

GUIDELINE FOR RECRUITMENT METHODS AND MATERIALS

Recruitment of potential research subjects is the initial step of the informed consent process. As such, RSRB review of recruitment methods and materials is essential to ensure the selection of subjects is equitable, is free from coercion and undue influence, and that subject privacy is protected. For the RSRB to adequately make this review determination, the Investigator must provide the RSRB a description of the recruitment plan, including methods and materials to be used (refer to the RSRB [Protocol Templates as guidance](#)). This document supplements OHSP Policy 703 Recruitment and Subject Payment to provide additional guidance to Investigators regarding recruitment plans and methods, as well as requirements when the RSRB is the Reviewing IRB.

RSRB approval is required for subject recruitment materials **prior to use**, including, but not limited to:

- Recruitment letters
- Scripts for telephone or in-person discussion
- Flyers, posters, postcards, newspaper ads, press releases intended for recruitment with study team contact information
- TV and/or radio spots
- Websites/internet ads
- Electronic mailings (e.g., email, text)
- Social media pages, ads, blogs, tweets, etc.

Recruitment methods and materials must be consistent with the information contained in the protocol materials submitted to the RSRB. Any changes to RSRB approved recruitment methods or materials, or any changes to the recruitment plan, must be submitted to the RSRB as an amendment for review and approval prior to use.

Table of Contents to Topics:

1. [What to Consider When Developing a Recruitment Plan](#)
2. [What to Consider When Developing Recruitment Materials](#)
3. [Direct Advertising](#)
4. [Access to Potential Subjects](#)
5. [Recruiter/Receptionist Scripts & Screening Logs](#)
6. [Recruitment and Future Contact Databases](#)
7. [Investigator Checklist – Summary of Criteria for RSRB Approval](#)
8. [Review of Recruitment Materials When the RSRB is the Reviewing IRB](#)
9. [Watermarked Recruitment Documents When the RSRB is the Reviewing IRB](#)

1. What to Consider When Developing a Recruitment Plan

a) Feasibility assessment

A feasibility assessment can be based on prior experience recruiting the population, assumptions based on expertise with this population, or the literature. When appropriate to the study design, the Investigator should assess the feasibility of meeting the recruitment goal. The following items should be addressed:

- Identify where subjects will be drawn from (e.g., hospital clinic, treatment center, nursing home, student pool).
- How many potential subjects are available in the targeted recruitment area or facility?
- If recruiting from multiple sites, approximately how many subjects are anticipated from each site?
- What percent of individuals will be screened for eligibility? What percent would be eligible and what percent would consent (i.e., contribute to total enrollment goal)? Be aware of underestimating the length of time it may take to meet enrollment goals and consider how a longer enrollment period could affect the outcome of the study. It may be helpful to include a flow chart of the planned recruitment funnel to help identify where potential subjects may be lost and where techniques could be implemented to enhance recruitment.

b) Anticipated recruitment period

Based on the planned rate of accrual, how many subjects per day/month/year will be enrolled? How long will it take to enroll all the subjects needed for the study?

c) Plans for the identification and recruitment of subjects

The University of Rochester prohibits “cold-calling” of potential research subjects. See Section 4 below. This description should include how the population will be identified, how initial contact will be made with potential subjects, and whether those making initial contact have **routine access** to the subjects' identities and the subjects' information. Describe the setting in which an individual will be interacting with the study team (e.g., clinic, hospital, study site, community location). If applicable, describe proposed outreach programs for recruiting women, minorities, and other underserved populations as subjects in clinical research.

NOTE: As with participation of students in research, participation of UR employees is acceptable; however, when there is the potential for employees to be recruited (even when not the targeted population) recruitment methods should describe how undue influence will be minimized (e.g., the subject cannot be a direct subordinate of the Investigator).

d) Specify any advertising that will be performed

Subjects may be recruited through a variety of methods, including but not limited to: print advertising, the internet and social media (UR Health Research webpage and Facebook page), electronic newsletters and ListServes, research subject registries (ResearchMatch.org and the UR Research Participant Registry), paid TV and print advertising, and outreach/community engagement activities such as fairs and festivals. These ads should be targeted to the population of interest, and, if possible, reviewed with a representative group of that population to maximize the impact of the advertisement plan.

e) Evaluation of recruitment plan

How will the recruitment plan be evaluated to determine whether enrollment goals are being met? Indicate if any tracking tools will be used to determine recruitment methods that are successful or that changes may need to be implemented.

