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, site clause documents
- new advertising material,
- administrative changes such as updating email addresses, CVs, HREC Indemnities.
- addition of a satellite study site,
- submission of new documents for review by the HREC.

For applications via eProtocol:

Post approval submission type	Multi-site studies – who submits?	Form type
General amendment • *change in personnel, sponsor, tax details.* • *temporary or permanent change in site PI.*	• Each site is responsible for updating their application form	Amendment Question 1
Protocol amendment *In line with GCP, Principal Investigators must submit any study updates impacting participant safety without undue delay.*	• Any approved site can submit. • To be submitted once, on behalf of all. • If protocol amendment requires update to PICF, they must be submitted together.	Amendment Question 2
IB amendment *In line with GCP, Principal Investigators must submit any study updates impacting participant safety without undue delay.*	• Any approved site can submit. • To be submitted once, on behalf of all. • If IB amendment requires update to PICF, they must be submitted together.	Amendment Question 3
PICF Update *In line with GCP, Principal Investigators must submit any study updates impacting participant safety without undue delay.*	• Any approved site can submit. • To be submitted once, on behalf of all.	Amendment Question 4
Lifting of a caveat	• Any approved site can submit. • To be submitted once, on behalf of all. • Please outline how the submission meets the requirements to lift the caveat.	Amendment Question 4
Sponsor termination or suspension of a trial • *or any other unforeseen events or any other matters not covered elsewhere with material impact on the study*	• Any approved site can submit. • To be submitted once, on behalf of all.	Amendment Question 4
Safety reporting (see MAR G2) • *DSUR/ASR* • *Significant Safety Issue.* • *Any other safety documentation.*	• Any approved site can submit. • To be submitted once, on behalf of all.	AER
Serious Breach (local) (see MAR G3)	• Submitted by site where event occurred.	PVR
Serious Breach (global issue) (see MAR G3)	• Any approved site can submit. • Submitted once, on behalf of all	PVR
Progress report (see MAR G4)	• Each PI responsible for submission of a progress report, relevant to their site. • 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, please submit the PRE first, and contact Bellberry requested expedited review of the PRE.	PRE
Final report (see MAR G4)	• Each PI responsible for submission of a final report, relevant to their site.	FR

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, they 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 p.m. (ACST) on the Friday after the meeting.

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

The HREC requires an amendment to be submitted in eProtocol advising of the change. If the Principal Investigator continues to be responsible for the study, the application generally does not need to be changed to the temporary Principal Investigator. However, the Principal Investigator and site should consider a range of factors, including the following but not limited to:

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