

# Recruitment of Research Participants

## Background

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Recruitment of research participants takes many forms that involve presenting potential participants with information about the study, prior to their enrollment, to help establish interest and willingness to serve as a research subjects. It is often the first information participants see about a study, and is considered by federal regulations and the IRB to be the beginning of the informed consent process. Thus, it is imperative that the information clearly and accurately represents the research. It is also important that the recruitment process be handled in an ethical manner.

Toward these ends, **all recruitment plans and materials must receive IRB approval before any potential participants are invited to take part in any non-exempt research project.** Only those materials approved by the IRB may be used for participant recruitment; any changes to the processes or materials must receive IRB approval prior to implementation.

The IRB does not review recruitment materials for exempt research. However, researchers are responsible for conducting recruitment in a manner consistent with the ethical considerations outlined in this document (i.e., promoting voluntariness, protecting privacy, accurately informing potential participants, etc.).

## Ethical Considerations

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The IRB reviews recruitment materials and processes to ensure they are handled in a manner that addresses the following ethical considerations:

**Respect for privacy** – In some cases, simply being invited into a study may involve privacy concerns. For example, sending an email or leaving a voice message inviting an individual to take part in a study of individuals with a specific disease or stigmatizing condition may “out” them to others. Recruitment methods must take into account privacy concerns.

**Lack of pressure or undue influence** – Participation in research must be voluntary. Thus, the study should be introduced in a manner that allows participants adequate time and ability to freely consider whether or not they wish to take part. Undue pressure because of the timing of the request, who makes the request (e.g., a participant’s teacher, boss, physician, etc.), method of request or the offering of undue inducements should be avoided.

**Accurate and clear description of the study** – Information shared with participants should be accurate and clearly presented. Number of visits, expected time commitment, any eligibility criteria, etc., should fully align with the proposed research plan. Information must be clear and understandable, and free from technical or scientific jargon. Participant literacy needs to be considered; it is unethical to rely solely on written recruitment procedures with individuals who cannot read, or without proper language interpretation. When participants who cannot read or speak English are involved in research, information shared during recruitment must be translated into appropriate language(s).

**Unbiased presentation of the study** – Information should be balanced and free of misleading emphasis that makes the study excessively attractive (e.g., avoid wording such as “free medical treatment,” “guaranteed weight loss,” “new and improved,” etc.). Anticipated benefits should not be overstated.

**Avoiding the therapeutic misconception** – Patients often think that taking part in a clinical trial—or any research proposed by a health care provider—will benefit them. The recruitment methods and materials should avoid contributing to this misconception. Careful wording, such as using “research subject” instead of “patient,” avoiding the term “treatment,” etc., can help.

## Who May Recruit?

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Individuals initiating contact to recruit participants must have basic knowledge about the study (so they can answer questions) and training on ethical human subjects research. In nearly all cases, these individuals must be included as study personnel on IRB applications.

In most cases, individuals whose role is limited to the following situations do not need to be included as study personnel:

- Forwarding IRB-approved recruitment materials to potential participants;
- Securing permission from potential participants to share their contact information with the research team;
- Providing contact information to the research team, if it is otherwise allowable (e.g., a staff person in the ISU Registrar’s Office who provides Directory Information to a researcher).

## IRB Submission Requirements

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Researchers should describe in the IRB application how potential participants will be identified and invited to take part in the study. This description should include the following information with enough detail that the recruitment plans can be fully understood by the IRB. Recruitment processes and materials vary greatly, and may involve formal letters, posting flyers, sending emails, announcements in classes or other settings, postings to online bulletin boards or social media sites, or informal personal conversations.

As a general rule, any recruitment materials that will be seen by research subjects require IRB review and approval. Thus, with the IRB application (or modification application), researchers must send final copies of any and all recruitment materials. Materials should be personalized as needed for each study phase or participant group; in some cases, multiple versions may be needed.

At the end of this document there are tables summarizing the information to include in the IRB application to describe recruitment plans.

**NOTE:** In some circumstances, the IRB can approve protocols in which researchers obtain information or biospecimens for the purpose of screening, recruitment, or otherwise determining the eligibility of potential participants prior to implementing a recruitment and informed consent process. Please review our [informed consent-related policies and guidance](#) to learn more.

## Guidance on Content of Recruitment Materials

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Content of recruitment materials varies with the nature of the study. In general, it should be limited to information that helps potential participants assess their interest and eligibility. Information should be presented clearly, concisely, and using lay person’s language; technical or scientific jargon should be avoided.

The IRB recommends that recruitment materials include:

- A clear statement that this is RESEARCH (use the word RESEARCH, rather than “treatment,” “program,” or “project”), particularly if the study involves an intervention
- A general description of the purpose of the research
- When applicable, the regulatory status of a drug or device (investigational, approved)
- In summary form, the criteria that can be used by the subject to determine his/her own eligibility (e.g., age range, any medical restrictions in lay person’s terminology, etc.)
- Time or other commitment required of the participants (e.g., total number of visits, expected duration, etc.)
- Contact information for interested individuals
- Location of the research

When appropriately worded, the following items may also be included:

- Potential direct or societal benefits (must be truthful and reasonable; benefits must not be overstated)
- Compensation plans, provided they are stated simply and not overly emphasized

The following items are **not appropriate** for inclusion in recruitment materials

- Overly emphasized payment amounts
- Claims that the research will improve a participant’s medical condition
- Any promise of free treatment or care
- Language that overstates or overpromises the expected benefits of participation
- Any exculpatory language (where rights are waived)

For FDA regulated studies, recruitment materials **should not** include:

