Progress Report Single Date Submission

Frequently Asked Questions

What has changed?

Barwon Health is implementing a single due date for annual progress reports, as opposed to the anniversary of project approval. Progress reports for all projects are now due on 1 August each year.

This applies to all projects reviewed by the Barwon Health HREC and those reviewed by external HRECs with Barwon Health governance authorisation.

In addition, the annual progress report template has changed to a REDCap survey that is easier for Investigators to complete, and collects data that is more relevant to Barwon Health's requirements. Investigators no longer need to submit a progress report via ERM.

Complete your progress report via this link: https://redcap.link/BHAnnProg (link will be made active on 1 July 2024)

Questions? Find the answers below or contact the Barwon Health Research Development Unit at rdu@barwonhealth.org.au or (03) 4215 3374.

Why implement a single due date for progress reports?

A single due date for all progress reports will be easier for Investigating teams to remember, especially those that are managing multiple projects. In the past, some Investigators have not submitted progress reports by their required dates, thus jeopardising the Ethics approval status of their study.

A single due date will also improve reconciliation and reporting by the Research Development Unit, to better:

- Meet the requirements of reporting on research activity under the National Clinical Trials Governance Framework
- Gain an understanding of overall research activity at Barwon Health

How do I submit an annual progress report?

Investigators need to submit an annual progress report to the Barwon Health Research Development Unit via the below REDCap link on the RDU website by 1 August every year (starting 2024). Continued ethical approval of a project is contingent upon the Research Development Unit receiving an annual progress report. A failure to do so may result in withdrawal of ethical approval.

Do not submit an annual progress report via ERM. ERM progress reports are no longer accepted for Barwon Health projects. QA and negligible risk projects do not need to submit a progress report.

Follow these steps to complete an annual progress report

1. Follow this link to begin your progress report: https://redcap.link/BHAnnProg (link will be made active on 1 July 2024)
2. Enter details of your project, including reference numbers, Principal Investigator details, project title, project type and HREC approval details
3. Provide a brief lay summary of the project and a brief update of progress
4. Provide updates about changes to protocols, PICFs, Investigators
5. Provide updates about recruitment, challenges faced
6. Complete the declaration
7. Click submit

What happens after I submit an annual progress report?

On submission of the report, Investigators will receive an acknowledgement of receipt by email explaining that RDU will only be in contact again if the report is deemed unsatisfactory.

What if my project was approved in June or July?

Annual progress reports for projects that have been approved in June to July in any year do not need to be submitted until 1 August the following year.

What if my project was approved in 2024?

To make the transition to a single due date as undemanding as possible for Investigators, new projects approved between 1 April 2024 and 31 July 2024 do not need to submit a progress report until 1 August 2025.

Why do I need to submit a progress report each year?

Submission of annual progress reports is a requirement of the NHMRC National Statement on Ethical Conduct in Human Research 2023 and for CTN/CTA clinical trials, the Therapeutic Goods Act (1989).

Continued ethical approval of a project is contingent on the RDU receiving an annual progress report by the 1 August due date. A failure to do so may result in a suspension of the study or a withdrawal of ethical approval.

QA and negligible risk projects do not need to submit a progress report.

When do I submit a final report?

Do not wait for the August deadline to submit **final reports**. Investigators should submit a final report following study completion via ERM as usual. Please note:

- For commercially sponsored clinical trials, a study is considered complete once the closeout visit has been completed.
- For investigator initiated clinical trials, a study is considered complete once the last patient has completed follow-up and the data have been analysed.
- For all other research projects, a study is considered complete once data collection is complete and there is no further contact with patients or access to medical records or other sources of personal health or information.

When do I submit an amendment?

Where Investigators are required to submit an amendment for their study, please do so in ERM as usual.

Still have questions?

Please contact the Barwon Health Research Development Unit at rdu@barwonhealth.org.au or (03) 4215 3374.