

SESLHD PROCEDURE COVER SHEET



Health
South Eastern Sydney
Local Health District

NAME OF DOCUMENT	Research Ethics and Governance Complaints
TYPE OF DOCUMENT	Procedure
DOCUMENT NUMBER	SESLHDPR/733
DATE OF PUBLICATION	August 2022
RISK RATING	Low
LEVEL OF EVIDENCE	National Safety and Quality Health Service Standards: Standard 1 – Clinical Governance
REVIEW DATE	August 2027
FORMER REFERENCE(S)	N/A
EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director, Research
AUTHOR	Aideen Sheehan Project Officer
POSITION RESPONSIBLE FOR THE DOCUMENT	Research Ethics & Governance Office Manager SESLHD-RSO@health.nsw.gov.au
FUNCTIONAL GROUP(S)	Research
KEY TERMS	Complaints, Complaint handling, Research, Research Ethics, Research Governance, HREC, Human Research Ethics Committee, Clinical Trial.
SUMMARY	Procedure for management and handling of research related complaints made in relation to clinical trials, clinical research and health research/social science.

COMPLIANCE WITH THIS DOCUMENT IS MANDATORY

**This Procedure is intellectual property of South Eastern Sydney Local Health District.
Procedure content cannot be duplicated.**

Feedback about this document can be sent to SESLHD-Policy@health.nsw.gov.au

1. POLICY STATEMENT

This procedure accords with the following NSW Health guidelines and policies:

- [GL2013_009 - Human Research Ethics Committees: Standard Operating Procedures for NSW Public Health Organisations](#)
- [GL2010_014 - Operations Manual: Human Research Ethics Committee Executive Officers](#)
- [GL2010_015 - Operations Manual: Research Governance Officers](#)
- [PD2020_013 - Complaints Management](#)
- [PD2018_032 - Managing Complaints and Concerns About Clinicians](#)
- [PD2020_047 - Incident Management](#)
- [SESLHDHB/026 - SESLHD Complaints Management Framework](#)

2. BACKGROUND

The SESLHD Research Directorate provides clinical research governance service provisions overseeing all research and clinical studies on sites within the District. The Directorate has the responsibility to receive, register, acknowledge, escalate, investigate and report on all complaints relating to:

- Conduct of an HREC member
- HREC decisions on ethical or scientific review of a project
- Conduct of the HREC during reviews or appeals
- Conduct of a Research Directorate staff member
- Conduct of an approved research project or trial process
- Conduct of trial site staff.

This procedure will be followed when addressing complaints received by the Research Directorate. Complaints are to be escalated appropriately depending upon the nature of the complaint. Refer to [APPENDIX B](#) for escalation pathways.

If a complaint raises a potential breach of the [Australian Code for the Responsible Conduct of Research 2018](#), the complaint will then be investigated as per the [NHMRC Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research](#).

3. DEFINITIONS

- **Complainant:** A person or organisation making a complaint.
- **Complaint handler:** The SESLHD employee liaising with the complainant.
- **HREC:** the SESLHD Human Research Ethics Committee (or its Low Risk Subcommittee as relevant).
- **HREC Chair:** The Chairperson of the SESLHD Human Research Ethics Committee (or its Low Risk Subcommittee as relevant).
- **CE or delegate:** The SESLHD Chief Executive or their delegated complaints handling Officer (SESLHD Research Development Manager).

4.0 RESPONSIBILITIES

Responsibilities of the various parties are described below.

4.1 Employees will:

- Comply with this procedure.
- Take all complaints seriously.
- Be respectful in all dealings with complainants.
- Provide details of site Aboriginal Liaison Officers to Aboriginal and/or Torres Strait Islander complainants or staff members involved in investigations.
- Take due care to protect stakeholders' reputations and anonymity, especially when dealing with complaints of a sensitive nature.
- Attempt to resolve the complaint in the first instance.
- Endeavour to seek resolutions that are acceptable to all parties (i.e. best possible outcomes)
- Exercise sound judgment when assessing complaints escalation.
- Seek assistance from their direct supervisor or line manager/ Research Development Manager if help or advice is needed to follow any part of this procedure.

4.2 Line Managers will:

- Ensure that this document is publicly available.
- Ensure their team members understand and comply with this procedure.
- Provide risk training to team members to mitigate risks associated with poor complaint handling and management.
- Monitor complaint handling and the complaint register to ensure complaints are handled appropriately and within specified timeframes.
- Provide support or, if appropriate, take over handling of complaints where greater experience or skill is required.