2. What to Consider When Developing Recruitment Materials

- a) Materials must clearly state that the purpose for recruitment is for research.
- b) Recruitment materials should generally contain the following elements:
 - The name of the Investigator or research facility (letterhead is acceptable if it includes this information).
 - The condition under study or the purpose of the research.
 - A brief summary of the criteria used to determine eligibility for the study (e.g., healthy adults between X and U age, children with diabetes ages X to Y).
 - The location where the research will be conducted.
 - Time or other commitments required by the study.
 - A brief list of benefits, if any. Note: Payment to subjects for participation is not a benefit.
 - Payment, if applicable – Note: The terms “payment” or “reimbursement” are preferred for use on recruitment and advertising materials rather than “compensation”.
 - The person or office to contact for further information.
 - Using generic terms, like *Study Coordinator at INSERT*, rather than a specific person’s name is advisable to prevent amending the recruitment materials.
 - For multi-site research, create generic materials without site-specific information for RSRB review and approval (each participating site may then enter the site-specific information without further RSRB approval).
- c) Additional considerations:
 - Information provided in the recruitment materials may indicate that reimbursement or payment will be provided. If a payment amount is indicated, avoid emphasizing the payment or amount to be paid. Whether the amount of payment is included in the ad is left to the discretion of the RSRB. Refer also to the *Guideline for Subject Payment*.
 - Excessive monetary amounts that could be interpreted as inappropriate or posing undue influence may not be offered.
 - There should be no enticements, such as “free treatment”, “free medical care”, or “free medication.”
 - “Treatment” should not be used, as this implies medical care, and not a research study.
 - For drug, device, or biologic studies:
 - Recruitment materials may not claim, either explicitly or implicitly, the superiority, safety or effectiveness of the drug, biologic, or device. A phrase such as “you will receive new treatments” incorrectly implies that all study subjects will receive products of proven worth newly approved by the FDA.
 - The terms “new treatment,” “new medication,” or “new drug” may **not** be used because it inappropriately implies that safety and effectiveness have been determined. It must be clear that the drug or biologic is investigational, meaning non-FDA approved.
 - Proprietary names of study products may not be used.
 - Recruitment materials must not include the promise of “free medical treatment” when the intent is only to say the subjects will not be charged for taking part in the research.

3. Direct Advertising

- a) All direct advertising for potential subjects (i.e., advertising that is intended to be seen or heard by prospective subjects) must be submitted to the RSRB and approved prior to implementation.

- **Documents that should be submitted for review:**

- Websites, web postings, postcards, [ResearchMatch request forms](#), newspaper, radio and TV advertisements, press releases (intended for recruitment that includes contact information), posters, flyers, scripts (phone/oral) that are intended for prospective subjects, doctor-to-patient letters.

- **Documents that do not need to be submitted for review:**

- Communications intended to be seen or heard only by health professionals, such as "dear doctor" letters and doctor-to-doctor letters (even when soliciting for study subjects),
- News stories or press releases (without specific contact information),
- Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors,
- Directory listings of clinical trials on the internet: According to the FDA*, RSRB review and approval of listings of clinical trials on the internet provide no additional safeguard and is not required when the system format limits the information provided to basic information, such as: the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information.

*FDA Information Sheet – Recruiting Study Subjects

(**Note:** Although RSRB approval of the language provided in the listing service may not be required, as with all recruitment methods, if the listing is intended for recruitment purposes, the use should be identified in the protocol/application as such.)

Examples that do not require prospective RSRB approval:

- *National Institutes of Health (NIH) ClinicalTrials.gov*
- *National Cancer Institute's cancer clinical trial listing (Physician Data Query [PDQ])*
- *Government-sponsored AIDS Clinical Trials Information Service (ACTIS)*
- *UR Research Participant Registry on the University of Rochester Medical Center's health research website*

- b) When advertisements are to be recorded for broadcast, the Investigator should request RSRB review and approval of the wording of the advertisement (i.e., the script) prior to taping to avoid having to re-tape due to inappropriate wording.
- c) If an ad will be posted on the Internet, the Internet address (URL) and/or content of the webpage(s) or internet ad must be provided with the protocol submission so that the RSRB can verify the website material.
- d) The RSRB must review both the information contained in the advertisement, the mode of its communication as well as other visual effects, such as type size. This review is to confirm the procedures for recruitment do not unduly influence participation and the recruitment material does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol. This is especially important when a study may involve subjects who are likely to be vulnerable to undue influence, for example, financially constrained subjects, students, or employees.

