Advertising for Research Subjects

Modified: May 2018

1. Q: What does the UF IRB need to know about recruitment of study subjects?

Federal regulations (both DHHS and FDA) require that IRBs make sure that the selection of subjects for a study is equitable. Each protocol submitted to the UF IRB for review must explain how subjects will be identified and recruited for the study. Once the pool of potential subjects is identified, the IRB must consider how the investigator proposes to approach those individuals. Any approach to subjects must be non-coercive and the potential subjects must voluntarily participate in the recruitment process. The IRB and the investigator must respect and protect subject privacy – the subject’s right to control access to him or herself. In order to assure that these principles are met, the UF IRB will review the study recruitment plan and all recruitment materials to determine how the materials will be used, whether the plan will reach the target audience, and how communication between the investigator and the potential subjects will occur.

Note: The UF IRB will also review a recruiting plan to make sure that it complies with HIPAA and institutional requirements. Certain populations, such as students and employees, receive added protections from the UF IRB to ensure that their decision to participate in a study will be truly voluntary and not vulnerable to coercion or undue influence exerted by the teacher/supervisor. Patients also receive added protection. Under HIPAA, the use of a person’s protected health information (PHI) in research generally is not permitted without authorization from the subject or an IRB waiver of authorization. Therefore, HIPAA requires either authorization from the subject or a full or partial IRB waiver of HIPAA authorization for recruitment.

2. Q: What types of recruiting tools may be used to inform potential subjects about a study?

Advertising and other recruiting tools may be used to inform potential subjects and/or other clinicians, supervisors, or others about a study. All proposed printed advertisements or brochures, web postings, “crowdsourcing” task descriptions (i.e., on Mechanical Turk), social networking site advertisements (i.e., on Facebook), or audio/video advertising, and all communications with primary care physicians, other investigators, or potential subjects informing them about a study must be submitted for IRB review and approval prior to use.

The UF IRB will consider the text of the recruitment material and its placement. These tools are considered to be part of the subject selection and the informed consent process for the study. The type of recruiting tool should be specified (e.g., posted flier, website notice, newspaper ad, radio, newsletter from support groups, social networking site post or ad, etc.) Also, the specific location (e.g., name of the newspapers, radio stations, specific social media sites, pages and/or groups, etc.) of the tool must be provided. All proposed recruiting tools associated with a recruitment plan must be reviewed and approved by the UF IRB prior to use. This includes any recruitment plans, tools, or campaigns that will be undertaken by the sponsor or any contract research organization involved in the research. When needed, the social media advertisement will be reviewed by the Social Media in Research Committee, which is comprise of the IRB, Privacy Office, IT Security, and the CTSI.
Any significant proposed changes to previously approved recruiting tools, including how the tool will be used or placed, must be submitted to the UF IRB for review and approval before they may be used to recruit subjects for a study.

3. **Q: When is IRB review of clinical trial websites not required?**

Clinical trial websites that provide only directory listings with basic descriptive information about clinical trials in general, do not need to be reviewed by an IRB. Basic descriptive information includes:

- Study title
- Purpose of the study
- Protocol summary
- Basic eligibility criteria
- Study site location(s), and
- How to contact the study site for further information

Clinical trial websites that include more than this basic descriptive information must be reviewed and approved by the IRB prior to posting. Examples of clinical trial listing services that do not need IRB review and approval include the UF CTSI website, the National Institutes of Health (NIH) ClinicalTrials.gov website, the NIH National Cancer Institute's cancer clinical trials listing (Physician Data Query [PDQ]), and the government-sponsored AIDS Clinical Trials Information Service (ACTIS). See [http://www.hhs.gov/ohrp/policy/clinicaltrials.html](http://www.hhs.gov/ohrp/policy/clinicaltrials.html)

4. **Q: Are informed consent and a HIPAA privacy authorization needed for recruitment?**

The UF IRB generally will require informed consent and HIPAA privacy authorization for recruitment unless it is impracticable to obtain consent/authorization for the recruitment process. If the UF IRB determines that it is impracticable to obtain consent/authorization, the UF IRB may grant a partial waiver of privacy authorization. (Please note that waiver of consent generally is not available for FDA studies.) Again, the investigator should describe the exact plan for the recruitment process in the protocol and request a partial waiver of informed consent/privacy authorization if the investigator believes it is needed for the protocol.

5. **Q: What privacy issues arise in the context of subject recruitment?**

The DHHS, the FDA, and the Privacy Rule (HIPAA) regulations require that investigators protect the privacy of potential study subjects. The potential subject has the right to control access to him or herself and what information about themselves they choose to share with researchers, and that right extends to the entire subject selection, recruitment, and enrollment process. Any recruitment plan proposed for a research study must address privacy issues.

It is always important to inform the potential study subject how the researcher has obtained the potential subject’s name and contact information. In cases where the UF IRB approves a waiver of consent and HIPAA privacy authorization for the purpose of recruiting subjects for a study, the individual being recruited will most likely not know how the investigator obtained his/her PHI. If a
recruiting letter or phone script is used, even if it is coming from the individual's treating physician, it is advisable to include the following language (or something similar):

“The researchers have been given permission to contact you by a University of Florida committee established under federal law to review uses of patient information.”

6. **Q:** Does the University of Florida allow “cold calling” potential study subjects in an attempt to recruit them into a research project?

