

## GUIDE TO COMPLETION OF THE IRB APPLICATION FORM

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

### 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 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 impacted by your study. This number should include the total number to be contacted, not just those expected to respond or participate.
- 5) Describe the length of time the subjects will be actively involved in the study, including the number of individual interactions.
- 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. Please refer to IRB web site or handbook for guidance.

### Questions 3 – 9                      Methodology

- 3) Provide a detailed description of the methodology of the research.

Describe and inclusion and exclusion criteria.

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. If 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.

**If research will involve only the analysis of existing data or specimens, provide a detailed description of the data set or specimens including if identifiers will be accessed and or recorded.**

- 4) 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.)
- 5) If medical clearance is required for participation, explain how this will be obtained and documented.
- 6) If subjects are to be deceived or misled in any way for purposes of the research, please explain and justify why the methodology required deception. Subjects that have been deceived must be debriefed at the completion of the study about the true or complete intent of the research. Please detail debriefing procedures.
- 7) 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.
- 8) 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.
- 9) Describe any compensation (financial, extra credit, etc) to be offered for participation, when it will be given, and any conditions of full or partial payment. Describe any alternatives to participating in the research.

#### Question 10. Consent Process

The informed and voluntary consent of each potential subject is required for all human subject research.

Indicate if a written informed consent form will be used. A guide for the preparation of an informed consent is available on the IRB website at and in Appendix C of the IRB handbook. If a written consent will not be used, provide detailed explanation of how informed and voluntary participation will be obtained. Include copies of all related materials that will be used

to explain to the subjects of all the elements of informed, voluntary consent.

Question 11.

Confidentiality should be retained in human subject research. Identifying information should not appear on data with out justification. If identifiers of any sort ( names, ID numbers, email addresses, etc) are to be associated with data, justification must be provided.

Question 12.

Address how the data will be handled and stored such that the privacy of the subjects is protected. This information should include where the data will be stored, who will have access, how long the data will be kept and how the data will be reported. The increasing vulnerability of networked, internet accessible computers may dictate that sensitive data be stored on a computer that is independent of both. **Be aware that some funded projects mandate that data be retained for a specific period of time.** Specifically address the use, storage and disposition of audio/video tapes. If tapes are to be used for future research or training, this must be specifically stated in the consent form.

Question 13.

If the subjects' participation in the study will be made part of a record accessible by a supervisor, teacher or employer, please address the risk to the subject that this information could generate.

Question 14.

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 your response to question 9. If there are no known benefits to the subjects, please so state.

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