4.3 District Managers/ Service Managers will:

- Foster a research environment in which complaints are seen as valuable learning opportunities and assignation of blame is avoided.

4.4 Clinical Trial Investigators and Coordinators will:

- Direct all complaints from participants or colleagues relating to the conduct of research or research personnel to the Research Directorate **as soon as possible**.
- Give due seriousness to the complaint and any findings or rulings arising.
- Where appropriate take action to remedy the cause of the complaint in accord with recommendations and ruling arising from resolution of the complaint.
- Where the complaint exposes a safety issue the investigator will take appropriate action to mitigate risk immediately without waiting for resolution of the complaint.

5.0 PROCEDURE

The Research Directorate will adhere to the following procedure when managing research complaints.

5.1 Receiving complaints

Complaints relating to research within SESLHD should be made in writing. Complaints may be received by any of the following personnel:

- Research Directorate staff
- Human Research Ethics Committee & Executive Officer or delegate
- District Chief Executive or delegate
- Research/ trial site staff
- Public or Private Health Organisation or trial site where research is being conducted

The staff member receiving a complaint will ensure to collect the complainant's contact information and a detailed description of the issues involved. This is to include relevant dates, any staff members' details that the complaint relates to, and any desired resolutions the complainant may have.

If a complainant identifies themselves as an Aboriginal and/or Torres Strait Islander person, the staff member is to tell the person that there are Aboriginal Liaison Officers based at each site that can provide support or assist in the complaint by attending meetings or communicating with the investigator. If the person wishes to speak with an Officer, either provide details of site Aboriginal Liaison Officers or provide the complainant's contact details to the site Officer to contact the complainant.

5.2 Registering complaints

The staff member who has received a complaint must register the complaint in IMS+ through the Complaint Notification Form. This is to be done **as soon as practicable**, but no later than **5 calendar days**, after first correspondence with the complainant.

During initial registration of the complaint in IMS+, the staff member must allocate an IMS+ Harm Score.

For information on assessing a complaint's Harm Score, please see [NSW Health Policy Directive PD2020_047 - Incident Management](#).

Complaints will also be recorded in the 'Research Complaints Log' by the Research Directorate staff. The Log is stored on the Research Directorate private shared drive. Complainant identity and contact details are not to be kept in the complaint log, but in a separate and secure file kept by the complaint handler.

5.3 Escalating complaints

Staff who have received a complaint aim to manage and resolve that complaint in the first instance. Some complaints may need to be escalated to a more senior staff member, the CE, the Research Development Manager or external entity, depending on circumstances.

Complaints are to be escalated to the appropriate representative if:

- Actions beyond initial staff member's responsibilities are required
- Relating to an HREC decision or an HREC member
- Relating to a colleague
- They remain unresolved
- Complainant has requested an escalation
- Requiring reporting to an external entity
- Involving a serious or complex complaint, such as alleged research misconduct, possible media coverage or any legal issues

If the complaint is regarding an incident at a **public SESLHD site**, the complaint will be initially assessed by the SESLHD Research Development Manager and will include involvement and/or consultation with the HREC chair and the Director of Research.

If the complaint is regarding an incident at a **private site**, the complaint will be initially assessed by the SESLHD Research Development Manager and will include involvement and or consultation with the HREC chair. The Research Development Manager will contact the private site's Research Governance Office and request them to investigate the complaint, reporting outcomes back to the Research Development Manager.

If the complaint is regarding an incident at a **public health site outside of SESLHD**, the complaint will be referred to the Research Governance Office overseeing that site and should involve consultation with the SESLHD Research Development Manager and the SESLHD HREC Chair.

Refer to [APPENDIX B](#) for escalation pathways for complaints.

5.4 Acknowledging complaints

All complaints are to be acknowledged within **5 calendar days** of the complaint being received. This is regardless of whether the complaint complexity or management pathway has been established.

If the complaint is being escalated, the Manager taking over management will acknowledge the complaint. If the complaint is not to be escalated, the staff member who received the initial complaint is to acknowledge the complaint.

A receipt of acknowledgement should contain at a minimum:

- Contact details of the person or persons managing the complaint
- Summary of issues to be addressed
- Timelines for the management process

When the complainant is likely to receive further correspondence.

5.5 Assessing complaints

Research Directorate staff are to follow the below steps when undergoing the assessment of a complaint:

5.5.1 Identifying the issues

Identify each separate issue needing resolution. Where an issue is unclear, the complainant will be contacted for clarity.