No. The IRB, in conjunction with the Privacy Office and General Counsel’s Office confirmed that UF would not allow “Cold Calls” for recruitment. Research studies recruiting targeted patients due to some knowledge of the medical condition or other PHI, may not approach the patient directly. This includes any clinical patient care area either in the hospitals or clinics. This decision was reached after each group benchmarked with numerous universities around the country. The sequence of such recruitment is as follows:

- Patients must first be approached by a clinical staff member, (one who has reason to have knowledge of their PHI or condition.)
- The clinical care provider can then offer the patient the opportunity to “learn more about a research study that may be of interest to them” by the clinical staff. This can be in the form of an IRB approved recruitment letter or flier, or simply a verbal communication by the individual who has a clinical role with that patient.
- If patient is interested in hearing more about the research, the clinic staff can invite the research staff to meet and discuss the study with the patient/family.
- The clinical staff “pitching the idea of a research study, to open the door to research staff” do not need to be listed as study staff on the IRB protocol, as long as they are not actively recruiting or consenting.
- Any research staff discussing, recruiting, or enrolling/consenting research participants must be listed on the IRB protocol and approved by the IRB.
- An MD or clinical nursing staff, who may be involved with a research study that provides clinical care/intervention for treatment, may discuss the protocol/research with the patient directly.

7. **Q:** What information must be included in recruiting ads? What other information may be included?

The content of the recruiting ads must be informative to the potential subject. The information must be accurate and delivered without “overselling” the concept to the reader. The recruiting advertisement may not unduly influence the participant’s decision to participate in the study. The advertisement may not state or imply a certainty of favorable outcome or other benefits beyond those that are outlined in the consent document and protocol. The following information must be included in any proposed printed recruiting ad:

- The name and affiliation of the principal investigator;
• The contact information to learn more about the study;
• The condition under study and/or the purpose of the research;
• A specific reference to “research study” in the text; and
• The UF IRB protocol number.

(This information is not required on social networking site advertisements if its inclusion is impossible due to the small size of the advertisement. Investigators should include this information on linked websites whenever possible.)

Audio and video recruitment tools do not need to include the UF IRB protocol number. In addition, recruiting tools may include the following additional information:
• The criteria that will be used to determine eligibility for the research;
• A brief list of the benefits offered to participants, if any;
• The type or amount of “payment” to participants may be stated, but should not be emphasized by the use of font enhancement or distinction;
• The time or other commitment required from participants; and
• The location of the research.

8. Q: What are restrictions on recruitment ads?

• Advertisements that are unduly coercive or promise a certainty of cure or another benefit beyond what is outlined in the consent and the protocol.
• Advertisements that make claims, either explicitly or implicitly, that the drug, biologic, device, behavioral intervention or other research procedures are safe or effective for the purposes under investigation, or that the test article or other research procedures are known to be equivalent or superior to any other drug, biologic, device, or procedure.
• Advertisements that use terms such as "new treatment," "new medication," “new therapy” or "new drug" without explaining that the test article or the research procedures are investigational or experimental.
• Advertisements that promise "free medical treatment," when the intent is only to say subjects will not be charged for taking part in the investigation.
• Advertisements that emphasize the payment or the amount to be paid, by such means as larger or bold type, although it may state that subjects will be paid.
• Advertisements on social networking sites that target subjects under the age of 21 for studies involving illegal activities (i.e., underage drinking, illegal drug use) or for studies involving subject matter that the IRB determines is too sensitive for direct targeted advertising.

9. Q: How does the IRB approve an advertisement that will be videotaped?

When advertisements are to be taped for broadcast, to prevent the need for re-taping because of inappropriate content, the IRB must review and approve the wording of the advertisement prior to taping. The final taped advertisement prepared from IRB-approved text must be submitted for final review and approval by the IRB.

10. Q: What requirements are there for using stock photos with likenesses in recruitment ads?
Use of a stock photo with an individual’s likeness in recruitment materials must comply with any licensing requirements and/or terms of use of the website or other entity which is the photo’s source. Ads which assert or imply that the pictured individual(s) engages in illegal or immoral conduct or suffers from diseases or conditions are of particular concern. It is the investigator’s responsibility to explore any such requirements or restrictions prior to submitting these recruitment ads to the IRB for approval.

If the advertisement is written as a first-person testimonial (either actual or fictitious), the IRB will require the addition of a disclaimer to the advertisement conveying that the individual(s) in the photo is not an actual patient(s). This may appear in small type at the bottom of the advertisement as follows:

“Person(s) depicted in this photo is not actual patient or study subject.”

11. Q: Are there special requirements when using a social media site to post a research ad?

Yes. If an investigator wishes to post a research advertisement on social media, currently Facebook is the only UF formally approved platform. The research advertisement must simply indicate the type of study subjects one is recruiting (i.e., males between the ages of 25 and 40), and how that potential subject can contact the UF investigator for further information.

Only right-column advertisements will be allowed; others advertisements will be approved on a case-by-case basis. Since Facebook must approve advertisements, and since you need to inform Facebook of the timeframe you wish to run the ad, the sequence of submitting a Facebook advertisement to the UF IRB is as follows:

1. Draft the advertisement per Facebook guidelines.
2. Submit the draft advertisement to the UF IRB either in the initial protocol submission or as a revision to your protocol. Please include some description of whom the advertisement is targeting.
3. The UF IRB will approve the advertisement “contingent” on Facebook’s approval.
4. Unless Facebook makes substantial changes, you can indicate to Facebook the “run” time.
5. Submit the final Facebook-approved advertisement, along with documentation that Facebook has approved the advertisement, to the IRB for final approval.

When needed, the social media advertisement will be reviewed by the Social Media in Research Committee that involves the IRB, Privacy Office, IT Security, and the CTSI.

12. Q: Is “cold calling” allowed to recruit potential subject via email, a letter, or any other direction communication that is not face-to-face?

No, if the communication comes from study staff that has knowledge of the patient’s medical
condition or PHI. Such a communication can come from the clinical care provider, in which they indicate how the patient may contact the researcher if the patient is interested in hearing more about the research.