

## FAQs - POST APPROVAL

### Why is submitting an annual progress report important?

- » It is a requirement of the HREC and NHMRC.
- » Ongoing HREC approval is contingent on the provision of annual progress reports. Failure to submit annual progress reports means that you no longer have ethics approval to conduct your research.
- » Submission of annual progress reports is also a requirement of NHMRC guidelines.

### Can my annual progress report cover more than a 1 year period?

- » Yes. However you do not have to submit a separate report for each year that the report is overdue. Submit one form to cover the entire period that your report is overdue. Remember, you **MUST** state the entire period clearly on the form using the "Report period start date" and "Report period end date".

### What if my project has been completed?

- » Complete a Project Final Report/Site Closure Report (HREC) form only
- » Why is the Head of Department included in the email notification of closure of the project?
- » The Head of Department will be included in the email because we expect that many of the projects with progress reports outstanding for three (3) years or more are projects where the PI has left the organisation.

### Why is submitting an annual safety report important?

- » It is a requirement of the *NHMCR Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016)*
- » The report should allow the HRECs to assess whether ongoing safety monitoring is being conducted appropriately and that the trial's safety monitoring plans are being followed and where necessary, are being adapted to take into account new findings as the trial progresses

### What forms do I use for post-approval reporting?

- » Use the Department of Health & Human Services forms for post-approval reporting. The forms can be accessed from links located on the post-approval-project-management webpage  
<https://www.thermh.org.au/research/researchers/governance/post-approval-project-management>