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| **Overview** |

Purdue University Institutional Review Boards (IRBs) and investigators share the responsibility for creating a recruitment environment that is not only effective but also ethical and compliant with all applicable regulations. The identification, initial contact, screening and recruitment of potential human participants is the beginning of the informed consent process. Screening and recruitment processes must demonstrate respect for the dignity and autonomy of potential participants by avoiding any potential undue influence and by protecting both the privacy of the individual and the confidentiality of any information obtained for recruitment and/or screening. Including a complete description in IRB applications helps investigators avoid delays in the IRB review process.

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| **Ethical Concerns and IRB Review** |

The IRB reviews the recruitment methods and materials for all studies in consideration of the purpose of the research, the setting in which the research will be conducted and participant population. Investigators should consider the following ethical issues when planning their recruitment strategies. These are the same considerations the IRB uses to evaluate studies.

* **Equitable selection of participants:** The recruitment plan ensures the selection of research participants is equitable and appropriate for the study. According the [NIH Glossary of Common Terms](https://www.nih.gov/health-information/nih-clinical-research-trials-you/glossary-common-terms), “Inclusion/Exclusion Criteria are factors that allow someone to participate in a clinical trial are inclusion criteria. Those that exclude or not allow participation are exclusion criteria.”

Therefore, inclusion criteria should bring the study population closer to your study and exclusion criteria should disqualify those who may not participate (i.e. due to study variables, contraindications, or safety concerns).

* **Respect for persons:** The recruitment plan ensures appropriate procedures are used for the study population, especially if the population presents any special problems requiring specific safeguards. Such populations may include vulnerable populations such as children, prisoners, pregnant women, economically disadvantaged persons and cognitively impaired persons or those lacking of decision-making capacity. Other populations (e.g., employees, students, etc.) may be considered a vulnerable population depending on their circumstances in relation to the research.
* **Lack of pressure:** The study is introduced to potential participants in a way that allows them ample time to consider, with no undue pressure because of the ***timing*** of the request, ***who*** makes the request, ***how*** the request is made, or the offering of excessive inducements. Consider if adolescents whose parents give them permission to be in the study will feel they cannot say “no”. Will students be hesitant to say “no” to a professor or teacher? Will employees be placed in a situation where they may be hesitant to say “no” to an employer or manager? How will such pressure be minimized?
* **Respect for privacy:** Recruitment plans should respect an individual’s reasonable expectations for privacy. Will potential participants identified using confidential information such as school, employee or patient records, have given permission beforehand for this use of their information? If investigators ask screening questions, will the questions be asked in a private setting where others will not overhear the answers? Some measures could be as simple as sending a recruitment letter in an envelope rather than sending a post-card or conducting recruitment after business hours.
* **Method of Presentation:** All information used for recruitment should be accurate, balanced, and free of misleading emphases that make the study excessively attractive. Is the information as complete as is appropriate for each stage of recruitment?

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| **Information to Include in the IRB** **Application** |

The IRB must be able to assess recruitment activities for a study. Below is a list of questions often asked of investigators about their studies. Though not an exhaustive list, this summary provides an outline to pertinent items that must be part of an IRB application.

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| **Common Recruitment Topics** | **What to Include in the IRB Application** |
| Identification of Participants from Specific Populations | Describe how participants will be identified.Detail who will identify potential participants. Does the researcher have permission from the site (e.g. school or workplace) to conduct research? Include a copy of this permission.  |
| Recruiting Procedures via e-mail, phone, social media, flyers, advertisements, etc. | How/when will participants be approached?Who will be the point of contact for the message/call/post?Describe how frequently and in what manner individuals will be contacted.How are phone lists, social media IDs, e-mail addresses, etc. obtained?Include a copy of all content used for recruitment and a general idea of the sites and locations for posting advertisements. |
| Frequency of Contact | If your recruitment plan involves contacting individuals multiple times in an effort to secure their initial enrollment in the study, describe how frequently and in what manner individuals will be contacted. Provide a timeline when contact will cease. |
| Screening Procedures | Will you collect any information/data from potential participants during the recruitment and/or screening process? How will it be collected (i.e., what procedures will be used)? Identify all data points that will be collected prior to their enrollment in the study.If participants do not qualify for the study based on the screening procedures, describe any data that will be kept or how/when screening data will be destroyed.  |
| Privacy During Recruitment  | Describe any provisions to protect the privacy and/or confidentiality of potential participants. This is particularly important when conducting research on sensitive topics, controversial issues, and health-related studies.  |
| Recruiting Students | Investigators must recognize that student participation in such research may not be truly voluntary because of a desire on the part of students to appear cooperative or highly motivated.Investigators must use recruitment procedures that minimize the possibility of undue influence and coercion. |

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| **Examples of Acceptable Forms of Recruitment and Study Advertisement** |

**The following methods of recruiting subjects are generally acceptable.** In reviewing recruitment activities, the IRB reviews the mode of communication, the content, and how content is presented. There may be circumstances in which one or more of the methods may not be appropriate for a particular study. The method(s) of recruitment must be discussed in the IRB application.

