

Updates to post approval reporting

Important updates to the post approval reporting for HREC approved projects have been made including the addition of two new processes.

The changes have been implemented due to updates of guidelines and to ensure that research reviewed by Melbourne Health HREC or undertaken at Melbourne Health sites complies with the applicable requirements and best research governance practice.

Summary of updates and changes

1. OVERDUE Annual Progress Reports – July Amnesty, August Reconciliation, conditions for withdrawal of ethical approval
2. Annual Site Audit Report – NEW PROCESS – for all projects with a MH site from 1 September 2017
3. Annual Safety Report – NEW PROCESS – for all Clinical trials approved by the MH HREC or with a MH site from 1 September 2017

There is a FAQ sheet to answer some of your queries which can be downloaded from the Office for Research website at: <https://www.thermh.org.au/research/researchers/governance/post-approval-project-management>

Please forward any queries to ResearchGovernance@mh.org.au

1. OVERDUE Annual Progress Reports – July Amnesty and Reconciliation

The Office for Research is conducting a reconciliation of annual progress reports to update our database as we note that there are number of projects that have an overdue annual progress report.

Submission of annual progress reports is a requirement of the HREC and NHMRC. The reports are required to be submitted by the anniversary of HREC approval and it is the researcher's responsibility to submit annual progress reports to the HREC.

Amnesty - The annual progress report amnesty will run for the month of July to allow researchers to review their project files and submit an annual progress report for projects where they have identified the report as being overdue.

Reconciliation - From August, the Office for Research will undertake a reconciliation of annual progress reports starting with a search of the database to prepare a list of projects with an overdue annual progress report. Follow-up actions for projects identified will be a two tier process consisting of:

- 1.1 Annual progress reports that are overdue for **less than three (3) years**
PI, contact person and Melbourne Health Head of Department will be emailed request an annual progress report covering the overdue period and confirmation on whether ongoing approval is required. If a response is not received within one on the email request then the ethical approval for project will be automatically withdrawn and an email notification of this will be forwarded to the PI, contact person and Melbourne Health Head of Department.
- 1.2 Annual progress reports that are overdue for **three (3) or more years**
The ethical approval for project will be automatically withdrawal. An email notification of this will be forwarded to the PI, contact person and Melbourne Health Head of Department. If you require ongoing approval you will need to write to the OFR and request this and provide and

explanation of why reports were not submitted as per requirements and confirm that reporting requirements will be met in future.

Ongoing Reconciliation – from 2018 ongoing reconciliation of annual progress reports will be conducted quarterly and reports will be requested for projects with overdue progress reports. If a response is not received within one on the email request then the ethical approval for project will be automatically withdrawn and an email notification of this will be forwarded to the PI, contact person and Melbourne Health Head of Department.

Please submit the annual progress reports on the DOH form according to the process outlined on the Office for Research website <https://www.thermh.org.au/research/researchers/governance/post-approval-project-management>

2. Annual Site Audit Report – NEW requirement

This is a new requirement to help researchers and Melbourne Health maintain high standards of research conduct and governance.

An annual site audit report is to be submitted with the annual progress report for all projects with a Melbourne Health site.

This requirement is effective from 1 September 2017.

Ongoing Reconciliation – from 2018 ongoing reconciliation of annual site audit report will be conducted quarterly and reports will be requested for projects with overdue annual site audit reports. If a response is not received within one on the email request then the ethical approval for project will be automatically withdrawn and an email notification of this will be forwarded to the PI, contact person and Melbourne Health Head of Department.

Please submit the annual site audit report on the Department of Health & Human Services form according to the process outlined on the Office for Research website <https://www.thermh.org.au/research/researchers/governance/post-approval-project-management>

3. Annual Safety Report - NEW requirement

This is a new requirement as per the NHMCR Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016).

An annual safety report will be required for all Clinical trials Clinical Trials Involving Therapeutic Goods (sponsored and investigator initiated) and approved by the Melbourne Health HREC or undertaken at a Melbourne Health site (with ethical review from another HREC). The annual safety report is to be submitted with the annual progress report for all applicable.

This requirement is effective from 1 September 2017.

Ongoing Reconciliation – from 2018 ongoing reconciliation of annual site audit report will be conducted quarterly and reports will be requested for projects with overdue annual site audit reports. If a response is not received within one on the email request then the ethical approval for project will be automatically withdrawn and an email notification of this will be forwarded to the PI, contact person and Melbourne Health Head of Department.

Please submit the annual site audit report on the Department of Health & Human Services form according to the process outlined on the Office for Research website <https://www.thermh.org.au/research/researchers/governance/post-approval-project-management>