

For applications submitted in eProtocol, it is preferred that a Progress/Final report is completed and submitted in eProtocol. For applications submitted in REGIS, the report will need to be provided through REGIS. Please see MAR G4 Progress & Final Report Guidance for further information.

Protocol No.

Protocol Title

Principal Investigator Name

☐ PROGRESS REPORT
(To be completed for annual monitoring requirements.)

☐ ETHICS APPROVAL EXTENSION
(Note: Bellberry grant one-year terms of extension/approval in line with the lead site approval date.)

Current Study Close Date:

New Study Close Date:

Please advise why an ethics extension is requested.

Date of Study Progress Report:

(This date must be the date of submission.)

The number of participants entered should reflect the cumulative total from the commencement of the study (i.e., not just the number since the last Progress Report submission).

(Please complete for Progress Reports and Ethics Extensions.)	Number	Comments
Number of Participants screened (use comments field for screen failure #)		
Number of active Participants		
Number of Participants completed the study		
Number of Participants withdrawn		
Number of site-based safety events reported to Bellberry		

Reason for participant withdrawal. Include number of participants for each reason.

Provide brief details of Safety Events leading to participant withdrawal.

Provide an update on any conflict of interest changes for the research team in the last 12 months. 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.

The declaration is inclusive of the Principal Investigator's interests and members of the study team.

Bellberry recommends that when 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).

A response of "N/A" and "No" are not acceptable answers. 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.).

Who has access to these records?

Has this changed during the course of the study at this site? Describe any changes.

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

Are participant records are stored separately?

Provide information on the location and access to participant information.

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

Example response:

Management of the study occurs in accordance with the study protocol, ICH GCP guidelines, and international and local participant privacy protection guidelines.

Each participant is de-identified and given a study-specific participant identification number on enrolment. This participant identification number is used to enter participant data in the clinical trial database, labelling tissue and blood samples, and upon transfer of these samples to the laboratory for analysis.

Participant medical records include both electronic (eMR) and hard copy files. Study staff have individual access to eMR and are accountable for access and data entry. In addition, the system provides an audit trail, timestamp functionality and affixes electronic signatures on data entry.

Study-related data is captured in the clinical trial database, a secure, validated electronic system meeting ICH GCP E6(R3) requirements. Trained and delegated study staff hold write access. Monitoring and data management personnel have permissions that do not allow them to enter or update the participant data. Revocation of access occurs when personnel leave the study team.

Participant samples collected for analyses are stored at sites and transferred to LabsAus, an analytical laboratory in Australia, as defined in the protocol. This laboratory operates in accordance with all applicable quality and regulatory standards, including the principles of GLP.

2. Compliance of the study with the approved application, consent procedures and documentation.

Considerations:

Who has delegated responsibility for consenting?

Reflect on the response given to the consenting question in the initial submission. Has anything changed?

Have there been any protocol deviations or violations concerning participant consent?

You may wish to upload a copy of your site 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 (Please attach relevant documents in the Attachments section under the heading "Progress Report / Ethics Approval Extension Attachments Only."). It is important to accurately name the Attachments as you want them to appear in the Approval Letter.

Considerations:

Provide a summary of any currently available scientific information not previously reported to the HREC.

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 submission after completing the Progress Report.*

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? (Please attach relevant documents in the Attachments section under the heading "Progress Report / Ethics Approval Extension Attachments Only."). It is important to accurately name the Attachments as you want them to appear in the Approval Letter.

Considerations:

Provide a brief discussion of any new information not previously reported to the HREC.

Are there any implications to the risk-benefit ratio?

Describe any measures taken or proposed to minimise risks.

**Note: any updated study information (such as a protocol, PICF or IB update) must be provided to the HREC by way of an amendment following completion of this Progress Report.*

If relevant, indicate the estimated timeframe for the HREC submission of any updated documentation.

"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 and site approvals; submission of amendments; safety reporting; annual progress reporting; 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, sites are responsible for ensuring executed indemnities, contracts, and appropriate insurances are in place before the commencement of the study at the site. Sites are also responsible for basing site-specific documents on current approved master versions.

Comment on the management of the above processes at your site.

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: has a regulator (TGA, FDA, other) audited the site/study? Has the HREC been informed?

*Note: Informing the HREC of sponsor audits is not necessary. Any findings from such audits will be submitted to the HREC by way of an amendment/safety/serious breach notification, as required.

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.

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

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

6. Any unforeseen events/new information that may affect continued ethical acceptability of the project?

Considerations:

Provide any information regarding unforeseen circumstances/events that may impact the conduct of the study (consider staffing issues, facility issues, access issues, i.e. pharmacy, sponsor monitoring). Such unforeseen events may be due to the global pandemic or other unforeseen circumstances.

A response of "N/A", "No", "None", and "Nil" may only be accepted if there are no issues outlined in the previous questions of the Progress Report. Otherwise, the HREC will return the submission.

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.

Please attach relevant documents in the Attachments section under the heading "Progress Report / Ethics Approval Extension Attachments Only." It is important to accurately name the Attachments as you want them to appear in the Approval Letter. Please note that no changes to the submission should be made in a Progress Report. Any changes to the submission (e.g., Personnel Information page updates) must be submitted via an amendment.

Attachment Type	Attachment Name	Attached Date

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