Purpose

To provide guidance to researchers and sponsors regarding their responsibilities in relation to the submission of Progress and Final Reports as per Chapter 5.4.8 of the *National Statement on Ethical Conduct in Human Research (2025).*

Definitions

Due date: The date a Progress Report is due for submission.

FR: Final report.

Grace period: Additional sites that are approved within 60-days of the progress report due date will be designated a Progress Report due date the following year.

PRE*:* Progress Report/Ethics approval extension.

Clinical Study Report (CSR): A detailed report including information from all sites, that summarises the conduct, results and safety findings of a clinical study,

Guidance

Progress reports

Each Principal Investigator is responsible for completing a site-specific progress report that outlines items such as the study's progress, the maintenance and security of records, compliance with the approved proposal, and compliance with any conditions of approval (such as caveats). Responsibility should only be delegated to site staff with an appropriate understanding of site-based activities. Questions in the Progress/Final Report form must be answered and submitted via eProtocol. Reporting opens within 30 days of the due date. Progress reports submitted earlier than this time frame will be returned.

When a study has been reviewed and approved, Bellberry grants one-year terms of approval. To extend the approval period for an additional year, a PRE must be submitted by the due date. The due date for a Progress Report is set one year after the initial approval date of a study. After a Progress Report is submitted and approved, the due date shifts to the corresponding date in the following calendar year. For additional site applications, the due date is aligned with the next occurrence of the study's initial approval date. For example, for a study initially approved on 1 January 2024, the due dates for Progress Reports would be 1 January 2025, 1 January 2026, etc., until the study is completed. A grace period has been applied to prevent sites from having to submit multiple reports in proximity.

60-day exception rule explained below:

- The lead site is approved on 22 Jan 2025.
- Additional site one (-AA) is approved on 18 Mar 2025.
- Additional site two (-AB) is approved on 22 Dec 2025.

The following will occur:

- The lead site and additional site one (-AA) have their first Progress Report due on 22 Jan 2026.
- As approval for site two (-AB) is within 60 days of the Progress Report being due, they are an exception, and their first Progress Report is due on 22 Jan 2027.

The system will alert the researcher that a Progress/Extension request report is due 30, 14 and 7 days before the due date.

Appendix 1 serves as a comprehensive guide for the completion of Progress and Final Reports, ensuring sites are well-informed of the expectations and requirements.

If any discrepancies are identified when completing the Progress Report, the researcher should:

1. Note the disparity in the appropriate question field in the Progress Report before the Progress Report is submitted.
2. Provide the HREC with the relevant documentation through the appropriate pathway immediately post Progress Report acknowledgement (e.g. submission of an Amendment, Safety, or Serious Breach form).

Often sites require submission of Amendments and Progress Reports in a similar timeframe. eProtocol does not allow concurrent submissions of Amendments and Progress Reports. To ensure that continuous ethical approval is maintained, where a Progress Report is due to be submitted (i.e., within 30 days of the due date) and an Amendment is also required (e.g., protocol/IB update), the site must:

1. Submit the Progress Report*.
2. Phone or email bellberry@bellberry.com.au to request expedited review of the Progress Report
3. Submit the Amendment immediately post Progress Report acknowledgement.
4. When applicable, please phone or email Bellberry to request urgent processing of Progress Reports where they may prevent an Amendment submission.

Please note the Progress Report is different from an Annual Safety Report. Both are required to be submitted annually to the HREC, however must be submitted via different forms in eProtocol. See MAR G2 Safety Reporting for further information.

*When considering whether to attach documents to the Progress Report, please note that only documents directly relating to the Progress Report should be included. Any other documents must be submitted by the appropriate pathway (e.g., an Amendment, Safety, or Serious Breach form) as these reports are categorised and reviewed according to the extent and impact of any changes. Please see *BA F1.1.1 Submission Requirements Checklist* for further information.

If the HREC does not receive a Progress Report/Extension request by the expiry date, researchers must ensure:

- All research activities stop.
- New enrolment of participants does not occur.
- If the site has participant visits scheduled, the HREC will decide if it is in the best interests of individual participants to continue participating due to an over-riding safety concern or ethical issue.
- Without delay, the site must notify the HREC via email bellberry@bellberry.com.au quoting the study ID in the subject line. This notification must outline what participant visits and other study-related conduct have occurred in the period between the report being due and the submission of the notification.

The HREC will undertake an assessment of the study application and decide what action the researchers may need to take before extending ethical approval. Steps taken may include (but are not limited to) requesting the site complete a desktop audit; the inability to use or publish data; requesting additional training of staff; or

requiring participants to be reconsented. The researcher must address the steps taken via the summary of progress to date section of the progress report.

After 45 days following ethical expiry, a site may request via email to have the application reactivated, which will incur a fee (See BA G6 Application Fees). Researchers will need to provide information regarding what steps have been taken to ensure compliance with continuous ethical approval before the application may be reactivated. After reactivation, the site will need to submit a Progress report within 7 days. Bellberry will administratively withdraw applications for studies where ethical approval has expired after 60 days and a reactivation request or PRE has not been received. After withdrawal, Bellberry cannot reactivate the study. In this circumstance, if you are intending to proceed with the study, a new application will need to be submitted and new application fees will apply (please refer to BA G6 Application Fees).

