Guide to Completion of the IRB Application Form

This guide is intended to provide helpful hints for the completion of the IRB application form.

Question 1. Research purpose and objectives

Clearly describe the purpose of the research and the problem to be investigated. This also sets the stage for the reviewers to understand the proposed project.

Question 2a. Subject description

1) Describe the population from which the subjects will be selected. Be as specific as possible. Specify if they are members of a vulnerable population as defined by IRB policy.

2) Describe the subject selection methodology, i.e. random, snowball, etc.

3) Describe the procedures to be used to recruit subjects. Include copies of scripts, flyers, advertisements, posters, letters that may be used.

4) Include an estimate of the maximum number of subjects that may be contacted and asked to participate in the study, not just those expected to respond or participate.

5) Describe the length of time the subjects will be actively involved in the study, if more than one session will take place, specify the duration of each session.

6) Provide the calendar time frame during which active data collection will occur.

7) Describe any possible follow-up you may have with subjects. This might include later clarification of responses, providing reports from the study, recommendation of further treatment/assistance.

Question 2b.

If your subjects are under 18, you must comply with special regulations for using children as subjects and must comply with OSU’s policy 1-0135. Anyone affiliated with OSU that will be working on a project that involves minors must complete the training associated with this policy and provide the IRB office with the date of completion of said training before IRB approval can be obtained. Please refer to IRB handbook for guidance.
Questions 3 – 10. Methodology

3) Describe where the study will take place. The IRB requires documentation of approval from appropriate authorities for research at any location outside OSU. Describe what the subjects will be asked to do. For observational studies, describe any manipulations of the subjects and the behaviors to be recorded. Include copies of all questionnaires, tests, surveys, instructions or scripts to be used. Describe exactly what each subject will be asked to do including:
   - the topic areas of any instruments or tests;
   - interviews;
   - medical procedures;
   - physical exercises;
   - any other activities that the subjects will be asked to complete;
   - audio or video taping;
   - identification of any procedures or products that are experimental;
   - any possible discomforts or inconveniences that the subject might experience.

4) List by position any additional personnel (undergraduate assistants, graduate research assistants, members of the community) who will be involved in the recruitment or consent process or data collection and/or analysis. Names are not necessary. Describe the training in the protection of human subjects in research that these individuals will be required to complete.

5) Describe any expected or potential risks to the subjects including emotional, psychological, legal, pain, inconveniences. Describe any efforts that will be made to reduce risks (i.e. counseling services, CPR trained personnel, informational contacts, etc.)

6) If medical clearance is required for participation, explain how this will be obtained and documented.

7) If subjects are to be deceived or mislead in any way for purposes of the research, please explain and justify why the methodology required deception. Subjects who have been deceived must be debriefed at the completion of the study about the true or complete intent of the research. Please submit detailed debriefing procedures.

8) If data of a personal or sensitive nature will be requested, detail what information will be collected and any risks associated with compromise of confidentiality.
9) If materials that might be interpreted as threatening, degrading or offensive are to be presented to subjects, please explain their role in the research and any planned measures for intervention if subjects react adversely.

10) Describe any compensation (financial, extra credit, etc.) to be offered for participation, when it will be given, and any conditions for full or partial payment. Describe any alternatives to participating in the research.

Question 11. Consent Process

Voluntary consent must be obtained from each subject prior to participating in the research. Indicate if a written informed consent form will be used. A guide for the preparation of a consent form is available on the Office of University Research Compliance (URC) website at [http://compliance.vpr.okstate.edu/IRB/forms.aspx](http://compliance.vpr.okstate.edu/IRB/forms.aspx) and in Appendix D. If a written consent form will not be used, provide a detailed explanation of how informed consent will be obtained. Include copies of all related materials that will be used to explain to the subjects all elements of consent.

Question 12.

Indicate if a waiver of documentation of consent is being requested. Provide justification based on one of the two criteria hyperlinked in the application.

Question 13.

Indicate if you are requesting a waiver of some of the elements of consent/assent or parental permission or if you are requesting a waiver of the entire consent/assent or parent permission process. Provide justification based on each of the four criteria hyperlinked in the application.

Question 14.

Confidentiality must be maintained in human subject research. If identifiers are to be associated with data, justification must be provided.

Question 15.

Address how the data will be handled and stored such that the privacy of the subjects is protected. The increasing vulnerability of networked, internet accessible computers may dictate that sensitive data be stored on a computer that is not networked. Detail how long data will be kept. Some funded projects mandate that data be retained for a specific period of time. Specifically address the use, storage, and disposition of audio and video tapes. If audio or
video tapes are to be used for future research or training, this must be specifically stated in the consent form.

Question 16.

If the subjects’ participation in the study will be made part of a record that may be available to a supervisor, teacher, or employer, please address the risk posed to subjects that this might generate.

Question 17.

If any documents will be translated into non-English versions the Translator Declaration Form must be included with the application.

Question 18.

Discuss any direct benefits to subjects resulting from their participation (i.e. results of testing, etc.). Do not include payments or extra credit, as these are considered compensation and should be addressed in your response to question 10. If there are no known benefits to the subjects, please state this.

Discuss benefits to the general population of subjects (i.e. veterans with PTSD, etc.) and/or society at large.