

Union Institute & University: Human Subjects Research General IRB Application and Research Proposal Preparation Guidelines

Use the accompanying Word template for completing a description of the proposed research. Researchers must provide sufficient information for **each** listed item so that the IRB can evaluate their applications.

1. Research Purpose: (principle of beneficence)

- Describe the purpose and significance of the study—the benefit and value.
- Describe specific objectives and expected outcomes—general and specific.
- Include hypotheses, research question(s), or goals of project.
- Where and how will the data be presented after study completion?
 - Small group presentation
 - Dissertation, thesis, final document, professional journal, professional presentation, seminar, methods course, internship, capstone learning experience, other (specify)

Where and how will the data be presented? The venue for the data presentation relates to the value and the risk involved with the research.

2. Characteristics of Participant Population: (principles of respect and justice)

To properly evaluate the risks, reviewers must be informed about the probable level of the ability of the subjects to understand their rights as a subject and give consent. Reviewers must know the nature of the culture of the potential subject population or know that the researcher has adequate knowledge of the culture to determine whether measures to protect subjects are incorporated into the study design.

- Describe anticipated number of participants, age ranges (e.g., gender, ethnic background, etc.).
- Identify the use of any protected or vulnerable populations—populations vulnerable to coercion or undue influence such as children under the age of 18, prisoners, mentally disabled, economically or educational disadvantaged, pregnant women, or other.
- Explain rationale for using participants whose ability to give voluntary informed consent may be in question.
- Describe participants' culture and whether they will be able to understand their rights such as non-English speakers.
- Describe criteria for inclusion and exclusion—factors that will exclude an individual.
- Identify derived materials or publicly available data involving human subjects.

3. Research Procedures and Methods:

a. Recruitment and Selection of Subjects:

- Describe how participants will be recruited. Describe the recruitment process (in person, by telephone, letter, or e-mail), media used (ads, flyers, letters, brochures, posters, e-mail messages, or Web site notices, etc.), including for non-English speaking potential participants.
- Explain how you want potential participants to contact you for questions and/or to volunteer (in person, telephone, e-mail).
- Describe the nature of the relationship between PI and subjects.
- If potential participants are members of a group that may be construed as stigmatized (e.g., spousal abusers, members of support groups, people with AIDS, etc.), initial contact should be through advertisements or fliers or through people who interact with potential participants because of their job duties. These people may describe the study to potential participants and ask them to contact you if they are interested in the study.
- If potential participants, or parents, are not primary English speakers, describe how will contact and attach translated recruitment documents.

Attach, describe, and refer to any advertisements, letters, and e-mails used for recruitment. Provide telephone and presentation scripts used for recruitment.

- Describe data collection method and analysis procedures. Provide validity/ reliability data on instruments not developed by the researcher.

b. Research Location:

- List all sites where the research will be conducted. Include school districts, day care centers, nursing homes, Internet, etc.
- Arrange for letters granting permission to recruit participants and conduct research at these locations to be submitted to the IRB on letterhead.
- Letters should grant your permission to use the facilities or resources; they should indicate knowledge of the study that will be conducted at the site.
- If letters are not available at the time of IRB review, approval will be contingent upon their receipt.
- Indicate whether project has had or will receive review by another IRB. Attach a copy of the approval letter. UI&U's IRB will usually accept versions of consent forms approved by IRBs affiliated with hospitals or other medical facilities.

Attach all consent forms, consent presentation scripts, surveys, testing materials, questionnaires, interview questions, structured and non-structured; include permissions to use instruments if required, site approval letters, and other IRB approval letters.

c. Informed Consent Procedure:

- Describe who will conduct the consent process, where it will be conducted, and when it will be conducted; e.g., written form presented at time of interview, mailed or e-mailed to participants prior to in-person or telephone interview. Attach consent form.
- If oral or abbreviated consent form is used, explain why and provide script of the presentation.
- Children under the age of majority (in state(s) where study will be conducted) need parent/ guardian/ legal representative consent to participate. Participants between ages 7 and 17 should be given an opportunity to assent to their participation.
- Explain that consent forms will be placed into an envelope and separated from paper surveys, questionnaire, or interview notes to avoid associating names with surveys, etc.

d. Research Activities—Research Protocol:

Part of the beneficence consideration of the review process is the efficacy of the project being proposed. If a project is logistically problematic or the researcher and assistants are not qualified to conduct the project, the good of the project is diminished.

