OFFICE *of* RESEARCH & GRADUATE STUDIES

IRB Guidance on Preparing an Application for IRB Review

It is essential that the entire application be prepared carefully and completely according to the guidelines on the online forms and in the policies & procedures. The applications become permanent IRB records and are subject to inspection and review by funding agencies and, where applicable, by the FDA and DHHS.

Because funding sources have different application requirements, IRB application forms are designed to allow flexibility in the format of materials submitted for review. Certain elements are required but may vary in form.

There are five essential elements of the IRB Application:

1. Application Form
2. Faculty Supervisor Agreement (if PI is a student)
3. Research Protocol
4. Consent Documents
5. Instruments Used for Data Collection
6. CITI training on research involving human subjects

Application Form

This form provides basic information on the PI, Faculty Supervisor (if PI is a student), other project personnel, the planned research activities, and any funding sources. Additional details on personnel and roles follows:

Principal Investigator: Indicate the name, phone number, e-mail address, mailing address, department, and CITI training date of the individual who assumes responsibility for the overall conduct of the study and preparation of results. The principal investigator will be the responsible correspondent.

Faculty Supervisor: If the Principal Investigator is a student, then a Faculty Supervisor or Thesis/Dissertation Chair must supervise the project. Supervision is defined as:

1. Direct knowledge of and responsibility for the direction and completion of the project
2. Assurance of student compliance with University and Federal human subject protection policies
3. Filing of required documents which verify revision, amendment, annual continuation, or completion of the supervised protocol.

For protocols with a planned duration equal to the duration of a course, the Course Instructor or Faculty Supervisor must ensure that the participating student investigator(s) are informed of the requirement to submit appropriate UIW IRB completion or continuation documents. If it is anticipated or determined during the study that the IRB approved protocol will extend beyond the duration of an investigating student's involvement in the course or graduate program, then a long-term Faculty Supervisor must be designated prior to course, thesis or dissertation completion.

Other Project Personnel: Indicate the name(s), role(s), CITI training date(s), and email address(es) of the individual(s) who will take part in the actual conduct of the study and/or preparation of results. When research staff will perform procedures under the supervision of an investigator, include their names as well. Roles of non-investigator research staff should be specified (e.g., residents, fellows, or research nurses who might perform physical examinations.)

Research Protocol

The protocol must include a complete description of the research plan.

Although the main purpose of IRB review is to safeguard the rights and welfare of human subjects who take part in research, the IRB also considers scientific design. It is unethical to put humans at risk as subjects of poorly designed research which does not meet the tests of the scientific method. Therefore, attention should be given to the preparation of an IRB Application so that it demonstrates that the proposed project is well-planned, that the sample size is justified by appropriate methodology, that it will be executed properly, documented accurately, and that the results will be analyzed appropriately.

The following sections are required in the Research Protocol and should be included as complete sentences with appropriate consideration of grammar and syntax.

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.

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.

3. Location, Facility and Equipment to be Used

   This section should identify the location, facility and equipment used to carry out the research project.

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.

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. The following guidelines may help investigators in their choice of monetary compensation and payment schedules.

a. The amount of payment provided subjects should not be out of proportion to the level of inconvenience and expected expenses accrued by the subject. If the level of payment is excessively high, this will be considered coercive.

b. Payment for participation should be given to the subject on a prorata basis. This implies that the subject will be paid in direct proportion to his/her actual degree of participation. For example, if a subject completes half of the study, he/she should receive half of what would have been paid for completing the study. Large "balloon" payments at the completion of a study are deemed coercive and will not be approved.

c. Informed consent must, in the case of compensation, contain a detailed account of the terms of payment, including the amount to be paid and a description of the conditions under which a subject would receive partial payment or no payment.

6. Duration

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

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).

Note: If performing clinical research be sure to differentiate which procedures are to be done (a) experimentally or (b) routinely. If a proposed study involves patients, identify which procedures

are experimental and which are part of routine patient care. This information is important to the IRB in assessing risks to subjects.

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.

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.

10. Literature Cited

    Literature cited should list relevant references utilized in sections 1-9.

Consent Documents

Consent documents are used in the process of obtaining informed consent to ensure all required information is given consistently to all potential subjects. They serve to document that the consent process took place to the satisfaction and understanding of both the subject and the investigator. All consent documents must be included as part of the Application.

Templates for adequately detailed, stylistically acceptable consent documents are available on the IRB's website. The templates include the required and recommended elements of consent, with additional elements recommended by the UIW IRB and suggested language for each section. It is strongly recommended that UIW investigators use the templates to develop informed consent documents, modifying them as appropriate for their specific studies.

Instruments Used for Data Collection

All surveys, interview questions, and other instruments must be included as part of the Application.

Certificate of Human Research Training

A Collaborative Institutional Training Initiative (CITI) certificate documenting completion of online training to ethically conduct research on human subjects must be current for every investigator on the proposal, including faculty supervisors. An overall score of 85% is required. Initial, CITI human subjects training is good for three years, per UIW IRB policy. Once initial training has been completed, renewal training is also good for three years.

For those investigators that have previously met IRB human subjects training requirements by taking courses offered elsewhere, that training is also good for three years. When training needs to be renewed, investigators may take the CITI refresher course. The CITI courses may be accessed at https://www.citiprogram.org.