- Claims, either explicitly or implicitly, that the drug, biologic, or device is safe or effective for the purposes under investigation.
- Claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, or device.
- Terms, such as new treatment, new medication, or new drug without explaining that the test article is investigational.
- Promise of a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

## Special Issues in Recruitment

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### Use of Social Media

Social media use is increasingly common, but there continues to be varying levels of knowledge and awareness about issues surrounding privacy, public availability, interaction norms, etc. Individuals may believe their comments

in response to a recruitment advertisement are private, when in fact, the information they share (which may be private) is available to all users or the public. Individuals may also make comments about the perceived validity of the study, efficacy of the intervention, or other issues that can adversely affect willingness to enroll. The [NIH recommends](#) that researchers consider the following before social media as a recruitment venue:

1. Have I considered the full implications of privacy in this new and less-controlled environment?
2. I need to carefully consider how my materials will be used.
3. Have I controlled my informational data in a locked format?
4. Have I made the contact for further information site protected for the privacy of interested individuals?
5. Do I clearly understand that the interactive nature of social media escalates the speed of interaction, allowing for greater opportunities for errors in protecting private information? Have I planned to obviate those errors?
6. Have I accounted for problems related to the portability and secure handling of information, including the encryption of all government laptops, the encryption of sensitive information during transport, including but not limited to transport across the network or on portable media, and the reporting of unintended breaches of sensitive personal information in the government's possession?
7. Have I included my complete strategy for use of the social media and my strategies for protection of privacy and strategies for informed consent explicitly in my proposal to the IRB?
8. Have my team and I clearly understood the invasive nature of joining groups (i.e., support groups, disease groups, advocacy groups, etc.) for the purpose of recruitment? This can undermine the trust of government research and your IC.

More detail about each of these questions is available in the [NIH Guidance Regarding Social Media Tools](#).

## Recruitment of Vulnerable Populations

### **Researchers' students and staff**

Except in unusual circumstances, researchers should not directly ask their students or staff to be research subjects, as it may be hard to refuse such a request. Instead, students or staff may be recruited indirectly (e.g., through flyers, large-group emails in which all students in a department are included, etc.) and allow volunteering students or staff to initiate contact. Students or staff should never be pressured.

In cases where very personal or private information is collected during the study, researchers must have compelling scientific justification for including their students or staff due to privacy concerns.

### **Recruitment in classrooms**

Participation in research must be presented as a voluntary option. In cases where course credit or extra credit is offered, students must be informed of non-research alternative methods of earning the same amount of credit; those alternatives must be genuinely comparable in terms of time and effort.

## Recruitment incentives ("Finder's fees", bonus payments)

Finder's fees, where payment or other compensation is provided in exchange for referring or enrolling subjects in research studies, are not allowed.

# Information to Include With IRB Applications

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## Obtaining Contact Information

**When applicable, describe how participants' contact information will be obtained for recruitment purposes.** The following is a list of common sources of contact information, along with information that the IRB will need to know to assess these plans.

Item	Information to Describe in IRB Application
<b>Review of Public Records</b> (e.g., voter lists, utilities lists, phone directories, ISU directory, etc.)	Specify the source(s) of the records.
<b>Review of Private Records</b> (e.g., medical records, student records, employment records, etc.)	Identify the specific records to be reviewed, along with a description of how the research team will be granted permission to access the private records.
<b>Purchased Mailing Lists</b>	Specify the source(s) of the lists.
<b>Personal Contacts/Knowledge</b>	Provide a description of how potential subjects are known to the researcher.
<b>"Snowball" sampling</b>	Provide a description of what information about participants will be provided as part of the snowball sampling.
<b>Referrals</b> (e.g., from medical care providers, colleagues, teachers, etc.)	Describe the process for obtaining referrals, and how any privacy concerns will be addressed.

## Method for Contacting and Inviting Participants

**Describe the method for contacting and inviting participants.** The following is a list of common methods of contact, along with a description of the information to be included in the IRB application and corresponding materials that should be submitted for approval.

Recruitment Method	Describe in IRB Application	Submit with IRB Application Materials
<b>Directly Contacting Participant</b>		
Written communication, such as letter or email sent to potential subjects	Describe the specific plans, including frequency, timing, how any privacy concerns will be addressed, etc.	Final text of letter(s), email(s), or other written communication.
Verbal communication, such as via phone call, personal announcement, or word-of-mouth	Describe the specific plans, including frequency, timing, how any privacy concerns will be addressed, how undue influence or coercion will be minimized, etc.	Phone script(s), script(s) for announcement(s) and/or list(s) of talking points to be covered
<b>Indirect Contact Methods</b>		
Flyers	Indicate where flyers will be placed	Final copy of all flyer(s)
Website announcements, including SONA, online bulletin boards, Listserve distribution, etc.	Indicate where announcement(s) will be placed, specific Listserves to be used, etc.	Final text of website announcements, or text to be distributed.
Personal or verbal announcements	Indicate where announcements will be made, who the intended audience is, etc.	Script(s) for announcement or list(s) of talking points to be covered
Informal personal communication	Describe expected setting(s) and targets of the communication	Script(s) or list(s) of talking points to be covered

Television or radio advertisements	Indicate where advertisements will be placed	Final content of the advertisements.
Social media postings	Indicate social media sites to be used and describe procedures to address privacy concerns inherent with social media use (see below)	Final text of social media posting(s)
Referrals (researcher asks colleague to provide study information to potential participants)	Describe these plans, including the relationship between the colleague and potential subjects, and how any concerns related to privacy or undue influence will be addressed.	Final text of information to be shared with potential participant.

Document History

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