Phone Scripts and Minimal PHI, Oh My!

When using telephone calls to recruit potential participants responding to advertisements or enrolled in an IRB-approved contact registries, a script must be submitted and approved by the IRB before recruitment or screening implementation.

Guidelines for writing a phone script:
1. An introduction.
2. Discreetly verify that the correct person is on the phone, if not, offer to call back later.
3. Describe the purpose of the study, and how you obtained the potential participant’s name and phone number.
4. Ask if the potential participant wants to hear more about the study. If no, thank them and you’re done.
5. Tell them participation is entirely voluntary, and saying “no” will not affect their care in any way.
6. Explain the study in 8th grade-type language.
7. If screening subjects over the phone, the IRB does allow the collection of “minimal” PHI; whereas, potential participants are instructed to answer “Yes” or “No” after the entire inclusion criteria list is read so that you do not know the specific reason(s) for why inclusion criteria was not met.
8. At the end, thank them for their time.

Please refer to the Guide: How to write a “Telephone Script” for recruiting subjects position paper on the IRB-01 website at http://irb.ufl.edu/irb01/researcher-information/irbposition.html for more information.

Do I need to keep a regulatory binder for myIRB studies?

No, a regulatory binder is “optional” for studies submitted electronically because all correspondence, approval letters, protocols, informed consents, etc. are in myIRB; however, there are many researchers who opt to keep paper copies of everything as well (especially, if the research is sponsored and routine monitor visits are expected). If you do choose to keep a separate regulatory binder, a regulatory records checklist may be found on the IRB-01 website at http://irb.ufl.edu/irb01/forms/qaqi-tools.html.
**myIRB Tips**

- **REDACTING ICFS:** When submitting a continuing review or conversion study in myIRB, please remember to redact the subject’s signature on the last signed ICF with a peel-off china marker. Executive reviewers and/or the full Board cannot approve the submission if the subject’s signature is still showing.

- **AN EPIC REMINDER:** Researchers cannot use their clinical EPIC access to review EMRs for a retrospective chart review. In order to access medical records from EPIC for research you must provide a copy of your IRB approval and a list of inclusion criteria to Decision Support Services (DSS) or the Integrated Data Repository (IDR). Please refer to [http://privacy.ufl.edu/uf-health-privacy/access-to-epic/](http://privacy.ufl.edu/uf-health-privacy/access-to-epic/) for more information.

*Please also describe your inclusion criteria and specify how you will access EPIC for your chart review on the Study Description SmartForm page in myIRB to prevent any delays in your approval.*

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**Education Opportunities**

**Basic IRB-01**

**Part 2**

Broad Building, Room 104
12 PM – 2 PM
July 27, 2016

**LEARNING OBJECTIVES:**

- Describe steps how to submit a new reportable event
- Describe steps how to submit a new continuing review or study closure
- Describe steps how to submit a new revision
- Discuss how to edit modified study, effectively navigate SmartForms, and appropriately handle attachments.
- Discuss how to copy a study.

For additional information, or to RSVP, contact Ivana Simic at 352-273-9604 or e-mail isimic@ufl.edu.

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**August Brown Bag Series**

Broad Building, Room 104
Noon - 1:30 PM
August 10, 2016

“Who can consent when the subject can’t”

B. Dianne Farb, J.D., C.H.R.C.
Associate University Counsel for Research and Health Affairs
University of Florida

**Objectives:** TBA

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