GUIDELINE FOR RECRUITMENT MATERIALS AND PAYMENT OF RESEARCH SUBJECTS

Recruitment of potential research subjects is the initial step of the informed consent process. As such, RSRB review of recruitment methods and materials and subject payments 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 a review determination the Investigator must include a recruitment plan in the protocol, which addresses the questions within the RSRB Protocol Templates, and must address the questions related to recruitment in the RSRB on-line submission system (ROSS). This document supplements OHSP Policy 703 Recruitment Materials and Subject Payment to provide additional guidance to Investigators regarding RSRB review requirements.

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RSRB approval is required for any subject recruitment materials prior to use and includes, but is not limited to:
- Recruitment letters
- Scripts for telephone or other personal contact
- Flyers, posters, newspaper ads, press releases intended for recruitment with contact information
- TV and/or radio spots
- Websites/internet ads
- Electronic mailings
- Social media pages, ads, blogs, tweets, etc.

Recruitment materials and advertisements must be consistent with the information contained in the submitted protocol and consent document(s). Any changes to the RSRB approved recruitment method or materials, or any newly developed materials, must be submitted to the RSRB as an amendment for review and approval prior to use.
1. **What to Consider When Developing Recruitment Materials**

   a) Materials must clearly state that the purpose for recruitment is research.

   b) Recruitment/advertising 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: Payments to subjects for participation are not benefits; they are given for incurred expense for participation. Advertisements may state that subjects will be paid, but they should not emphasize the payment or the amount to be paid;
      - 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.

   c) Additional considerations:
      - Information provided in the recruitment/advertising materials may indicate that reimbursement or payment will be provided. Whether the amount of payment is included in the ad is left to the discretion of the RSRB.
      - Excessive monetary amounts that could be interpreted as inappropriate, posing undue influence, or are coercive 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.

2. **RSRB Review of Recruitment and Advertising Materials**

   The RSRB will review recruitment methods and advertising 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 mode of communication is consistent with the material provided;
• for FDA-regulated research:
  o they do not make claims, either explicitly or implicitly, about the drug, biologic or device under investigation that are inconsistent with FDA labeling,
  o 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.

3. Direct Advertising

a) All direct advertising for study 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, ResearchMatch scripts, newspaper, radio and TV advertisements, press releases (intended for recruitment and including 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, press releases not intended for recruitment purposes, and publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

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. The final audio/video should also be submitted upon completion.

c) 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 are not coercive 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.

4. Advertising over the Internet

a) 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)
- University of Rochester Medical Center’s health research website

b) When the opportunity to add additional descriptive information is not precluded by the database system, RSRB review and approval is required to assure that any additional information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the consent document. Similarly, any other type of recruiting completed via websites, web postings or the use of social media must be submitted for RSRB review and approval.

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 submission so that the RSRB can verify the website material.

5. Access to Potential Subjects

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 social and behavioral research for which HIPAA typically does not apply.

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.
- 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, they may not contact these potential subjects directly (i.e., no “cold calls”). 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”). The treating physician 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.

• 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.

c) Recruiting Subjects from Other Institutions – Depending upon the level of engagement of the staff at the other institution, IRB 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 IRB approval may not be required. A letter of support may be sufficient; however, the Investigator must verify with the local regulatory oversight to ensure IRB approval is not required. If the site does not have an IRB, a letter of support is sufficient.

• If study staff will be obtaining consent or performing research procedures, that institution is engaged in the research and IRB approval is required. If the study is not federally funded, a letter of 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.

6. Recruiter/Receptionist Scripts & Screening Logs

The first contact prospective study subjects make is often 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 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 handled. 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 protocol 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 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?

Similarly, these same issues must be taken into consideration when screening logs will be utilized. Generally, this information should be collected 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.

7. **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.

8. **RSRB Watermarked Recruitment Documents**

Upon approval, only RSRB watermarked recruitment documents may be used to recruit subjects (e.g., posting flyers or presenting documents to potential subjects). Only the most recently approved version of the document should be used and, when applicable, must be printed on department letterhead. Exceptions to this 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.