UIW Application for IRB Approval
Part II: Research Protocol

This form is retired. All IRB applications must now be submitted online at https://uiw.forms.ethicalreviewmanager.com/. This form is to be used for planning purposes only; the online application form will ask for the same information.

Provide the requested information and develop your research protocol in accordance with requirements specified in the UIW IRB Manual. Submitted protocols must be in the following format: single-spaced, 11-12 pt. sans-serif (e.g., Arial, Calibri, Helvetica) font.

Submit this completed form as part of the application to the Office of Research Development electronically for IRB review. **Do not submit applications directly to the IRB representative**, as this form will be electronically routed to them for review after it has been checked for completion and logged into the IRB database.

Section 1: Purpose: This section must briefly and succinctly state the purpose of the study and should derive logically from the summary of background and significance.

Section 2: Background and Significance: This section should review appropriate literature to provide a clear rationale for the study including the anticipated outcomes and their significance. It should include discussion of how the proposed project will relate to or differ from what is already known. If the proposed research is a pilot study, make this clear and describe why pilot data are needed.

Section 3: Location, Facility and Equipment to Be Used: This section should identify the location, facility and equipment used to carry out the research project.

Section 4: Subjects and Informed Consent: This section should describe the subject population and procedures for obtaining subject informed consent. In describing the subject population, include number of subjects, source, and demographic factors. Describe how subjects will be identified, approached, and recruited. Describe specific criteria for inclusion or exclusion in the study and provide justification based on the hypothesis tested. Describe in detail how, when, and where signed Informed Consent will be obtained (particularly for any studies involving special populations or sensitive information), if subjects will be given a copy of the signed informed consent document, and how and where the consent forms will be securely maintained.

Section 5: Subject Compensation: This section should describe in detail whether compensation will be provided as an inducement to subjects to participate in the study. Compensation is commonly offered to offset any inconvenience or expense that the subject may have. State the type and amount of compensation to be offered and when it will be paid. If there will be a delay in the receipt of payment,

state the length of time. Whether a particular type of compensation for subject participation in research is appropriate or not will be evaluated on a per-protocol basis.

Section 6: Duration: This section should describe the anticipated duration of the study including total time required for subject recruitment, data collection, and analysis.

Section 7: Research Design (Description of the Experiment, Data Collection and Analysis): This section should describe how the study will be conducted including the methods to be used, experimental design, subject assignment and randomization procedures, duration of testing, data collection methods, and all other details necessary to fully describe the study. If subjects are involved with the study for more than one session, include the length of each session, and the total time required of each subject. Include information such as power analysis to justify the number of subjects to be recruited for the study. Describe who will perform which actions (e.g., which tasks will be performed by the principal investigator or co-investigator(s) or research staff under the supervision of an investigator).

Section 8: Risk Analysis: This section should identify all risks subjects will be subjected, including their frequency (e.g., x in 100) and severity. The level of risk categorization (e.g., no risk, minimal risk, more than minimal risk) must be stated and special precautions to minimize risk must be described (particularly for any subjects requiring specific precautions). Although medical emergencies are not expected, accessibility to CPR trained health care professionals should be described, if necessary for the proposal. In greater than minimal risk studies, the IRB may require use of a medical monitor.

Section 9: Confidentiality: This section should describe how individual subject records and computer files will be safeguarded. Describe methods to ensure confidentiality and to whom information will be given, what information will be furnished, and the purpose of the disclosure.

Section 10: Literature Cited: Literature cited should list relevant references utilized in sections 1-9.