Protocol Preparation Guide

Protocol must be assembled and submitted in the order described below.

1. The Cover Sheet must be fully completed. All investigators must sign it. The advisor section must be signed and fully completed.
   If for any reason co-investigators are not able to sign the cover sheet, letters of support signed by them must be inserted into the document after the cover sheet.
2. See Section 8 for instructions regarding renewals, modifications, reconsiderations, terminations, and requests for additional information.
3. The protocol guide must follow the format below and **must not exceed five (5) pages in length for sections A-J**. Protocols longer than five pages (for sections A-J) will be returned to the investigator for revision and resubmission. The bolded subtitles **must** be used in the proposal submission and each area must be fully addressed.

Protocol Guide

A. Proposal details

i. **Investigator's name(s)**
ii. **Title of the study**
iii. **Course of study** (e.g., PhD Leadership, MEd HESA, MIT, MEd, Exercise Science, Nursing, Social Work, Psychology, Political Studies, Environmental Studies, etc.)
iv. **Advisor name**

B. Project Description:

i. **Purpose of the Research** Describe
ii. **Methods and the Data Collection Procedures** Describe fully
iii. **Special Conditions or Procedures for the Subjects** If applicable, describe any features of the research design that may involve special conditions or procedures for the subjects.
iv. **Risks to Subjects** Identify any risks to which subjects may be exposed.

C. Subject Recruitment:

i. **Number of Subjects to be Recruited** Identify
ii. **Subject Recruitment** Identify how and where subjects are recruited
iii. **Selection and Inclusion Criteria** Identify the criteria used to select and exclude subjects.
iv. **Characteristics of Study Population, Institution Status, and/or General Mental and Physical Health**. 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.
v. **Necessity of Including Certain Participants** 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."
vi. **Incentive or Cost** 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.

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

i. The following standard statement may be used (if accurate)**:**

"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."

OR

"The names of participants will not appear on any materials containing their responses. All identifying materials such as the digitally completed consent forms will be electronically stored in a password protected file on a computer."

ii. Policy for how data will be stored or deleted after the completion of the study (if different than i.)

E. 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.)

i. Describe the precautions that you have taken to minimize these risks.

ii. Identify and include the resources that you will point participants to so they can receive support for the risk that was incurred as a participant in the study.

F. Benefits: Describe the anticipated benefits to subjects, science, and/or society which may occur as a result of this study.

G. Bodily Fluids (If Applicable): 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.

H. Substances (If Applicable): 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.

I. 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.

J. Literature Cited (if applicable).

K. Final Proposal Version of the Survey, Interview, and/or Data Gathering Process (to include all applicable)

The committee may require revisions.

To include the proposed:

i. Consent Language specific to your proposed study from the list:

a. Implied Consent Form.
b. Participant Consent Form.
c. Parental/Guardian Consent Form .

ii. Introduction: The exact language that will be read to, read by, or carried out with participants in the proposed interview questions guide, survey, data gathering process, etc. Edit to reflect your project (i.e. remove generic language).
iii. Actual Questions (protocol, etc.)
iv. Resources shared with participants to mitigate risk incurred through participation in the study