

## **Guidelines for Completing the *Application for Approval***

### **PART A**

#### ***Cover Sheet***

Most of the sections on this page are self-explanatory. In addition, here is further information about:

- **Project Period:** Provide both the start date (month, day, year) and projected end date (month, day, year) of the project. The start date cannot occur before the date of IRB approval of the project. The project period may be any length of time.
- **Proposal for Funding:** If extramural or intramural (e.g., CISR) funding is being sought for this project, provide the deadline by which your funding proposal must be submitted to the funding agency.

#### ***Signature Page***

##### **Assurance Statement**

- The protocol form constitutes legal documentation of the research plan. Before signing the Assurance Statement, be sure to read it and be certain that you are abiding by its provisions.
- If you are a faculty mentor, read the Approval Statement before signing it (it is part of the legal documentation of the protocol). As a faculty mentor, you are responsible not only for supervising the student conducting the research and for ensuring that project documents are properly maintained, but also for ensuring that the student conducts the study appropriately and ethically. You are also responsible for ensuring that the design and procedures of the study are appropriate for the research question/hypothesis and for making sure that all sections of the protocol application are complete and accurately and clearly written.

##### ***Required Information***

- Unless a particular type of information is not applicable to your project, each of the categories of information must be submitted with your protocol.

##### ***Level of Review***

- Indicate the level of review you are requesting. Refer to the *IRB Procedures and Guidelines* for information on the levels of review. If you have any questions about which is the appropriate level to request for your study, contact the IRB Coordinator, Sally Mateja (809-2916).

### **PART B**

Part B consists of a screening checklist to help you determine the correct level of review for your study. Based upon your answers to these items, complete the appropriate final part (Part C for Level 1 review, Part D for Level 2 review).

## **PART C (for Level 1 review)**

### **I. Project Significance**

- Describe the purpose of your proposed study along with a rationale for the project, including what the research outcomes may be and what the outcomes may add to existing knowledge (in the area, field, discipline, etc.)

### **II. Participant Selection**

- Check the appropriate categories. If you are using only previously collected (existing) data or documents and not collecting new data from human subjects, then check N/A for items b – e.
- Specifically describe the procedures you will use to recruit participants (or acquire the existing data/documents). If you will be obtaining mailing lists or other contact lists, indicate how and from whom you will obtain the lists and how you will use them. If you will be recruiting via flyers, e-mail, or other advertising, describe the nature of those materials (and include a copy) and how/where those materials will be posted/disseminated. If you will contact people in person or over the phone, describe how and where you will do that (and include a copy of the script you will use when speaking to them). If the research session will take place after a class has been dismissed, describe the procedure by which class will be dismissed and students not interested in participating will be allowed to leave as well as what will be said to those interested in staying (and include a script).

### **III. Procedures and Methods**

- *a.* State your specific research question(s) and/or hypotheses. The IRB needs to know what you want to find out in order to effectively evaluate the procedures/methods you intend to use. Even if the study is exploratory, you need to give the reviewers a description of the direction of your exploration.
- *b.* Be as detailed as possible in describing the procedures and methods that you will use. Provide the location and duration of each procedure (and, if the procedures occur in a single session, the overall duration of the session).
- *c.* Compensation means any kind of remuneration that participants receive for participation (e.g., money, gift certificates, gift items, etc.). Describe it and how it will be awarded. If there will be no compensation, then state “none.”

### **IV. Informed Consent Process**

- The consent form is not the process. Describe step by step how the method of obtaining consent will be conducted, the procedures used to inform participants of the nature of the project and of their rights as participants, etc.

### **V. Confidentiality and Anonymity**

- Describe how participant privacy will be protected. Participant responses do not have to be anonymous, but if identifying information is collected, that information must be kept confidential. State who will see the identifying information and the secure location (building, room number) where materials with identifying information will be kept. If the investigator is a student, the materials with identifying information must be retained by the faculty mentor, not the student. Materials with identifying information may be kept as long as desired but must be maintained for at least 3 years after the end of a study with adults and until participants reach the age of 18 for a study using minors.

### **VI. Conflicts of Interest/Problems of Undue Influence**

- Indicate if potential participants include students in any class(es) taught by the investigator (and/or faculty mentor) during the project period. “Project period” includes students currently in classes and students that may be in classes that the investigator/mentor teaches in subsequent semesters while the project is ongoing.
- For research requirements and extra credit alternatives, describe in detail the equitable alternative(s) offered in place of research participation. “Equitable” means (but is not limited to) similar to research options in time and effort required and in the way credit is allotted. If an equitable alternative is not offered, then students in the investigator’s (and mentor’s) classes may not participate in this project (although other students may participate in this project and the investigator’s/mentor’s students may participate in other projects), and you must describe the procedures used to ensure that the investigator’s/mentor’s students do not participate in the project.
- If other categories of conflict of interest apply, you must describe in detail the procedures you will use to reduce or, if possible, eliminate the conflict or undue influence.

## **PART D** (for Level 2 or 3 review)

### **I. Project Introduction/Review of Literature**

- Describe the purpose of your proposed study along with sufficient background literature so that reviewers can understand the context for your study. Provide citations within the text and a reference list at the end (using the citation and reference format appropriate for your discipline).

### **II. Project Significance**

- Provide a rationale for your proposed project, including what the research outcomes will add to existing knowledge (in the area, field, discipline, etc.).

