

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 or situation that is studied. All recruitment efforts must respect personal rights to privacy and confidentiality, be compliant with Health Insurance Portability & Accountability Act (HIPAA) regulations or other privacy regulations where applicable and avoid coercion or undue influence 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 students as research subjects, please review the "Guidance for enrolling University Students as Research Subjects" document or the "Guidance for Enrolling K-12 Students as Research Subjects".

Describe all potential recruitment activities in the IRB application and include any recruitment or advertising materials.

Contacting Prospective Subjects Who Were Identified From Medical Records

Access:

- Access to review medical records for review of protected health information (PHI) for the purpose of designing a research study or identifying potential subjects is limited to individuals in the covered entity. Researcher's outside the covered entity must request access from the UK Healthcare Privacy Officer.
- In the IRB application, submit a request for a Waiver of HIPAA authorization in order to directly access or obtain PHI from the covered entity, including from the Center for Clinical and Translational Science (CCTS) Data Trust, Bioinformatics, or other healthcare entity.

Contact where a treatment relationship exists:

- A healthcare provider who has a treatment relationship with a prospective research subject may contact or approach patients about participation in an IRB approved protocol. The provider 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.
- 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 or undue influence 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.

Contact where no treatment relationship exists:

- For a hospital-based study, a potential subject's provider must give approval before the patient is contacted by an investigator. The electronic health record may alert providers that a patient is a potential candidate for a research study. The provider may choose to inform the patient about a particular study and indicate in the record that the patient is interested in being contacted to learn more about the study. 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.
- For post-hospitalization follow-up studies (either prior to discharge or at a follow-up visit), researchers must inform prospective participants that they may be contacted. For example, a flyer could be included in discharge materials, indicating the patient may be called and invited to take part in a voluntary research survey for which he/she is free to decline.

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

- Contacting outpatients for recruitment to research studies requires the potential subject's primary provider or applicable specialist related to the study condition, to give approval before the subject is contacted. The prospective subject's provider or specialist may correspond with a potential subject about a study and invite him/her to participate by contacting the investigator in charge of the study. The communication should not contain any information that may be perceived as undue influence or coercive to potential participants and must be approved by the IRB prior to sending.
- 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 provider is no longer employed by the University of Kentucky, the Chairperson of the Department, in which the provider 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 relies on an existing subject, sharing solicitation materials (letter, study brochures, return postcard, etc.) with other potential recruits. For example, an investigator may employ this chain-referral method to recruit family members of a subject for a genetic study. To respect privacy, investigators generally should allow the potential recruits to decide whether to respond to the recruitment material, rather than make direct "cold" contact with the potential recruits. Name or contact information should not be shared with the investigator without permission from the potential subject.
- Response Driven Sampling (RDS) is a type of secondary recruitment. Sometimes referred to as "snowball" recruitment, this method may be used to reach specific socially disadvantaged "hidden populations" that need representation in health research. The difficult to reach populations may include drug users, sexual and gender minority participants, and individuals with HIV. The method may involve providing remuneration to current research subjects who refer individuals to the research project. The practice is not considered the same as "finder's fees" which is the prohibited practice of compensating healthcare professionals for referrals.

While not prohibited, there are ethical issues to consider with snowball recruitment. The IRB may approve under certain circumstances. Investigators should provide the IRB with materials used, a detailed description of the procedures involved, and justification for using this method in the context of the research, study population, and other attempted recruitment strategies. Current subjects should not feel obligated to provider referrals and they should be advised not to pressure potential recruits. The IRBs will makes a case-by-case decision on such requests based on study context, study population, other attempted methods of recruitment, potential subject-level or long-term health benefit and other applicable considerations.

Clinical Research Website Listings

Generally, the IRB is not required to review clinical trial website postings, (e.g., clinicaltrials.gov), unless the information goes beyond directory listings of basic descriptive information. The following federal guidance documents provide rational and interpretation of "basic descriptive information":

- FDA Recruiting Study Subjects - Information Sheet
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm>
- Office for Human Research Protections (OHRP) Guidance ON IRB Review of Clinical Trial Websites -
<http://www.hhs.gov/ohrp/regulations-and-policy/guidance/clinical-trial-websites/index.html>

