

Policy Number: 30

Title: Recruitment Methods & Tools

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I. Introduction

The identification, initial contact, and recruitment of potential human subjects forms the foundation of the informed consent process. The sponsor, research team, and the IRB share the responsibility for creating a recruitment environment that is ethical and complies with the federal regulations and guidance. The ethical and regulatory responsibilities require consideration of the appropriate procedures for the initial identification, contact, and recruitment of potential subjects. The recruitment process should demonstrate adequate respect for the dignity and autonomy of the potential subjects while honoring and preserving confidential information that may be necessary to directly identify and contact potential subjects, minimize coercion and undue influence, and balance the risks and benefits of the proposed procedures.

II. Recruitment Methods

- A. As part of the Application to Involve Human Subjects in Research, investigators are asked to describe the proposed method(s) to identify, contact, and recruit prospective subjects, and to submit a copy of all related materials/tools for IRB review and approval.
- B. In reviewing recruitment materials the IRB should take into account the purpose of the research, the setting in which the research will be conducted, and be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons [45 CFR 46.111].
- C. IRBs review and approve the identification and recruitment process for each subject population within a proposed study to ensure that the identification and recruitment methods incorporate sufficient safeguards such that the identification and recruitment of all subjects is free of coercion, undue influence and invasion of privacy.
 - 1. Investigators requesting approval to recruit subjects from their own patient population must describe the methods that will be implemented to in order to avoid any real or perceived elements of coercion, undue influence, or conflict of interest in the recruitment of their patients. Please refer to [OPRS/IRB Policy 63: Investigator Financial Interests and Conflicts of Interest](#) for details.

- D. The IRBs are concerned about the potential for breach of confidentiality or invasion of privacy when investigators propose to directly recruit subjects by using confidential documents such as employee, medical or school records to which the investigator does not have legal and legitimate access for the purposes of identifying, contacting, and recruiting subjects.
1. Medical record review for the purpose of identifying, contacting, and recruiting participants is subject to HIPAA regulations. See [OPRS/IRB Policy 49: HIPAA](#).
 2. The review of student records for the purpose of identifying, contacting, and recruiting participants is subject to the rules set forth in the Family Educational and Rights Privacy Act (FERPA). See [OPRS/IRB Policy 47: FERPA](#).

II. Recruitment of Patients

- A. HIPAA regulations apply to the identification and recruitment process if they involve review of medical records. Investigators must obtain prospective HIPAA authorization or apply for a waiver of HIPAA authorization and informed consent before accessing medical records for research purposes. Please refer to [OPRS/IRB Policy 49: HIPAA](#).
- B. When appropriate, the IRBs suggest the use of recruitment tools and strategies which allow potential subjects to initiate contact with the research team to express interest.
- C. In order to minimize the potential for breach of confidentiality or invasion of privacy, the IRBs may require investigators to provide treating physicians with IRB approved recruitment tools, such as flyers or other notices. The physicians may then provide the written information to their patients, and interested individuals may then initiate contact with the study doctors. The process ensures that potential subjects are provided with research related recruitment information while securing patient privacy and confidentiality. Alternatively, the IRB will consider requests for treating physicians to contact the investigators on the patient's behalf if the treating physician documents the patient's approval in the medical record.

III. Family Member Recruitment

- A. The IRBs are concerned about maintaining respect for the privacy of family members who may be identified as potential subjects by probands.
- B. In order to respect and preserve the privacy of family members, the IRBs suggest that investigators develop a strategy that allows subject-probands to provide explicit recruitment tools to family members and thus allow potential family members to initiate contact with the research team to express interest.

IV. UCLA Employee/Student Recruitment

- A. If UCLA employees and/or students are asked to participate in a research study, the investigators may be asked to provide written assurance and indicate in the informed consent form that willingness to enroll in the research study will in no way affect subjects' grades/employment or standing with the University.
- B. The IRBs must evaluate the appropriateness of investigators enrolling individuals they directly supervise or instruct. Such enrollment must be explicitly justified and may require additional protections. See [OPRS/IRB Policy 25: Special Subject Populations–Students & Employees.](#)

V. Recruitment Tools

- A. Investigators must submit all recruitment materials for IRB review and approval prior to implementation and the IRB application must describe how the materials will be used.
 - 1. Recruitment materials may include, but are not limited to, flyers, newspaper, radio or television advertisements, posters, brochures, press releases and web site postings.
 - 2. Web site postings that are limited to basic trial information, such as title, purpose of the study, basic eligibility criteria and study site location, intended for informational purposes and not for recruitment purposes may not require IRB review and approval.
 - 3. The IRB reviews both the information contained in recruitment materials and the modes of communication.
 - 4. Investigators are not required to submit to the IRB the final version of an advertisement produced from an IRB-approved template or script (such as a newspaper, television or radio advertisement). However, investigators are responsible for ensuring that the final product matches the IRB-approved template or script. Investigators are responsible for maintaining copies of the final product in the research files for possible IRB audit.
- B. IRBs suggest that advertisements include the following items:
 - 1. Name, address, and departmental affiliation of the investigator
 - 2. Condition under study or the purpose of the research
 - 3. Criteria that will be used to determine eligibility (in summary form and usable by the intended audience)
 - 4. A brief list of significant risks and possible benefits directly resulting from the research procedures