### **III. Participant Selection**

- Identify the age range of participants. If you have no maximum age limit, then you may write “no limit” after *To*.
- Provide the minimum number of participants needed to adequately complete the project. The minimum is only your baseline; you may collect information from more participants than the minimum if circumstances warrant.
- Specifically describe the procedures you will use to recruit participants. If you will be obtaining mailing lists or other contact lists, indicate how and from whom you will obtain the lists and how you will use them. If you will be recruiting via flyers, e-mail, or other advertising, describe the nature of those materials (and include a copy) and how/where those materials will be posted/disseminated. If you will contact people in person or over the phone, describe how and where you will do that (and include a copy of the script you will use when speaking to them). If the research session will take place after a class has been dismissed, describe the procedure by which class will be dismissed and students not interested in participating will be allowed to leave as well as what will be said to those interested in staying (and include a script).

### **IV. Procedures**

- *a.* State your specific research question(s) and/or hypotheses. The IRB needs to know what you want to find out in order to effectively evaluate the procedures/methods you intend to use. Even if the study is exploratory, you need to give the reviewers a description of the direction of your exploration.
- *b.* Be as detailed as possible in describing the procedures and methods that you will use. Provide the location and duration of each procedure (and, if the procedures occur in a single session, the overall duration of the session).
- *c.* Describe the materials (including citations and references for standardized/published materials). If you have adapted materials from another source, identify the original source (with citations and references) and describe how you adapted it. If you developed the materials yourself, state that and describe how you developed them (e.g., if they were based on previous research, theory, etc.) along with relevant citations and references. For each item, explain why it is appropriate to the method you are using and to the purpose of your project.
- *d.* Explain why your participants and your minimum sample size are appropriate to your design, including why participant characteristics are appropriate and why your minimum sample size is sufficient for your project.
- *e.* Compensation means any kind of remuneration that participants receive for participation (e.g., money, gift certificates, gift items, etc.). Describe it and how it will be awarded. If there will be no compensation, then state “none.”
- *f.* Identify the specific building and room where the data will be retained and for how long. You may keep the data as long as you wish, but you must keep it for at least 3 years after completion of a study using adults and until participants reach the age of 18 in a study using minors.
- *g.* Be precise in describing how the information will be analyzed/evaluated. Identify the variables of interest, including, where appropriate, which is/are the dependent variable(s) and which is/are the independent/predictor variable(s). Be explicit about the types of analyses used. For quantitative designs, identify the specific statistical procedures (e.g., independent t-test, 2 x 3 ANOVA, 3 x 3 chi square, linear multiple regression, etc.). For qualitative designs (grounded theory, ethnography, phenomenology, etc.), describe the particular analysis steps/procedures to be used as appropriate to that design.

### **V. Investigator Qualifications**

- Identify the specific training, background work relevant to this project, experience, etc. that makes the investigator qualified to conduct this particular study using these particular participants, materials, procedures, and analyses. Simply having a degree in a particular field does not necessarily satisfy the qualification requirement. The same applies for faculty mentors. Experience supervising student research alone does not satisfy the requirement. What background, training, knowledge, etc. does the mentor have relevant to the topic and design of this specific project?

## **VI. Informed Consent Process**

- The consent form is not the process. Describe step by step how the method of obtaining consent will be conducted, the procedures used to inform participants of the nature of the project and of their rights as participants, etc.

## **VII. Confidentiality and Anonymity**

- Describe how participant privacy will be protected. Participant responses do not have to be anonymous, but if identifying information is collected, that information must be kept confidential. State who will see the identifying information and the secure location (building, room number) where materials with identifying information will be kept. If the investigator is a student, the materials with identifying information must be retained by the faculty mentor, not the student. Materials with identifying information may be kept as long as desired but must be maintained for at least 3 years after the end of a study with adults and until participants reach the age of 18 for a study using minors.

## **VIII. Risks**

- Describe in detail all known or anticipated risks or discomforts of any kind (emotional risks/discomforts, physical risks/discomforts, academic risks, social risks, economic risks, etc.). If risks/discomforts are anticipated, describe any procedures to be taken to reduce or ameliorate them. If you are not aware of and do not anticipate any potential risks or discomforts, then state that there are no anticipated risks or discomforts.

## **IX. Benefits**

- You must describe the general benefits that will accrue from the completion of the study (i.e., the type and general importance of the knowledge gained from the research). Describe any individual benefits that may accrue to participants. Benefits do NOT include compensation. If there are no individual benefits, then say so.

## **X. Conflicts of Interest/Problems of Undue Influence**

- Indicate if potential participants include students in any class(es) taught by the investigator (and/or faculty mentor) during the project period. "Project period" includes students currently in classes and students that may be in classes that the investigator/mentor teaches in subsequent semesters while the project is ongoing.
- For research requirements and extra credit alternatives, describe in detail the equitable alternative(s) offered in place of research participation. "Equitable" means (but is not limited to) similar to research options in time and effort required and in the way credit is allotted. If an equitable alternative is not offered, then students in the investigator's (and mentor's) classes may not participate in this project (although other students may participate in this project and the investigator's/mentor's students may participate in other projects), and you must describe the procedures used to ensure that the investigator's/mentor's students do not participate in the project.
- If other categories of conflict of interest apply, you must describe in detail the procedures you will use to reduce or, if possible, eliminate the conflict or undue influence.