It is also important to identify any cultural, linguistic or accessibility needs of the complainant or that may be required to resolve the complaint.

5.5.2 Identifying relevant parties

The complaint handler must recognise and notify the relevant managers that are to assist in the complaint management. Staff that the complaint relates to must be advised of the issues at this stage and given the opportunity to respond.

The identity of the complainant is to be protected and is to remain anonymous where appropriate. Disclosure of complainant details will only occur when necessary to pass onto persons involved in resolving the complaint, or where required by relevant NSW privacy laws or Organisational obligations.

5.5.3 Identifying if an investigation is needed

The staff member should consider alternatives to an investigation as not all complaints need to be investigated. Possible alternatives can include:

- Providing an apology
- Organising a meeting between the complainant and staff involved for reconciliation.
- Ensure staff training or education to avoid similar complaints in the future.

5.6 Investigating the complaint

Each complaint will be investigated differently depending on the situation and severity. Generally, if a complaint requires investigation, involvement of and consultation with the Chair of the approving HREC and the SESLHD Director of Research should be sought before any investigative action is taken.

The staff member managing the complaint is to take all reasonable steps necessary to collect and analyse sufficient information or evidence to determine an outcome and possible actions. The amount of evidence collected will be proportionate to the seriousness of the complaint.

The staff member managing the complaint should prepare an investigation plan outlining evidence to be collected and timeframes for the investigation process.

Investigation into a research complaint may include the following:

- Interviewing the complainant, witnesses or staff members involved
- Obtaining medical records, trial documents or other relevant information
- An audit or the trial site if necessary
- Liaising with other Research Directorates (where complaint relates to external sites)
- Requesting related persons (or their managers) to investigate the complaint and report back

- Meetings or mediation with parties involved

5.7 Finalising the complaint

The managing staff member should complete a report based on their recommendations after analysis of the investigation.

Outcomes are to be determined based on the investigation, with consultation with the managing staff member's line manager, or with the Director of Research.

If the complaint has been referred to the HREC Chair, the Chair is able to decide on appropriate actions. It is standard that the complaint is described to the investigators and the investigators are asked to respond and include their own suggestions for any remedial actions needed.

If the complaint is relating to the conduct of a trial, the HREC Chair is empowered to suspend that trial (or part of that trial) either permanently or temporarily. For example, suspending further recruitment until the complaint is resolved, or permanently closing the clinical trial if ethics issues exposed by the complaint are insurmountable.

Amendments to research projects arising from a complaint should be submitted by the researchers in accordance with standard processes. The complaint handler will follow up with researchers to ensure that such amendments are submitted in a reasonable and agreed to timeframe.

Complaints management process should not take longer than **35 calendar days**.

If delays result and the 35 calendar days will be exceeded, the complaints manager must contact the complainant to explain the delay.

If the complainant is not satisfied with the outcomes of the investigation, they may appeal the decision to the Director of Research to escalate and further investigate the issue. The Director may develop a panel consisting of 3 members (consisting of members of the Research Directorate, the Collaborative Research Committee, the HREC or outside of the Directorate if necessary) to assist in the investigation.

Upon resolution, the complaint handler should notify the Director or Research of the outcome **as soon as practicable**, but no later than **5 calendar days**.

5.8 Filing of complaint documents

Any findings, reports, correspondence, or other applicable materials must be filed within the Research Directorate's share drive.

The complainant's identity and contact details will be deleted upon resolution of the complaint unless there is sound reason to retain such information. Similarly, where required, their details will be redacted from any correspondence to protect their identity.

The complaint will be marked as closed in the Research Complaint Log.

Please refer to [APPENDIX A](#) for complaints management procedure flowchart.

6. DOCUMENTATION

Research Complaints Log.

7. AUDIT AND QUALITY REVIEW

The complaint log will be reviewed at least annually, more frequently at the discretion of the HREC Chair and Director of Research.

File reviews (of saved correspondence and materials) will be quality checked for completeness by the Research Ethics and Governance Manager (or delegate) upon the finalisation of a complaint.

