Office of Human Research Ethics Training Tips
Recruitment, November 2016

PURPOSE

Federal regulations require investigators to use fair and equitable recruitment practices. This policy establishes requirements for the recruitment of human subjects research participants.

PROCEDURES

- **Recruitment advertisements: Must be reviewed by the IRB**

Recruitment advertisements must be written in plain language (6-8th grade reading level) and clearly state that the project is a "research study". The following information *should be included*:

  - Name of researcher or research team
  - Condition under which the study and/or purpose of the research
  - Summary of the eligibility criteria
  - The location of the research and the person to contact for further information
  - UNC IRB study number

- **May Include:**
  - Brief list of participation benefits, if any (e.g., a no-cost health examination)
  - The time or other commitment required of the participants
  - A straightforward and truthful description of the incentives to the subject for participation in the study (*e.g.*, payment)

The following may *not be included*:

- 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 **[No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. --- 45 CFR 46.116]**
- Emphasize the payment or the amount to be paid, by such means as larger or bold type
- Use of inappropriate pictures or images
- Use of misleading acronyms

If a study involves investigational drugs or devices, the following *may not be included:*

- Claims of safety, effectiveness, equivalence or superiority in reference to the drug, device or procedure under investigation
- Use of the term **"new treatment"** or **"new drug"** in reference to a drug or device without explaining that the test article is **"investigational"**
- Use of the term **"free"** in reference to procedures

Advertising on clinical trial websites: OHRP issued guidance on internet advertising on September 20, 2005.

- Clinical trial listing services that **do not need IRB review** and approval include:
  - National Institutes of Health (NIH) ClinicalTrials.gov website,
  - NIH National Cancer Institute's cancer clinical trials listing (Physician Data Query [PDQ]), and
  - AIDS Clinical Trials Information Service (ACTIS).
- IRB review is not needed for internet advertisements (e.g., listing of studies on department or research website) provided that the information is limited to:
  - study title
  - purpose of the study

- protocol summary
- basic eligibility criteria
- study site location(s), and
- contact information for the study site

- IRB Review needed when posting is for subject recruitment:
  - Posting goes beyond basic descriptive listing
  - descriptions of clinical trial risks and potential benefits, or
  - solicitation of identifiable information from potential research subjects.

Direct solicitation

- **Direct appeal to students, employees or trainees**: Cannot be to students or employees in a direct power relationship
- "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

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

- When non-University researchers wish to solicit human subjects on the UNC-Chapel Hill campus, it should be determined if the recruitment activity:
  - *engages* UNC-Chapel Hill in human subjects research and/or
  - has been approved by an external IRB
- Even when further 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, hospital or clinic supervisors). For example, a clinic supervisor may decide not to allow posting of an external recruitment advertisement for an asthma treatment study if a similar or competing study is being conducted at UNC.

Recruitment of patients

- The IRB discourages investigators from recruiting patients with "cold calls" based on information derived from the medical records of another practitioner when the investigator has no prior relationship with the potential subject.
- A letter of introduction from a direct care provider or a representative of the clinical area in which the patient is receiving health care. The letter should provide a brief description of the research and contact information for the investigators.
- If 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.***
- Researchers using demographic data obtained from the **Carolina Data Warehouse (CDW-H)** should introduce themselves to patients as a representative of UNC-CH and explain that they are being contacted because their UNC Health Care records indicate that they may be eligible to participate in a research study. Please refer to the CDW-H guidance document for recommended language for letter and telephone recruitment scripts.

References:

FDA IRB Information Sheet: "Advertising for Study Subjects" (1989)
Recruiting Study Subjects – Information Sheet (FDA)
IRB Review of Clinical Trial Websites (2005) – HHS Guidance
OHRE SOP 502: Recruitment Incentives
Engagement of Institutions in Human Subjects Research (2008)-HHS Guidance
Suggested Language to use in Recruitment Letters and Telephone Scripts – Carolina Data Warehouse for Health (CDW-H) Guidance