Advertising for Research Subjects

Modified: January 2017

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 an authorization from the subject or an IRB waiver of authorization. Therefore, HIPAA requires either an authorization from the subject or a full or partial IRB waiver of HIPAA authorization for recruitment.

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 ad will be reviewed by the Social Media in Research Committee, that involves 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.

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

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.

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

The DHHS and FDA regulations require that investigators protect the privacy of study subjects. The regulations do not, however, define what privacy means. Invasion of personal privacy is a subjective matter and it is difficult to assess what each individual subject will consider to be an invasion of privacy. The 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.

When the UF IRB approves a partial waiver of consent and HIPAA privacy authorization for the purpose of recruiting subjects for a study, the individual being recruited will not know how the investigator obtained his/her PHI. If a recruiting letter is used, even if signed by the individual’s referring 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.”

Remember: Even when the IRB partially waives HIPAA authorization for recruitment purposes, in most cases the investigators must still obtain subject informed consent and a HIPAA privacy authorization in a Hopkins-approved form for the use of subject information in the study itself.

**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 ad may not unduly influence the participant’s decision to participate in the study. The ad 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 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 use of font enhancement or distinction;
- The time or other commitment required from participants; and
- The location of the research.

**Q: What are restrictions on recruitment ads?**

- Advertisements that are unduly coercive or promise a certainty of cure or other 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.

Q: How does the IRB approve an ad 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.

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 ad is written as a first-person testimonial (either actual or fictitious) the IRB will require the
addition of a disclaimer to the ad 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 ad as follows:

“Person(s) depicted in this photo are not actual patients or study subjects.”

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 ad on social media, currently Facebook is the only UF
approved location. The research ad 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. 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 ad to the UF IRB is as follows:

1. Draft the ad per Facebook guidelines
2. Submit the draft ad to the UF IRB either in the initial protocol submission or as a revision to your
protocol. Please include some description of who the ad is targeting
3. The UF IRB will approve the ad “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 ad, along with documentation that Facebook has approved
the ad, to the IRB for final approval.
When needed, the social media ad will be reviewed by the Social Media in Research Committee that involves the IRB, Privacy Office, IT Security, and the CTSI.