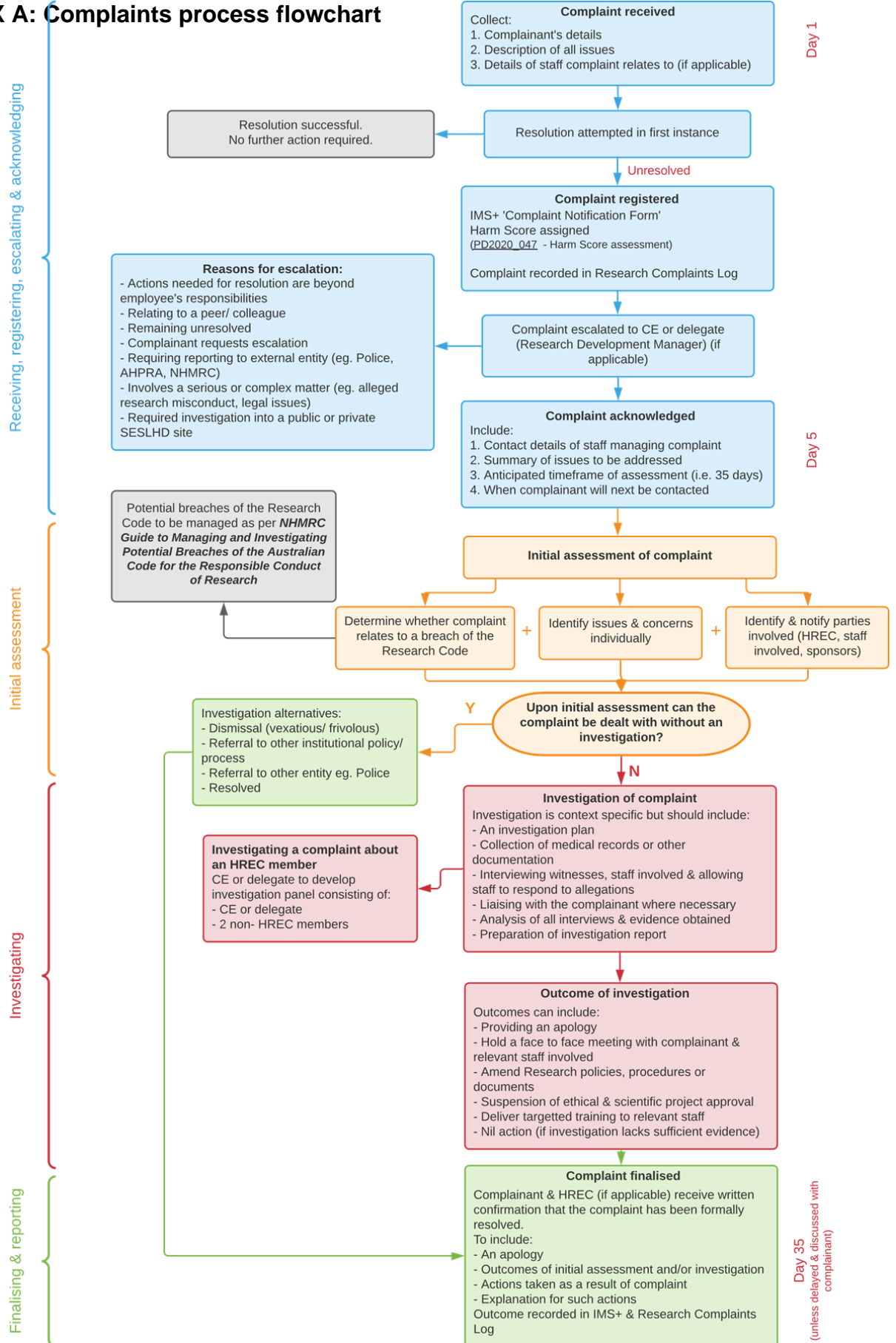
8. REFERENCES

- [GL2013_009 - Human Research Ethics Committees: Standard Operating Procedures for NSW Public Health Organisations](#)
- [GL2010_014 - Operations Manual: Human Research Ethics Committee Executive Officers](#)
- [GL2010_015 - Operations Manual: Research Governance Officers](#)
- [PD2020_013 - Complaints Management](#)
- [PD2018_032 - Managing Complaints and Concerns About Clinicians](#)
- [PD2020_047 - Incident Management](#)
- [SESLHDHB/026 - SESLHD Complaints Management Framework](#)
- NHMRC Australian Code for the Responsible Conduct of Research 2018
- NHMRC Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018)

9. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
March 2022	Draft	Draft version. Published on Draft for Comments page.
June 2022	Draft	Updated by Aideen Sheehan, Project Officer Approved by Professor Christopher White, Director Research Office, Executive Sponsor.
August 2022	1	Approved by Clinical and Quality Council.

APPENDIX A: Complaints process flowchart



SESLHD PROCEDURE

Research Ethics and Governance Complaints

SESLHDPR/733

APPENDIX B: Escalation pathway flowchart

