the function and purpose of phone screening
- To be able to identify the core components of a phone screen
- To have tools to apply the appropriate process in conducting phone screens
- To improve the construction of phone screening materials

**RSVP:** Tiffany Danielle Pineda
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**IRB-01**

**BOOTCAMP**

**Broad Building, Room 104**

**10 AM – 1 PM**

**June 25, 2015**

**RSVP:** Tiffany Danielle Pineda
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