Protocol Preparation Guide

(1) The cover sheet must be properly completed. All investigators must sign it. The faculty advisor must also sign the cover sheet if students are involved. The department IRB designate must also sign the cover sheet.

(2) If for any reason co-investigators are not able to sign the cover sheet, letters of support signed by them must appear directly beneath the cover sheet.

(4) The protocol must follow the format below and must not exceed five (5) pages in length. Protocols longer than five pages will be returned to the investigator for revision and resubmission. The following paragraph subtitles must be used.

(A) Project Description: Describe the purpose of the research and the methods to be used, including data collection procedures.

(B) Subject Recruitment:

1. 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.

2. 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.

(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 _____ Department at the University of Puget Sound."* **If this statement is used, it should appear in the same type font as the rest of the protocol. Do not use italics.**

(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.

Note: Projects that involve the use or handling of body fluids in any amount must describe how the researcher(s) will conform to the University of Puget Sound Bloodborne Pathogen Exposure Control Plan and Policy. The policy can be found at: PROVIDE LINK.

(5) Qualifications of investigator(s), briefly summarized. (Please, do not include CV's or biographical sketches). Students and other non-faculty investigators must be sponsored by a faculty member, whose signed, sponsoring letter must be included.

(8) Consent form(s). (See page 15 for consent form requirements. See Appendix 3 for consent form examples.)