

### TARGET AUDIENCE and SETTING

All staff and students conducting research on the campuses of Monash Health and the individual research institutes and groups for whom the Monash Health Human Research Ethics Committee (HREC) provides research governance and services.

### PURPOSE

This procedure:

- covers all research undertaken by Monash Health that is governed by the National Statement on Ethical Conduct in Human Research (NHMRC 2023);
- provides guidance on how research related feedback (including complaints and compliments) should be handled;
- sets out the roles and responsibilities of Monash Health and its HREC;
- outlines the processes in place in relation to managing feedback that may be received about research undertaken at Monash Health.

The following principles underpin this procedure and the management of any feedback received:

- Feedback management must be sensitive towards the rights, needs and concerns of reporters, complainants, patients, research participants, researchers, and administrative staff.
- Feedback 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 feedback should be managed in a timely and sympathetic manner and be treated confidentially.
- It is the responsibility both Research Support Services and the Chair of the relevant research-related committee to ensure that the process is easily accessible to all concerned.
- The evaluation of feedback helps to inform the Research Support Services and the relevant research-related committee about areas where processes can be improved, particularly in relation to research governance and management.

### DEFINITIONS

**Feedback:** any oral, written or in-person information provided as a complaint or compliment received about any aspect of Monash Health’s treatment, care or service provision.

**Complaint:** a formal expression of concern or grievance.

**Informal complaint:** verbal expressions of dissatisfaction that can usually be dealt with promptly and to the complainant’s satisfaction at the point of service. Employees should attempt resolution at the point of contact with escalation to the line manager if further assistance is required.

**Formal complaint:** written complaints and any verbal complaints that cannot be dealt with as an informal complaint. Formal complaints are coordinated by the Patient Relations Coordinator and are recorded in the Victorian Health Incident Management System (VHIMS) Feedback module.

**Compliment:** an expression of thanks, praise, commendation, or admiration about any aspect of Monash Health’s treatment, care or service provision.

**Consumer:** People who use health services as well as their family and carers. This includes people who have used a health service in the past or who could potentially use the service in the future.

PROMPT Doc No: SNH0019859 v6.0		
Date loaded on PROMPT: 18/11/2011	Page 1 of 5	Review By: 30/11/2027
Version Changed: 17/11/2023	Document uncontrolled when downloaded.	Last Reviewed Date: 17/11/2023

## Research Related Feedback (Complaints and Compliments)

## Procedure

**Research participant:** A consumer who is participating voluntarily in a research study being conducted at Monash Health or under a Monash Health HREC approval.

**Research-related committee:** A committee that deals with research at Monash Health such as the HREC and Research Council.

### PRECAUTIONS/CONTRAINDICATIONS

All researchers at Monash Health must strive to conduct research in the manner indicated in the Human Research Policy. Research should be conducted in accordance with the National Statement on Ethical Conduct in Human Research (NHMRC 2023) and the Australian Code for the Responsible conduct of Research (2018). 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).

### STANDARD REQUIREMENTS

When undertaking any clinical interaction with a patient, staff are expected to;

- Perform routine hand hygiene. Refer to the [Hand Hygiene Procedure](#).
- Introduce themselves to the Patient and Carer/ Family if in attendance
- Check patient identification. Refer to the [Patient Identification Procedure](#).
- Obtain consent as per the [Consent to Medical Treatment Procedure](#).
- Keep the patient/carer informed and involve them in decision making.
- Document interaction in the electronic medical record or health record using black pen; including date, time, signature and designation.

### PROCEDURE

#### Consumer complaints and compliments

All Monash Health employees should follow the [Consumer Feedback \(Complaints and Compliments\)](#) when dealing with feedback from consumers. For research-related complaints, the specific requirements outlined below also apply.

#### Feedback from research participants:

1. At the time of being invited to participate in research, all research participants must be provided with the following contact details so that they can lodge feedback directly to Research Support Services:

Email: [research@monashhealth.org](mailto:research@monashhealth.org)

Phone: 03 9594 4611

2. A research participant may also provide feedback through the existing Monash Health feedback mechanisms:
  - via email;
  - by phone;
  - online through the Monash Health website;
  - feedback forms dropped in feedback boxes throughout our sites;
  - face to face (in person or Virtual platform); or
  - in writing by mail.