Final Report

Each Principal Investigator is responsible for completing a site-specific Final Report, which is submitted in eProtocol on the Final Report form. Responsibility should only be delegated to site staff with an appropriate understanding of site-based activities. This can only occur after all study activity at a site has finished, including the submission of Amendments, Serious Breach Reports, Safety Reports, and any other correspondence. This generally occurs after the close-out visit (clinical studies) or final reconciliation of study activities (non-clinical studies). Once the form is submitted and acknowledged by the HREC, the study will be closed out. No further documentation can be submitted or processed in eProtocol.

Submission of the eProtocol Final Report does not end the researcher's responsibility to publish the outcomes of the project or to notify the HREC if any safety concerns become known related to the study. Bellberry do not routinely require the submission of the Sponsor's final CSR, however as per the HREC terms and conditions of approval, this must be provided where there are newly identified study outcomes that the HREC should be aware of or should have been previously reported (see MAR G2 Safety Reporting and MAR G3 Serious Breaches). Where this review is required, the specific information relating to participant safety within the CSR that requires HREC review should be clearly identified or provided in alternative documentation. Any required safety information following the study closure should be provided via email to bellberry@bellberry.com.au with the HREC ID, study title and PI names included in the body of the email.

References

National Statement on Ethical Conduct in Human Research (2025)

BA F1.1.1	Submission requirements checklist
BA G6	Application Fees
MAR G2	Safety Reporting
MAR G3	Serious Breaches
MAR F4.1.1	Progress report (eProtocol questions)
MAR F4.1.2	Final report (eProtocol questions)

Appendix 1: Completion of Progress and final report guidance

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).

Clinical

	Number	Comments	Definition
Number of Participants screened (use comments field for screen failure #)	Enter total number screened	**N** = X Screen Fails *If Pre-screening applicable* **N** = X Total Participants Pre-screened **N** = X Pre-screening Eligible (**N** = X Eligible but not screened; **N** = X Eligible and screened) **N** = X Pre-screening Ineligible (**N** = X Negative result; **N** = X Not tested) **N** = X Pre-screening pending eligibility	
Number of active Participants	X	**N** = X On Treatment **N** = X In Follow-up	Participants that are receiving the study drug Participants in follow-up (i.e. where their data is still being collected without receiving IP).
Number of Participants completed the study	X	**N** = X Due to disease progression and completed follow-up **N** = X Due to disease progression and passed away during follow-up **N** = X Due to disease progression and lost to follow-up	Participants that were not withdrawn, and no longer considered active on the study (including death). Participants taken off the study due to disease progression or SAEs as per study criteria and passed away prior to completion or follow-up. Participants taken off the study due to disease progression or SAEs as per study criteria and were lost to follow-up.
Number of Participants withdrawn	X	**N** = X Total withdrawals	Participants formally withdrawn from the study (i.e. signed the withdrawal of consent, participants confirmed withdrawal via any other form of communication) participants withdrawn due to SAE or toxicity (and are not being followed up as they have withdrawn consent) participants withdrawn as evidence of them meeting an exclusion criterion is uncovered

Number of site-based safety events reported to Bellberry	X	**N** = X Significant Safety Issues/ Urgent Safety Measures that impacted your site.	Significant Safety Issues/ Urgent Safety Measures (see MAR G2)

Non – Clinical

	Number	Comments	Definition
Number of Participants screened (use comments field for screen failure #)	Enter total number screened	A screen failure in a non-clinical study typically refers to individuals who were initially considered for participation but were later deemed ineligible or unsuitable based on predefined criteria.	The total count reflects the sum of all participants who contributed data to the study, irrespective of the consent mechanism used.
Number of active Participants	X	**N** = X	An active participant in a non-clinical study is currently engaged in the study's activities and contributing data or responses as required by the study's protocol. This could involve completing surveys, attending interviews, participating in focus groups, or being involved in observational research.
Number of Participants withdrawn	X	**N** = X	Participant withdrawals in a non-clinical study occur when individuals leave before the study is completed, which can affect the results by reducing sample size or introducing bias. Reasons for withdrawal might include discomfort, personal changes, or loss of interest.
Number of site-based safety events reported to Bellberry	X	**N** = X	Could involve any unforeseen incident that risks harm to participants. Such an issue may need reporting to the HREC to review and adjust the study's design, consent process, and risk strategies. The key is that the issue deviates from the expected risks in the approved protocol and could harm participants, even if not physically.

Conflict of Interest

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 5.3.11 or Chapter 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).

"N/A" and "No" are not acceptable answers. The HREC will return reports with these responses.

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.

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.*

"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?

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.

"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.

"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 ."N/A" may only be accepted if participants were not screened. Otherwise, the submission will be returned.