Roger Williams University

HUMAN SUBJECTS REVIEW
APPLICATION TEMPLATE

A. Faculty/Staff/Graduate Student New Individual Research Projects

1. Project Description

State the purpose of the research and rationale. Indicate what participants will be told, what will be done to them, and what they will have to do.

2. Participants

If the subjects are from a special population, such as children and prisoners, researchers should see *Section XIII* of this document before writing a proposal. If the participants are mentally or physically disabled, or are institutionalized, particular care is required to ensure that participation is not coerced and participants' rights are protected. If advertisements are used to recruit subjects, copies of the ads must be included with the proposal.

3. Research Procedures and Methodology

This section provides a comprehensive description of the research methodology including:

- Setting of the research study
- Procedures
- Data collection
- Data analysis
- How participants will be affected by the research.

In this section describe any illegal activities and/or deception that may be involved in the research. Also include why these methods are necessary. The use of deception in no way reduces the need for informed consent. Deception includes not only the presentation of false information to subjects, but also the intentional withholding of information in a manner designed to mislead subjects. Under no condition can deception involve the withholding or falsification of information likely to affect the willingness of subjects to participate in the research.

- If monetary payment is used, it may be considered a benefit to the subject. However, neither the amount of payment nor the method of disbursement should present problems of coercion or undue influence. Such problems might occur, for example, if the entire payment were contingent upon completion of the study or if the payment were unduly large.
- Finally, in an appendix include any informal and formal testing instruments, surveys, questionnaires, etc. Citations are also necessary if you are using published materials.

4. Consent Procedures

Informed consent must be obtained from each subject who is legally, mentally, and physically able to provide it. Submit a copy of the written consent form. See *Section*

IX for informed consent procedures. For subjects not able to provide informed consent themselves, written informed consent must be obtained from others (e.g., parents, guardians, etc.) *Section IX* also addresses informed consent of children and prisoners.
In all cases, describe how informed consent will be obtained. If the subjects are children or challenged mentally/emotionally, describe how their "assent" will be obtained.

5. Data Confidentiality
Maintaining anonymity is an ethical consideration. Describe how you will report the findings of the research while maintaining participants' confidentiality.

6. Risks /Discomfort to the Participants
Participants are at risk if they are exposed to the possibility of physical, mental, or social discomfort, harm or danger, or otherwise beyond minimal risk. If subjects are at risk, describe all steps to minimize risk, and, if necessary, attach a justification for these procedures based on the scientific literature.

7. Benefits of the Study
Anticipated benefits to any one individual or society should be described such that a risk/benefit judgment may be made.

8. Signatures
All investigators must read and sign the cover sheet (*see Section* X) assuring compliance with the ethical code for researchers.

9. Appendix
Attach any additional sheets, along with any supporting documents (e.g., consent forms, instruments, questionnaires, tests, interview protocols, etc.) to the Research Protocol Form if appropriate.