Guidelines for Recruitment Plan, Recruitment Materials and Screening Plan, for NIH Intramural Research Program Protocols

What are Recruitment Activities?

Activities intended to provide prospective study participants with their first introduction to the research study by providing study related information. Recruitment is considered part of the informed consent process.

Investigators ***must*** describe the plan for recruitment in the protocol so that the Institutional Review Board (IRB) can determine whether the proposed process respects potential participants' autonomy, is not coercive, and does not predispose the potential participant to undue influence.

The IRB will:

- determine that the process and materials used for participant recruitment promote fair and equitable participant selection based on the scientific question that the study will address.
- review the plan to make sure that it avoids unfairly targeting any specific groups.
- review the plan to assure that it is not unduly coercive, especially to those considered to be vulnerable to undue influence.
- evaluate if the recruitment plan includes provisions to protect the privacy and confidentiality of the prospective participants.

What are Recruitment Materials?

"Information potential subjects will see or hear that is used as part of the research recruitment process, including but not limited to websites, flyers, posters, newspaper ads, television or radio ads, brochures, doctor-to-patient or investigator-to-subject letters, and social media ads." These are described in greater detail below.

The plan and proposed recruitment materials *should ideally* be submitted at the time of the protocol's initial review. If materials are added later, they are to be submitted as a protocol modification and cannot be utilized until the IRB approves these materials.

WHAT RECRUITMENT MATERIALS DO REQUIRE IRB REVIEW AND APPROVAL?

Publicly posted recruitment materials.

Examples include:

- Advertisements
- Brochures
- Bulletin board tear offs
- Doctor-to-patient / Investigator-to-participant /Dear patient letter - Letter signed by the treating physician and informs patients how to contact the study investigators
- Flyers or Posters
- Newspaper advertisements
- Public service announcements (PSA) with the intent to recruit participants
- Recruitment Letters

- Scripts or guides to be used for in-person or telephone recruitment interviews
- Social Media Postings (e.g., Facebook, Instagram, Twitter) - NIH investigators who plan to use social media for recruitment purposes should be familiar with the: NIH Social Media Guidelines and Guidance Regarding Social Medial Tools
    - Note: the US government prohibits the use of TikTok (For more information see the NIH Social Media Guidelines)
- Television and/or Radio Advertisements
- Third Party Vendor Recruitment Websites
- Videos:
    - IRB Review of the video script dialogue is required *prior* to filming the video(s).
    - This script should be submitted to the IRB for review and approval *before* filming.
        - Once the script is approved, proceed with the actual video recording. Once that is complete, submit a modification to the IRB to review the final video product.
        - A link to the final video should be provided in a supplemental document so the IRB can review the final video.
        - MP3 or MP4 files are not acceptable.
        - Make it clear that the IRB previously reviewed and approved the video script, by referencing the previous IR/MOD where this video script was approved in the MOD Summary or your Cover Memo.
    - If you wish to use snippets/video shorts originating from a previous IRB approved video, those should be reviewed by the IRB. This will ensure all necessary requirements for recruitment materials are met, and that no required information was edited out.

Contact the NIH IRBO for consultation before creating the video **if** you have any questions or concerns about the requirements outlined above.

WHAT RECRUITMENT MATERIALS DO NOT REQUIRE IRB REVIEW AND APPROVAL?

Generally, any materials that are not targeting potential participants and are not intended to recruit subjects do not need to be reviewed by the IRB.

Examples provided include, but are not limited to, the following:

- Doctor-to-Doctor Letters soliciting study participants- Letter to colleagues asking for referrals. Study investigators can provide colleagues with a short letter describing the basic details of the study so their colleagues can determine which patients may be eligible.
- Clinical trial websites
    - So long as the website provides **only** general direct listings with basic information about clinical trials (e.g., clinicaltrials.gov) **AND**
    - Posting includes **only** basic descriptive information limited to the following:
        study title
        purpose of the study
        protocol summary
        basic eligibility criteria
        study site location(s), and
        how to contact the study site
- Medical society/ healthcare provider newsletters not targeted at participants
- Newsletters with participants as the target audience, for the purpose of only providing general information and **with no intent to recruit**

- News Stories that are unsolicited
- Public Service Announcements (PSAs) - that are not study specific or used for purposes of recruiting (e.g., "Get your annual flu shot" PSAs)
- General Press Releases – that are not study specific or used for the purposes of recruiting
- Previously approved recruitment materials where the only change(s) include:
  - PI name & contact info
  - Institute Name or Logo
  - Insertion of QR code that takes participants to general contact information, previously approved recruitment material and/or clinical trial website (see below for more information regarding QR codes)
- Professional association/ organization - materials created solely for professional society meetings with no intent to recruit
- Subject Teaching Materials - instructions that are simply standard of care in the medical community, for example:
  - video explaining how to cut a pill
  - video how to administer a subcutaneous injection (SQ)
  - pamphlet explaining how to pack a saliva sample
  - pamphlet explaining how to check blood sugar glucose

What are Recruitment Methods?

