

For applications submitted in eProtocol, it is preferred that a safety report is completed and submitted in eProtocol. For applications submitted in REGIS, the report will need to be provided through REGIS.

Protocol No.

Protocol Title

Principal Investigator Name

Please see QM G10 Safety Reporting Guidance for submission guidance.

1. Individual event

This form must be completed for Local Serious Unexpected Suspected Adverse Events (SUSARs) or Local Significant Safety Issue (SSI) for participants enrolled at a Bellberry approved site and can be used for other individual event reporting.

Please note that individual SUSARs are not required to be reviewed by the HREC but can be submitted if they are supporting documentation to another safety notification, e.g. an SSI.

Date of the SUSAR OR SSI:

Participant ID (if applicable):

Date the PI learned of the event:

Is the participant enrolled at a Bellberry approved site? Yes ☐ No ☐

Description of the safety event (including impact on study regime, participant withdrawal).

Principal Investigator's opinion re the relationship of the event to the study drug/device.

Definite ☐ Likely ☐ Possible ☐ Unlikely ☐ Uncertain ☐ Definitely not ☐

Sponsor's opinion re the relationship of the event to the study drug/device.

Definite ☐ Likely ☐ Possible ☐ Unlikely ☐ Uncertain ☐ Definitely not ☐

2. Summary report

This form is to be completed for Summary Reporting. (DSUR, ASR, Global SSIs). Please note, if this submission is multi-centre, the review of your safety summary report will be on behalf of all sites. If it is multi-centre, and not applicable to all sites, please explain in the text box below (including which sites the submission relates to). *Bellberry administration will list all currently active multi-centre/sites including sites that were open during the time the document covers on the acknowledgement letter.

Is a multi-centre application? (Please note, to avoid duplication, if this submission is multi-centre, the review of your submission will be on behalf of all Bellberry approved sites) Yes ☐ No ☐

If you answered 'yes' to the multi-centre question and the submission 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.

Attach the reports in the attachments section.

Complete this section for all submissions.

Are there any ethical implications of the event(s) on the conduct of the study?

Please indicate if any of the safety notification/s necessitates an amendment to the Protocol or the Participant Information Sheet/Consent * **(If multi-centre, please consider requirements for all Bellberry approved sites).**

Yes ☐ No ☐

If yes start an Amendment and reference this report.

Has the sponsor or data safety monitoring board been notified of the event (if relevant)? *

Yes ☐ No ☐ Not Known ☐

If no provide reasons.

3. Attachments

Attach relevant documents. It is important to accurately name the Attachments as you want them to appear in the Acknowledgement Letter. Please note that no changes to the submission should be made in a safety report. Any changes to the submission (e.g., Personnel Information page updates) must be submitted via an amendment form.

Attachment Type	Attachment Name	Attached Date