

## Conditions of approval

### 1. Monitoring of Approved Research Projects

Monitoring is the process of verifying that the conduct of research conforms to the approved ethics application. Compliance with monitoring requirements is a condition of approval.

The *National Statement on Ethical Conduct in Human Research* indicates that institutions are responsible for ensuring that research is reliably monitored. Monitoring of approved projects is to establish that a research project is being, or has been, conducted in the manner approved by the Ethics Committee. Researchers also have a significant responsibility in monitoring, as they are in the best position to observe any adverse events or unexpected outcomes. They should report such events or outcomes promptly to the Ethics Committee and take prompt steps to deal with any unexpected risks.

All projects approved by an ECU Ethics Committee are approved subject to the following conditions of approval:

- If the research project is discontinued before the expected date of completion, researchers should inform the Ethics Committee as soon as possible, giving reasons.
- An annual report (for projects that are longer than one year) and a final report at the completion of the research will be provided to the Ethics Committee. You will also be notified when a report is due. The ethics report form can be found on the ethics website [http://www.ecu.edu.au/GPPS/ethics/human\\_ethics\\_resources.html](http://www.ecu.edu.au/GPPS/ethics/human_ethics_resources.html)
- Researchers must also immediately report anything that might warrant review of the ethical approval of the protocol, including:
  - Any serious or unexpected adverse effects on participants
  - Any unforeseen events that might affect continued ethical acceptability of the project.

The Ethics Committee retains the right to require a more detailed and/or more frequent report if the research is deemed to be of high risk, and to recommend and/or adopt any additional appropriate mechanism for monitoring including random inspections of research sites, data and signed consent forms, and/or interview, with their prior consent, of research participants.

### 2. Changes and amendments

Compliance with the approved research protocol is a condition of approval, and any changes to the research design must be reported to the Ethics Committee. Amendments to the research design that may affect participants and/or that may have ethical implications must be reviewed and approved by the Ethics Committee before commencement.

Any changes to documents and other material used in recruiting potential research participants, including advertisements, letters of invitation, information sheets and consent forms, should be approved by the Ethics Committee.

In order to request approval for a change, please send an email to the Ethics Office outlining why the change is needed, describing the change (e.g. the new participants or new research procedures), and attach a copy of any amended documents.

### 3. Extension of ethics approval

All research projects are approved for a specified period of time – from the date of approval until the date of completion provided in the ethics application. If an extension of the approval period is required, a request must be submitted to the Ethics Committee. Please ensure that requests for extension of approval are submitted before the original approval expires.

In order to request an extension of ethics approval, please send an email to the Ethics Office providing a brief reason why the extension is needed and giving the new expected date of completion.