

University of Kentucky

A Principal Investigator's Guide to Identification and Recruitment of Human Subjects for Research

Recruitment of subjects is one of the most challenging aspects of research involving human subjects. Recruitment of subjects must be equitable and include racial, ethnic, educational, socioeconomic, and gender diversity appropriate to the condition that is studied. All recruitment efforts must respect personal rights to privacy and confidentiality, be compliant with Health Insurance Portability & Accountability Act (HIPAA) regulations and avoid coercion of subjects.

Subjects with specific diseases or conditions are often identified as potential subjects through some type of record (e.g., registries for cancer cases, surgical or X-ray log books, employment, medical or school records). Controls may come from the same population as the subjects (e.g. randomized clinical trial), be persons with unrelated conditions or be volunteers from the general population. For information on enrolling university students as research subjects, please review the "Guidance for enrolling University Students as Research Subjects" document.

Contacting Prospective Subjects Who Were Identified From Medical Records

- In research projects where prospective subjects are identified through review of private records, initial telephone contact or mail/internet questionnaire to invite participation in a research study by an unknown investigator (cold call) or direct mailings is not acceptable unless specifically approved by the IRB. There is a potential for coercion and potential subjects may be offended, especially in research on sensitive topics, by the investigator's having direct access to their name, address, and phone number.
- A physician who has a treatment relationship with a prospective research subject may approach that patient about participation in any IRB approved protocol. The physician may approach the potential subject about participation in his or her own protocol or on behalf of another investigator. If the protocol is by another investigator, the permission of a potential subject is required before identifying information is given to the study investigator.
- For a hospital-based study, a potential subject's physician must give approval before the patient is contacted by an investigator. If the subject is in the hospital, someone on the hospital staff involved in the subject's care must inform the patient that he or she is going to be invited to participate in a study.
- Contacting outpatients for recruitment to research studies requires the potential subject's physician to give approval before the subject is contacted. The prospective subject's physician may send a letter informing a potential subject about a study and inviting him/her to participate by contacting the investigator in charge of the study. The letter should not contain any information that may be perceived as undue influence or contain coercive material to potential participants and must be approved by the IRB prior to sending the letter.
- If an investigator wants access to a potential subject's contact information and/or records to invite them to participate in a study and the potential subject's physician is no longer employed by the University of Kentucky, the Chairperson of the Department, in which the physician was employed, should be contacted for permission to access the records. The Chairperson should then send a letter to potential subjects informing them of the study.

Follow-up in Mail Questionnaires

- An investigator may contact potential subjects by mail and enclose a card to be returned indicating the desire to be contacted to participate in a study. Potential subjects may be sent two to three letters, but if the person does not respond the investigator must remove that person from the contact list. Failure to respond cannot imply consent to contact. Letters must be approved by the IRB prior to sending the letter.

Secondary Recruitment

- Secondary recruitment (for example, when an investigator wishes to obtain the names of family members of a subject for a genetic study) should be done by giving a stamped envelope containing the solicitation materials (letter, study brochures, return postcard, etc.) to the subject. The subject is then asked to address the envelope to his or her relative and mail it. If the investigator does not receive a response from the secondary recruit, it is reasonable to ask the study subject to contact the individual to be sure that he or she received the materials. If the person does not respond the investigator should remove that person from the list of potential subjects.

“Passive” Consent – Requires Waiver of Informed Consent

- An investigator may not invite participation of potential subjects by a letter that requires the subject to send back a postcard (or to telephone) only if he or she does **not** wish to participate. Subjects may become unwitting participants if, for example, they never receive the letter, don't read English, or are simply confused by the instructions. This approach also raises privacy concerns for certain types of research (e.g., research involving sexually transmitted diseases or psychiatric illness, or drug or alcohol abuse). IRB only approves “passive” procedure if the federal criteria for waiving informed consent is met.

Finders’ Fees

- Consistent with state law, the UK IRB does not approve finder’s fees in research studies. Finder’s fees are any payments to physicians or other professionals for referring individuals to research studies.

Recruitment Materials

Direct advertising for study subjects is the start of the informed consent and subject selection process and IRB review is required for direct recruitment materials that are intended to be seen or heard by prospective subjects to solicit their participation in a research study. The IRB reviews the final copy of printed advertisements to evaluate the relative size of type used and other visual effects. The IRB assures that the advertisements do not state or imply a favorable outcome or other benefits beyond what is outlined in the consent document and the protocol or include exculpatory language. Advertisements to recruit participants are limited to the information the prospective participants need to determine their eligibility and interest. Examples of direct advertisement include: newspaper, radio and television advertisements, bulletin board announcements, recruitment posters, flyers, dear doctor letters, video recruitment tapes, and Internet postings.

- Claims should not be made in recruitment materials, either 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.
- Recruitment materials for investigational drug, biologic or device studies should not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational. A phrase such as "receive new treatments" leads prospective study subjects to believe they will be receiving newly improved products of proven worth, and is inappropriate.
- Recruitment materials should not promise "free medical treatment", when the intent is only to inform subjects that they will not be charged for taking part in the investigation. Recruitment materials may state that subjects will be paid to compensate for their time and/or travel, but should not emphasize the payment or state the amount to be paid.
- When recruitment materials are to be taped for broadcast, the IRB reviews the final audio/video tape or may review and approve the wording of the recruitment materials prior to taping to preclude re-taping because of inappropriate wording. The review of the final taped message prepared from IRB-approved text may be reviewed through expedited procedures.
- When appropriately worded, the following items may be included in recruitment materials:
 - the name and address of the investigator and/or research facility;
 - the condition under study and/or the purpose of the research;
 - in summary form, the criteria that will be used to determine eligibility for the study;
 - a brief list of participation benefits, if any (e.g., a no-cost health examination);
 - the time or other commitment required of the subjects; and
 - the location of the research and the person or office to contact for further information.

Payment to Research Subjects

- The proposed method and timing of disbursement should not be coercive or present undue influence.
- Payment should not be contingent upon completion of the entire study. Any credit for payment should accrue as the study progresses.
- Payment to participants who withdraw from the study should be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn, unless it creates inconvenience or a coercive practice.
- Payment of a small portion as an incentive may be allowed upon completion of a study when such incentive is not coercive.

- Payment to research participants for participation in studies should not be included as a benefit in the analysis of risks and benefits.
- Any amount paid as a bonus for completion should be reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.
- All information concerning payment, including the amount and schedule of payments should be set forth in the informed consent document.
- Compensation for participation in a trial offered by the sponsor should not include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.
- Payments to the organization or research staff designed to accelerate recruitment and are tied to the rate or timing of enrollment is prohibited.

Guidance materials compiled from OHRP IRB Guidebook: Chapter IV, Consideration of Research Design, "Identification and recruitment of subjects", FDA information sheet "Recruiting Study Subjects" and references 21CFR50.20,21CFR50.25,21CFR56.111(a)(3),21CFR56.111(b), 21CFR 812.20(b)(11)

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