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| Department of Health | | 2011-03-07 - 2010_TAS_Gov_Logo |
| P007\_ETH: Managing Research Ethics Queries and Complaints | | |
| SDMS Id Number: | P24/87 | |
| Overarching Policy: | Research Governance Policy Framework (P20/299), Complaint and Feedback Management Policy (P22-328), Low Risk Research Procedure (P22/332) | |
| Effective From: | 2 October, 2023 | |
| Replaces Doc. No: | NA | |
| Custodian and Review Responsibility: | Research Governance Office | |
| Contact: | Dr Raisa Cassim Research Governance Coordinator | |
| Applies to: | All External and Internal Researchers/Investigators | |
| Review Date: | 2 October, 2026 | |
| Key Words: | Research, Ethics, Queries, Complaints | |
| Routine Disclosure: | Yes | |

**Approval**

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| Prepared by | Dr Barbara Kameniar | Research Ethics Officer | 6165 4004 | 22 August 2023 |
| Through | Dr Raisa Cassim | Research Governance Coordinator | NA | October 2023 |
| Through | SCMOU | Statewide Complaints Management Oversight Unit | NA | October 2023 |
| Through | RISc | Research Innovation Sub-committee | NA | 15 November 2023 |
| Cleared by | Dr Allison Turnock | Deputy Chief Medical Officer | 6166 1322 | 24 November 2023 |

**Revision History**

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| **Version** | **Approved By Name** | **Approved By Title** | **Amendment Notes** |
| 1.0 | LCPC |  | 13/12/2023 |
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### Introduction

* This document sets out the procedure for handling participant or prospective participant queries or complaints that may arise from the **conduct of research** being undertaken within the Tasmanian Department of Health (DoH), Tasmanian Health Service and Ambulance Tasmania (AT) that receive ethics approval from the Low Risk Human Research Ethics Committee (LRR Ethics Committee).
* It is intended to complement the **Statewide Complaints Management Framework** (2023) ([Statewide Complaints Management Framework | Tasmanian Department of Health Intranet](https://intranet.health.tas.gov.au/resources/statewide-complaints-management-framework)) **that applies to a broad spectrum of activities of DoH/** Tasmanian Health Service **/AT employees and adopts the relevant definitions, principles, policy statements and procedures described in that policy.**
* This procedure satisfies the requirements set out in the NHMRC *National Statement on Ethical Conduct in Human Research* (2023) and the *Australian Code for the Responsible Conduct of Research* (2018. Hereafter referred to as ‘The Code’) and is informed by the *Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research* (2018).
* This procedure applies to **queries** and **complaints** received from participants or prospective participants, or their representatives, such as family members, carers, or other substitute decision-makers, in **research projects** conducted within the DoH and having received ethics approval from the LRR Ethics Committee.
* A **complaint in research** is an expression of dissatisfaction or concern regarding the provision of a service, decision or action **by an Investigator/Researcher conducting research**, including Quality Improvement (QI) and/or audits projects reviewed by the LRR Ethics Committee which has personally affected an individual and which requires a response to address possible harm and/or promote resolution between the parties concerned.
* A **query in research** is usually a question that relates to the specific details of a project and frequently can be addressed at the point of inquiry with no further action required.
* **Complaints** may require immediate action or trigger other processes if a serious breach of The Code is identified. Likewise, a complaint may be dismissed if found to be made in bad faith or if vexatious.
* This procedure will be revised from time-to-time in response to amendments to the State and National documents that inform it.
* This procedure will be evaluated through the Policy Effectiveness Program.
* Performance indicators for this procedure are found below.

### Mandatory Requirements

* All investigators/researchers involved in research, and/or QI and Audit projects that quality for ethics review within the DoH/ Tasmanian Health Service /AT, all LRR Ethics Committee and subcommittee members, and all Research Ethics Office staff must follow and comply with the information set out in this procedure.
* Complaints may be received through any of the following ways:
  + [Reporting Concerns of Inappropriate Behaviour Form (health.tas.gov.au)](https://forms.health.tas.gov.au/221008315290040)
  + [General Enquiries Form | Tasmanian Department of Health](https://www.health.tas.gov.au/contact-us/general-enquiries)
  + Via email, letter, telephone, or in person.
* Regardless of how they are received, **ALL** complaints must be entered into the Safety Reporting and Learning System (SLRS) [Datix: Log in to Safety Reporting and Learning System (health.local)](https://srls.health.local/index.php?action=login).
* Anonymous complaints must be received and given due consideration in the same way as complaints from an identifiable person(s). See below for further advice about anonymous complaints.
* The Research Ethics Office, or other members of the DoH/ Tasmanian Health Service /AT, must assist a complainant to lodge a complaint if they express a desire to do so.

