

RECRUITMENT METHODS

Description

The IRB reviews the process of screening, recruiting, and determining eligibility. The IRB reviews proposed recruitment procedures and advertisements to ensure that they do not violate the regulatory requirements of consent. For more information on advertisements (including advertising guidelines, internet advertising, etc.) please see the Investigator Guidance Series: Advertisements.

RECRUITMENT GUIDELINES

Advertising

Advertising is a common method used by researchers to recruit potential participants. Please refer to the Investigator Guidance Series: Advertisements for the University of Illinois Urbana-Champaign IRB advertising guidelines.

In-Person Recruitment

A researcher may have direct contact with potential participants. For example, a professor is conducting a psychology study and may have students who would be interested in participating in a study. The professor would like to invite his students to participate in his research study. Or, a treating physician is conducting a study on diabetes and may have patients who would be interested in participating in the study. The treating physician would like to invite some of her patients to participate in the research study. In both of these examples, the researcher has direct contact with potential participants and plans to introduce the study directly. The researcher must present a plan to the IRB describing how contact is made with potential participants and how coercion is eliminated or reduced.

Recruitment Letters

Recruitment letters may be sent to potential participants. A recruitment letter template is available (on the IRB website under Forms) with suggested language. If an investigator plans to send a recruitment letter, consider the following issues when formulating a recruitment plan:

- Do you plan to re-send the recruitment letter (and questionnaire or survey, as applicable) to individuals who do not respond to the initial mailing? If yes, you should describe this plan in your initial letter so respondents do not become upset if they receive multiple mailings.
- Do you wish to include a return postcard in the initial mailing on which potential participants may indicate whether they have interest? This model may prevent multiple mailings and allow the investigator to know who is interested and who should not be contacted any further.
- Is the research topic of a sensitive nature? For example, if a study is looking for volunteers for a study regarding sexually transmitted diseases, efforts must be made to protect the privacy and confidentiality of the potential participant. An investigator cannot guarantee that the mailing will be opened by the intended recipient. Efforts should be made to ensure that the return address or any materials that will be sent back are vague and do not embarrass the potential participant. It is important to consider what impact the materials may have on the potential participants' privacy and confidentiality and to take appropriate precautions to avoid any real or perceived breach of privacy or confidentiality.
- Do you plan to follow-up by telephone? If so, you should describe this plan in your initial letter so respondents do not become upset if they receive an unsolicited phone call. Further, you should outline a plan or a script so that research staff is prepared, e.g. whether to leave a message (keep in mind privacy and confidentiality must be protected), what information to provide to the respondent, etc.

Please contact the OPRS Office at (217) 333-2670 or irb@illinois.edu for additional guidance.

Telephone Calls

Generally, the University of Illinois Urbana-Champaign IRB does not allow “cold calling” in order to recruit participants. Cold calling is the process of contacting prospective participants, via telephone, who were not expecting such an interaction. If a researcher wishes to contact potential participants by telephone, a recruitment letter should be sent prior to the telephone call. The IRB strongly recommends that this letter include contact information for a potential participant to call in the event they chose to “opt out” of forthcoming telephone contact. This policy is designed to protect the privacy of potential participants. It should be noted that the IRB generally does not consider cold calling to be contacting an individual in relation to a career or position at their place of business. Potential participants contacted while at work may be acceptable as long as such a recruitment method is clear in the application and approved by the IRB.

If individuals have given prior written permission to be contacted by researchers, the IRB will allow the researcher to contact those individuals by telephone without sending a letter recruitment letter before the call. Please see the Simple Referral Template (available on the IRB website under Forms) as an example.

Researchers may want to contact individuals using a random sampling method. A random sampling method means the investigator doesn’t have any information about a person other than their contact information. Or, the investigator is simply calling randomized phone numbers. The IRB will approve this recruitment strategy on a case-by-case basis. There should be sufficient safeguards to protect privacy and the study would likely need to be minimal risk.

Recruitment and Enrollment of U.S. Military Personnel

For research subject to Department of Defense regulations, additional protections for military research participants are required as follows:

- Officers are not permitted to influence the decision of their subordinates
- Officers and senior non-commissioned officers may not be present at the time of recruitment.
- Officers and senior non-commissioned officers have a separate opportunity to participate.
- When recruitment involves a percentage of a unit, an independent ombudsman is present.