5. Time or other commitment of subjects
 6. Contact information
 7. Clear indication that the recruitment is for a “UCLA Research Study”
- C. Recruitment materials may describe payments for participation, but a payment should not be characterized as a benefit and should not be the focus of the material.
 - D. For clinical trials, recruitment materials should not make any claims, either explicitly or implicitly, that the experimental agent is known to be safe or effective, or equivalent or superior to any currently available treatment. Additionally, recruitment materials should not promise a certainty of cure or of other favorable outcomes or benefits beyond what is outlined in the consent and the protocol.
 - E. For research involving the use of experimental drugs or devices, recruitment tools should clearly indicate whether a test agent is FDA approved for the given indication.
 - F. Recruitment tools should not use terms such as “new treatment,” “new medication” or “new drug.”
 - G. For studies involving the use of placebo, recruitment tools should describe the possibility of receiving placebo.
 - H. Recruitment tools should not promise “free medical treatment” when the intent is to say that subjects will not be charged for taking part in the research.
 - I. Recruitment tools should not include any exculpatory language appearing to waive any potential subjects’ rights or any liability for negligence.

VI. Screening Activities

- A. All screening procedures are part of the IRB review of proposed research. Although screening activities do not necessarily result in data that are used to evaluate study outcomes, such procedures are reviewed by the IRB during consideration of proposed protocols in order to ensure appropriate consent is obtained, when required, and so that all potential risks of invasion of privacy to subjects may be evaluated.
- B. Screening procedures may include: (a) any interaction or intervention with the subjects to determine eligibility that would not otherwise have been performed if not for the study, or (b) accessing the results of interventions that were performed for purposes other than the study. In other words, collecting data directly from subjects such as through written screening tools or oral responses to questionnaires, or accessing private information, i.e., grades, medical test results, legal records, or any other non-public information linked to a

potential subject, for purposes of eligibility screening constitutes a research intervention or interaction that must be reviewed and approved by the IRB.

- C. Investigators are asked to provide the following information regarding screening procedures:
1. The screening instruments which may be used
 2. Data, if any, that will be acquired
 3. Whether the investigator intends to retain data from subjects who are ineligible upon screening
 4. How the data collected during the screening procedures will be stored.
- D. The IRB and investigators are required to consider the ethical and regulatory informed consent requirements for data collected through screening procedures. If such screening activities will take place prior to the subject providing informed consent for participation in the research, the IRBs may waive the requirement for informed consent or signed informed consent for screening activities in accordance with 45 CFR 46.116 and 45 CFR 46.117 if the screening activities meet the criteria for such waivers. For FDA-regulated research, the IRB may only waive the requirement for signed informed consent for screening activities in accordance with 21 CFR 56.109(c)(1). Please refer to [*OPRS/IRB Policy 29: Informed Consent Process and Documentation*](#) for details regarding these waivers.
1. If screening activities will take place only after the subject has provided informed consent for participation in the research, then the waivers described above are unnecessary.
- E. If the IRB determines that screening activities for a particular research study qualify for a waiver of signed informed consent, the investigators are asked to develop a consent script to screen for research to be used for the oral informed consent process. Please see the OPRS website (<http://www.oprs.ucla.edu/human/forms/screening>) for the Sample Consent Script to Screen for Research. For sample screening materials designed for non-medical research, see <http://www.oprs.ucla.edu/human/forms/informed-consent-general>.
- F. HIPAA regulations apply to the screening process if it involves review of medical records. Investigators must obtain prospective HIPAA authorization or apply for a waiver of HIPAA authorization and informed consent. Please see [*OPRS/IRB Policy 49: HIPAA*](#) for details.

Regulations

21 CFR 50.20
21 CFR 56.111
45 CFR 46.111
45 CFR 46.116
45 CFR 46.117

References:

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research, April 18, 1979.

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>

FDA, *IRB Information Sheets: Recruiting Study Subjects*, 1998 Update.

<http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting>

FDA, *IRB Information Sheets: Screening Tests Prior to Study Enrollment*, 1998 Update.

<http://www.fda.gov/oc/ohrt/irbs/toc4.html#screening>

OHRP, *Guidance on Institutional Review Board Review of Clinical Trial Websites*, September 20, 2005. <http://www.hhs.gov/ohrp/policy/clinicaltrials.pdf>

Attachments:

OPRS-4 UCLA OPRS Human Research News, "Informed Consent Procedures for Screening Potential Research Subjects and Interim Protocol Requirements for Research Banking Human Tissue or DNA," December 14, 2001.
http://www.oprs.ucla.edu/human/news/item?item_id=181264

OPRS-64 UCLA IRB/OPRS General Consent to Participate in Research Screening.
<http://www.oprs.ucla.edu/human/forms/informed-consent-general>

OPRS-69 UCLA IRB/OPRS Oral Consent Script.
<http://www.oprs.ucla.edu/human/forms/informed-consent-general>

OPRS-83 UCLA IRB/OPRS General Screening Consent Script
<http://www.oprs.ucla.edu/human/forms/informed-consent-general>