

For Applications submitted in eProtocol, it is preferred that an Amendment Form Safety Report is completed and submitted in eProtocol. For Applications submitted in REGIS, the Amendment Form will need to be provided through REGIS. Please see MAR G1 Post-Approval Submission Guidance.

Attach a tracked and clean version of all updated documents in the Attachments section below using the appropriate heading. Do not delete previous document versions. It is important to accurately name the attachments as you want them to appear in the approval letter (see BA G12 Version Control & Document Naming Conventions).

Protocol No.

Protocol Title

Principal Investigator Name

Date of report

1. Administration - other correspondence

Please use this section for any administrative change or general correspondence, for example adding/removing study staff, updating email addresses, HREC Only Forms of Indemnity, CV updates etc. For updates or other changes to approved documentation that is related to a protocol amendment, investigator brochure etc, use sections 2, 3 or 4. Please be aware that if you use this section you will not be able to use any other section of the form.

Complete the box below outlining the changes required. Ensure you make any necessary changes in the personnel information section of the application.

2. Protocol amendment

Yes ☐

No ☐

Version no.

Date

Are changes required to the Participant Information Sheet and Consent Form (PICF) ? (For multi-centre studies: Please confirm with the sponsor as to the status of participants at all Bellberry approved sites, noting that if a site has any active participants or if the amendment contains a major protocol/safety update, the submission may require an updated PICF).

Yes ☐

No ☐

Please explain the protocol update (if this results in changes to the PICF, please outline these in Q4).

3. Investigator brochure update

Yes ☐

No ☐

Where there are significant changes to the IB, provision of both summary of changes and a tracked IB will help facilitate the review.

Investigator brochure name, version no. and date.

When was the IB last medically / pharmacologically / technically reviewed?

Do the changes alter the safety or efficacy of the product? Please comment.

Are changes required to the Participant Information Sheet and Consent Form (PICF)? If yes, please explain outline in Q4 (For multi-centre studies: Please confirm with the sponsor as to the status of participants at all Bellberry approved sites, noting that if a site has any active participants or if the amendment contains a major protocol/safety update, the submission may require an updated PICF.

Yes ☐

No ☐

If not, please explain.

4. Other amendments

Yes ☐

No ☐

(PICF, questionnaires, advertisements, other)

Summarise the proposed changes.

Is this a multi-centre study?

Yes ☐

No ☐

Please note, to avoid duplication, if this submission is multi-centre, the review of your amendment will be on behalf of all Bellberry approved sites.

If you answered 'yes' to the multi-centre question and the amendment relates to all sites, please write 'All Sites' in the text box below.

If you answered 'yes' to the multi-centre question and the submission DOES NOT relate to all sites, please explain why in the text box below.

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5. Attachments

Attach relevant documents. It is important to accurately name the Attachments as you want them to appear in the Approval Letter.

Attachment Type	Attachment Name	Attached Date