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**UNIVERSITY**

**INSTITUTIONAL REVIEW BOARD**  
**PROTOCOL FORMAT**

The protocol as defined below follows the Protocol Approval Form. In writing your protocol, follow the outline below plus appendices. Use the same numbering system and headings below to enable the IRB to easily find your responses to these questions. For a full discussion of these questions and requirements, see the Protocol Guidelines that follow. Be sure to answer every section. If any part of a section is not applicable, indicate with N/A. Number all pages, including appendices.

- A. Description of Research
  - 1. Provide a brief synopsis of the study, including:
    - a) Short literature review.
    - b) Rationale for the proposed study,
    - c) Hypotheses to be tested.
  - 2. Participants:
    - a) Describe the subjects
    - b) Sample size
    - c) How will the subjects be selected for participation?
    - d) Diagnostic criteria for inclusion
    - e) Criteria for exclusion.
- B. Experimental Design
  - 1. What kind of controls will be used.
  - 2. Single-blind, double-blind, or other.
  - 3. If randomized, explain how.
  - 4. Plans for statistical analyses.
- C. Data Collection Procedures
  - 1. Describe exactly what will be done to subjects, including:
    - a) Instructions to participants.
    - b) Instruments to be used.
    - c) Frequency and duration of each procedure.
    - d) Site of data collection
    - e) Total amount of subject's time required for participation.
  - 2. Informed Consent
    - a) How will subjects be informed of the purpose, procedures, risks, and benefits of the study?
    - b) Who will administer the information?
    - c) If minors are involved, submit a child's consent form as well as a parent/guardian consent form.
    - d) If non-English speaking subjects are involved, how will the information be translated?
    - e) If requesting a waiver of written, signed consent, justify this request.

3. A consent form should include:
  - a) The purpose of the study.
  - b) Why the subject has been selected to participate in the study.
  - c) A thorough explanation of exactly what will be done to the subject.
  - d) The amount of time each procedure will require and the total amount of time required for participation by the subject.
  - e) A description of any foreseeable risks or discomforts.
  - f) A description of any benefits possible to the subject or to others which might be expected from the research.
  - g) A statement concerning the confidentiality of records.
  - h) An explanation of whom to contact for answers to questions about the research and research subject's rights. The names and phone numbers of the principal investigator(s) and SMUIRB Chair must be included.
  - i) A statement that participation is voluntary, that there will be no penalty due to refusal to participate or continue participation, and that the subject may discontinue participation and withdraw from the study at any time without penalty.

D. Risks

1. What are the potential risks to subjects participating in this study?
2. How will you protect against these risks?
3. How will you treat any adverse effects?
4. Are subjects restricted from using other drugs or treatments?
5. What are the risks of being in the control group?
6. What details of the study, if any, are kept secret from the subjects?

E. Benefits

1. What are the potential benefits to the subject?
2. Analyze the risk: benefit ratio. Do the benefits outweigh the potential risks to the subjects?

F. Cost

1. Will participation in the project require any out-of-pocket expenditures?

G. Payment

1. Will subjects be reimbursed for their participation?

H. Confidentiality

1. How will subjects remain anonymous?
2. How will records be kept confidential?

I. References

J. Appendices

1. Letters of support from institutions or agencies.
2. Letters of support from special consultants.
3. Copies of all data collection instruments.
4. Copies of project flyers and/or recruitment advertisements.
5. Copies of educational materials to be distributed to subjects.
6. Copy of human consent documentation forms.
7. Copy of Experimental Subject's Bill of Rights.
8. Copy of the complete curriculum vitae of the principal investigator.
9. Copy of complete curriculum vitae of research committee members only if they are not faculty at Samuel Merritt University.