Institutional Review Board Application Process

In compliance with university policy and federal guidelines, the Institutional Review Board (IRB) facilitates the review of research studies and projects involving human subjects at the University of Puget Sound. All university-funded or affiliated research projects involving human subjects must go through the IRB approval process. Students applying for an IPE Summer Research Fellowship, University Summer Research Grant in the Arts, Humanities, and Social Sciences, or a Richard Bangs Collier Scholar Award must acquire IRB approval for any research projects that involve human subjects.

Students considering applying for a summer research award are encouraged to begin the IRB process early in order to ensure that deadlines are met. In particular, since protocols need to be submitted to the IRB committee for approval in advance of submitting summer research award applications, students need to plan ahead and get an early start on the process. The good news is that some of the work that needs to be done to prepare IRB protocols can be applied to the summer research award applications (for example, both the IRB protocol and summer research award application require a description of the research project).

Below are step-by-step guidelines for acquiring IRB approval for summer research projects.

- 1. Download and read the full IRB document (entitled *Institutional Review Board (IRB) for the Protection of Human Subjects: Principles and Procedures Governing the Use of Human Subjects in Research*). The document is available at http://www.pugetsound.edu/files/resources/irb-handbook.docx.
- 2. Meet with the IPE Director (currently Brad Dillman) to discuss the IRB application process.
- 3. Assemble the 'protocol' (protocol is the term for the substantive portion of the IRB application, where research goals and methods are discussed). The protocol must not exceed five (5) pages in length. The IRB requires that the following paragraph subtitles be used:
 - a. **Project Description**: Describe the purpose of the research, the methods to be used including data collection procedures and any features of the research design that may involve special conditions or procedures for the subjects.

b. Subject Recruitment:

- i. Identify the number of subjects to be recruited for the research. Identify how and where subjects are recruited and the criteria that will be used to select and exclude subjects.
- ii. Describe the characteristics of the subjects with regard to age, sex, race, or other special affiliations or attributes which cause them to be included in the study population, institution status (i.e., patients

or prisoners), and their general state of mental and physical health. Explain why it is necessary to use any particular population subgroups or special populations.

- c. **Confidentiality of Data:** Explain how data will be secured to safeguard identifiable records of individuals and how long such records will be kept before being destroyed.
 - (The following standard statement may be used: "The names of participants will not appear on any materials containing their responses. All identifying materials such as the consent forms will be kept in a locked file in the IPE Program offices at the University of Puget Sound.")
- d. **Risks to Subjects:** Describe in detail any immediate or long range risks to subjects that may arise from the procedures used in the study. (Risks may be physical, psychological, social, legal or economic.) Clearly describe the precautions that will be taken to minimize these risks.
- e. **Benefits:** Describe the anticipated benefits to subjects, science, and/or society which may occur as a result of this study.
- f. **References** (include this section only if applicable).
- 4. Put together consent form(s) to be used in the research. See page 17 of the Full IRB document for consent form requirements. See Appendix 3 of the Full IRB document for examples of consent forms.)
- 5. Put together any questionnaires, interview questions, or other survey instruments to be used in the research.
- 6. Once you have assembled the protocol, download and complete the *IRB Application for Approval of Research Involving Human Subjects* cover sheet. The IRB Cover Sheet is available at http://www.pugetsound.edu/files/resources/irb-proposal-form.doc.
- 7. Submit complete IRB application (in the following order: cover page, protocol, consent forms, and questionnaires/interview questions) to faculty supervisor for review and signature (on the cover sheet).
- 8. Submit IRB application as a hard copy to the IRB in Jones 212 (CMB 1020) and as an electronic copy (irb@pugetsound.edu).
- 9. You will hear back from the IRB when it has reviewed your application.