Protocol Title

This should be brief and self-explanatory. It will form part of the identifying criteria of the protocol and also needs to appear on information sheets and consent forms.

Investigators and Qualifications

This should include the address and contact telephone number of the Principal Investigator and any Co investigators. Applications for multi-centre trials should have the name of the principal investigator of all participating institutions appended.

Site Location

Name the site/location, address and contact phone number from which the study will be conducted. Applications for multi-centre trials should list all sites requiring Bellberry HREC review.

Purpose of Study

A brief statement as to why the study is being undertaken, e.g. “to test the hypothesis that Drug A is superior to Drug B in the treatment of X Disease”. (No more than ten lines).

Background Information

- a succinct review of literature should allow the Committee to appreciate the importance of the proposed project. (No more than one page.)
- name and description of the investigational product(s).
- a summary of findings from non-clinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial.
- summary of the known and potential risks and benefits, if any, to human participants.
- description of and justification for the route of administration, dosage, dosage regimen and treatment period(s).
- a statement that the trial will be documented in compliance with the protocol, GCP and the applicable regulatory requirements(s).
- description of the population to be studied.
- references to literature and data that are relevant to the trial and that provide background for the trial.

Hypothesis/Aims and Objectives

- clearly and concisely stated, the Hypothesis should contain only the predictions. It must be testable and specific enough to be investigated. If using Aims and Objectives, these must be detailed and precise.
- in the early phases of empirical studies where there may not be sufficient information to justify a rigorous hypothesis and where the intent is to merely assess the interplay of several variables, the possible interplay must be defined and the problem statement formulated as precisely as possible.

Methodology

This section should contain:

- a complete, detailed description of the study's participants, expected duration of participation, and a description of the sequence and duration of all trial periods, including follow-up, if any.
- a description of the stopping rules or discontinuation criteria for individual participants, parts of trial and entire trial.
- accountability procedures for the investigational product(s), including the placebo(s) and comparator(s), if any.
- maintenance of trial treatment randomisation codes and procedures for breaking codes.
- a detailed trial design description of the instrumentation and design.
- a specific statement of the primary end points and the secondary endpoints, if any, to be measured during the trial.
- a description of the type/design of trial to be conducted (e.g. double-blind, placebo controlled, parallel design) and a schematic diagram of trial design, procedures and states.
- methods of data collection should be described, identifying precisely what is to be investigated and how.
- statistical justification of participant numbers using a power calculation must be submitted. If an active controlled trial seeking to define non-inferiority the margin of non-inferiority specified must be justified.
- a description of the measures taken to minimize/avoid bias, including randomisation and blinding.
- if a pilot study is to be carried out, it should be briefly described.
- concepts and terminology must be clearly defined.
- the principles of 'informed consent' (information disclosure requirement) and confidentiality are very important and are to be clearly addressed in the study.

Selection of Volunteers/Participants:

Researchers should note that volunteers involved in research projects must remain true 'volunteers' i.e. the participation in the research is the result of choice made by the participant. A participant cannot be induced to remain in a study for financial or other reward.

Participants who are employees or students within a researcher's department should be excluded from any research protocols conducted by the principal investigator.

It should be ascertained whether the participant is insured or uninsured. Whilst this factor should not influence selection, care should be taken if it is foreseeable that the participant may require hospitalisation. In that event it should be clearly stated who will pay for any necessary treatment and any support services required. Refer to National Statement on Ethical Conduct in Human Research (2007).

Advertising

Click here to access Advertising Policy No. 8 (PI008).

Research Involving Ionising Radiation

Click here to access Ionising Radiation Policy No. 7 (PI007).

Inclusion Criteria

The following must be clearly stated:

- specify sex and age range where necessary.
- specify disease status and severity when applicable.
- specify the patient's ability to give informed consent.
- specify the patient's ability to co-operate sufficiently to allow the proposed study to progress.
- specify allowable concomitant medications during the study.

Exclusion Criteria

The following must be clearly stated:

- age range
- whether women of child bearing age are to be excluded, and specify what are acceptable contraceptive measures
- development of serious, adverse events/reactions (to be defined) and any associated decisions
- medications which are not allowed
- previous sensitivity to medications which might exclude patients.

Withdrawal Criteria

The following must be clearly stated:

- when and how to withdraw participants from the trial/investigational product treatment
- the type and timing of the data to be collected for withdrawn participants.
- whether and how participants are to be replaced.
- the follow-up for participants withdrawn from investigational product treatment/trial treatment.
- patient request
- the development of any exclusion criteria
- patient's non-compliance with the study protocol
- the development of any serious adverse drug reaction.

Other Participants

For Research involving people in dependent or unequal relationships, children and young people, people with intellectual or mental impairment, people highly dependent on medical care or research involving Aboriginal and Torres Strait Islander people please refer to the NHMRC National Statement on Ethical Conduct in Human Research (2007 incorporating all updates). Chapter 4.

Efficacy

It is important that researchers comment on the efficacy of the drug or the research procedure. This information will assist Committee Members in their deliberations of the benefits to be gained versus any risks or potential harm.

Amendments

The Investigator(s) should inform the HREC, and seek its approval, of amendments to the protocol including amendments that:

- are proposed or undertaken without prior HREC approval in order to eliminate immediate risks to participants;
- may increase the risks to participants; or
- significantly affect the conduct of the trial.

Investigators must also inform the HREC as soon as possible of any new safety information from other published or unpublished studies that may have an impact on the continued ethical acceptability of the trial or may indicate the need for amendments to the trial protocol.

Data Analysis and Reporting of Results

This should be set out in some detail, including the methods to be used to ensure that information is not accessible to unauthorised persons and that wherever possible an indication is given of how results will be disseminated to the scientific community.

Time Frames

Date of commencement as well as the study time frames should be stated.

Other Ethics Committees to Which This Study Has Been Submitted

Submission to other Ethics Committees must be disclosed as well as written evidence of any decisions made by other committees.

Other Relevant Information

Any other information including letters of support from heads of university departments or other institutions.
In addition, every protocol requires a separate participant information sheet and consent form. Participants should be provided with copies of both.

Student Research

Applications must be accompanied by a letter of support from the supervisor stating that they have reviewed the design and approve the study. A letter from the relevant university is also required stating that approval is granted for the review process to be undertaken by Bellberry HREC.