Study Proposal

Why write a proposal? To capture everything that is known or planned about the study. It should be clear enough so that someone new could jump in at any time and know what to do, or so someone could evaluate whether or not it's a good study.

Introduction and Background
- what is the research objective and why is it being studied?
- discuss what is currently known about the research topic

Methods and Materials

Clinical
study population
- why is it important to focus on that particular population?
- age: why is this age range being selected?
- gender: females, males, both?
- inclusion criteria, exclusion criteria, if any

study design
- what is/are the treatment/s of interest?
- does the study have a control? If so, is it a negative or positive control?
- when is/are the treatments being applied? (how much, how often, and for how long?)

what is the primary response?
- how exactly should it be measured?
- when is/are the measurement/s taken? Can this be justified?
- is the response of interest a difference or change from baseline?
- how variable is the primary outcome? Would it be better to measure it in duplicate or triplicate?

Statistical
discuss the sampling plan to obtain Islanders for the study
- will there be strata? if so, why?
- how will the individuals be chosen?

what is the randomization scheme?
- how will treatments be randomized to Islanders?
- will treatments be balanced for various strata of interest (gender?, age?, etc.)
- how will this be done, i.e., what software package will be used?

what is the planned statistical analysis?
- how do you plan to examine demographics at baseline?
- what exploratory data analysis techniques (descriptive statistics, graphs, and/or tables) will be used to understand the data better?
- how will you check test assumptions?
- what will you do if assumptions are violated?
- what test of hypotheses will be performed?
- what are the null and alternative hypotheses?
- is your test directional (one-sided) or differences (two-sided)?
- how will you estimate the difference between treatments (this may not be appropriate for all studies)?
- is there any plan for follow-up procedures such as multiple comparison tests (this may not be appropriate for all studies)?

justify the sample size
- what meaningful difference should the study be able to detect 80% of the time?
- what estimate of variability did you base the sample size information on?
- where did you obtain this estimate from?
- what did you set Type 1 error to?
- how was the sample size calculated, i.e., what software package was used?

what is the data format that you expect data to be in?
- what software will be used to capture the data?
- what data will be collected?
- what format do you want to use to collect the data?
- A mocked up Excel datasheet needs to be included to illustrate the desired format.

Deliverables to Investigator group
-Study proposal
-Sample size
-Random sampling scheme for selecting Islanders for the study
(this responsibility may be worked out within team)
-Stratified randomization plan (after the sample size has been agreed to)
-Data format – mocked up Excel file