

Purpose

To provide 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 that is requested by a single stakeholder (e.g., a CRO, site or sponsor) which includes identical changes that may apply to multiple related applications. Bellberry administration will submit the requested changes via the appropriate form in eProtocol on behalf of the Principal Investigator.

Guidance

The Batch Submission pathway has been developed to support sites and sponsors by providing a streamlined process to ensure consistency in changes across multiple applications.

A Batch Submission can be requested by approved site or CRO personnel or a sponsor representative and submitted by emailing a completed Batch Submission Application Form (MAR F8.1.1) to bellberry@bellberry.com.au. Examples of Batch Submission requests may include:

- A notification of change to a sponsor's name which is applicable across multiple applications and/or multiple sites A notification of change to a site's physical address.
- An urgent submission, applicable to one study that is unable to be entered into eProtocol.

Completing and submitting MAR F8.1.1 Batch Submission Application grants Bellberry the authority to process the submission in eProtocol on behalf of the Principal Investigator(s). 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 administrative details of a research site or sponsor, e.g., site or sponsor name or address, are required to be submitted via the batch pathway.

Where required, document versions of the relevant eProtocol submission forms should be completed and submitted with the MAR F8.1.1 Batch Submission Application along with any supporting documents, e.g., a letter from the sponsor. Submission form templates are available from the Bellberry website and are included in the references section below.

On receipt of a batch request, Bellberry will acknowledge receipt via email. 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
QM F10.1.1	Safety Reporting eProtocol Questions
QM F10.1.3	Serious Breach (PVR) eProtocol Questions
MAR F1.1.6	Change of Principal Investigator Form Template