### Procedure

When receiving a query or complaint **regarding a research project**, or a QI, or audit project that has been reviewed by the LRR Ethics Committee, the Research Ethics Office must ensure that the query or complaint is acknowledged within **five (5) working days**. Unless the complaint is serious, complex or requires organisational oversight (see Tier 1 and Tier 2 of Attachment 1), complainants should receive a final response within **35 working days**. See below if these deadlines are unable to be met.

Any complaint entered into the SLRS [Datix: Log in to Safety Reporting and Learning System (health.local)](https://srls.health.local/index.php?action=login) must also be accompanied by an email addressed to the Research Ethics Office [research.ethics@health.tas.gov.au](mailto:research.ethics@health.tas.gov.au) indicating that a complaint has been entered into the system.

Upon receipt of the email, the Research Ethics Office must locate the complaint and follow the procedures outlined below.

* **Recording details of query or complaint**
  + Gather and record the following details from the complainant for DoH record:
    - The participant’s treating hospital/health service (if a patient), **project title, project number**, Coordinating Principal/Principal/Site Principal Investigator (or any project details that can be provided) of the research, QI, or audit project **reviewed by the LRR Ethics Committee** that the complainant wants to discuss.
    - The participant or prospective participant’s preferred **contact details** (if they wish to provide these details) to allow further correspondence regarding the query/complaint.
    - The **nature of the query/complaint** including all information they hold pertinent to the complaint.
    - **Anonymous** **complaints** must be received and given due consideration because they may identify potential breaches of The Code and require action. Persons making anonymous complaints will not be able to receive feedback on the outcome of their complaint and, should additional information be required, those investigating the complaint will not be able to speak to them. If speaking directly to a complainant who wishes to remain anonymous, ensure they are made aware of these factors. However, their wish to remain anonymous must be respected.
* **Pathway**
  + Complaints related to the **ethical conduct or scientific/scholarly design/implementation of research project** should be sent to the Research Ethics Office: [research.ethics@health.tas.gov.au](mailto:research.ethics@health.tas.gov.au)
  + Complaints related to the **governance of research** should be sent to the Research Governance Office: [research.governance@health.tas.gov.au](mailto:research.governance@health.tas.gov.au) .
* **Person(s) responsible**
  + Determine the appropriate person to follow up the query/complaint if it is related to the ethical conduct or scientific/scholarly design/implementation of the project from the table below:

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| **Nature of query/complaint** | **Person responsible for following up** |
| Logistic or management issue specific to individual participant’s management – **simple** **query**.  (eg do I fulfil eligibility requirements?) | Principal Investigator and/or Site Principal Investigator at participant’s treating hospital or service (if a patient) or participant’s place of work (if staff) and, if applicable, the Coordinating Principal Investigator/Principal Investigator of the research project (or their delegate(s)).  A simple query related to logistic or management issues should **not** be entered into the SRLS. |
| Overall scientific/scholarly design, structure, or implementation of a research project, but NOT related to the participant’s or prospective participant’s own individual care (if a patient) or work conditions (if staff).  (eg is it possible to speak to the interviewer one-on-one rather than participate in a focus group? Or “I don’t understand what I am being asked to do” - **query**) | In the first instance, Principal Investigator/Site Principal Investigator at participant’s treating hospital or service (if a patient) or participant’s place of work (if staff).  **The Research Director should be notified, when applicable**.  If unresolved, forward to the Research Ethics Office ([research.ethics@health.tas.gov.au](mailto:research.ethics@health.tas.gov.au)).  The Research Ethics Office will ensure the Research Unit and Research Governance Office is notified, as applicable.  If unresolved, and the query escalates to a complaint, a complaint can be made through the General Enquiries Form on the Department of Health website ([General Enquiries Form | Tasmanian Department of Health](https://www.health.tas.gov.au/contact-us/general-enquiries)) or directly to the Consumer Liaison Manager at the complainant’s treating hospital or service. Details regarding regional Consumer Liaison Managers or Complaints Officers are available at the following website: [How to provide feedback | Tasmanian Department of Health](https://www.health.tas.gov.au/patients/your-rights-and-responsibilities/how-provide-feedback) Complaints made through the website must be forwarded to the Research Ethics Office. |
| **Ethical elements** of the research project or its conduct or process involved in research participation.  (eg distressed by wording in consent forms; questioning if it is appropriate that their relative was consented to participate in research without their next-of-kin being present; distressed by the type of approach undertaken to seek their participation in research, etc. - **complaint**) | In the first instance, Principal Investigator or Site Principal Investigator at participant’s treating hospital or service (or their delegate). If resolved, note in the SRLS and record in annual report.  If unresolved, enter in the SRLS and forward to the Research Ethics Office ([research.ethics@health.tas.gov.au](mailto:research.ethics@health.tas.gov.au)). The Research Ethics Office will forward the complaint to the Chair of the reviewing Ethics Committee. This may be an ethics committee external to the DoH.  If still unresolved, Consumer Liaison Manager or Complaints Officer at participant’s treating hospital or service.  **Inform Deputy Chief Medical Officer**. |
| **Complaint** related to breach of data, misuse of health records, breach of anonymity/privacy | **Data Breach:**  *Refer to Data Breach Management on the Intranet* - [Data Breach Management | Department of Health Intranet (health.tas.gov.au)](https://doh.health.tas.gov.au/intranet/health_ict/strategy_information_management_and_governance_office_simgo/programs/records_management/data_breach_management) *and inform the Research Ethics Office and Research Governance office – see emails below..*  Misuse of Health Records or Breach of Anonymity/Privacy:  Inform the Research Ethics Office: [research.ethics@health.tas.gov.au](mailto:research.ethics@health.tas.gov.au) and the Research Governance Office: [research.goverance@health.tas.gov.au](mailto:research.goverance@health.tas.gov.au)  **Inform Deputy Chief Medical Officer**. |
| **Complaint** regarding quality of care or outcome | Consumer Liaison Manager or Complaints Officer, at participant’s treating hospital and/or service: [How to provide feedback | Tasmanian Department of Health](https://www.health.tas.gov.au/patients/your-rights-and-responsibilities/how-provide-feedback)  **Inform Deputy Chief Medical Officer.** |

