

# How to Prepare an IRB Application?

## Guidance for Student Researchers

### 1. Correct terms:

- a. You are submitting an “application” for IRB review, not an “IRB” for IRB review
- b. Adults (over age 18) provide “Consent”
- c. Children provide “Assent”
- d. Parents provide “Parental Permission” for their children to participate in research and sometimes also “Consent” to participate in research with their child (e.g., mother-daughter dyads).
- e. The study cannot be both “anonymous” and “confidential.” The study is **anonymous** when the data cannot be linked to participants through direct (e.g., name) or indirect (e.g. pseudonym, numeric code) identifiers. Example: on-line survey with no identifiable information (e.g., names, emails, IP addresses). The study is **confidential** when the data can be linked to participants through direct (e.g., name) or indirect (e.g. pseudonym, numeric code) identifiers. Example: interview data.

### 2. Study Design:

- a. Be realistic about what you can accomplish with limited resources in a limited timeframe. Unless it is a doctoral dissertation, do not attempt to tackle sensitive topics or vulnerable populations that require additional protections and the highest level of IRB review. **The IRB strongly recommends that students design minimal risk studies that can be granted an exempt determination or approved by the expedited process.**
- b. The study should be placed in a broader scholarly context. Cite 2-3 sources to demonstrate your knowledge of the literature on the topic that is being investigated.
- c. Choose appropriate research methods and analytical techniques. Quantitative methods are used to *test the relationship between specific variables*. Example: What factors are associated with student success? Qualitative methods are used to *understand the meaning of or experience* with a social condition or phenomenon. Examples: How do students define success in college? What are the experiences of language-minority students in the classroom? **Review SAMPLE RESEARCH DESIGNS for QUANTITATIVE and QUALITATIVE studies**
- d. When doing qualitative research, do not attempt to make far-reaching conclusions – the results will likely be limited to the specific situation or sample population you are studying.
- e. When using secondary data, i.e., data collected by someone other than the user, submit a list of variables that will be analyzed and provide evidence (e.g., letter of support) that you have permission to access and use the data for your research.
- f. Make sure your research questions and methods are described consistently throughout all application materials. Review the application, recruitment materials, and consent documents for consistency in regards to number of subjects, procedures, compensation of subjects, etc.

### 3. Study Procedures:

- a. Ask the following questions: Does the timeline make sense? Is the sample size justified and appropriate for your chosen methods and analytical technique?

- b. Is there a logical path for subject recruitment, screening, consent, data collection, compensation (if any), and follow-up?
- c. Submit RESEARCH INSTRUMENTS: surveys, interview guides, observation guides, as appropriate.

#### **4. Recruitment Procedures:**

- a. Explain your method(s) of recruiting subjects, including how the subjects will be identified, invited to the study, and screened for eligibility.
- b. All recruitment efforts must respect personal rights to privacy and confidentiality and avoid coercion of subjects.
- c. Secure support letters or IRB approvals from external performance sites, at which recruitment materials will be disseminated, permissions to use listservs for distributing email invitations, and permissions to access records for the purpose of identifying, contacting, and recruiting participants, and attach them with your application.
- d. Submit all relevant RECRUITMENT DOCUMENTS: email invitations, information sheets, flyers, verbal invitations, and screening scripts, as appropriate. The text of recruitment materials must be approved by the IRB. **Review GUIDANCE FOR RECRUITMENT DOCUMENTS.**

#### **5. Consent Procedures**

- a. Explain how consent will be obtained.
- b. Submit CONSENT DOCUMENTS: adult consent forms, assent forms, parental permissions, as appropriate.
- e. Make sure your consent documents are written in plain, understandable language free of professional jargon. For participants recruited from the general population, the documents should be written at the 8<sup>th</sup> grade reading level. **Review GUIDANCE FOR CONSENT DOCUMENTS.**
- c. For consent documents written in a foreign language, submit a translator statement. The statement should attest to the accuracy of translation and should be signed and dated.

#### **6. Risks and Benefits:**

- a. Most social-behavioral studies have limited to none benefits to participants.
- b. Research risks may include not only physical harms, but also potential damage to the participant's social standing, employability, and reputation. Consider all risks and describe how those risks will be minimized.

#### **7. Compensation:**

- a. Compensation is never a research benefit.
- b. The amount of compensation should be appropriate to the study population so that it does not create coercion or undue influence.
- c. The information about compensation should be stated in the consent document, including the odds of winning a prize or a gift card.
- d. Compensation should not be contingent upon completing the entire study because this could unduly influence a subject's decision to participate. Payments should be prorated for subjects who are not able to complete the entire research study.
- e. If course credit or extra credit is offered to a student population, a nonresearch activity that is equivalent in effort and time/duration to research participation must be offered.

**8. Data management:**

- a. Identifiable data should be coded and kept in a secure location.
- b. A list of codes should be kept separately from the data.
- c. Signed consent forms should be kept separately from the data.
- d. Sensitive data should be encrypted.
- e. If there are no plans for a follow up study on the same participants, the codes should be destroyed at the end of the study and the data should be permanently de-identified. De-identified data with no links to human subjects can be retained indefinitely.