Office of Human Research Ethics Training Tips
Recruitment of Research Subjects: OHRE SOP 25

25.1 Advertisements

All advertising **MUST** clearly state that the project is a "**research study**," and may include, where appropriate:

- The purpose of the research,
- the eligibility criteria
- A straightforward and truthful description of the incentives to the subject for participation in the study (e.g., payment);
- The location of the research
- the person to contact for further information; and
- The time or other commitment required of the participants.

Advertisements **should not:**

- State or imply a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol;
- Include exculpatory language; or
- Emphasize the payment or the amount to be paid, by such means as larger or bold type.
- If a study involves investigational drugs or devices, no claims should be made, that the drug or device is safe or effective for the purposes under investigation, or
- that the drug or device is in any way equivalent or superior to any other drug or device.

Such representation would not only be misleading to subjects, but would also violate FDA regulations concerning the promotion of investigational drugs and investigational devices. The FDA specifically discourages the use of terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational and that its effectiveness has not been proven.

25.2 Direct solicitation

- UNC-Chapel Hill may not solicit by direct appeal to students, employees or trainees in that researcher's department or class in an effort to recruit subjects for a study. See also SOP 32.9 Employees, students or trainees as research subjects.
- Could be construed as coercive by the potential subjects being solicited.
- ***The IRB should evaluate*** the proposed method of recruitment as it would be applied to students, employees or trainees to make sure that recruitment materials are not presented in a manner that could suggest that their decision regarding research participation could have an effect on their relationship with instructors, mentors or employers.

- Describing opportunities to participate in research to individuals in a subject pool is permissible, and the prospective subject's inclusion in the subject pool implies his/her desire to be apprised of such opportunities.
- Creation and use of such pools or registries must be reviewed by the IRB.

25.2.1 "Dear Colleague" Letters

The use of "Dear Colleague" letters intended to solicit the help of professional peers in recruiting subjects should be reviewed by the IRB and will be considered on a case-by-case basis.

25.3 Requests from outside researchers to solicit on the UNC-Chapel Hill campus

- Does this request engage the University in the research (e.g., involve University personnel to access records or potential subjects), (see SOP 8.0) and
- Do the investigators have approval from an external IRB.
- Depending on the nature of the research, and what is involved, it may or may not be necessary to enlist the support of a UNC-Chapel Hill sponsor.
- For example, the IRB may under some circumstances require that a local collaborator be designated when the targeted populations are UNC-Chapel Hill students or UNC Health Care patients.
- But when direct access for recruiting may be gained publicly, e.g., faculty lists from the UNC-Chapel Hill website, the IRB may determine that a local collaborator is not required.
- Even if IRB oversight is not required, external researchers may still need to obtain approval from various "gatekeepers" who are responsible for the target population or facility (e.g., student affairs offices, deans offices, dorm supervisors).

25.4 Recruitment of patients

Under most circumstances, it is preferable for patients to first hear about a research study from someone they would recognize as having reason to know of their medical condition or other eligibility criteria. The intent is to avoid scenarios where patients feel as if they have received a "cold call" from a complete stranger who appears to have inappropriate access to their medical records. This might be accomplished by a letter of introduction from a direct care provider or a representative of the clinical area in which the patient is receiving health care, providing a brief description of the research and contact information for the investigators.

When this approach is not practicable (e.g., there is a large number of patients in multiple clinics and the physicians are unable or unwilling to serve as intermediaries), researchers may be given permission to contact patients directly. Extra care should be taken by both researchers and the IRB to construct a recruitment approach that respects the privacy concerns of patients and anticipates their reaction to the contact.