

## **DRAFT [due to be finalised by 30/06/11]**

### **Withdrawal of ethical approval**

Ethical approval may be withdrawn for a range of reasons, for example:

- Risks to participants or patients
- Risks to the institution
- Risks to the researchers
- Research misconduct
- Failure to comply with the protocol
- Failure to submit an annual progress report.

The decision to withdraw ethical approval for a particular project can be made by the Ethics Committee, the Ethics Office (in the case of failure to submit an annual progress report) or the institution. In some cases, such as in instances where there is an immediate danger to patients or participants, the Chair may withdraw ethical approval.

In the case of failure to submit an annual progress report, the Ethics Office informs the Principal Investigator of the decision to withdraw approval. 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.

In all other cases, the Ethics Committee informs the Principal Investigator, Head of Department, Director of Research and the CEO (as a representative of the Alfred Health Board) of the decision to withdraw approval. In projects involving Monash or other university departments, the research governance officer of the university department may also need to be informed of the decision to withdraw ethical approval.

The implications of conducting research without ethical approval are serious and may include:

- placing participants at unacceptable risk
- contravening sections of the Victorian Health Records Act, the Privacy Act 1988 (Commonwealth) and other relevant legislation
- not covered by insurance policies or clinical trial agreements
- required to destroy the data you have collected
- breaching the Australian Code for the Responsible Conduct of Research and CPMP/ICH Note for Guidance on Good Clinical Practice
- unable to publish findings in peer reviewed journals
- jeopardising funding from bodies such as the NHMRC.