* **Advertisements, flyers, information sheets, notices, internet postings on electronic bulletin boards, social media and/or web pages.** The text of these needs to be included within or as an attachment to the IRB Application. ***The IRB must approve the text to be used****.* Prospective participants who respond to these will contact the study investigators directly.
* **Direct contact with potential study participants.** Researchers may directly contact potential participants either in person (face-to-face), by giving a presentation to a group, over the phone, or on the internet through social media. Considerable care must be taken when using any of these methods so that the person contacted does not feel pressured to participate. The IRB must approve a script or overview of recruitment material for non-exempt research.
* **Recruitment letters, social media posts, and/or emails.** Ideally the recruitment letter or email would come from someone or some agency or clinic known to the prospective participant informing them about the study. Preferably, the letter or email would ask the person to call for additional information, return a post card or send an email if interested in participating in the study.

The recruitment letter, social media post, or email can be brief but it should include:

* information about how the person was identified to be sent the letter,
* who is doing the study and why,
* what is involved if the person participates,
* an overview of any risks or potential benefits,
* information about how to contact the study team if interested in participating,
* where to get answers to additional questions, and
* when using email, proper notification about the confidentiality issues associated with email communication.
* **Referrals.** Referrals may be from non-investigator healthcare providers, snowball sampling, participants referring other participants. Investigators may provide their colleagues with a “Dear Potential Study Participant” letter describing the study. Or researchers may provide information sheets to colleagues or associates who can pass them on to potential participants.
* **Participant pools.** These are pools for which potential research participants have given permission for future contact. Participant pools accessed at Purdue should be described in a protocol and records kept accurate by the lead investigator identified to the IRB.
* **Another IRB-Approved Screening Protocol, Recruitment Protocol and/or Recruitment Database.** This protocol describes how potential research participants will be asked for and will give permission for future contact. Investigators contact these potential participants about particular studies according to their approved protocol and the consent of the prospective participant. In many cases prospective participants will have given permission to be contacted for future studies by means of a check-off box in a consent form for a previous study.
* **Review of medical records to identify potential research participants.** Such procedures must be conducted in accordance with HIPAA requirements. Approval must be granted by the respective Privacy Office or Privacy Board from the institution supplying access to medical records.
* **Review of education records.** Such procedures must be conducted in accordance with FERPA requirements permission is granted by the Office of the Registrar (for Purdue data) or responsible official/Records Custodian at any external educational institutions.
* **Justified styles of snowball sampling.** Snowball sampling is a recruitment technique in which research participants are asked to assist the researcher in identifying additional participants by providing the contact information for potential participants. The researcher then contacts the potential participants to see if they wish to serve as research participants. Snowball sampling should not be employed as a method of convenience solely to increase the number of individuals participating in the research.

The IRB advises recruitment methods that minimize risk.Researchers must take considerable care to avoid placing pressure on potential research participants. Snowball sampling recruitment styles should occur only when the research would otherwise (i.e., examining dyads within relationships). The following information should be provided within the IRB submission when snowball sampling will be utilized:

* A rationale for the use of a snowball sampling strategy within the context of the specific study and target population, including why the research would be impracticable without utilizing snowball sampling.
* Justification for why the focal participant is unable pass along recruitment materials (i.e., email, flyer, information sheet) informing potential participants that they may contact the researcher directly if they are interested in participating.
* Steps the study team will take to minimize the risk of violating an individual's privacy when obtaining their information in order to make direct contact.
* A detailed description of how the researcher will obtain the information for the snowball
sampling. As a best practice, the researcher should ask the focal participant to obtain permission from potential participants prior to disclosing their contact information.
* Confirmation that focal participants will not receive incentives, compensation, or other inducements for providing referrals for potential participants.

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| **Examples of Unacceptable Recruitment Methods** |

* **Use of Incentives, Finder’s Fees or Bonuses** of any type in exchange for referral of potential participants or tied to the rate or timing of enrollment is prohibited. Such payments may encourage recruiters to put inappropriate pressure on prospective participants.
* **Sharing of Participant Names and Contact Information:** Researchers may not share names and/or contact information of previous research participants with other researchers without permission from those participants or prior arrangement through an approved IRB method.
* **Medical Record Access:** When protected health information is involved, investigators who are not the health care providers or part of the clinic providing health care are prohibited from having access to patient names, addresses, phone numbers, medical record numbers or any other form of protected health information. Patients must initiate contact unless there is documented permission from the patient (i.e., a note in the medical record that the primary care provider spoke with the patient who agreed to be contacted) that the patient agreed to be contacted.
* **Student Education Records:** Use of identifiable student education records other than directory information for research purposes without either the student’s consent (or parent’s consent if student is under age 18) or receipt of an exception to FERPA granted by the Records Custodian of the institution owning the records, is prohibited.
* **Enrollment by instructors of students in research** Investigators should propose additional procedures to ensure against actual or perceived undue influence or coercion. Considerations include:
* The investigator must not indicate direct or implied benefit or competitive advantage over other students who do not volunteer as potential participants.
* Students have the right to have class time devoted to classroom activities appropriate to meeting the objectives for the scheduled course. The IRB disallows recruitment of potential participants during class time. The instructor and all others associated with the conduct of the class (e.g., teaching assistants, etc.) must not be present during announcement of the research opportunity or any recruitment activity. Instead, the approved personnel should make an announcement in advance indicating that class will either start later than usual or end earlier than usual for optional recruitment activity.