

HREC Standard Operating Procedure

5.14 Complaints Handling

Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to fulfilling Section 5.7 of the National Statement on Ethical Conduct in Human Research (2023) by ensuring a process for the handling of complaints and the investigation of research misconduct.

Definitions

Informal Complaint is defined as 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 is defined as written incident reports or complaints and any verbal complaints that cannot be dealt with as informal incidents/complaints.

Research Misconduct is defined as:

- Intent and deliberate recklessness or gross and persistent negligence;
- Actions which have serious consequences, such as providing false information; and
- Actions which cause adverse effects on research participants, animals or the environment.

Research misconduct also 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.

Seriousness of complaints

Complaints will be rated on a scale for seriousness when they are first received by the Deputy Director of Research 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 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.

Procedures

SVHM Research Policy requires that all research in which SVHM is involved complies with all relevant codes of practice, ethical guidelines and legislation including the National Statement on Ethical Conduct in Human Research (2023), the Australian code for the care and use of animals for scientific purposes (2013), the Gene Technology Act (2000) and the Australian Code for the Responsible Conduct of Research (2018).

This policy for handling research related complaints has been developed to clearly set out the roles and responsibilities of SVHM 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 SVHM.

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. Research should be forwarded to the Deputy Director of Research or Director of Research in the first instance. The Patient Liaison Officer must also be contacted if the complainant is a patient or service user of SVHM.

Formal complaints should be recorded by the Research Governance Unit (RGU) 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 application. Formal complaints related to Human Research are also reported to the NHMRC's Australian Human Ethics Committee (AHEC) as part of the HREC Annual Report.

Complaints Handling

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. 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.

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. For human research, information regarding the contact person for complaints must be included in Participant Information and Consent Forms.

Complaints will be recorded on the Research Complaints Register, held in the RGU. 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 Deputy Director of Research in consultation with the Chair of the relevant Committee and, where necessary, the Director of Research.

At SVHM, the first person designated to receive complaints from research participants is the Deputy Director of Research. It is expected that most complaints from research participants will be able to be dealt with by the Deputy Director in conjunction with the relevant principal researcher.

Serious complaints, which cannot be readily resolved, will be referred for consideration by the Deputy Director, Chair or the relevant research related committee and, where necessary, the Director of Research.

In circumstances where a complaint cannot be resolved using SVHM 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 researcher. Complaints will also be reported to the relevant committee and an update provided on each subsequent committee meeting agenda.

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 Deputy Director. The Deputy Director will liaise with the principal researcher and, where necessary, the Chair of the relevant 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 and, if necessary, the SVHM Chief Medical Officer or Chief Executive Officer. In some circumstances, external independent advisors may be consulted to provide assistance and advice.

Complaints from research related committee members or other interested persons should be directed in the first instance to the Deputy Director. 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 Deputy Director 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 Chair of the relevant research related committee.

Serious complaints will be referred to the Director of Research. Consultation with the SVHM 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 the RGU. Electronic 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.

Associated Procedures/Instructions

Reference Documents

- The National Statement on Ethical Conduct in Human Research (2023)
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)
- Australian Code for the Responsible Conduct of Research (2018)
- The Australian code for the care and use of animals for scientific purposes (2013)
- The Gene Technology Act (2000)
- Victorian Information Privacy Act 2000
- Victorian Health Records Act 2001
- Victorian Health Services (Conciliation and Review) Act 1987

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Date Issued: 2011

Date Revised: 2024

Next Review: 2027






5.14 Complaints Handling

Final Audit Report

2024-06-30

Created:	2024-06-30
By:	Sue Ngeow (sue.ngeow@svha.org.au)
Status:	Signed
Transaction ID:	CBJCHBCAABAAy9OgK3N2gALCDwUOaNqeqTOgB1YFchsN

"5.14 Complaints Handling" History

-  Document created by Sue Ngeow (sue.ngeow@svha.org.au)
2024-06-30 - 11:54:27 PM GMT
-  Document emailed to Megan ROBERTSON (megan.robertson@svha.org.au) for signature
2024-06-30 - 11:54:42 PM GMT
-  Email viewed by Megan ROBERTSON (megan.robertson@svha.org.au)
2024-06-30 - 11:55:49 PM GMT
-  Document e-signed by Megan ROBERTSON (megan.robertson@svha.org.au)
Signature Date: 2024-06-30 - 11:55:58 PM GMT - Time Source: server
-  Agreement completed.
2024-06-30 - 11:55:58 PM GMT