Guidelines for Handling Complaints in Research

Barwon Health

Handling Research Related Complaints Policy

1. Purpose

This policy has been developed to set out the roles and responsibilities of Barwon Health research staff and research committees and the processes for managing complaints about research undertaken at or under the auspices of Barwon Health. 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, staff or others. All complaints should be handled promptly and sensitively.

Barwon Health Research policy requires that all research undertaken by or auspiced by Barwon Health must comply with all relevant codes of practice, ethical guidelines, and legislation, including the *National Statement on Ethical Conduct in Human Researc*h 2007*,* 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.

2. Scope

This policy relates to all research undertaken by *Barwon Health, or under the auspices of Barwon Health.*

3. Definitions

A research complaint may entail one or more of the following:

- **Independent Participant Representative** contact person for complaints **– c**omplaints should firstly be directed to the Independent Participant Representative as named on the Participant Information and Consent Form.
- **Informal Complaint** – an informal complaint is a verbal expression of dissatisfaction that can be dealt with promptly and to the reporter's/complainant's satisfaction at the point of service (informal complaints do not need to be recorded).
- **Formal Complaint –** a formal complaint includes all written incident reports or complaints and any verbal complaints that cannot be dealt with as informal incidents/complaints. Formal complaints should be recorded in the Research Complaints Register and reported to the relevant committee. A written file note of the complaint should also be placed in the relevant file associated with the research project. Formal complaints related to human research should also be reported to the NHMRC's AHEC as part of the HREC Annual Report.
- **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:

a) An alleged breach of this Code;
b) Intent and deliberation, recklessness or gross and persistent negligence;
c) Serious consequences, such as false information on the public record; and
d) 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.

4. Applicability

This policy applies to all staff and students conducting research on the campuses of Barwon Health and the individual research institutes and groups for whom the Barwon Health HREC provides research governance and services.

5. Principles

Complaint management must be sensitive towards the rights, needs and concerns of reporters, complainants, patients, research participants, researchers and administrative staff.

Complaint management must comply with the *Victorian Information Privacy Act* 2000, the *Health Records Act* 2001 and the *Health Services (Conciliation and Review) Act* 1987.

All reporters, complainants, patients, research participants and investigators have a right to report or complain either in person or through a representative.

All complaints should be managed in a timely and sympathetic manner and be treated confidentially.

It is the responsibility both of the RGU and the Chair of the relevant research related committee to ensure that the process is easily accessible to all concerned.

The evaluation of complaints helps to inform the RGU and the relevant research related committee about areas where processes can be improved, particularly in relation to research governance and management.

6. Procedures

Complaints will be recorded on the Research Complaints Register, held with REGI. 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.

The decision as to whether an incident/complaint is minor or serious will be made by the Independent Participant Representative in consultation with the Chair of the relevant committee and where necessary, the Director of Research (or equivalent).

For human research, information regarding the contact person for complaints should be included in the Participant Information and Consent Forms. Examples are as follows:

- **Complaints –** if you have any complaints about any aspect of the study or the way in which it is being conducted, you may contact the Independent Participant Representative at Barwon Health on (03) 4215 3372. You will need to tell the Independent Participant Representative the name of the person who is noted as the Principal Investigator (PI) at the top of this form.

Under the heading 'Research Participant Rights' insert the following paragraph:

- **Research Participant Rights –** if you have any questions about your rights as a research participant, then you may contact the Independent Participant Representative at *Barwon Health* on: *[telephone number].*

7. Formal Complaints from Research Participants

Research participant is a Barwon Health patient

Where the research participant is a Barwon Health patient, the institution's patient complaint policy should be referred to. Complaints will be reported to the relevant committee and an update provided on each subsequent committee meeting agenda.

Research participant is not a Barwon Health patient

At Barwon Health, the first person designated to receive complaints from research participants is the Independent Participant Representative. It is expected that most complaints from research participants will be able to be dealt with by the Independent Participant Representative in conjunction with the relevant Principal Investigator.

Serious complaints, which cannot be readily resolved, will be referred for consideration by the Independent Participant Representative, Chair or the relevant research related committee and, where necessary, the Director of Research (or equivalent).

In circumstances where a complaint cannot be resolved using *Barwon Health* internal complaint resolution processes, 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 relevant research related committee who will provide written advice to the Principal Investigator.

Complaints will be reported to the relevant committee and an update provided on each subsequent committee meeting agenda.

8. Formal Complaints from Researchers

Complaints from researchers about any aspect of the management of their research project by the RGU or a research related committee should be directed in the first instance to the Independent Participant Representative.

The Independent Participant Representative will liaise with the Principal Investigator and, where necessary, the Chair of the relevant Independent Participant Representative research related committee, and the committee itself to resolve the matter.

Serious complaints which cannot be resolved using the process outlined above will be referred to the Director of Research (or equivalent) and, if necessary, the Barwon Health Chief Medical Officer or Chief Executive Officer. In some circumstances, external independent advisors may be consulted to provide assistance and advice.

9. Complaints from Committee Members and Other Interested Persons

Complaints from research related committee members or other interested persons should be directed in the first instance to the Independent Participant Representative. Other interested persons may include heads of departments whose services are required by researchers to support their research project and staff in wards or service departments whose assistance or support is required to facilitate the research. The Independent Participant Representative will endeavour to resolve the problem directly with the complainant and/or the Principal Investigator (as applicable) and, where necessary (and if appropriate), with the Chair of the relevant research related committee.

Serious complaints (refer to section 7) will be referred to the Director of Research (or equivalent). Consultation with the *Barwon Health* Chief Medical Officer or Chief Executive Officer and external independent advisors, as outlined above, will be sought if required.

In all cases, details of a complaint will be recorded in the Research Complaints Register held in REGI. Hard copies of the details of the complaint, actions taken and outcomes will also be kept in the relevant project file and the RGU Research Complaints file. It is important to identify either the project number or project title when registering a complaint or enquiry related to a specific project.

All research related complaints will be reported to the Chair of the relevant research related committee. All complaints involving human research will also be reported to the NHMRC's AHEC as part of the HREC Annual Report.

10. Categories of Complaints

Complaints will be identified as relating to research activities or to review research proposals by the relevant research related committee 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; and/or
- Other.

11. Seriousness of Complaints

Complaints will be rated on a scale for seriousness when they are first received by the Independent Participant Representative 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** – 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** – those involving incidents such as misunderstandings, access to records, disputes about costs, discourtesy, protocol violations, breaches of privacy without serious consequences, and diagnostic or treatment errors without serious consequences
- **High Rated Complaints** – 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 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.

12. Post-Complaint Enquiries

Any enquiries regarding the handling of incidents or complaints related to research activities should be directed to the Independent Participant Representative.

13. References

These guidelines should be read in conjunction with:

- The Barwon Heath Complaint Managements Procedure (Prompt)
- The Barwon Heath Acceptable Behaviours Policy (Prompt)
- The Australian Code for the Responsible Conduct of Research
- National Statement on Ethical Conduct in Human Research (NHMRC 2007)