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

Recruitment using social media

- Using social media and online techniques must be approached with caution and regard for applicable policies and guidance such as the [UK Social Media Policies and Guidelines](#) (AR 10:4) and the online platform's Terms of Use (TOU) and Conditions or established policies and procedures (e.g., [Craigslist FAQ](#)).
- IRB review and approval prior to implementation of social media or online advertising is required. Describe specific media intended for use. Provide a copy or screen shot of the ad or post including text, images, tags, etc. Indicate hashtags that will be associated with the post if applicable. Indicate where the ad will be posted (e.g., University site/page, Clinical Trial page, Paid Online Advertising)
- Posting ads directly on others personal pages (e.g. personal Facebook page) or linking ads to individuals is discouraged as it may be considered an invasion of privacy.
- Provide a process for handling user-generated content including frequency of monitoring and individual who will review comments or public postings. User comment function may be disabled on some social media platforms. This option may be useful for pages that have potential to elicit comments that could bias study results or inadvertently disclose private or confidential information (e.g., un-blind treatment, effectiveness claims).
- If making or responding to comments, identify your views as your own. If you identify yourself as a UK faculty or staff employee online, it should be clear that the views expressed are not necessarily those of the institution.
- If posting in Online Classified Ads or Job Posting Websites, (e.g., Craig's List or LinkedIn), limit posting to one appropriate category such as miscellaneous or health/medical. Posting in multiple categories may be perceived as nuisance or harassment by the venue's users. In addition, identify and comply with the TOU including privacy policies, prohibited content, posting location and frequency.
- Seek permission to access or interact with closed groups or online forums. As a rule, do not engage online in a manner that would be improper in an equivalent live setting. For instance, it would be inappropriate to show up unannounced to a private support group meeting to recruit research participants. Obtain approval and request an introduction from the administrator or moderator before engaging in a similar activity online.
- **Recruiting on TikTok:** In June 2023, the federal government issued an interim rule that prohibits use of the social media app TikTok on any device being used in furtherance of a contract or project funded by federal monies. That includes UK-owned devices, as well as devices that are the employee's own but used for work as part of a bring-your-own-device ("BYOD") program. There are still some questions as to the scope of this rule, and the UK Office of Legal Counsel is working to provide more general guidance to the university community. Until further university-wide advice is given, Legal Counsel advises that UK employees should not have TikTok on any devices being used for work or use TikTok for research study recruitment purposes.

"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, do not 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

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

- 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 Bonuses

- A recruitment bonus is a additional payment from a sponsor to a researcher or UK based on rate or timing of recruitment is prohibited (e.g., additional payment beyond fixed negotiated fee to accelerate recruitment). This may place potential subjects at risk of coercion or undue influence or cause inequitable subject selection.

Recruitment Materials

Public-facing advertising with the intent of subject recruitment are subject to UK public relations review. For instructions and optional recruitment services see the [Participant Recruitment Advertising](#) website.

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.

Obtain approval for placement of advertising in facilities or common areas. Follow the [University Signage policy](#) administered by the [Office of University Events](#). Some communities have anti-litter ordinances that prohibit placing flyers in areas such as on utility poles or parked cars.

- Advertising must:
 - state clearly that the program of study is research;
 - show affiliation with the University of Kentucky;
 - provide contact information; and
 - be respectful and appropriate.
- 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 that are inconsistent with Food and Drug Administration (FDA) labeling.
- 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.
- Noting that the study is IRB approved may be misconstrued by potential participants as an endorsement or approval of an investigational product or intervention.
- 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;

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

- ❑ a brief list of participation benefits, if any (e.g., a no-cost health examination);
 - ❑ the time or other commitment required of the subjects;
 - ❑ *that subjects will be compensated (see restrictions below); and
 - ❑ the location of the research and the person or office to contact for further information.
- *Recruitment materials may state that subjects will be paid to compensate for their time and/or travel. For Phase I-III clinical trials and other significant risk research it is not permissible to state the amount to be paid to potential subjects. For all other research protocols the IRB will make the decision of whether amount to be paid may be posted in the recruitment materials on an individual protocol basis. Payment should not be emphasized in the recruitment materials. Generally, use of the word “paid” or equivalent term in an advertisement headline would be emphasizing and not permitted for greater than minimal risk research. UK does not allow a company name to be included for gift cards on public advertising, as it may be misconstrued as an endorsement. For recruitment where a limited number of respondents will be entered to receive a gift card or incentive, the term “drawing” is preferred over “raffle” in public ads.
 - 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.

Pre-screening Interested Potential Subjects Who Contact the Investigator in Response to Advertising

Pre-screening of potential subjects to determine initial eligibility and interest in a study is considered part of the recruitment process and therefore requires IRB review. The IRB should assure the procedures followed adequately protect the rights and welfare of prospective subjects.

Pre-screening with interested candidates may be done in person, over the phone, or online. If prescreening information provided by the potential subject will be retained, additional requirements may apply. See the Guidance on [Pre-screening Potential Subjects to Determine Eligibility \[REDCap Instructions\]](#)

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. For select studies, the IRB may permit including payment in the key information section of the informed consent.
- 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.

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

- 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.

Ongoing Participant Communication and Outreach

If you plan to provide outreach communications to enrolled participants via newsletters, study-specific social media or webpages, indicate plans in the Research Description portion of the IRB application. If the IRB has reviewed and approved the outreach plan, the individual participant-facing materials or communications do not require additional IRB review, as long as they do NOT involve recruitment, compliance, or retention messages. Participant communications that include recruitment referrals or encourage retention/compliance, must be reviewed by the IRB.

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)

University of Kentucky Office of Research Integrity

Rev 1-16-24 J:\Master Outreach Documents\Survival Handbook\D - Guidance-Policy-Educational\7-Recruitguidance.doc