Purpose

This document provides a brief overview of the amendment processes available to investigators involved with research approved by Bellberry.

Definitions

Amendment: An 'amendment' is any change to a research project or an approved document that occurs after a Bellberry HREC has approved it.

Substantial amendment: A 'substantial amendment' is a particular type of amendment, which is a change to the protocol or other factors that may affect:

- the aims and objectives of the study or the study design,
- participants' safety or physical or mental integrity,
- the scientific value of the study,
- the conduct or management of the study,
- the quality or safety of any investigational medicinal product used in the study.

A substantial amendment must be reviewed at a full HREC meeting. Other amendments may be reviewed out of session.

Guidance

The Bellberry HRECs are constituted as per the National Statement, and relevant expertise is available to ensure all research is scientifically and ethically reviewed. Any amendment to the approved research study is required to be submitted to the reviewing HREC before implementation.

General requirements for studies post approval

An investigator planning to amend a Bellberry-approved research project, or an approved document must submit an amendment form via eProtocol or agreed platform for the HREC to review. It is recommended that the investigator/site reviews the submission responsibilities form (BA F1.1.1) prior to completion of the amendment form. The Principal Investigator is responsible for ensuring they comply with any site-based governance requirements relating to amendments to their research.

All amendments, except for a change in site or site name, must be submitted via an amendment form in eProtocol or agreed platform. Amendments are categorised according to the extent and impact of any change or changes. Changes in site or site name must be submitted via a batch submission (see MAR G8).

The committee will review the submitted amendment(s). Most amendments are reviewed out of session and do not require full HREC reviews. Examples of amendments that are reviewed out of session are:

- changes to the investigator/s or study staff,
- changes to the participant information and consent form, protocol, Investigator's Brochure or study documents,
- new advertising material,
- administrative changes such as updating email addresses, CVs, indemnities or insurance certificates,
- addition of a study site to a multi-centre project,
- submission of new documents for review by the HREC.

Investigators are also required to submit progress reports, final reports that include a summary of the research outcomes, safety reports, serious breach reports, Investigator or sponsor termination or suspension of a trial, or general correspondence (i.e. unforeseen events or any other matters not covered elsewhere with material impact on the study). Where applicable, it is the Investigator's responsibility to action when reports may require submission to regulatory authorities. Upon completion of the clinical trial, the Investigator must also inform their organisation.

If a site is due to submit a progress report (i.e. within 30 days of the progress report due date) and are also required to submit an amendment, the site can use the batch submission pathway (using MAR F8.1.1 Batch submission application) to have the amendment processed via email.

Substantial amendments

Some amendments involve a greater level of change to the approved study. The committee will determine whether additional review is required. Only the HREC can determine whether the change can be assessed as a substantial amendment, or whether it is significant enough that it constitutes a different study and will require a new study submission. The HREC may also request further documentation to support the review of the substantial amendment.

Once notified that the amendment is deemed substantial, the Principal Investigator has two courses of action:

1. On advice that the Principal Investigator does not wish to proceed with the submission, the HREC will issue a letter withdrawing the amendment application. The initial project may continue, as only the amendment has been withdrawn.
2. If the Principal Investigator has acknowledged that the amendment is substantial, he/she will be notified when it has been allocated to a HREC meeting for a full review.

Following the HREC review, comments will be sent to the Principal Investigator via eProtocol by 5 pm (ACST) on the Friday after the meeting.

Caveat approval

Monitoring arrangements should be commensurate with the risk, size and complexity of the research. Upon review of the study the committee may determine that more regular progress reporting is required. The reporting requirements for the study will be outlined in the study approval letter in the form of a caveat.

Changing a Principal Investigator

Permanent change

The HREC requires an updated HREC Form of Indemnity, CV (if not already provided to the HREC within the previous 12 months) and an amendment form in eProtocol advising of the change. The change to the Principal Investigator will need to be made in the Personnel Information section. Although not mandated, the HREC has provided templates if sites wish to formalise the change (please see references).

Temporary change

If the Principal Investigator will continue to be responsible for the study, the application generally does not need to be changed over to the temporary Principal Investigator. However, the Principal Investigator and site should consider a range of factors including the following (but not limited to:

- phase of the study, for example, if it is a phase I study and participants are being dosed in this time period,
- if the study is on hold during this time period,
- no assessments of participants will occur during this time period – e.g. the participants are in follow up.

Approval letters

Once the amendment has been approved, a copy of the approval letter will be provided to the Principal Investigator. It will list the approved documents and approved site/s. Investigators should review the approval letter to ensure the updated documents are listed correctly and are approved at their site.

References

BA F1.1.1	Submission requirements checklist
MAR F1.1.2	Amendment form (eProtocol questions)
MAR F1.1.3	Amendment pathways flowchart
MAR F1.1.6	HREC notification template - change in PI
MAR F1.1.7	HREC notification template - change in CPI
MAR G8	Batch submissions
MAR F8.1.1	Batch submission application