

1.10.16 Monitoring research

Monitoring process

The Ethics Committee is required to monitor all approved research in accordance with the [National Statement on Ethical Conduct in Human Research \(2007\)](#). Part of the monitoring process includes the review of progress reports.

Researchers' responsibilities

Submission of progress reports

Researchers are required to submit a [progress report](#) to the Ethics Manager for each research project approved by the Ethics Committee. Reports are usually due on the anniversary of approval, but occasionally they are requested at a more frequent interval. Reports are also due on the completion of a project or if the research is discontinued before the expected date of completion.

Please email your completed progress report and any attachments to [s 47F](#). If the email is sent by the Principal Investigator, then the emailed report is sufficient and you are not required to send a hard copy. Receipt is acknowledged by return email. If the emailed report is not sent by the Principal Investigator, then you are also required to send a report in hard copy, signed by the Principal Investigator, to [s 47F](#), Ethics Office, The Alfred, 55 Commercial Road, Melbourne, Vic, 3004

NOTE

The Ethics Committee will notify researchers about the due date of the progress reports at least a week in advance.

Ethics approval is ongoing but will lapse if the progress report is not received by the anniversary of the approval date, or, is not deemed satisfactory by the Ethics Committee.

If the Committee is not satisfied with the progress report, researchers will be informed about subsequent action.

Monitoring adverse events

Researchers must monitor their research in accordance with guidelines contained in the [National Statement on Ethical Conduct in Human Research \(2007\)](#). They must report adverse events where necessary, to the appropriate authorities including the [Ethics Office](#).

Audits of research projects

Self Audit

A [Self Audit Tool](#) has been designed to help research personnel reflect on their research conduct and comply with guidelines for responsible research conduct.

The Ethics Committee requires that a member of the study team complete the Self Audit annually, discuss and obtain sign-off from the Principal Investigator, and then submit the signed document with the annual progress report and file a copy with the study documents

Audit by the Ethics Committee

As part of the Committee's research governance obligations, the Research Governance Officer regularly conducts short audits of a range of research projects. This involves meeting with researchers to:

- Examine relevant documentation including signed consent forms, completed Case Report Forms, data spreadsheets, medical records, correspondence and approval certificates

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- Check on arrangements to protect privacy and confidentiality of participant data
- Check source data

This process usually takes around two hours. The Research Governance Officer will contact researchers a fortnight before the audit to set a mutually convenient time.

Occasionally, the Ethics Committee may recommend that a full audit of a project is undertaken. This involves the Research Governance Officer examining all of the study files, observing randomisation procedures etc. This may take two to three days and can be spread over several sessions if necessary.

Within a week of completion of the audit, researchers will receive by e-mail, an audit report including a summary of the main findings and a list of items that require action in order to comply with guidelines for good clinical practice. Researchers are expected to take appropriate action and notify the Ethics Secretariat within a month of receiving the report. If this is deemed satisfactory by the Committee, the audit will be considered closed. If the Committee is not satisfied, the researchers may need to discuss the issues with nominated members who can assist with resolving specific issues.

If researchers do not notify the Ethics Secretariat of the action taken within a month of receiving the audit report, the Ethics Committee can recommend that approval for the project be withdrawn.

Common problem areas

Issues that surface most often during audit of research projects include compliance with privacy and confidentiality requirements, participant recruitment numbers and timelines, notification of research participation in the participant's medical records and registration of clinical trials with the WHO trials registry.

Complaints

Researchers must direct all complaints regarding the conduct of the audit to:

Ethics Manager
Research & Ethics Unit
The Alfred hospital
55 Commercial Road
Melbourne VIC 3004

e-mail on research@alfred.org.au