



1. The HREC has a written procedure for managing complaints about the conduct of an authorised research project. The procedure is publicly available on the HREC web site.
2. Complaints about the ethical conduct of a research study, approved by Adventist HealthCare Limited HREC are handled in compliance with Chapter 5.6 of the *National Statement on Ethical Conduct of Human Research 2007* and the *Australian Code for the Responsible Conduct of Research (2007)*.
3. Details of the HREC Executive Officer is provided to participants and includes the name, position and contact details together with the procedure for raising concerns or obtaining additional information on the research.
4. In the event that a complaint may be the subject of an investigation or action under more than one process, such as complaints resolution or disciplinary processes specified in other policies, the matter is considered in a manner that minimises duplication of processes.
5. All complaints received and the relevant action/s taken, are reported to Group Board of Directors in the HREC Annual Report to the Board of Directors.

Single-Centre Research

6. Complaints about the conduct of an authorised research project will be reported to the HREC Executive Officer who provides acknowledgement of the complaint in writing, in a timely manner.
7. The Executive Officer will refer the complaint to the HREC for consideration at the next scheduled meeting. Where there is a risk of harm to participants, researchers or other persons, the matter will be referred to the HREC for immediate review.
8. Following consideration of the complaint, the HREC will make a recommendation/s to the Group Chief Executive Officer on the appropriate course of action. Recommended action may include:
 - Determining the allegations have no substance and dismissing the complaint
 - Determining that there is no evidence of misconduct or fraud but issue a caution
 - Initiating increased monitoring by the Committee
 - Requesting an amendment to the research plan / protocol
 - Suspending ethical approval
 - Terminating ethical approval
9. The Group Executive Committee will considers the recommendation/s of the HREC at the next meeting (or earlier if required) of the AHCL Executive Officers

Complaints about the Conduct of an Approved Research Project

Committee and determine what action should be taken in relation to the complaint.

10. Where the complaint relates to suspected research misconduct, the matter is dealt with in accordance with the *Australian Code for the Responsible Conduct for Research* (2007). Where an allegation of misconduct is upheld by the Group Executive Officers Committee, the Group Chief Executive Officer will:
 - Advise the Principal Investigator, in writing, of the outcome of the investigation
 - Inform grant funding bodies and/or other parties with a direct interest in the matter including the Director of Medical Services, Director of Risk Management and Chairperson of the Ethics Committee
 - Take other action as may be necessary to protect the interests of the Group and exercise a duty of care towards staff members, students, the public and any other parties involved in the matter
 - The Group may exercise its right to take legal or other action against the researcher or a third party

Multi-Centre Research

11. Where the complaint involves multi-centre research, the complaint may be made directly to the reviewing HREC who informs the site Governance Officer that the study is the subject of a complaint.
12. The Governance Officer follows the procedure outlined for single-centre research.