Protocol (Project Plan)

A Protocol/Project Plan is a required for all studies. This document should describe the objective(s), background, rationale, study design, methodology, statistical considerations, and overall support for the research. There are a number of templates available. As a guidance to the information to be included in social and behavioural studies the following outline is the information that would be required to enable the Committee to complete their review.

- General Information to be included:
  Study title, protocol identifying number (your own reference name/number for the study), name and address of the sponsor (if there is one), name and title of the person(s) authorized to sign the protocol, name and title of the investigator(s) who is (are) responsible for conducting the trial, and the address and telephone number(s) of the study site(s).

- Background Information:
  Provide a description of the study, description of the population to be studied, references to relevant literature and data that are relevant to the study as background for the research.

- Study Objectives and Purpose:
  Include a detailed description of the objectives and the purpose of the study.

- Study Design:
  Provide a description of the methodology and design of the research including an outline to describe how the aims and objective will be met, including
  - where the study will be conducted
  - the expected duration of the project
  - the number of participants planned to be enrolled
  - who will be participating (define the study population and describe the inclusion and exclusion criteria)
  - how the participants will be consented*
  - the identification of any data to be recorded
  - criteria for the participants to be involved
  - any statistical methods to be employed
  - timing of any planned interim analysis

- Study Procedures:
  Describe what is going to happen during the study. This should include how participants will be recruited, what tools will be used to collect and analyse the study information or data, what the participants will be expected to do, and what will happen to them.

- Participant Population:
  How many participants will be needed? How has that been determined?

- Data Handling and Record Keeping:
  Provide information regarding how data will be collected, who will have access to the data, how will Privacy and Confidentiality be managed and maintained.

- Data Analysis:
  Provide detailed information regarding the data analysis plan that will be used to meet the study objectives, including what methods will be used, what procedures are in place for accounting for missing, unused, and spurious data, procedures for reporting any deviation(s) from the original statistical plan.

- Direct Access to Source Data/Documents:
  Specify that the investigator(s)/institution(s) will permit study-related monitoring, audits, HREC review, and regulatory inspection(s), providing direct access to source data/documents.

- Ethics:
  Provide a description of ethical considerations relating to the trial with reference to the National Statement on Ethical Conduct in Human Research, and any other relevant guidance. Include a statement of who the HREC is that is providing the review.

- Financing and Insurance:
  Detail how the study will be funded, and what insurance is in place.

- Publication Policy:
  Include the information that will be provided to participants (if any), and what the publication policy and plan for the study is.

- Formatting:
  It is recommended that the protocol has a footer that includes the study title, date, version number and page number. This will enable the reviewers to identify items for discussion, and assists in ongoing document control.

*Consenting Participants – refer to the National Statement on Ethical Conduct in Human Research Chapter 2.2: General Requirements for Consent.

If Participants are not providing written, implied or opt-out consent, refer to the National Statement on Ethical Conduct in Human Research Chapter 2.3: Qualifying or Waiving Conditions for Consent. As stated "Only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information." To request consideration for waiver of consent each paragraph of section 2.3.10 must be addressed individually and clearly in the protocol.