Narrative: UNC IRB Application

Use the following Headings (A – E) and all applicable Sub-Headings when composing the narrative portion of the UNC IRB Application. Write the narrative so that a reviewer from outside your discipline may understand it.

A. Purpose

1. Provide a clear statement of the question(s) being asked, or hypothesis(es) being tested, *and supporting rationale.* Stating that "more research is needed on this topic" will be of little help. Explain why more research is needed. What are the potential benefits of the research? Note that a complete literature review is not necessary. Please do not copy and paste thesis/dissertation proposal chapters. Most statements of purpose can be adequately explained in less than a page.

2. Justify selection of category type: exempt, or full-board. Using guidelines in the UNC IRB Procedures document, explain in a brief paragraph why you chose a particular category.

B. Methods – Be specific when addressing the following items.

1. **Participants**
   Describe sampling procedures, sample size, and the characteristics of your sample.

   Be sure to address the age(s) of participants; whether or not participants come from a vulnerable population (e.g., children or adolescents, individuals with cognitive disabilities, pregnant women, prisoners); the exact source(s) for all participants; how participants will be initially contacted.

2. **Data Collection Procedures**
   Provide a step by step protocol of **everything** participants will be asked to do in your study.

   Stipulate the nature of all data to be collected. For example, rather than saying that "subjects will be observed" and "artifacts will be collected," specify what will be observed, and specify the nature of the artifacts. Make sure that this same information is provided in the consent form.

   If any form of deception is to be used, it must be thoroughly justified and procedures for debriefing must be included (see guidelines).

   Describe any plans for debriefing your subjects. As a compensation for participation, it is considered appropriate to provide subjects with additional information concerning the nature and purpose of the study. It is also desirable to provide them with some information, presented in a form they are likely to understand, about the basic concepts and theories related to the study. In the UNC IRB Application, include a copy of any debriefing information provided to subjects.

3. **Data Analysis Procedures**
   Describe what will be done to the data after it has been collected. How will you address your questions/hypotheses? A brief explanation of the statistical design may be helpful to reviewers.

4. **Data Handling Procedures**
   Describe where data will be stored, who will have access to data, how the identity of participants will be protected (e.g., data will be recorded by geographical area or group rather than by individuals, numeric identifiers will be used for interview or field data, records will be stored in locked file cabinets etc.), when data will be destroyed (e.g., in the case of test scores of interview recordings). If the lead investigator is a student, please bear in mind that consent forms must be retained by the Research Advisor for a period of three years.

   If subjects are to be anonymous (i.e., no one, including the researchers, knows their identity), explain how this will be accomplished. Explain whether or not the data can be traced back to the original source from identifiers used in the records.

   Remember that it is impossible to *guarantee* confidentiality. Information submitted electronically or in a group setting cannot be considered secure, and there is a legal obligation to report suspected mistreatment of children and serious threats against self or others. It is also possible that a court might order the release of data or a list of subjects. Again, focus on the steps you will take to maximize confidentiality.

4. **Data Handling Procedures (continued)**
   Describe any special arrangements to protect the safety of atypical populations, if applicable (e.g., hospital patients, developmentally disabled, young children, prisoners, etc.).

C. Risks, Discomforts and Benefits

The IRB is required to insure that the potential risks to participants (however minimal) are clearly justified by the potential benefits of the research. You have already provided the rationale for the research in Section A of the narrative. Here you must delineate any risks to subjects. **A single statement saying "risks are minimal" will require that your application be returned to you for explanation of the minimal risks.**

A statement that "there are no foreseeable risks" is acceptable and is likely to be the case for ***some*** research. Another acceptable form for the risks statement is referring to the comparability of participants' experiences in the research to activities in everyday life (e.g., "the risks inherent in this study are no greater than those normally encountered during regular classroom participation"). On the other hand, foreseeable risks must be fully disclosed, for example the discomfort of having your views challenged by others in a focus group, the stress one may encounter when completing an exam-like instrument, the discomfort associated with negative feedback about a learning assessment, or the physical fatigue and discomfort associated with exercise.

It is possible that participants will benefit directly from their participation by gaining knowledge or skills; however, if the subjects do not stand to benefit directly from their participation, say so plainly. Indirect benefits should also be mentioned (e.g., benefits to the discipline as a result of what is learned from the research project).

D. Costs and Compensations

Any costs and compensation must also be identified. Compensation might include extra credit in a class. If this is the case, be sure to stipulate here that an alternative form of extra credit of comparable effort and equal value is also available. In other words, extra credit must be available to all students, whether they volunteer for a given research study or not. Other compensation might be refreshments, gifts, money, raffle tickets, or an educational debriefing. **If compensation is provided, it must not be so great as to coerce participation.**

Costs might include missed instructional time, expense associated with transportation to and from the data collection site or the loss of artifacts (e.g., artwork, homework) to the researcher.

The IRB expects that any risks and benefits identified here will be communicated to the participants (e.g., through the informed consent document).

E. Grant Information (if applicable)

If the study is, or will be, funded by a grant, please explain fully. Explain any restrictions imposed by the grantor. Evidence of ethics training is required of all researchers working on federally funded research that involves human participants. Complete the training module available at http://www.unco.edu/osp/ethics/citi.html and submit the certificate provided with the tutorial as proof of completion with this application.

Attach all relevant materials to the application.
These materials may include, but are not limited to:

- ✓ Consent Documents – Follow the guidelines for construction of consent documents.
- ✓ Letters of Permission – Attach written permission from site of data collection if external to UNC. Letters or forwarded e-mails should document the permission of appropriate officials to recruit participation from and collect data in schools, child care centers, hospitals, clinics, and other universities.
- ✓ Survey Instruments – Copies of widely used standardized tests are not necessary.
- ✓ Questionnaires
- ✓ Interview Questions/Potential Questions/Protocols/Range of Topics
- ✓ Debriefing Materials (if applicable)
- ✓ Documentation of IRB Training (required for federally funded research and for full board review protocols)

The UNC Application Narrative must be accessed at: www.irbnet.org

In addition, the UNCO Application Narrative is common for all types of IRB review (exempt, expedited, and full board)