"Methods used to identify potential research subjects, or to draw a potential research subject's attention to participation in research, including but not limited to identification through records review, in-person discussion, and use of recruitment materials."

What Should the Recruitment Plan Include?

Describe the **Who, What, Where When** and **How** details of the recruitment plan.

The following information should be considered and included in the recruitment plan described in the protocol, as applicable:

- **Who** will be conducting recruitment activities?
  If a specific individual is performing recruitment activities, the plan should indicate why the individual is qualified and appropriate. The person to whom the potential participant is directed to for information must be knowledgeable and able to answer relevant questions.

  NOTE: NIH investigators, or their supporting ICs, are not permitted to provide, or receive, finder's fees (e.g., payment in exchange for referrals of individual prospective research participants, these are sometimes also referred to as "recruitment incentives"), from any source in connection with research at NIH.

- **What** is the source of your targeted population?
  Describe how you will locate or find the proposed population based on the study's objective(s) (e.g., participants who are seen in a clinic, convenience samples, healthy volunteers who contact NIH to sign-up or volunteer to be contacted regarding NIH studies, or those who have a specific disease/ health issue.)

- Where is the location you will be recruiting participants?
  This should be described in the protocol. Locations include inpatient settings, clinics e.g., NIH waiting rooms, community centers, public spaces, social media website(s) or application(s), professional societies, direct referrals, or video such as, TV Monitor displays on the Clinical Center TV (CCTV) Network.

- When is a participant approached about the study?
  Describe when potential participants will be approached/contacted (e.g., after the potential participant reached out to the study team or contacted the recruitment office; when the potential participant calls/emails the recruitment office or study team in response to a recruitment ad./or information posted on clinicaltrials.gov; or the potential participant is referred by their personal/home physician).

- How are potential participants identified and contacted?
  Particular care should be taken when developing your study and considering how potential participants will be identified and contacted.

Other things to consider:

- When family members will be considered potential participants, how will the privacy of the family member be protected? The investigator cannot just call the family member who is not yet known by the investigator (referred to as "cold-calling"). Cold-calling potential research participants is prohibited unless this method was previously approved by the IRB.
- Acceptable methods to recruit family members are when the investigator:
  - Asks the participant (proband) to first discuss possible study participation with a family member, or
  - Creates an information sheet that the proband can provide to a family member.

  The IRB must prospectively approve either method used.

- What is "Cold-calling"? It is the practice of investigators or research staff, unknown to the potential research participant, initiating contact with the potential participant based on the investigator's prior knowledge of private health information (e.g., through history and physical of the proband, or review of the potential participant's private health records as discussed further below.)

Does the proposed recruitment plan promote fair and equitable selection of participants?

- This is based on the protocol's scientific question(s).
- It should reflect populations burdened by the disease under study.
- No specific group of people should be unfairly targeted nor unfairly excluded from the research.

Are there special considerations that should be addressed if the cohort(s) will include individuals from vulnerable populations?

- Do recruitment plans take any cultural and social practices into consideration (e.g., community, group or family recruitment before individual recruitment)?
- If you are targeting non-English speaking populations, recruitment materials should be translated to the non-English language of the target population and must be provided with a certified translation to the IRB. The materials must be approved by the IRB prior to use.

- NIH Employees - if the study permits enrollment of NIH staff, additional protections are required per NIH policy.

Forms of Recruitment Methods

- Direct recruitment (e.g., physicians talk to their own patients about the study): In this case, it is preferable that a knowledgeable investigator from the study team who is not providing direct care for the patient approach the potential participant to discuss the study to prevent undue influence or pressure on the potential participant.

- NIH recruitment office: Potential Subjects call about the study from information provided on clinicaltrials.gov, a posted recruitment flyer/poster/etc. on a website or social media to get more information regarding a study (this could also involve screening if part of the approved protocol and based on an IRB approved script of questions)

- Recruitment letters: Communications sent to prospective participants should indicate how ` the individual was identified and include study information and a contact person who can provide additional details.

