



RESEARCH COMPLAINTS (ALBURY WODONGA HUMAN RESEARCH ETHICS COMMITTEE)

Definition / Description:

This procedure for handling research related complaints has been developed to clearly set out the roles and responsibilities of Albury Wodonga Research Ethics Committee (AWHREC) and the processes in place in relation to managing any complaints that may be received about research undertaken.

Complaints may be made about researchers or the conduct of research or about the conduct of a research-related committee or other review body. Complaints may be made by research participants, researchers, and staff of institutions or others. All complaints should be handled promptly and sensitively.

All complaints will be dealt with in accordance with the principles of natural justice.

Personnel Able to Perform or Assist with Procedure:

- AWHREC Chair.
- AWHREC.

Expected Outcomes:

This Research Complaints Procedure requires that all research complies with all relevant codes of practice, ethical guidelines and legislation including the *National Statement on Ethical Conduct in Human Research 2007 (Updated March 2014)*, the *Code of Practice for the care and use of animals for scientific purposes 2007*, the *Gene Technology Act 2000 (Cwlth)* and the *Australian Code for the Responsible Conduct of Research 2007*.

Equipment:

- Research Complaints Register (J:\J_Ethics\Complaints\ComplaintsRegister.xls).

Process Standards:

DEFINITIONS:

Complaint:

A complaint includes:

- A verbal expression of dissatisfaction that can be dealt with promptly and to the reporter's / complainant's satisfaction at the point of service.
- All written incident reports or complaints.
- Any verbal complaints that cannot be dealt with at the point of service.
- Any complaints or allegations relating to research misconduct. The *Australian Code for the Responsible Conduct of Research 2007* defines research misconduct as follows:
A complaint or allegation relates to research misconduct if it involves all of the following:
 - An alleged breach of this Code.
 - Intent and deliberation, recklessness or gross and persistent negligence.
 - Serious consequences, such as false information on the public record.
 - Adverse effects on research participants, animals or the environment.

Research misconduct includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and failure to declare or manage a serious conflict of interest. It includes avoidable failure to follow research proposals as approved by a research ethics committee, particularly where this failure may result in unreasonable risk or harm to humans, animals or the environment. It also includes the wilful concealment or facilitation of research misconduct by others.

Applicability:

This procedure applies to all researchers (including staff and students) conducting research following approval from AWHREC.

Procedures:

The following procedures relate to all research related complaints:

- Complaints will be reported to the AWHREC and an update provided on each subsequent committee meeting agenda.
- All complaints will be recorded on the Research Complaints Register. The register includes information to track the progress of the complaint and provide a history of all referrals and action taken, as well as dates of receipt and resolution of the complaint.
- A written file note of the complaint (including actions taken and outcomes) will also be placed in the relevant file associated with the research project and the Research Complaints file.
- All research related complaints will be reported to the Chair of the AWHREC.
- All complaints related to human research are also reported to the National Health & Medical Research Council's (NHMRC) Australian Health Ethics Committee (AHEC) as part of the Human Research Ethics Committee (HREC) Annual Report.
- The decision as to whether an incident / complaint is minor or serious will be made by the AWHREC.
- Serious complaints which cannot be resolved using the processes outlined below will be referred if necessary to the CEO of the participating organisation. In some circumstances, external independent advisors may be consulted to provide assistance and advice.
- For human research, information regarding the contact person for complaints must be included in Participant Information and Consent Forms.

Complaints from Research Participants:

- The first person designated to receive complaints from research participants will be the contact person as detailed on the Health Research Participant Information Sheet as approved by the AWHREC.
- If unable to be resolved, the matter must be referred to the Chair of the AWHREC who will liaise with the organisations Research Governance Officer as required.
- In circumstances where a complaint cannot be resolved using an internal complaint resolution process, external, independent advice will be sought. This may include consultation with the Office of the Health Services Commissioner or with senior staff from other organisations.
- Complaints which highlight problems warranting amendments to the research protocol will be reviewed by the Chair of the AWHREC who will provide written advice to the principal researcher.

Complaints from Researchers:

- Complaints from researchers about any aspect of the management of their research project by the AWHREC should be directed to the Chair of the AWHREC.
- Complaints from researchers about any aspect of the management of their research project by participating organisations shall be referred to that organisation.

Categories of Complaints:

Complaints will be identified as relating to research activities or to review of research proposals by the AWHREC and will be categorised to allow analysis of trends. Categories may include:

- Breaches of privacy / confidentiality.
- Misappropriation / falsifying data / dubious authorship / plagiarism / misrepresentation.
- Careless or inappropriate collection, analysis, use or disclosure of information.
- Conflicts of interest.
- Coercion / failure to appropriately obtain consent.
- Departures from good research practice.
- Animal welfare related matter.
- Non-compliance with relevant legislation.
- Unethical behaviour.
- Other.

Seriousness of Complaints:

Complaints will be rated on a scale for seriousness when they are first received by the AWHREC and again when they are closed, in order to help with more accurate assessment of seriousness. The level of seriousness does not reflect the amount of resources that may go into the management of a particular complaint. It is not uncommon for less serious complaints to consume large amounts of time and other resources and for more serious incidents to be resolved comparatively quickly. A complaint can often raise several issues with different levels of seriousness:

- Low rated complaints: are those that ought to be easily resolved by a telephone call or letter and an explanation. These may include misunderstandings or misconceptions where a detailed investigation is unwarranted.
- Medium rated complaints: are those involving incidents such as misunderstandings, coincidental access to records that occurs during the research process, disputes about costs, discourtesy, protocol violations, and breaches of privacy without serious consequences, and diagnostic or treatment errors without serious consequences.
- High rated complaints: are those involving significant quality assurance implications, practices that need changing to avoid recurrence of the event, such as amendments to the study protocol, or development of new policy or procedures. In addition, they may include complaints about protocol violations, breaches of privacy, personal injury, professional misconduct, fraud, unlawful or unethical acts, lack of informed consent and diagnostic or treatment errors with serious adverse outcomes.

Annexes:

Related AWH Documents: Complaints Management (Patients and Consumers) Policy (POL0521).
Complaints Management (Patients and Consumers) Procedure (PRO0335).

Accreditation Standards: EQUIP National Standard: 15.10.1, 15.11.1, 15.11.2

Other Relevant Information:

References: Research Governance Toolkit for Victorian Public Hospitals and VMIA Insured Medical Research Institutions, VMIA, April 2010.
National Statement on Ethical Conduct in Human Research 2007, Australian Government / National Health & Medical Research Council, 2007.
Australian Code for the Responsible Conduct of Research 2007, Australian Government / National Health & Medical Research Council, 2007.

Contact Point: Research Governance Officer.

In consultation with:

TITLE / POSITION
Albury Wodonga Human Research Ethics Committee
Director of Medical Services
Director of Infrastructure

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