

Public

Purpose

This document provides an overview of an alternate pathway available for the submission of amendments and/or notifications to the Bellberry HREC.

Definitions

Batch submission: An amendment or notification submitted to Bellberry via email, which is subsequently entered into eProtocol by Bellberry staff, on behalf of the Principal Investigator.

Guidance

The batch pathway has been established as an alternative method for the submission of amendments and/or notifications to the Bellberry HREC. This pathway has been developed to further support sites and sponsors and is primarily beneficial when a submission is applicable across multiple studies.

A batch request can be submitted to Bellberry by emailing a completed batch submission application form (MAR F8.1.1) to batch@bellberry.com.au. Batch requests may be submitted via site personnel or a sponsor representative. Batch requests may include:

- A single submission applicable across multiple studies and/or multiple sites (for example, a site's COVID-19 pandemic contingency plan, applicable to all approved studies at the site).
- An urgent submission, applicable to one study that is unable to be entered into eProtocol at present. For example, sites have the requirement to submit a progress report before approval lapses; however, an amendment in cycle comments blocks the progress report.

Completing and submitting MAR F8.1.1 grants Bellberry the authority to process the submission in eProtocol on behalf of the Principal Investigator. Before completing this form, the requestor must ensure they have discussed the submission with the relevant sites/sponsor to avoid duplication of work.

To streamline processing, updates to a site name or changes to a research site are required to be submitted via the batch pathway.

The batch submission should reference and respond to relevant eProtocol questions. Templates are available from the Bellberry website and are included in the references section below. Where relevant, template forms should be completed and submitted in conjunction with the MAR F8.1.1 batch submission application form.

On receipt of a batch request, Bellberry's dedicated batch submission team will acknowledge receipt within 48 hours of delivery. If acknowledgement of a batch submission has not been received within 48 hours, please contact Bellberry on 08 8361 3222.

Following receipt, Bellberry's standard procedure of review and decision outcome will take place.

References

- MAR F8.1.1 Batch submission application
- MAR F1.1.2 Amendment form (eProtocol questions)
- MAR F2.1.1 Safety reporting (eProtocol questions)
- MAR F3.1.3 Protocol violation form (eProtocol questions)
- MAR F4.1.1 Progress report (eProtocol questions)
- MAR F1.1.6 HREC notification template - change in PI
- MAR F1.1.7 HREC notification template - change in CPI