- Doctor-to-Patient /Dear Patient Letters: Letter signed by the treating physician that informs patients how to contact the study investigators.

- Referrals: Clinicians who are not part of the research can provide their patients who are potentially eligible for the protocol with IRB approved recruitment materials or letters that describe the study. The potential participant, if interested, can then contact the investigator directly. Alternatively, after obtaining any required authorization, the clinician who initiated the discussion may share the potential participant's contact and relevant health information with investigators so that they can contact the individual.

- Review of medical records: Identification of potentially eligible participants via prospective review of private medical information: When a protocol will target individuals with specific health concerns/diseases, review of medical records, patient registries, clinical databases and referrals from local treating physicians may be helpful resources for recruiting.

WHAT MAKES UP A GOOD RECRUIMENT PLAN/ MATERIALS?

The plan/materials are:

- Consistent: Plan and materials are consistent, e.g., do not submit social media postings if the protocol does not indicate social media will be used as a recruitment method. For example, do the recruitment material(s) for a Phase 1 study make it clear that the research is only intended to evaluate the safety, and not the efficacy of the investigational product?
- Fair and Equitable: No specific group of people should be unfairly targeted nor unfairly excluded from the research.
- Clear: Plan and materials should be clearly described. Materials in particular should use clear and understandable lay language as much as possible. Should also include information that prospective participants need to determine interest and eligibility.

WHAT INFORMATION IS REQUIRED TO BE INCLUDED IN RECRUITMENT MATERIALS
(For FDA Regulated Clinical Trials see below as well)

- Research project title or identifier (e.g., Hypertension Study)
- A clear statement that the study is a ***research*** study. It is not enough to imply that the subject is being recruited for research by just using the word "study."
- Name of the investigator conducting the research and their affiliation with the NIH and specific Institute Center.
- The purpose of the research and condition under study
- Summary of eligibility criteria
- A brief discussion of what study participation involves (duration of the study, number of study visits/time commitment, study procedures)
- If compensation is provided
- Research location(s)
- Who to contact for further information
- HHS/ NIH and Institute logo for branding purposes (3rd party recruitment websites have different requirements regarding this)
- Footer with protocol #, version and date
- If more than one page, pagination

FDA requirements for Clinical Trials, in addition to the requirements listed above, the following are also required:

- Recruitment materials must state that the test article (drug, biologic or device) is investigational.
- Do not make claims either explicitly or implicitly that the test article is safe or effective for the purposes under investigation, or that it is equivalent or superior to currently available treatment.
- Do not use the terms “new treatment,” “new drug,” or “new medication” without explaining that the test article is investigational.
- Do not promise “free medical treatment or care,” when the intent is only to inform participants that they will not be charged for participating in the study.

Materials MAY also include the following, if applicable:

- Brief list of significant risks
- Brief list of possible benefits
- Payment/compensation information

Recruitment materials May NOT:

- State or imply benefits or outcomes beyond what is stated in the consent and the protocol.
- Include exculpatory language (language that suggests that the participant could be made to waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence).
- Overemphasize payment (e.g., list payment information in a larger font) or characterize payment as a benefit.

QR CODES:

- A QR code is a two-dimensional code that you can scan with a smartphone.
  The code contains information/site address, once you scan it, the code connects to resources of a website that can include information, pictures, or videos about the study.
- Not all individuals own the technology (e.g., a cell phone) they can use to scan a QR code to access information about the study. In addition to a QR code, alternative materials should also be developed that include all the required information, and to ensure recruitment is fair and equitable.
- If the QR code links to material on a website that contains information beyond the criteria noted in the *clinical trial websites* section above, you are required to submit the information that the QR code links to, for IRB review, if not already approved.

Identification of potentially eligible participants via prospective review of private medical information

When a protocol will target individuals with specific health concerns/diseases, review of medical records, patient registries, clinical databases and referrals from local treating physicians may be helpful resources for recruiting.

- Under the *pre-2018 Common Rule* regulation(45 CFR 46), unless the research qualified for specific exemptions, consent from the potential participant for recording their identifiable private information being obtained for recruitment was required unless waived by the IRB.

- Under the *revised 2018 Common Rule* (effective January 21, 2019) at 45 CFR 46.116(g), there is an exception to informed consent for certain recruitment activities. For those protocols subject to the 2018 Common Rule, the IRB may approve research "*in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:*
  (1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
  (2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens."

