

Guidance: Recruitment Materials and Content Requirements

Introduction

The recruitment process and the materials used to conduct the recruitment process are considered the beginning of the consent process for expedited and full review protocols and the informational process for exempt studies. Direct advertising or recruitment refers to any activity that solicits research participation directly from potential subjects. Federal regulations (45 CFR 46.111) require that the IRB review all research documents and activities that have a direct impact on the rights and welfare of the human subjects in the proposed research and must ensure that subject selection is fair and equitable. The content of recruitment materials and the recruitment process must be clear and accurate, not be coercive or demonstrate undue influence (especially in the case of vulnerable populations), and should not compromise the privacy of the individual or the confidentiality of information about the individual. To ensure that the recruitment process and materials meet these requirements, they must be reviewed by the IRB and/or the Office of Research Protections as part of the IRB protocol submission materials. Recruitment materials may be submitted at the same time as all other application materials or via an amendment as soon as the researcher decides recruitment materials are necessary. Subjects should not be approached or recruited for research until the IRB has approved the research overall, the methods of recruitment, and the recruitment materials.

General Requirements

When describing the recruitment process, the investigator should explain who they plan to contact (i.e. the target subject population) and how they will initially contact the subjects for the purpose of recruiting them in the research (i.e. the mode of communication). Common recruitment strategies include emails, recruitment letters, recruitment flyers, posters, brochures, media advertisements (advertisements in newspapers, magazines, or radio advertisements), informational sheets, verbal scripts for word-of mouth or in-person recruiting, on-line postings, and verbal announcements made by others on behalf of the researcher (e.g. teacher of a specific class, minister in a church, managing official in an organization).

Similar to the consent and information sheet process, recruitment materials must be written at a language level understandable to the subject population the researcher is targeting, generally the 6th-8th grade reading level. Depending upon the age, maturity, and expected abilities of the targeted subjects, the reading level may need to be adjusted, such as when recruiting children or persons with diminished capacity. Also, depending upon the age range of the target population, there may be a need for materials at differing reading levels, such as when researchers communicate both with the parent and the child about the research or if the researcher plan on recruiting grade school students and high school students.

Generally, the content of recruitment materials should be limited to the information the prospective subject needs to determine whether they are eligible to be in the research

(investigator inclusion/exclusion criteria contained in the protocol) and whether they are interested in participating in the research.

Required content includes:

- The names of the investigators conducting the research, identification of DePaul university by name as the location of the research or the researchers main affiliation (Department or School), and contact information for the researchers (name and contact information e.g. email, phone number);
- The purpose of the research;
- A statement that the volunteers are being recruited for “research” purposes (not just ‘a survey’ or ‘a study’);
- The general eligibility requirements;
- A brief description of what would be involved in participation, including the anticipated amount of time for participation (i.e. number of visits, how long it takes to complete the survey or questionnaire);
- A brief description of the risks and benefits of the research, if any. Do not promise a direct benefit when there is none. Differentiate between direct and indirect benefits to the subjects. If benefits are discussed they must be balanced by a discussion of the anticipated risks of the research;
- A description of any compensation or reimbursement that may be provided. Statements regarding compensation or payment must not be bolded, enlarged, or use other methods of emphasizing payment (i.e. dollar signs, pictures of gift cards) and should not be the header or lead sentence in the recruitment item;
- The IRB protocol# and version date of the document, preferably in a footer.

Information that should not be included in recruitment materials:

- Materials should not claim, explicitly or implicitly, that the research is safe and effective treatment or therapy when the safety and efficacy of a treatment or therapy is what is being tested, or that a research intervention is equivalent or superior to other standard interventions or is superior to any current practice when it is not proven.
- Statements like “new treatment” or “new therapy” should not be used, as this implies to the subject that the intervention is a tested and approved standard of care intervention.
- Materials should not promise “free treatment” when what is meant is that subjects will not be charged for study-related procedures and tests.
- Materials should not include catchy words, like “exciting opportunity” or “Here’s your chance to help,”
- Materials should not include any statement or implication that the DePaul IRB endorses the research study.

- When recruiting children, the materials must indicate that parent/guardian permission is required for the child to participate, unless parent/guardian permission has been waived by the IRB.

Materials requiring review:

- Any item used to directly contact subjects for the purpose of soliciting them to participate in research. Recruitment materials include emails, recruitment letters, recruitment flyers, posters, brochures, media advertisements (advertisements in newspapers, magazines, or radio advertisements), informational sheets, verbal scripts for word-of mouth or in-person recruiting, on-line postings, and verbal announcements made by others on behalf of the researcher (e.g. teacher of a specific class, minister in a church, managing official in an organization)
- First contact scripts. These are the scripts used to first talk to the potential subjects when they are contacted directly by the researchers or when they respond to a recruitment item. If initial information is gathered about the subject in order to determine eligibility (e.g. using a screening checklist), the IRB protocol should explain what information will be gathered, how it will be recorded, where it will be recorded, and what happens to information if the person decides not to be in the research or does not meet the eligibility criteria.

