Phillips Graduate Institute

Guidelines for Completing Description of Proposed Research

I. Methods

The applicant must answer the questions of Form B "Description of Proposed Research." The following material suggests the kind of material and level of detail that must be presented. The material is presented as a synopsis of that material. The applicant must write in full sentences with the intent to convey as clearly and comprehensively as possible the requested information. The material presented in the "Description of Proposed Research" must be consistent with what is presented in the applicant's Methods section, in the consent form, if applicable, and in any other relevant material (cover letters, advertisements etc.) submitted with the application, for example, in the appendices. Inconsistency among any parts of the written materials will automatically trigger a revision of the application. The length will vary but to be complete, the applicant should expect to write from 5 to 15 pages.

A. PARTICIPANT RECRUITMENT

1. What is the relationship, if any between the P.I. and the potential participants?

   In other words, are the participants known by or in some already established relationship to the P.I. (friends, co-workers, supervisees, etc.). Appropriate recruitment procedures must be selected in those situations in which role conflicts (between personal and professional or between different professional relationships) exist. The applicant must discuss in detail any relationships of participants to the P.I. other than the research relationship. If a multiple relationship exists, the applicant must detail in the following section, e.g., recruitment, procedures, confidentiality, how special precautions have been taken to avoid ethical problems such as inadvertent coercion or violation of confidentiality.

2. How will participants be contacted and recruited? (Be very specific)

   - *By whom (if applicable indicated training or degrees)*
   - *Where (locale or situation)*
   - *Method of approach (P.I or teacher discusses study at end of class; newsletter; email, internet; flyers; mail randomly to names on a phone list; etc. Enough detail to indicate no coercion is involved). Is this a random sample (if so, describe what procedures). Do you select specific categories of persons (supervisors, managers). Presumably you are not selecting everyone in that category so you need to describe what criteria you use to select the individuals you do.*

3. Approximately how many participants will be studied? Describe the participants' primary characteristics (e.g., ethnicity, gender, age, SES, and other characteristics if important.

"Important" means that these characteristics could influence the variables in your study. E.g., those with a disability may answer questions about employee benefits differently from those who don't.

4. What is the rationale for the use of the sample that will be studied? Convenience sample is not acceptable as a rationale.

Why was the population chosen? Issues of social justice are involved: are certain populations overburdened or excluded unnecessarily. The trend in the past is for high risk studies to be performed more on non-Caucasian groups (where risk is is high) and low risk studies to be performed on Caucasians (where benefits from research are greater). This pattern must be avoided unless there are exceptional circumstances. For example, in organizational studies, you would justify why you are looking only at lower administrative level employees. If this is choice is based on your research question, then the rationale is justified. However, if this choice is made because you don't want to bother higher level administrator, then the choice is not based on an ethically acceptable reason.)

B. PROCEDURES

1. Briefly summarize the major objective of your research.

Explain the objective so that if a person only read this section, they would know what the point of this study is about. This can be done in a few sentences to one paragraph.

2. Describe all procedures to be conducted with human participants. The Procedures in this case refer to all interactions between the researcher and the participants after the participant recruitment which is described in the previous section. Give enough detail so that a reviewer can understand what you plan to do.

Also, put a copy of the following in the appendices of the application: 1) the Methods Section/Chapter of your proposed research, 2) all research instruments, including demographic background questionnaires, and 3) the informed consent form to be read and signed by participants prior to participation.

- *Summarize the major objective of study. The application does not include a literature review or a list of the hypotheses so this section is the only place where the major objective is discussed. Although this should be done in a few sentences, be as comprehensive as necessary for the reviewer to understand the main point of the study.*
- *Describe all procedures to be conducted with human participants. The Procedures are generally considered to include all interactions with the participants after their recruitment of participants. Provide enough detail so that it is clear there is no coercion and that there is no unnecessary risk of any sort (psychological, social, legal including issues of confidentiality).This is not simply a copy of the Procedures section of your proposal as this section should include an enhanced description of the key elements of the ethical guidelines (use of cover letter, if applicable, right to withdraw, participation is voluntary, how consent forms are distributed and collected, how all relevant procedures are explained to participants, how debriefing will be included (debriefing can be done orally if participant is present with the group at the end of the data collection or through the mail if not, e.g., a summary of results. Some information*

should be more developed in the Procedures section of the proposal and not in the application. This information is given a more cursory review because it has no ethical relevance or contains excessive detail. Examples would be the mechanism by which participants are randomly assigned to conditions, hospitality issues as long as they would not be perceived as an inducements to participate, and descriptions that involve excessive detail, such as scripts to be read to participants or description of individual stimuli in a study The latter material have ethical implications, but the reviewer can learn of this detail by reviewing the Methods section of the proposal.

C. RISK/BENEFITS

1. What are the potential benefits (if any) to participants and/or to others?

   If no direct benefits, then this must be stated. Benefits to others include gaining useful knowledge that will aid therapists, health practitioners, etc. in serving this population

2. What are the reasonably foreseeable risks to participants? What are the negative effects (if any) on participant's physical, psychological, social or legal well-being as a consequence of participation in this research?

