

TIP SHEET - Recruitment Materials

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310 AOB (MC 672)
1737 West Polk Street
Chicago, IL 60612-7227
Phone: 312 996-4995 Fax: 312 413-0238
www.research.uic.edu/protocolreview/irb

I. Introduction

The IRB must review, approve, and stamp all recruitment procedures and materials prior to their use by an investigator, since recruitment materials (e.g., advertisements, flyers, phone scripts, newspaper ads, radio and television announcements, bulletin board tear-offs, Internet postings, and posters) are part of the informed consent process.

A. When to Submit Recruiting Materials to the IRB

- Direct advertising for research subjects is considered the start of the informed consent process. Recruitment materials must be submitted with the research protocol for initial review.
- If the investigator decides at a later date to use recruitment materials in addition to the approved materials or to change the currently approved materials, the materials must be submitted as an amendment to the research protocol and must receive IRB approval before they are implemented.

B. Appropriate Content and Format for Recruiting Materials

- Recruitment materials are evaluated for the relative size of the type used and other visual effects. Therefore, materials should be submitted in their final format for review and approval.
- A description should be provided regarding the manner in which the materials will be distributed/utilized and by whom (i.e., clinic staff will hand flyer to patients or e-mail announcement distributed through UIC Massmail).
- Recruiting materials may state that subjects may be compensated or reimbursed, but specific dollar amounts should not be a major feature of the advertisement.
- For recruiting materials that are to be taped for broadcast, transcripts must be submitted for review and approval. The final taped message may be approved via expedited procedures.
- The recruiting material must not be unduly influential in its approach and/or should not promise a certainty of cure or other benefits beyond what is outlined in the informed consent document and the research protocol.
- If investigational agents are involved in the research, no claims may be made (explicitly or implicitly) that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device.
- Recruiting materials may not use the terms "new treatment," "new medication," or "new drug" without explaining that the test article is investigational, i.e., not approved by the FDA. A phrase such as "receive new treatments" leads subjects to believe they will be receiving newly improved products of proven worth.

- Do not promise "free medical treatment" when the intent is only to say that subjects will not be charged for taking part in the research investigation.

C. Items that Must Be Included in Recruiting Materials

- Research project title or identifier (i.e., "Smoking Cessation").
- A description of the type of research and purpose of the research.
- The word "research" must be included in the description. It is not enough to imply that the subject is being recruited for research by just using the word "study".
- A name of the person or office to contact and the number to call for further information.
- The UIC research protocol number, when available (this number will not be available at the first initial review submission), and the fact that the research is being performed at UIC.
- The Principal Investigator's name, department, and address.
- The specific location of the research.
- Footer with version # and date.
- Space for the UIC IRB approval stamp (approximately 2.5 x 1.5 inches).

D. Information that May be Included in Recruiting Materials

- In summary form, the criteria that will be used to determine eligibility for participation in the research.
- A description of the time commitment and duration of the subjects' participation and number of visits required for the research.
- A brief description of the benefits of the research, if any (e.g., smoking cessation).

E. What Does Not Require IRB Review

- Medical society newsletters.
- News stories (i.e. public service announcements) and
- Publicity intended for other audiences, such as financial page advertisements directed towards prospective investors.
- Dear colleague/doctor letters - only those announcing the existence of the research. Note that if the the letter asks the colleague/ doctor to help with recruitment, then IRB approval is required.