

Chapman University Institutional Review Board

Recruitment of Research Participants

Recruitment of research participants involves presenting potential participants with information about a study, prior to their enrollment, to help establish their interest and willingness to serve as research subjects. Recruitment takes many forms and often includes the first information participants see about a study. Recruitment is considered by federal regulations and the IRB to be the beginning of the informed consent process. Thus, it is imperative that recruitment 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.** 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.

Ethical Considerations

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 consider 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, or physician), 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. The number of visits, expected time commitment, and eligibility criteria should fully align with the proposed research plan. Information must be clear and understandable, and free from technical or scientific jargon.

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,” or “new and improved”). 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,” can help.

Who May Recruit?

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 Registrar’s Office who provides directory information to a researcher).

IRB Submission Requirements

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 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 request), 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. If recruitment materials are posted in non-public locations, then permission from the site owner is typically required. At the end of this document there are tables summarizing the information to include in the IRB application to describe recruitment plans.

Guidance on Content of Recruitment Materials

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 subjects to determine their own eligibility (e.g., age range or medical restrictions in lay person's terminology)
- Time or other commitment required of the participants (e.g., total number of visits and expected duration)
- Contact information for interested individuals
- Location of the research

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

- Potential benefits to the individual or society (these 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

Recruitment in Classrooms

One particular circumstance that raises special ethical concerns involves researchers recruiting students from courses that they are teaching. The primary issue with gathering data from one's own course is the potential for perceived coercion.

Potential for coercion – Instructors have inherent power over students (e.g., through their responsibility for assigning grades). Because of this power relationship it is likely that some students will feel pressure to comply with requests made by their instructors. This is true independent of whether the instructors actually try to pressure the students. For example,

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when instructors ask students to participate in research projects, some students may worry that not participating could influence the instructors' opinions of them or that their grade might be affected. Such potential concerns are problematic regardless of whether the instructor actually would think negatively of nonparticipation or whether the students' grades actually would be affected. Students' perceptions that such negative consequences could happen are enough to make them feel pressured to participate. **Thus, unless the research cannot be reasonably completed in another manner, instructors should not recruit participants from their own courses.**

Exceptions – There are cases in which research cannot be feasibly completed without recruiting students from a particular course. For example, if the research project concerns a teaching method that will be implemented in the course, then the only possible subject pool comes from the students enrolled in that course. If a research project has a reasonable chance of yielding benefits, and the only feasible way to complete the study is to recruit in the researcher's course, the research may be permissible if the researcher is able to sufficiently reduce the potential for students to feel pressured to participate.

Reducing the potential for students to experience coercion – In the rare instances in which recruiting from one's own class is permissible, researchers are expected to minimize the potential for students to feel pressured to participate. One way that researchers have reduced the potential for perceived coercion is to design the study so that the instructor is blind to the identity of the participants (at least until after the grades have been assigned). For example, a research collaborator can run the study and keep any identifying information from the instructor. If a researcher designs a study in this way, two points are crucial:

- Before being asked to participate, potential subjects should be informed that the instructor will not know who did and who did not participate (at least until after final grades have been assigned).
- The research should be designed so that the instructor cannot infer who participated through indirect means (e.g., by seeing who walks into a laboratory or by getting a list of who earned credit for participating in the study).

In short, due to the potential for undue influence, researchers generally should avoid recruiting subjects from their own classes. When recruiting from their own class is the only feasible way to do a study, researchers are expected to design the research in such a way that the potential for students to feel pressured is minimized.

Researchers Recruiting Participants from Their Workplace

Researchers who include colleagues or subordinates as research subjects must be able to provide a rationale for selecting them and must show that the recruitment method does not lead colleagues to believe they will be compromised by choosing not to participate. The compromised circumstances and fear of retribution, even subtle cues of compromise, can place colleagues or subordinates in a coercive position of involuntary participation in a research project.