Recruitment through an Established Database Containing Health Information

Potential participants that are identified via query of medical records or other established database(s) must be referred to the study team by a treating physician or, as appropriate, the database manager. In this model, the treating physician or database manager contacts the participant and asks whether he/she will allow the research team to make contact regarding the study. The treating physician or database manager makes a note indicating whether the potential participant agrees to be contacted and will keep this on file. The treating physician or database manager may use the Simple Referral Template (available on the IRB website under Forms) to collect the potential participant’s contact information and written permission to be contacted.

Alternatively, the researcher may create a recruitment letter to be approved and sent from the treating physician or the database manager (cost of sending the letter is the responsibility of the researcher). The letter must state that the patient is being contacted on behalf of the researcher. The purpose of this letter is to inform participants about a study and ask them to contact the researcher.

“Snowball” Sampling

Snowball sampling is a recruitment method in which an investigator enlists the help of a research subject in identifying, and possibly recruiting, additional subjects. It is useful when the investigator may not have access to a population of potential subjects who meet inclusion criteria, which might be stigmatizing.

Snowball recruitment where the researcher obtains names and contact information from one individual for another one, particularly for research involving sensitive topics, is generally not considered appropriate by the UIUC IRB. Using such a method could result in the researcher obtaining information about an individual that is sensitive and private without their permission. Alternatively, the researcher should ask other subjects to pass along flyers, emails, information sheets, etc. that contain contact information for the researcher to prevent a breach in confidentiality or an

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invasion of privacy. In instances where the research topic is not sensitive (i.e., consumer opinions), a snowball recruitment method where one person provides the name and contact information may be acceptable. If the topic is sensitive or personal, snowball sampling may be justified, but care should be taken to ensure that the potential subjects' privacy is not violated.

Some research topics may necessitate the participant to provide names and contact information of others, such as in a case where the intent of the research is to study the interactions of co-workers. Consideration should be given to the feasibility of the participant obtaining approval from others prior to providing contact information to the researcher.

The steps taken to minimize the risk of violating an individual's privacy should be articulated in the recruitment section of the protocol. Current participants cannot receive incentives or compensation for referrals. Current participants should also know that they will be asked to provide the names of other potential recruits, but that they have the right to decline to provide this information.

One means of reducing the risks in snowball recruitment is for the researcher to gently ask subjects whether they would be willing to pass some information about the study they just completed to other potential subjects. The researcher may give the original subject an information sheet or flyer that they can give to people they think might be interested and qualified. Then these potential participants can contact the researcher if they are interested. The researcher must provide the IRB with a copy of the recruitment item (which must include all of the same information that is in the initial recruitment script) he/she will give to the initial contact to distribute. If the potential subject were interested in study participation, they would be free to contact the researcher.

Use of Medical Records for Recruitment

The University of Illinois Urbana-Champaign IRB requires investigators to request a waiver of authorization if using medical records for screening or recruitment. Please refer to the **Appendix A** of this document for FAQs regarding recruitment of participants for research by University of Illinois Urbana-Champaign researchers and research staff acting on behalf of clinicians.

Recruitment of Students and Student-Athletes

Students and student-athletes are particularly vulnerable to the potential for undue influence on enrollment of research by instructors, coaches, and others within the academic institution. Please review separate guidance that address those specific groups for more information on recruiting them.

Points to Address

New Study Application:

1. **In Section 8:** In question 8.7, all appropriate methods of recruitment should be selected.
2. Please attach all recruitment materials for review. This includes recruitment letters, advertisements, flyers, scripts, etc. If a recorded advertisement is planned, audio or video files should be attached. Please note that if the final recorded version is not available at the time of review, the IRB must review the final script. Once the final audio or video is prepared from the IRB approved script, it must be submitted via amendment.
3. **In Section 8:** In question 8.8, please describe the process of screening, recruiting and determining eligibility in detail.

References & Links

Research Guidance

Document: Advertisements

See "Advertisements":

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Office for the Protection
of Research Subjects

Research Guidance Document

*FDA Information Sheet:
Recruiting Study Subjects*

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recruiting-study-subjects>

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