IRB Application Tips

Writing an IRB Application: Guidelines

1. Purpose:

Provide a brief literature review and research citations to support the study's purpose and rationale. Only include information that is critical to the present study and avoid reusing an entire literature review from a thesis or grant proposal. Instead, the purpose section should be concise and tailored to the IRB application and should conclude with clearly stated objectives. It should demonstrate that the proposed procedures are methodologically sound and capable of answering the questions they are intended to answer. If it is not clear from the purpose statement, the PI should also briefly explain why they believe the chosen level of review (full, expedited, exempt) is appropriate. Proofread the application, and work with the Writing Center if necessary to ensure that the application is readable.

2. Subjects:

Clarify how many participants will be involved and how the sample size will be determined. Researchers are responsible for enrolling only the number of subjects that were specified and approved in the protocol.

Equitable Selection

Clarify how the subjects will be selected. Subject selection must be equitable, or the PI must describe the rationale for the invitation of specific subjects.

Research in the Classroom

The PIs should clearly describe in what capacity they are employed at the school and whether they will be recruiting from among the students, parents or staff whom they already deal with in the course of their regular work duties. When possible, consider collecting data from a classroom other than your own. When this is not possible, justify the need to collect data from your students, and describe the safeguards that will be used to ensure that students and parents do not feel unduly influenced to participate. When describing action research, provide documentation to support the research procedures used in the classroom so that reviewers from other fields can sufficiently understand the rationale behind your methodology and safeguards.

Review Wenzhou-Kean University IRB guidelines and suggestions for additional safeguards for “Research in the K-12 Classroom” on the IRB website. Review the checklist for consent/assent forms and include all the required language (e.g., participation is voluntary, refusal to participate

involves no penalty or loss of educational benefits, deciding to participate will not affect grades, etc.). Be consistent between the protocol description and the language use on the informed consent, assent and debriefing forms. When possible, copy and paste material from the application to the forms to ensure consistency between the description of the research procedures and the forms. Verify that the reading level of the forms is appropriate for the intended audience.

Research in the Workplace

Review Wenzhou-Kean University IRB guidelines for "Research in the Workplace" on the IRB website. Clearly describe in the protocol and consistently state on informed consent and debriefing forms the safeguards the PI will use to minimize coercion and undue influence.

3. Recruiting:

Explain the recruitment process in detail including the methods that will be used, the timing, the location and the roles of all individuals involved. Provide a copy of all recruitment materials including any letters, emails, fliers, interview scripts, etc.

Recruitment Order

Research with minors should use the following recruitment procedure in this order: After IRB approval, a flier is sent home or emailed to parents; if parents are interested, they contact the PI to learn about the study. If they agree to allow their child to participate, they sign (or electronically sign) parental consent and receive a copy of the consent form for their records. After parental consent is obtained, the students are informed about the study. If they agree to participate, they sign the assent form and receive a copy for their records. PIs working with young children should detail how they will obtain assent using age-appropriate methods supported by literature relevant to their population.

Compensation/Gift Cards

The PIs must be careful not to entice participants with rewards for taking part in a research study. However, if the project involves time and effort from the participants that the PIs believe warrants individual compensation, they must provide justification to show that the compensation is reasonable given the level of commitment required and will not unduly influence participants. PIs using crowdsourcing sites, such as MTurk, for recruitment should likewise clarify the compensation that will be provided and explain the rationale based on the tasks assigned to participants. If justification for individual compensation cannot be

provided, as an alternative, participants can be entered into a lottery with other participants for the opportunity to win a gift card. PIs conducting research at WKU who wish to provide extra credit as compensation for student participants must provide alternate opportunities for students so that those who decline to participate can still earn the same level of credit. They must also explain the safeguards that will be in place to prevent coercion and clarify the number of times students can participate in the project for credit.

4. Duration:

Clarify the time or other commitment required of the participants including number of sessions, duration of each session, and total duration including any follow-up activities.

5. Location:

Specify where the research activities involving human subjects will take place. When possible, choose a research location that is a neutral site rather than a private a home. If this is not possible given the purposes of the study, the PIs must provide justification for using the chosen site.