Materials not requiring review by the IRB include:

- Study announcements to health professionals in trade or professional journals or resources. The intent of these announcements are to alert the professional community that a particular researcher may have a new study (or studies) dealing with a particular topic and could include contact information so that subjects can be referred to the researcher.
- Public service announcements or news stories where the intent is not to recruit subjects directly for an individual study. For example, a research unit may announce generally that they conduct research on a specific topic and should anyone be interested in future research participation contact information is provided.
- Clinical trial listing (e.g. Clinical trials.gov, National Cancer Institute's cancer trial listing PDQ, the AIDS Clinical trial Information System ACTIS or other listing sources) as long as the information is limited to basic trial information such as the title, purpose of the study, protocol summary, basic eligibility criteria, study location(s), and how to contact the researchers for further information. If the listings allow for additional information to be entered and the researcher lists additional information, IRB review and approval is required to ensure that there is no promise or certainty of benefit to the subject beyond what is outlined in the protocol and/or the consent document.

Other requirements:

- The IRB must review the materials in their final format, whenever possible. For example a recruitment flyer should be reviewed in the final format that will be used when posted, in order to evaluate the size of the type used and any pictures or visual effects. The IRB must ensure that the materials are not coercive and do not imply benefit or positive outcomes beyond what is outlined in the protocol and consent document. Investigators should carefully evaluate any images used to ensure they are communicating a message consistent with the intent of the research.
- Mock-ups of larger posters versus the full size poster are allowed. Recruitment materials submitted for review can include place holders such as Dear [parent's name], go to the following link [insert link], or the meeting will be on [insert date] at [insert time]. Adding the indicated information to the recruitment item would not require an amendment or additional IRB approval as long as the changes are limited to just the items indicated when approved by the IRB.
- If recruitment material is taped for video or audio advertisements, such as television or radio ads, the IRB must first approve the text of what will be recorded, and then the final tape to ensure it follows the script approved by the IRB.

Things to think about when designing the recruitment process and materials:

- The method used to obtain contact information and to make initial contact with the research subjects should be sensitive to the privacy of the individuals. For example, if the recruitment plan includes the researchers contacting the potential subjects directly, the source of the contact information should not be one that would be considered private by the subjects. If the potential subjects are public figures or contact information is readily available through public sources such as the internet, then it is not likely that the subjects would consider this private information or an invasion of privacy to contact them directly. However, if the researcher plans to use organizational list serves or other private sources containing contact information, it is best to have an organizational member send an email on behalf of the researcher. Direct contact by the research may be considered an invasion of privacy by the potential subject, because they have the expectation that their contact information and/or association with the organization or group are private.
- When obtaining names and direct contact information from third party individuals, the researcher should consider whether doing so would constitute a breach in confidentiality, or be inconsistent with privacy laws, or organizational policies.
- If research involves sensitive topics, such as mental health therapy or treatment, HIV/AIDS status, drug or alcohol abuse, or sexual orientation, the researcher should consider whether the recruitment process could result in a breach in confidentiality related to the subject being identified as having the targeted condition or being a member of a specific target group. For example, the researcher may plan to send mass emails to potential subjects or make direct phone calls to subjects. In this case the email should be blinded so others receiving the email do not see the contact information for the other

potential subjects receiving the email. When conducting phone recruitment, the phone script should be careful to not “out” the potential subject when they are not the one answering the phone or when leaving a message for the targeted person.

- Snowball recruitment where the researcher obtains names and contact information from one individual for another one, particularly for research involving sensitive topics, is generally not considered appropriate by the DePaul IRB. Using such a method could result in the researcher obtaining information about an individual that is sensitive and private without their permission. Alternatively, the researcher should ask other subjects to pass along flyers, emails, information sheets, etc. that contain contact information for the researcher to prevent a breach in confidentiality or an invasion of privacy. In instances where the research subject is not sensitive (i.e. opinions on politics, consumer opinions), a snowball recruitment method where one person provides the name and contact information may be acceptable. The following are examples of such recruitment materials:

Dear [name of person being recruited],

[Name of person referring them] suggested I talk to you regarding [include the topic of the research]. My name is [include your name] and I am conducting a research study on [insert short explanation of study].

Or

Dear [Name of person being recruited],

My name is [insert name] and I am conducting a research study on [insert topic of research]. Your name has been suggested to me as someone I may want to talk to regarding [insert explanation of research].

Rules for posting recruitment items:

- Organizations, website, newsletters, etc. may have internal policy that governs the posting of materials. An investigator should ensure they ask for and follow the rules. In some instances it may be required to obtain a letter of support from the head of an agency or organization that is specific to the recruitment method being used within that group.
- When using email recruitment methods where messages are sent on the behalf of the researcher by organizational members, the researcher should ensure that there is no coercive language included in the message to members. The materials should simply provide general information about the research and contact information for the researcher.
- Recruitment flyers or other materials posted on the DePaul campus require approval from the Department of Student Life before being posted on campus. Materials posted in residential locations on campus must be submitted to the Department of Residential

Education. Each department has their own requirements related to size, location, etc. Researchers should review these requirements when preparing materials to be posted on campus.