4. Access to Potential Subjects

The University of Rochester prohibits "cold-calling" of potential research subjects. "Cold-calling" is the practice of Investigators or other research staff, who do not have routine access to potential subjects' identity or subjects' information, initiating contact with the potential subject based on their

prior knowledge of private information. See 4b below for procedures to follow if the Investigator does not have routine access.

- a) Protecting privacy is an additional concern that must be considered in developing a recruitment plan. Therefore, only Investigators with routine access to their prospective subjects (or subject records) may recruit these individuals directly (“routine access” meaning the Investigator already has a clinical/academic reason to know/review a subject’s record). While this is particularly important with studies that involve the use of protected health information (PHI), it is equally as important in research for which the HIPAA Privacy Rule does not apply (i.e., when researchers are not part of the covered entity).

Examples of recruitment methods that would be permitted:

- A clinician approaches patients under his/her care about participation in a study in which the clinician is part of the study team.
 - Potential subjects can choose to contact the Investigator either by phone or in writing (e.g., returning a postcard provided in a mailing or calling the phone number provided on an advertisement) to gain further information and continue to consider the project.
 - The Investigator obtains permission from a clinic to set up a recruitment table in the waiting room. Interested patients receive information from the Investigator at the table.
 - The Investigator prepares a mailing that includes study team contact information, which is provided to the clinic to apply the mailing address.
 - A social worker who is not part of the study team approaches his/her clients about participation in a study and, if the client agrees, provides the study team with the client’s contact information for recruitment purposes only.
 - A professor who is not part of the study team announces a new study within the department during one of his/her classes. Interested subjects are provided a flyer that contains the study team’s contact information.
 - A daycare director who is not part of the study team mails RSRB approved letters to parents of children attending the daycare. Included in the letter is the study team’s contact information for parents to contact directly.
- b) When Investigators wish to recruit subjects from populations with which they do not have routine access (e.g., the patients of other physicians or students at a different school district) to a research study, the following procedures are to be used:
- The Investigator provides a written description of the project to the person with access to and a relationship with the potential subjects (e.g., the treating physician or a member of the “treatment team”, teacher or administrator at the school). The treating physician or teacher explains that he/she would like to recruit subjects for research.
 - The person with access makes the project description available so that potential subjects have the opportunity to consider whether or not they may wish to get more information about participation.
 - Someone with routine access may be added to the study team, if appropriate to the study design and recruitment plan.
- c) Recruiting Subjects from Other Institutions – Depending upon the level of engagement of the staff at the other institution, RSRB approval may or may not be required (see [Guideline for Determining Engagement in Research](#)).
- If study staff is only facilitating recruitment (e.g., posting flyers or providing potential subjects with study information), the institution is not engaged in the research and RSRB approval may

not be required. A letter of support may be sufficient; however, the Investigator must verify with the local regulatory oversight to ensure RSRB approval is not required.

- If study staff will obtain consent or perform research procedures, that institution is engaged in the research and RSRB approval is required, unless the study is exempt from the regulations and not federally funded. If the study is not federally funded, a letter of support/cooperation is adequate documentation. For example, if students will be recruited through a local school, documentation of the school district's approval must be submitted to the RSRB prior to initiating any study activities at the school.

5. Recruiter/Receptionist Scripts & Screening Logs

a) Recruitment Scripts

The first contact prospective subjects make may be with a recruiter/receptionist who follows a script to determine basic eligibility for the specific study. The Investigator should ensure the procedures adequately protect the rights and welfare, as well as the confidentiality of the prospective subjects. In some cases, personal and sensitive information is gathered about the individual. The protocol should document what information will be gathered during recruitment and how it will be stored. A simple statement such as "confidentiality will be maintained" does not adequately describe the procedures that will be used to protect confidentiality. The acceptability of the procedures would depend on the sensitivity of the data gathered, including personal, medical and financial information.

