

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

Please note, the submission of a Final Report can occur only after all study activity at a site has finished, including the submission of amendments, Protocol Violation or Serious Breach Reports, Safety Reports, and any other correspondence. Submission of a Final Report generally occurs after the close-out visit (clinical trials) or final reconciliation of study activities (non-clinical trials). Please see MAR G4 Progress & Final Report Guidance for further information.

Protocol No.

Protocol Title.

Principal Investigator Name.

Date of report (this date must be the date of submission).

Date Study Closed at Site.

Has the research project discontinued prior to its expected completion date? Please explain:

	Number	Comments
Number of Participants screened (use comments field for screen failure #).		
Number of active Participants at the time of close out.		
Number of Participants who completed the study.		
Number of Participants withdrawn.		
Number of site-based safety events reported to Bellberry.		

Reason for participant withdrawal.

Safety events leading to participant withdrawal.

Provide an update on any conflict of interest changes for the research team during the life of the study. The changes may be actual, perceived or potential, as per the National Statement Chapter 5.3.11 or 5.6.

Considerations:

The Principal Investigator is responsible for conducting a conflict of interest review annually. Comment on any actual, perceived, or potential conflicts for the life of the study. The declaration must be inclusive of the Principal Investigator's interests and members of the study team.

Bellberry recommends that in considering what may be a conflict, the Principal Investigator err on the side of caution (e.g. anything considered relevant be identified, even if the Principal Investigator does not believe the HREC will assess the interest as a conflict).

*Note: "N/A" and "No" are not acceptable answers, and the HREC will return reports with these responses.

Please comment on the following:

1. Maintenance and security of records held in relation to this study. Where is the data stored? Who has access to the data?

Considerations:

Identify the location of investigator site files (e.g. locked cabinet, compactus, electronic, etc.) during the life of the study. Who had access to these records?

Did this change during the study at this site? Describe any changes.

Outline what standards, guidelines and legislation apply to your research and the storage and access to this project's records/data.

Were participant records are stored separately? Provide information on their location and access to this information.

"N/A", "No", "None", and "Nil" are not acceptable answers. The HREC will return reports with these responses.

2. Provide details of compliance with the approved application (including consent procedures and documentation, submission of amendments; safety reporting; annual progress reporting).

Considerations:

Who held delegated responsibility for consenting?

Reflect on the response given to the consenting question in the initial submission. Did anything change during the project?

Consider any protocol deviations or violations concerning participant consent.

A site may wish to upload a copy of their deviation/violation log and reference any consenting discrepancies in this section.

Outline compliance with the National Statement on Ethical Conduct in Human Research, ICH/GCP and consenting requirements under the approved application.

"N/A", "No", "None", and "Nil" are not acceptable answers. The HREC will return reports with these responses.

3. Any new scientific information that may impact on the current conduct of the study (attach relevant information in the attachments table below.).

Considerations:

Provide a summary of the currently available scientific information.

A site may wish to attach and reference any relevant publications in this section.

*Note: any attachments and new safety information (such as a DSUR) should be provided to the HREC via an adverse event/safety report. **This submission is required to occur before the final report is submitted.**

A response of "N/A" is only acceptable for non-interventional studies. The HREC will return interventional studies with "N/A" responses.

4. Any new risk or benefit information related to the research not previously reported to Bellberry? (Attach relevant information in Attachments table below.).

Considerations:

Reflect on any new information not previously reported to the HREC. Describe any measures taken or proposed to minimise risks and implications to the risk-benefit ratio.

Note: any updated study information (such as a protocol, PICF or IB update) must be provided to the HREC by way of an amendment. **This submission is required to occur before the final report is submitted.*

"N/A" is not an acceptable answer. The HREC will return reports with this response.

5. Provide details of compliance with the following: institutional governance responsibilities (including contracts, indemnities, insurance), site approvals, notification to the HREC of regulatory audits; appropriate use of data; caveats placed on the approval; statutory and licensing obligations.

Considerations:

As per the terms and conditions of ethical approval, institutions are responsible for ensuring executed indemnities, contracts, and appropriate insurances are in place. Sites are also responsible for basing site-specific documents on current approved master versions. Comment on the management of these processes at your site during the life of this study.

Some sites have a dedicated research governance officer (RGO). Sites with alternative governance arrangements are still responsible for complying with all applicable institutional obligations.

Confirm the following:

Amendments/safety/progress reporting: comment on the actions taken to fulfil all HREC/governance requirements.

*Notification to the HREC of regulatory audits: comment on any regulator audits conducted throughout the life of the study (TGA, FDA, other). Was the HREC informed of the audit? **Note: Informing the HREC of sponsor audits is not necessary.**

Appropriate use of data: comment on any misuse of data during this reporting period. Was the study data used for another project? Was ethical approval obtained before use?

Caveats placed on the approvals: did the HREC place any caveats on the study? If so, how were they fulfilled?

Statutory and licensing obligations: comment on the activities taken to fulfil all statutory and licensing obligations.

"N/A", "No", "None", and "Nil" are not acceptable answers. The HREC will return reports with these responses.

6. If compliance issues have been identified, please discuss the corrective actions taken to rectify these.

7. Any complaints from participants you have received in relation to the study?

Considerations:

Provide a summary of any complaints received about the study and comment on the measures to resolve each.
A response of "N/A" may only be accepted if participants were not screened. Otherwise, the submission will be returned.

It is important to accurately name the attachments as you want them to appear in the approval letter.

Attachment Type	Attachment Name	Attached Date

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