Purpose

This document explains what must be included in the 'protocol', or project plan, that must accompany any submission and enables a HREC to complete its review.

There are several templates available for the protocol, which must describe the objective(s), background, rationale, study design, methodology, statistical considerations, and overall support for the study.

Guidance

Protocol title

The title should be brief and self-explanatory and must appear on all information sheets and consent forms related to the study. The protocol also requires a reference number (the Principal Investigator or sponsor's reference number for the study).

Study registration

If the study is to be registered, the protocol should include the trial identifier and registry name (e.g. ANZCTR).

Investigators and qualifications

The protocol must include the address and contact telephone number of the Principal Investigator and any Co-Investigators. Applications for multi-centre trials must include the name of the Principal Investigator of each participating institution.

Sponsor information

A sponsored study must include the name and address of the sponsor.

Site Location

The location where the study is to be conducted should be listed, including site name, address and contact phone number. Applications for multi-centre trials should list all sites requiring Bellberry HREC review.

Objectives and purpose

The protocol must include a detailed description of the study's purpose and objectives.

Background information

The protocol must include:

- A succinct review of literature should allow the Committee to appreciate the importance of the proposed project (no more than one page).
- A summary of the potential risks and benefits, if any, to participants.
- A statement that the study will be documented in compliance with the protocol and applicable regulatory requirements.
- A 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.

Study design and methodology

The protocol should describe the design and methodology of the research, and how the objectives will be met, including:

- the study population, including inclusion and exclusion criteria

- where the study will be conducted
- the study's participants, including the number involved
- the expected duration of participation and the sequence and duration of all trial periods, including follow-up
- how 'informed consent' principles will be followed
- how information will be managed including how confidentiality and privacy principles will be followed
- any data to be recorded and methods of collection
- any statistical methods
- the timing of any planned interim analysis
- any concepts or terminology that may not be known to the Committee

Some studies may need to consider the following ICH GCP guidelines:

- that an investigator is responsible for all trial-related decisions (ICH GCP 4.3.1)
- that a participant is informed about and provided with adequate medical care for any adverse effects that may occur (ICH GCP 4.3.2)
- that an investigator will follow randomisation procedures and will ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (ICH GCP 4.7).

Study procedures

The protocol must include enough detail about the following to allow the HREC to assess:

- 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.
- Ensuring that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
- Ensure that research staff are qualified (including but not limited to appropriate training, education, expertise, credentials and, when relevant, privileges) to perform activities assigned to them during the study.
- The protocol should provide adequate detail to allow the HREC to assess these responsibilities.

Selection of volunteers/participants

The protocol must describe the number of participants needed and how this number has been determined.

*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 the National Statement 2.3.10 must be addressed individually and clearly in the protocol.

Advertising

The protocol is required to include information on the advertising relating to the research project and its mode of communication to participants. If utilised, a Social Media Plan is also to be submitted.

Data Handling and Record Keeping

This should be set out in some detail, including the methods to be used to ensure that information is not accessible to unauthorised persons. Information is also required regarding:

- how data will be collected
- who will have access to the data
- how privacy and confidentiality will be managed and maintained.

Data analysis

The protocol must explain how data will be analysed, including:

- the methods to be used
- procedures to account for missing, unused and/or spurious data
- procedures for reporting any deviation(s) from the original statistical plan.

Time frames

The protocol must outline the study starting date and time frames.

Ethics

The protocol must describe how the study addresses any ethical considerations, with reference to the National Statement on Ethical Conduct in Human Research (2023) and other relevant guidance. It should identify the HREC responsible for reviewing the study and whether the study has been submitted to other ethics committees. Written evidence of any decisions made by other committees must be attached.

Direct access to source data/documents

The protocol must explain 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.

Financing and insurance

The protocol must describe how the study will be funded and what insurance is in place.

Publication policy

The protocol must outline the publication policy and plan and outline any information that will be provided to participants about publication.

Formatting

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

Other relevant information

The protocol may include other information such as letters of support from heads of university departments or other institutions.

Student research

The protocol for any research by a student must include a letter of support from the student's 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 relevant Bellberry HREC to undertake a review.

Amendments

The Investigator(s) should inform the HREC, and seek its approval, of amendments to the protocol. Information regarding the amendment process can be found in MAR G1 amending approved research – general overview.

References

National Statement on Ethical Conduct in Human Research (2023)

Guideline for Good Clinical Practice

BA G3 Protocol Development - Clinical

BA G5 PICF Development

MAR G1 Amending Approved Research