Protocol Preparation Guide

Protocols must be assembled in the order given below.

(1) The cover sheet must be properly completed. All investigators must sign it.

(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.

(3) See Section 8 for instructions regarding renewals, modifications, reconsiderations, terminations, and requests for additional information.

(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, 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. Identify any risks to which subjects may be exposed. Interview guide and/or copies of survey must be included (if applicable).

(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 used to select and exclude subjects.

2. Describe the characteristics of the subjects with regard to age, sex, race, special affiliations 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.

   If the study involves students from Saint Martin's University, the following standard statement may be used: “The subject population will resemble the subject pool at Saint Martin's University in terms of age, ethnicity and gender.”

3. Include any incentive, cost or payment to the subject, or reimbursement for related expenses. Mention any conditions affecting payment and time of payment. Be sure to clarify the source of the funding if applicable.

(C) Confidentiality of Data: Explain how data will be secured to safeguard identifiable records of individuals.

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 Saint Martin's University."

(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.) Describe the precautions that you have 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 Saint Martin's University Bloodborne Pathogen Exposure Control Plan and Policy.

(5) Qualifications of investigator(s), briefly summarized. (Please, no 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.

(6) Literature Cited (if applicable).

(7) Projects that involve the use of medications, dietary supplements, or any substances that will be introduced into the body must include referenced information regarding the known side effects of those substances.

(8) Consent form(s). (See Saint Martin's University Policy and Standards for Protection of Human Subjects in Research and Investigational Activities for consent form requirements. See consent form examples available on our web site.)

Number of copies required:

Full Board Review: **1 paper copy and a single pdf of entire proposal w/ coverpage**

Exempt and Expedited Review: **1 paper copy and a single pdf of entire proposal w/ coverpage**