Purpose

This document provides guidance to researchers and sponsors on their responsibilities in relation to the submission of progress and final reports as per 5.4.8 of the *National Statement on Ethical Conduct in Human Research (2023).*

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.

Guidance

Progress reports

Each Principal Investigator is responsible for completing a site-specific progress report that outlines items such as the project'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 2017, the due dates for progress reports would be 1 January 2018, 1 January 2019, 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 May 2020.
- Additional site one (-AA) is approved on 18 August 2020.
- Additional site two (-AB) is approved on 05 May 2021.

The following will occur:

- The lead site and additional site one (-AA) have their first progress report due on 22 May 2021.
- 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 May 2022.

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

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 preventing an amendment submission.

*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, access to the study in eProtocol will automatically lapse. 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 decide what action the researchers may need to take before granting access to the study and reinstating access to the application in eProtocol. 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.

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, protocol violation or serious breach reports, safety reports, and any other correspondence. This generally occurs after the close-out visit (clinical trials) or final reconciliation of study activities (non-clinical trials). Once the form is submitted and acknowledged by the HREC, the study will be closed out. No further documentation can be processed in eProtocol.

Submission of the 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. As per the HREC terms and conditions of approval, the site must also provide a copy of the Sponsor's final report where there are study outcomes that the HREC should be aware of, such as issues related to participant safety. If the Sponsor has an internal policy that mandates the submission of the CSR, the HREC will acknowledge receipt. Please email CSRs to bellberry@bellberry.com.au with the HREC ID, study title, PI names in the body of the submission.

References

National Statement on Ethical Conduct in Human Research (2023)

MAR F4.1.1 Progress report (eProtocol)

MAR F4.1.2 Final report (eProtocol)

BA F1.1.1 Submission requirements checklist