Recruitment through a third party who is not in a power relationship with the employee is usually the

best strategy. Research (e.g., focus groups, individual interviews, or surveys) in the context of a power relationship may be allowed if a third party collects the data and the data is de-identified when forwarded to the employer/administrator such that the employee cannot be identified from personal data and it cannot be determined whether the employee participated. If the researcher is using an extant database (e.g., employee work satisfaction surveys that have been completed as part of the workplace program evaluation) the data must also be de-identified before the research begins.

Recruitment Using Electronic Media

Recruitment conducted using electronic media creates new challenges for both investigators and those charged with maintaining protections for research participants. Examples of electronic media used for recruitment include advertising on a website or electronic bulletin board, text messages, email solicitation, chat rooms, instant messaging, banner ads, discussion forums, blogs, Amazon Mechanical Turk, YouTube, and other social media sites (e.g., Facebook or Twitter). Although technology grows swiftly, the requirements for research recruitment remain steadfast.

Recruitment procedures and materials used with electronic media must follow the IRB guidelines that apply to traditional media such as recruitment letters and flyers. Procedures should consider strategies to avoid perceptions of undue influence and maintain participant privacy. Materials must be written in clearly at a level likely to be understood by potential participants, be clearly presented as recruitment material, and cannot be published until they have received appropriate IRB review and approval.

Recruitment announcements on websites should be clearly identified as a recruitment ad for a voluntary research study. Such ads and announcements cannot be located or positioned in such a way that they could be easily mistaken for something else. For example, an investigator wanting to recruit students might use a recruitment plan that involves instructors notifying their students of that research opportunity. Oftentimes this is allowable so long as it is done so the instructor is merely passing on the information while making it clear to students the research is not related to the course and interested students contact the researcher directly.

Email invitations to potential participants should include the same elements as a recruitment letter. If potential participants are asked to contact researchers by email, the invitations should also contain proper notification of the confidentiality issues associated with email communication.

Use of non-public email list-servs and distribution lists may be used with permission of the list owner. This procedure must be detailed in the IRB application and, if possible, investigators should submit a copy of the list owner's permission with the IRB application.

Investigators recruiting through internet forums or other web-based communities should conduct their activities in accordance with that site's terms of use and/or privacy policy or, where such communities have a moderator or administrator, permission should be obtained in accordance with that community's requirements. These procedures should be detailed in the IRB application.

In sum, recruitment via electronic media should follow all recommendations that are relevant for recruitment via traditional methods. For additional help when recruiting specifically via social media, see [NIH guidance](#) on the topic.

Information to Include with IRB Applications

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 |
|---|--|
| Review of Public Records (e.g., voter lists, utilities lists, phone directories, or Chapman directory) | Specify the source(s) of the records |
| Review of Private Records (e.g., medical records, student records, or employment records) | 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 |
| Purchased Mailing Lists | Specify the source(s) of the lists |
| Personal Contacts | Provide a description of how potential subjects are known to the researcher |
| “Snowball” Sampling | Provide a description of what information about participants will be provided as part of the snowball sampling |
| Referrals (e.g., from medical care providers, colleagues, or teachers) | Describe the process for obtaining referrals, and how any privacy concerns will be addressed |

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 |
|--|---|--|
| Direct Contact | | |
| Written communication, such as letter or email sent to potential subjects | Describe the specific plans, including frequency, timing, and how any privacy concerns will be addressed | 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, and how undue influence or coercion will be minimized | Phone script(s), script(s) for announcement(s) and/or list(s) of talking points to be covered |
| Indirect Contact | | |
| Flyers | Indicate where flyers will be placed | Final copy of all flyer(s) if flyers will be posted in non-public locations, permission from the site owner, if possible. |
| Website announcements, including SONA, online bulletin boards, listserv distribution, etc. | Indicate where announcement(s) will be placed or the specific listservs to be used | Final text of website announcements, or text to be distributed permission from private listserv owner or web-based community, if possible. |
| Personal or verbal announcements | Indicate where announcements will be made and who the intended audience is | Script(s) for announcement or list(s) of talking points to be covered |

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| 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 NIH guidance on this topic) | 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 |