



RECRUITMENT METHODS

Description

The IRB reviews recruitment methods to ensure that it does not interfere with the equitable selection of participants. Additionally, the IRB considers recruitment to represent part of the consent process. The IRB reviews proposed recruitment processes and advertisements to ensure that they do not violate the regulatory requirements of consent. For more information on advertisements (including advertisement 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 Utah 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 the 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 exactly 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.

Telephone Calls

Generally, the University of Utah 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

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call in the event they chose to “opt out” of forthcoming telephone contact. This policy is designed to protect the privacy of potential participants.

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.

VA Research: VA researchers must make initial contact with a prospective participant in person or by letter prior to initiating any telephone contact unless there is written documentation that the participant is willing to be contacted by telephone about the study in question or a specific type of research (e.g. cardiovascular studies, etc.). During the initial telephone contact, a phone number or other means so that the prospective participant can verify that the study is VA research. Requesting social security numbers by telephone is prohibited. Any subsequent telephone contact must be limited to the scope of the IRB-approved protocol.

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.

Collection and Maintenance of Information for the Purposes of Recruitment

If a database or registry is created with the intent of using information in order to recruit participants for research purposes, and has information in it that WILL NOT be analyzed for research purposes, IRB approval is not required. University of Utah departments may create and maintain a research recruitment database or registry of individuals who have given permission to be called in the future for research opportunities. The information in the database must not contain information that will be analyzed for research. If the only purpose of the database is to contact individuals in the future to tell them about research opportunities, IRB approval is **not required** since information in the database will not be analyzed for research purposes.

A data manager should ensure the proper confidential storage of the information. When contact information is to be shared with multiple investigators, the data manager must verify IRB approval (including specific approval of the recruitment method) prior to releasing contact information to the interested investigator. Initial contact procedures must be approved by the IRB for each individual study. Informed consent procedures must also be approved by the IRB for each individual study.

If a database or registry collects information for recruitment but also collects additional information that will be analyzed for research purposes, IRB approval is required for that project.

Collection of Health Information

If information obtained from a medical record is included in a recruitment database, IRB approval and informed consent/authorization is required for creation of the database in order to satisfy HIPAA. Also, if medical records are screened as a part of the recruitment process, IRB approval is required (see “Use of Medical Records for Recruitment” below or refer to Appendix A of this document).

Participant Pools

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Some University of Utah departments create participant pools that collect contact information for recruitment in research studies. These participant pools typically collect additional information for research purposes. Since the participant pool is not only a recruitment resource but also collects and stores additional data about students that can be analyzed in the research, IRB approval is required. Also, Students are considered a vulnerable population (see the Investigator Guidance Series: Research Involving Students).

Recruitment through an Established Database Containing Health Information

Potential participants that are identified via query of the University of Utah Health Sciences Center’s Enterprise Data Warehouse (EDW), the Utah Population Data Base (UPDB), 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.

Use of Medical Records for Recruitment

The University of Utah 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 Utah researchers and research staff acting on behalf of clinicians

Points to Address

IRB Application

- 1. Study Information:** The following questions are asked:
 - How will participants be recruited or identified for inclusion in the study?
 - Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):
- 2. Documents and Attachments (Recruitment Materials, Advertisements, etc.):** Please attach all recruitment materials for review in the sub-section entitled Recruitment Materials, Advertisements, etc. This includes recruitment letters, advertisements, flyers, scripts, etc.

References & Links

<i>Investigator Guidance Series: Advertisements</i>	See “Advertisements”: http://www.research.utah.edu/irb/quidelines/investigator_guidance.html
<i>FDA Information Sheet: Recruiting Study Subjects</i>	http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting
<i>Recruitment Letter Template</i>	See the IRB HIPAA Forms Menu: http://www.research.utah.edu/irb/forms/healthScienceForms.html
<i>Simple Referral Template</i>	See the IRB HIPAA Forms Menu: http://www.research.utah.edu/irb/forms/healthScienceForms.html

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Appendix A: Frequently asked questions (FAQs) regarding recruitment of participants for research by University of Utah researchers and research staff acting on behalf of clinicians

1. Is research staff allowed to access their Principal Investigators' clinic schedules and look for potential research participants?

Yes, as long as this procedure was approved by the IRB. Research staff, listed as authorized personnel on the IRB submission, may review the list directly at the clinic site and identify potential participants.

a. Is research staff allowed to access these patients' medical records while looking for potential research participants?

Yes, as long as this procedure and a HIPAA waiver for recruitment was approved by the IRB. The research staff, listed as authorized personnel on the IRB submission, may access the patients' medical records and record pertinent information such as contact information and medical information to assess the pre-eligibility of the potential subject.

2. Is research staff allowed to approach a potential participant while in the clinic?

Yes, as long as this procedure was approved by the IRB and only after the physician has informed his patient that someone from the research team will come and talk to him/her and the patient has indicated his/her willingness to talk to the research team.

3. If potential participants do not respond to an initial IRB-approved letter, is it appropriate to follow-up with a phone call?

Yes, if the plan for follow-up is addressed in the IRB-approved letter. If potential participants do not respond to the letter within a given timeframe, the researcher or someone from the research team may call them.

4. After a researcher obtains information from a treating physician or from medical records, can someone from his/her research team call the participant directly, without previously mailing out a letter?

No. "Cold calls" outside of contacts in a clinic setting (e.g. waiting room) are not acceptable.

5. Can a researcher record available medical information from the chart to assess eligibility and suitability of the potential participant prior to that individual giving informed consent and authorization?

Yes, as long as this procedure and a HIPAA waiver for recruitment was approved by the IRB. The researcher may record the minimal information needed in order to contact eligible participants.

6. Which screening activities can be performed by researchers within a covered entity prior to obtaining the participants consent and authorization?

Researchers within a covered entity can pre-screen potential participants by accessing the available information required from the patient's medical records if a HIPAA waiver for recruitment was approved by the IRB. However, researchers may only record and remove the minimal information required to contact eligible participants in order to describe the study to them and seek their authorization for participation. Any additional screening tests required to determine the eligibility of the participants should be performed only after the consent form and authorization have been obtained from the participant.