

Research Complaints Procedure

This Research Complaints Procedure applies to all staff and students conducting research at Bolton Clarke as well as the individual research institutes and groups for whom Bolton Clarke provides research governance services.

This procedure for handling research related complaints has been developed to clearly set out the roles and responsibilities of Bolton Clarke and its research-related committees and the processes in place in relation to managing any complaints that may be received about research undertaken at and / or by Bolton Clarke.

Complaints may be made about researchers, the conduct of research, or the conduct of a research-related committee. Complaints may be made by research participants, researchers, staff or others.

All complaints will be handled promptly and sensitively.

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

This Research Complaints Procedure requires that all research in which Bolton Clarke is involved complies with all relevant codes of practice, ethical guidelines and legislation including:

- the *National Statement on Ethical Conduct in Human Research (2007)*,
- the *Australian Code for the Responsible Conduct of Research (2007)*,
- the *Commonwealth Privacy Act (1988)*,
- the *Health Records Act (2001) Victoria*, and similar legislation in other states
- the *Victorian Health Commissioner's (2002) Statutory Guidelines on Research for the Purposes of Health Privacy Principles 1.1 (e) (iii) and 2.2 (g) (iii)*, and similar Guidelines in other states.

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.
- All 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.

Procedures

The following procedures relate to all research related complaints:

- It is preferred that complaints are made in writing. Where a verbal complaint has been made, a request to put the complaint in writing will be made. Regardless of whether a complaint is verbal or written, the procedure will be the same.
- 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 research project file. All research related complaints will be reported to the Chair of the Bolton Clarke Human Research Ethics Committee (HREC).
- Complaints will be reported to the Bolton Clarke HREC and an update provided on each subsequent committee meeting agenda.
- 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 HREC Annual Report.
- Complaints about the conduct of the research project from research participants, researchers or other interested persons are made to the Chair of the Bolton Clarke HREC for resolution.
- Complaints that cannot be resolved in this manner will be referred to the CEO of Bolton Clarke for resolution.
- Complaints about an activity approved under Commonwealth or State privacy guidelines may be made directly to the relevant federal or state Privacy Commissioner.

Complaints from Research Participants

- Information regarding the contact person for complaints should be included in Participant Information Sheets and Consent Forms, for example:
 - If you have any complaints about any aspect of the study or the way in which it is being conducted you may contact the Principle Investigator on Tel. (0*) **** *.
 - If you have any questions about your rights as a research participant, then you may contact the Bolton Clarke HREC Chair via the secretary of the Bolton Clarke HREC on 03 9814 2736. Complaints which highlight problems warranting amendments to the research protocol will be reviewed by the Chair of the Bolton Clarke HREC who will provide written advice to the principal researcher.

Complaints from Researchers

Complaints from researchers about the conduct of the HREC will be referred to the Bolton Clarke CEO in writing, acknowledged and investigated by a third party as directed by the CEO. Complainants will be given the opportunity to present the complaint in person.

Complaints from HREC Members and other Interested Persons

Complaints from Bolton Clarke HREC members and other interested persons should be directed in the first instance to the Chair of the Bolton Clarke HREC. Other interested persons may include heads of departments whose services are required by researchers to support their research project and staff whose assistance or support is required to facilitate the research. The Chair of the Bolton Clarke HREC will endeavour to resolve the problem directly with the complainant and / or the principal researcher (as applicable) and, where necessary (and if appropriate), with the CEO.

Where it is not appropriate to refer the complaint to the HREC Chair, the complaint should be forwarded to the CEO who will identify an independent investigator.

Seriousness of Complaints

Complaints will be rated on a scale for seriousness when they are first received by the HREC Secretary or their delegate 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, 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: 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. Complaints that involve research misconduct by Bolton Clarke researchers will be dealt with as detailed in Bolton Clarke Institute Policy 8 Alleged Research Misconduct.

Contact details

Contact details of the Chair of the Bolton Clarke HREC are as follows:

The Chair
Bolton Clarke Human Research Ethics Committee
Level 1, 347 Burwood Hwy
Forest Hill VIC 3131

Email: ethics@boltonclarke.com.au

Phone: 03 9814 2736 (HREC Secretary)