PROMPT Doc No: SNH0019859 v6.0		
Date loaded on PROMPT: 18/11/2011	Page 2 of 5	Review By: 30/11/2027
Version Changed: 17/11/2023	Document uncontrolled when downloaded.	Last Reviewed Date: 17/11/2023

## Research Related Feedback (Complaints and Compliments)

## Procedure

3. A research participant may choose to provide feedback through either or both channels.
4. If the feedback is lodged directly with the Research Support Services team, the Director of Research Operations or the HREC Executive Officer will enter the feedback into Victorian Health Incident Management System (VHIMS) Feedback module (RiskMan).
5. The feedback will managed following the Monash Health [Consumer Feedback \(Complaints and Compliments\)](#) Procedure.
6. The feedback is reported by the Director of Research Operations to the relevant HREC and an update provided on each subsequent committee meeting agenda.
7. The Chair of the relevant HREC will provide written advice to the Principal Investigator if the complaint warrants an amendment to the protocol.
8. The outcome of the complaint/feedback will be recorded in the Victorian Health Incident Management System (VHIMS) Feedback module (RiskMan) by the Director of Research Operations.
9. A written file note of the complaint will also be placed in the relevant file associated with the application by the Director of Research Operations.
10. 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 by the HREC Executive Officer.
11. The Monash Health Research Council will receive a report on a quarterly basis of complaints/feedback received the outcome from the Director, Research Operations.

### Feedback from researchers:

1. Researchers can provide feedback about any aspect of the management of their research project by Research Support Services or research-related committees. This feedback should be directed to the Director, Research Operations via email address [research@monashhealth.org](mailto:research@monashhealth.org).
2. The Director of Research Operations will liaise with the Principal Investigator(s) and, where necessary, the Chair of the research-related committee, to resolve the matter.
3. If the issue is serious and cannot be resolved using the process outlined above, the Director of Research Operations will refer it to the General Manager Research Strategy and Program Director, Research Strategy or to Chief Medical Officer. In some circumstances, external independent advisors may be consulted to provide assistance and advice.
4. The Director of Research Operations will provide written advice to the Principal Researcher about the outcome of the feedback.

### Feedback from committee members and other interested persons:

1. Members of research-related committees and other interested persons can direct feedback to the Director of Research Operations via [research@monashhealth.org](mailto:research@monashhealth.org). Other interested persons may be heads of departments who support researchers or other ward or support staff who help facilitate research.
2. The Director of Research Operations will attempt to resolve the issue directly with the person who has lodged feedback. This may be done in consultation with the Principal Investigator of the project and/or the Chair of a research-related committee if appropriate.
3. If the issue is serious, it will be directed to the General Manager, Research Strategy and the Program Director, Research Strategy or the Chief Medical Officer. In some circumstances, external independent advisors may be consulted to provide assistance and advice.

PROMPT Doc No: SNH0019859 v6.0		
Date loaded on PROMPT: 18/11/2011	Page 3 of 5	Review By: 30/11/2027
Version Changed: 17/11/2023	Document uncontrolled when downloaded.	Last Reviewed Date: 17/11/2023

## Research Related Feedback (Complaints and Compliments)

4. The Director of Research Operations will provide written advice to the person who lodged the feedback about the outcome.

### Post-feedback enquiries

Any enquiries regarding the handling of research related feedback should be directed to the Director of Research Operations via [research@monashhealth.org](mailto:research@monashhealth.org).

### Seriousness of complaints

The Director of Research Operations will rate the complaint on the Incident Severity Rating 1-4 (ISR 1 as the highest or most severe and ISR 4 as a near miss) when they are first received. This will be done in consultation with the General Manager, Research Strategy and the Program Director, Research Strategy. A Patient Relations Coordinator will also be consulted if the complainant is a research participant. The nature and severity of the complaint will determine the pathway for investigation.

If it is a research participant complaint it will be managed under the [Consumer Feedback \(Complaints and Compliments\)](#) process.

### Complaint categories

All complaints will be identified as either:

- relating to research activities; or
- relating to review of research proposals by the relevant research related committee.

Each complaint will be categorised into the following categories to allow for analysis of trends:

- 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.

## RELATED DOCUMENTATION

---

[Consumer Feedback \(Complaints and Compliments\)](#)

PROMPT Doc No: SNH0019859 v6.0		
Date loaded on PROMPT: 18/11/2011	Page 4 of 5	Review By: 30/11/2027
Version Changed: 17/11/2023	Document uncontrolled when downloaded.	Last Reviewed Date: 17/11/2023

## Research Related Feedback (Complaints and Compliments)

### REFERENCES

---

[National Health and Medical Research Council, Australian Research Council. Australian Code for the Responsible Conduct of Research. NHMRC Australian Code\(2018\).](#)

[National Health and Medical Research Council, Australian Research Council. National Statement on Ethical Conduct in Human Research. NHMRC National Statement\(2023\).](#)

### KEYWORDS

---

Research complaint

Document Governance	
<b>Supporting Policy</b>	<a href="#">Human Research Policy</a>
<b>Executive Sponsor</b>	A/Prof Anjali Dhulia, Executive Director of Medical Services and Chief Medical Officer
<b>Service Responsible</b>	Research Support Services
<b>Document Author</b>	Deborah Dell, Director, Research Operations

PROMPT Doc No: SNH0019859 v6.0		
Date loaded on PROMPT: 18/11/2011	Page 5 of 5	Review By: 30/11/2027
Version Changed: 17/11/2023	Document uncontrolled when downloaded.	Last Reviewed Date: 17/11/2023