The revised Common Rule means that collection of private medical information for the purpose of participant recruitment can occur without informed consent or an IRB waiver of consent. However, the solicited information should be limited to the minimum necessary for screening or to determine study eligibility. The process needs to be clearly described in the protocol, so that the IRB can determine whether sufficient privacy and confidentiality protections are in place regarding these activities. Collection of private health information from a HIPAA covered entity may require authorization by the potential participant as further discussed below.

Implications of HIPAA on recruitment activities at non-NIH recruitment sites

NIH is not considered a covered entity and is thus not subject to the Privacy Rule Health Insurance Portability and Accountability Act of 1996 (the HIPAA Privacy Rule) but is, instead, subject to the Privacy Act of 1974. However, NIH researchers should be aware of the HIPAA Privacy Rule because it establishes the conditions under which covered entities can use or disclose PHI for many purposes, including for research. The HIPAA Privacy Rule (also known as HIPAA, or the Privacy Rule) regulates the

way certain health care groups or organizations called "covered entities" (such as health care providers in local medical practices, hospitals, academic medical centers), handle individually identifiable protected health information (PHI). The Privacy Rule may impact various areas of research, including clinical research, repositories and databases and health services research, as it establishes conditions under which covered entities can provide researchers access to, and use of, PHI when necessary to conduct research. As it relates to recruitment of potential research participants, the HIPAA Privacy Rule permits a covered entity to disclose PHI if it has obtained an individual's written permission in the form of an Authorization.

The Privacy Rule also permits covered entities to use and disclose PHI without Authorization for certain types of research activities if a covered entity obtains documentation that an IRB or Privacy Board has waived the requirement for Authorization or allowed an alteration. Since NIH is not subject to HIPAA, the NIH IRB does not provide such waivers. However, in the case of multisite research overseen by the NIH IRB, review by the local sites that are subject to HIPAA can be undertaken by that site's Privacy Board. There are other research related regulations under the HIPAA Privacy Rule (e.g., use of PHI under a waiver of HIPAA authorization such as for limited data sets, review of PHI preparatory to research or research on decedent's information) that are not directly related to recruitment. For additional information, see the HIPAA related documents in References and Links.

NIH researchers should be aware that even though NIH is not a HIPAA covered entity, it is essential that we are aware of and respect the restrictions placed by HIPAA on those entities that are subject to the Privacy Rule. The use or disclosure of information in violation of HIPAA can result in substantial penalties to the covered entity.

Screening Plan

If an investigator wishes to initiate a clinical procedure that will be performed solely for determining research eligibility, informed consent must be obtained. Clinical screening procedures for research eligibility are considered part of the subject selection and recruitment process and, therefore, require IRB oversight. These procedures must be described in the protocol. Screening should include the fewest and least risky tests/interventions necessary to determine study eligibility. Screening procedures should minimize participant exposure to potential harm for those who fail screening. The IRB should receive a written outline of the screening procedure(s) to be followed and how consent for screening will be obtained. If a separate consent for the screening portion of the protocol is used, the IRB may find it appropriate to limit the scope of the screening consent to a description of the screening tests and reasons for performing the tests, including a brief summary description of the study in which the individual may be asked to participate. Unless the screening tests involve more than minimal risk or involve a procedure for which written consent is normally required outside the research context, the IRB may decide that prospective study subjects need not sign a screening consent document.

References and Links

1. Policy 302 Subject Recruitment and Compensation
2. Policy 404 Research Involving NIH Staff as Subjects
3. Use of 3rd Party Vendors for Recruitment and Screening
4. FDA information sheet: Recruiting Study Subjects: Guidance for Institutional Review Boards and Clinical Investigators (January 1998)
5. FDA Information sheet: Screening Tests Prior to Study Enrollment (January 1998)
6. OHRP Guidance on Institutional Review Board Review of Clinical Trial Websites (Sept. 2005)

7. HHS Clinical Research and the HIPAA Privacy Rule (February 2004) NIH Publication #04-5495
8. HHS HIPAA webpage Research (HIPAA as it relates to research) (Revised December 2017)
9. HHS Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule Health Services Research and the HIPAA Privacy Rule (NIH Publication #03-5388)
10. HHS Research Repositories, Databases, and the HIPAA Privacy Rule. (January 2004)(NIH Publication #04-5489)
11. Doctor to Doctor Letter: https://www.wcgclinical.com/insights/does-the-irb-need-to-approve-doctor-to-doctor-letters/