NAIT Research Ethics Board
Study Protocol Template

Study Title:

Principal Investigator:

Co-investigator(s) (include names of all student researchers if this is a student-run project):

Research Sponsor Name(s) (if applicable):

Research Grant Name and Number:

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1. Purpose of the Study

Describe the purpose, specific aims, including primary and secondary objectives, of the study. Clearly state the hypotheses to be tested or the research questions that will guide the study. Include Outcome variables (independent and dependent).

2. Background / Literature Review / Rationale for the Study

Describe the relevant current context of the study and gaps in current knowledge. Provide the scholarly background, rationale, and significance of your study based on the existing literature and how will it add to existing knowledge. Include benefit and risks. For example, what are the gaps in the literature? How will this study help fill those gaps? Add relevant references at the end of the protocol.

3. Methodology

a. **Study Design**: Provide a detailed description of your study design and why it has been chosen. How does the study methodology satisfy your research objectives?

b. **Study Population**: Define the population you plan to recruit. Describe the sample size and sampling techniques. Include the criteria that will define the inclusion and exclusion criteria, such as age, gender, language…etc. You must provide appropriate justification for your inclusion/exclusion criteria. Provide specific details regarding recruitment strategies and make sure you have all of the recruitment documents uploaded into IRISS. Also include rationale for sample size and statistical power of the sample size. Address what will happen to data upon participant withdrawal.

c. **Research Methods/Data Collection Procedures**. Describe the study procedures and research methodology. Describe what participants will have to do. Include how long the study will last and the expected duration of subject participation. If there is deception involved, describe how subjects are deceived and the debrief processes. Include description of consent procedures. Who will obtain consent? How will this be done? Where will it be done?

d. **Data Analysis Procedures:** Include a description of the analysis plan by research objective. These will provide evidence the design will allow you to achieve your objectives. If applicable, include measures to avoid bias in the analysis.

e. **Confidentiality and Data Management**. Describe what information will be collected from participants. Describe where the data will be stored, for how long it will be stored and who will have access to it. Include provisions for keeping the data safe (e.g. password protected, encryptions, kept in locked cabinet, separation of identifiers and data).

f. **Strengths and Limitations**: Describe the strength and limitations of the study

4. Budget

If this research activity is funded, then please provide a detailed budget that includes costs of study staff/personnel, materials, travel, etc.

5. Conflict of Interest

Provide information about any real, potential or perceived conflicts of interest as well as any institutional conflicts of interest or community conflicts of interest that that may impact this research. Consider your financial, professional, corporate or personal relationships and any other factors that could influence the study's design, conduct or reporting. Conflicts must be avoided or managed and communicated to study participants where appropriate.