6. Obtaining Consent:

Describe informed consent process. Explain how potential participants will be told about the study and given the opportunity to ask questions. Describe how they will be given the opportunity to sign the informed consent form physically or electronically (recommended if surveys and other study activities are being completed online) and how they will be able to receive a physical or digital copy of the consent form for their records if they desire one. For example, an electronic survey may be set up so that the first screen contains the informed consent form. Participants may be asked to click yes that they consent to participate, and they could then print or take a screen shot of the signed consent for as desired. Explain what will occur if participants do not give consent (e.g., they will be thanked for their interest and will receive a debriefing form or be taken to a screen with an electronic debriefing form if completing their survey online).

7. Benefits:

Describe the benefits to the subject or to others that may reasonably be expected from the research. When the subjects are not expected to reap any direct benefits from the study, inform the subject that they will not personally receive any benefits, and then, describe how the study will benefit the larger community, our understanding of science, etc.

8. Risks:

Risk is exposure to harm, including physical, psychological, emotional, professional, social, financial, legal, or other types of harm. Note that this includes survey or focus group question topics that are potentially sensitive and could trigger emotional distress. An application must identify all possible risks that can result from participation in the study. If no risks are anticipated beyond the risks encountered in normal, daily life, the application and the documents shared with the subject must state that the risks are minimal.

Procedures to Protect from Risks

Specific strategies for minimizing or preventing the risks and protecting the welfare of the subjects must be explicitly described. This may include reminding participants that they can quit at any time without penalty, referring them to appropriate agencies for counseling, and providing contact information if they have questions about the study. Note that the Kean Counseling Center only assists Kean students. Research subjects outside of the Kean community who need counseling should be directed to a free, community-based counseling center or hotline. If such services are provided at the subjects' workplace, these services may be investigated and offered to subjects on the informed consent and debriefing forms.

9. Privacy:

Studies with human subjects must maintain confidentiality. Clearly outline the steps that will be taken to ensure that there are no links between the identity of the subjects and the results of the work. Please note that online survey responses are completely anonymous only if the online survey software has its IP collection mechanism disabled. The PIs should describe their plans to do this if they are administering an anonymous survey. If a platform such as Zoom will be used to conduct live sessions, the PIs should explain the security features and steps that will be used to maintain privacy and protect participants.

10. Data Storage:

Paper Files

If data collection will involve paper files, include the location of the locking file cabinets that will store the data. Include a statement that access will be provided to the IRB representative, if requested.

Electronic Files

If electronic files will be used, describe the safeguards that will be taken to protect the data, such as password protection of computers, cloud storage websites and databases where files are maintained. If data will be

downloaded and stored, include the location of the computer or devices that will hold the files. Include a statement that access will be provided to the IRB representative, if requested.

11. Disposal:

Describe how the data will be destroyed after 5 years (e.g., electronic files deleted, paper files shredded, etc.).

12. Measures:

Online Surveys

Verify that your survey addresses all the online survey guidelines found on the Kean University IRB website including the level of risk, collection of personally identifiable information, assurance that informed consent is obtained and participants are debriefed, and exclusion of forced responses (or the rationale for using them).

Survey/Measure/Forms Review

Submit the finalized survey or the interview or focus group questions you plan to use with your application. Minor adjustments to questions after IRB approval has been received are acceptable if the questions do not stray into areas that the IRB could not have anticipated from the application and that the subjects could not anticipate from the informed consent. If

significant modifications to the questions are made, the PI must submit a change form so that the IRB can review the updated questions.

ATTACHMENTS

Site permission - K-12 schools and external worksites or facilities

The IRB requires site permission documentation from an appropriate authority at each school, district, worksite or other external facility. Use the templates available at WKU IRB's website OR provide a signed approval letter on school/district/company letterhead that includes:

- Person or entity providing permission, including title, contact information and confirmation of appropriate authority to provide permission
- Title of the study
- Description of the project and activities to be conducted at the site

Surveys

Provide a printout of the online survey or provide a link to the online survey.

Provide permission to use measures and copyrighted material, or indicate that they are in the public domain.

Human Subjects Training

Provide documentation by including the completion certificates for all researchers interacting with human subjects and their data during the project.

Informed Consent, Assent and Debriefing Forms

When possible, copy and paste material from the application to these forms to ensure they are consistent with the protocol description. When writing the debriefing form, use past tense to summarize what participants did, and if the participants are students, do not include a thank you statement on the consent/assent forms. Use Wenzhou-Kean University contact information on the forms, such as WKU/Kean email addresses and office or phone numbers. If audio or video recording will occur as part of data collection (e.g., during an interview or focus group), a separate consent form for recording must be attached. (Please see the template on the IRB website.)