- Describe clearly all research activities in which some or all participants will be involved.
- Describe type of research information will be collecting from participants. Attach copies of all surveys, testing materials, questionnaires, and assessment devices. Attach copies of interview questions and topics and sample questions for non-structured interviews and focus group discussions.
- Explain the frequency and length of time participants will be involved in activities for the purpose of the research and the overall length of time of research participation.
- Describe the training and experience of persons administering treatment, collecting data, or accessing the data and relevance to human subjects protections.
- Describe the compensation or costs, if any, to subjects for their participation. Payment, if given, should be reasonable and prorated with partial payments to those who withdraw before completion of the study. Offering to reimburse parking fees, with a receipt, or mileage at the current rate is reasonable.

e. Privacy and Confidentiality of Participants:

Anonymity refers to the situation in which the dataset and/or research materials contain no personal identifiers through which anyone, including the investigator, could connect individual responses with a specific participant.

As long as personal identifiers are in the data set, the researcher is responsible for maintaining confidentiality of the data set.

Treatment of data as confidential is required when a dataset and/or research materials include personal identifiers, such as a name, photograph, sound recording, or personal references such as address, telephone numbers, ID number, or any information that may be used to connect a particular participant with his/ her data.

If identifiers are linked to participant data, risk of harm exists; therefore, the research project will receive periodic review (at least annually) to ensure that the procedures used to guarantee confidentiality are adequate. Progress reports are required at that time.

The identity of subjects is integral in some studies and, therefore, research material will contain identities such as in oral histories and qualitative clinical studies. The IRB will approve such studies when procedures for obtaining consent include explicit documentation that the participant consents to maintaining identity in the dataset.

- Describe how you will protect the privacy and confidentiality of participants.
- Privacy refers to control over content, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
- Confidentiality refers to the treatment of information or data that an individual disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure.
- Describe how data will be stored to ensure that it is secure and remains confidential.
- Describe precautions for taped responses that can be linked to a participant because his/her name is on the audiotape or because videotape is used. Include secure storage—flash drive, computer hard drive, locked file cabinet, other—limiting access. Include when other study data will be destroyed—a minimum of three years for IRB. Include longer term if required by researcher's professional association.
- Who will have access to the data for which participant identity is known or could be inferred?
- How will the data be disseminated?

f. Deception and Debriefing:

A special problem of consent arises when informing subjects of some aspects of the research is likely to impair the validity of the research. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research.

- Provide a rationale and justification for deceiving subjects about the research activities.
- Describing the debriefing process and attach a debriefing script.

Deceiving Subjects: Deception in research is justified only if the following is very clear:

1. Incomplete disclosure is necessary to accomplish goals of the research;
2. No undisclosed risks to subjects that are more than minimal exist; and
3. An adequate plan for debriefing is available.

g. Research Resources:

- Discuss assistants and others who will assist with consent process, data collection, data analysis, transcription, etc. Attach resumés for all individuals involved with study and study data.

g. Potential Risks and Discomforts:

- Describe any potential risks—physical, psychological, social, legal, or other—and assess their likelihood and seriousness. All studies involve some degree of risk—evaluate potential risks that can be reasonably anticipated.
- If research methods impose risks on subjects, include evidence that may justify their use such as previous experience with the procedures.
- Most studies pose some degree of risk, even though the risk may be minimal; e.g., one common risk is loss of confidentiality of participants' responses.
- One risk that may arise in studies with children or interviews with parents about their children is the

risk that you may acquire information about physical or sexual abuse. If you acquire this information, you are required to report it to the appropriate authority—family and child services, school administrators, police, school counselor, etc. Know where to report this information. If a child expresses a desire to harm her/ himself or other, this information must also be reported to the appropriate authority.

- Describe procedures for protecting against, minimizing, or mitigating any reasonably anticipated risks.
- Specify arrangements for providing psychological treatment if needed when a participant becomes upset when recalling a past or traumatic event or other emotional situation.
- If the study involves deception, describe the procedures for debriefing participants. Attach debriefing script.

After identifying risks, your emphasis should be:

- Describing procedures for minimizing risks.
- Describing provisions for insuring medical or professional intervention in the event of adverse effects on subjects.

h. Potential benefits:

- Describe and assess potential benefits, if any, to be gained by participants and benefits that may accrue to society in general as a result of the planned study. Discuss the risks in relation to the anticipated benefits to participants and to society. Use “may” not “will” when stating potential benefits—researchers cannot guarantee any benefits—just point out possibilities.
- Explain how benefits outweigh risks.

i. Context of Study – Brief Literature Review:

- Provide a brief (no more than five pages) literature review and accompanying bibliography or reference list that presents key research on study topic or related issues.
- Include discussion of other similar research studies, compare and contrast them with your study. Show that you are sufficiently familiar with related research investigations, thus demonstrating your qualifications to conduct the study and to confirm potential benefits of the study.

j. Attachments—consent forms, instruments, approvals, resumés, ethical guidelines: See b above.