Examples of questions that may need to be addressed in the recruitment plan depending upon the recruitment method:

- What happens to personal information if the caller ends the interview, declines participation, is found to be ineligible or simply hangs up?
- Are names of non-eligible subjects maintained in case they would qualify for another study?
- Are paper copies of records shredded? If so, at what time point (e.g., after recruitment ends, after study completion)?
- If an outside recruitment company will be used, will the information gathered be used for other purposes or sold to others? What does the agreement with the recruitment company indicate will be done with the data?

b) Screening Logs

Generally, information collected during the screening process should be recorded in a de-identified format (e.g., noting that potential subject 1 declined due to the time commitment to participate or that subject 2 was not eligible because their body mass index was too high). If the information being collected on the screening log is identifiable (e.g., a name or a date of service will be collected), additional protections must be put in place. A limited data set and data use agreement may be needed to share limited information outside of the covered entity, or waiver of HIPAA Authorization requested to collect identifiable information about screen failures.

6. Recruitment and Future Contact Databases

Under University policy, databases established solely for research purposes require RSRB review and approval. Therefore, separate approval for the creation of any recruitment or future contact databases may be required. Refer to the [Guideline for Research Involving Repositories](#) for more information.

7. Investigator Checklist – Summary of Criteria for RSRB Approval

The following list summarizes the criteria outlined within this guidance that must be met by the Investigator in order to gain RSRB approval. Recruitment materials:

- must contain the word “**Research**.”
- cannot state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the protocol and consent document;
- cannot state or imply that the drug, biologic, device or other type of intervention is safe or effective for the purposes under investigation;
- cannot state or imply that the test article or other research intervention is known to be superior or equivalent to any other drug, biologic, device or intervention;
- for a research study involving an investigational drug, biologic, or device should not use terms such as "new treatment", "new medication", or "new drug" without explaining that the test article is investigational;
- cannot promise “free medical treatment” when the intent is only to state that subjects will not be charged for taking part in the investigation;
- may state that subjects will be paid, but should not emphasize the payment or the amount to be paid by such means as larger or bold type;
- cannot include exculpatory language through which the participant or their legally authorized representative waive legal rights or releases the investigator, the sponsor or institution from liability for negligence;
- cannot include compensation for participation in a trial offered by a Sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing;
- should generally be limited to the information that potential subjects need to determine their eligibility and interest in the research (the following items may be included, but are not required):
 - condition under study and/or the purpose of the research;
 - brief description of eligibility to determine study participation;
 - brief list of benefits, if any;
 - time or other commitment required of the subjects;
 - contact information;
 - location where research will be conducted, if applicable;

8. Review of Recruitment Materials When the RSRB is the Reviewing IRB

The RSRB will review recruitment methods and materials to ensure that the considerations noted above have been applied, as applicable, including but not limited to the following:

- they do not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol;
- they do not include exculpatory language;
- they do not emphasize the payment or the amount to be paid, by such means as larger or bold type;
- payments are not designed to accelerate recruitment by being tied to the rate or timing of enrollment (i.e., “bonus payments”) - see [University of Rochester Policy on Enrollment Incentive Payments by or to University Clinical Trial Researchers](#);
- do not promise “free treatment” when the intent is only to say participants will not be charged for taking part in the investigation;
- the method of communication is consistent with the material provided;
- for FDA-regulated research:

- they do not make claims, either explicitly or implicitly, about the drug, biologic or device under investigation that are inconsistent with FDA labeling,
- they do not include payment for participation in a trial offered by a sponsor to involve a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

9. Watermarked Recruitment Documents When the RSRB is the Reviewing IRB

The RSRB will watermark recruitment documents upon approval. For single-site research, only the watermarked documents may be used to recruit subjects (e.g., posting flyers or presenting documents to potential subjects) and only the most recently approved version of the document should be used. When applicable, documents should be printed on department letterhead. Exceptions to use of letterhead may be permissible under certain circumstances (e.g., if a form letter has been approved and it is not possible to enter personalized names/addresses on the watermarked version, or if the poster or brochure will be printed at a printing company and the watermark cannot be included). Please contact your RSRB specialist if these circumstances arise.

For multi-site research, the RSRB will watermark generic/template versions of recruitment documents (without specific contact information). Each participating site will be instructed to fill in their site-specific contact information into the document and use that version for recruitment at their site.