   Description of risks (physical, psychological (e.g. discomfort, stress), social (e.g., stigma) and legal well being (e.g., immigration issues, effects of reporting abuse, if applicable).

3. What procedures will you use to protect against or minimize potential risks, and how will you assess the effectiveness of those procedures?

   Protect against or minimize risks: e.g., appropriate instructions to reduce stress, anonymous questionnaires and/or use of coded forms to protect confidentiality

4. If there are potential risks to participants, how will they be minimized prior to the implementation of the research? How will problems be handled if they occur during the implementation of the research? What other methods were considered and rejected in favor of the method chosen (provide rationale for choices)?

   Risks can be minimized prior to research by careful selection of subjects, by using anonymous questionnaires and/or coded forms to protect confidentiality. If problems occur, subjects can respond by notifying appropriate personnel (P.I, research advisor, Chair of ERC) if have questions, need referrals for psychological help. Describe other methods considered and give reason for choosing selected method.

5. How will the risks to participants be outweighed by the potential benefits to participants or by the importance of the knowledge gained?

   Statement of how risks will be outweighed by benefits.

6. If applicable describe and explain "no known risks" of any kind.

   If state "no known risks of any kind", must describe and explain (e.g., there is evidence in the literature or past experience in doing a similar project to justify this claim.).

D. INFORMED CONSENT

Are your proposed participants capable of giving informed consent? Is the research population in a free-choice situation? Or, are they constrained by age or other factors that limit their capacity to choose? For example, are they adults, or students who might be beholden to the institution in which they are enrolled, or prisoners, or children, or mentally or emotionally disabled? Does the inducement to participate reduce significantly their ability to choose freely or not to participate?

Are proposed participants capable of giving informed consent. Special procedures have to be in effect for children or other vulnerable groups or individuals who may be beholden, thus unduly influenced to individuals associated with the study. Is the inducement to participate non coercive (e.g., large monetary amounts to the poor are coercive; getting points toward a grade for participation in a study without alternatives for getting the same points is coercive).

E. CONFIDENTIALITY

1. What provisions will be made to safeguard the anonymity and confidentiality of personal data? Where will the data be stored (e.g., locked filing cabinet)?

   Use of anonymous questionnaires and/or coded questionnaires and consent forms; separating questionnaires from consent forms when collected, removal of names from written transcripts (qualitative data), etc.

2. Who will have access to the data?

   List all who will have access to the data (typically the P.I. and the research advisor if this is a student study; only individuals who are knowledgeable in the ethical guidelines should be in contact with any data in which individual's information could be disclosed)

3. What will be done with the data when the research is completed? When will the data be destroyed (e.g., "no later than [specific date]")? Who will destroy the data? How will the data be destroyed? When (e.g., "no later than [specified date]" and how (e.g., shredder) will data be destroyed. Who (the person responsible) will destroy the data.

F. OTHER

1. If the research involves deception, describe the debriefing procedures that will be used and submit a verbatim debriefing statement for review. Include procedures for removing possible negative effects of deception on participants. When deception is necessary, debriefing should be prompt and complete.

2. If participants are to be paid in cash, services, or benefits for participation, describe the amount and basis of payment or compensation.

3. In general, there should not be any feedback to the individual participant about his/her individual performance. Any special reasons for waiving this rule must be reviewed and approved.

4. Include any additional relevant information on protection of the rights and welfare of participants.

II. Consent Process

The consent form must include the following elements. The consent form templates do address all of these issues. However, the statements are generic to fit most studies. You may need to modify statements to make them most appropriate for your study. For example debriefing is handled in the template by providing the participant the option of obtaining a synopsis of the group results by mail. However, if the applicant's study involves data collection in person in a one-on-one or group format, then in person debriefing is the more appropriate approach, and the wording should be added or changed to reflect that.

1. A statement that the study involves research
2. An explanation of the purposes of the study
3. The expected duration of the subject's participation
4. A description of the procedures to be followed
5. Identification of any procedures which are experimental
6. A description of any reasonable foreseeable risks or discomforts to the subject
7. A description of any benefits to the subject or to others which may reasonably be expected from the research
8. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous.
9. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
10. For research involving no more than minimal risk, an explanation as to whether any compensation will occur.
11. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights.
12. A statement indicates that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. The description of loss of benefits should be appropriate to the context of the study. The template contains a generic statement, but if there are specific benefits to which that participant could perceive as possibly losing, a statement should specify those benefits.
13. A statement as to what the debriefing procedures will be, including whether a synopsis of the study will be offered to the participant. The templates include the offering of a synopsis which is an appropriate form of debriefing if debriefing is done by mail. The description should be consistent with the procedures described in Procedures, Question 2 of Form B. Debriefing should be done in a reasonable time frame given the context of the study, i.e., immediately and in person if this can be

done, or by mail e.g., offering a synopsis of the study, if data are not received in person from participants.

Be sure that the application contains the following material and is reviewed:

- A copy of the Methods section of proposal.
- A copy of all contact letters, flyers, advertisements, etc. used to recruit subjects
- A copy of surveys, questionnaires, etc, used in study
- A letter of assurance from another institution if IRB approval has been obtained elsewhere, if applicable.