* **Steps – to be undertaken by the Chair(s) of the LRR Ethics Committee in consultation with the Research Ethics Office**
  + **Review and evaluate facts and information**, and assess whether the complaint, if proven, is a **minor complaint/minor concern** (see Attachment 1, Tier 3 or Tier 4.) that can be resolved at the local level or if it potentially constitutes **a breach** of The Code and needs to be escalated (see Attachment 1, Tier 1 and Tier 2).
  + On how to **escalate complaints**, refer to the[Statewide Complaints Management Framework (health.tas.gov.au)](https://doh.health.tas.gov.au/intranet/ots/complaints/Statewide_Complaints_Management_Framework_-_Final.pdf).
  + Any **potential breaches to The Code** must also be referred to the Deputy Chief Medical Officer **through the Research Governance Office** for further investigation.
  + **Assess the severity of the risk** related to the complaint. This will assist in assessing the level of escalation (see Attachment 1).
  + Complaints considered ‘extreme’ or ‘high risk’ should be directed to the **Deputy Chief Medical Officer** for review and further advice.
  + Any Tier 1 complaints (e.g., an event resulting in significant harm, an alleged assault, or complaints from third party organisations) must be **escalated to the Statewide Complaints Management Oversight Unit (SCMOU)**.
  + Determine appropriate course of action.
  + All actions taken must be documented within the SLRS.
* **Management of complaint/query**
  + When entering a complaint/query, ensure the “Description” box provides enough detail that a person who is unfamiliar with the details is able to understand the issues and the level of urgency.
  + When selecting which area has responsibility for managing the feedback select as follows:
    - Location Level 1 – DoH
    - Location Level 2 – Clinical Quality, Regulation and Accreditation
    - Location Level 3 – Research Governance and Ethics
    - Location Level 4 – Research Ethics
    - Location Level 5 – Research Ethics
  + Ensure all details are submitted accurately and in sufficient detail.
  + Ensure the Research Ethics Office at the DoH is notified ([research.ethics@health.tas.gov.au](mailto:research.ethics@health.tas.gov.au)).
* **CARE Values, Open Disclosure, Trauma-informed approach, and Natural Justice**
  + Complaints/Queries should be approached in a way that reflects the DoH’s CARE values: compassion, accountability, respect, excellence.
  + The eight Open Disclosure principles outlined in the [Australian Open Disclosure Framework (safetyandquality.gov.au)](https://www.safetyandquality.gov.au/sites/default/files/migrated/Australian-Open-Disclosure-Framework-Feb-2014.pdf), [Course: Tasmanian Health Service Open Disclosure (dhhs.tas.gov.au)](https://theo.dhhs.tas.gov.au/course/view.php?id=1062), and the DoH Open Disclosure Protocol P19/000385 - [Strategic Document Management System (health.local)](https://cm.health.local/sdms/showdoc?recnum=P19/000385) should inform the approach to, and management of, all complaints:
    - Open and timely communication
    - Acknowledgement
    - Apology or expression of regret
    - Supporting, and meeting the needs and expectations of patients, their family, and carers
    - Supporting, and meeting the needs and expectations of those providing health care
    - Integrated clinical risk management and systems improvement
    - Good Governance
    - Confidentiality
  + Complaints should be investigated thoroughly and effectively in accordance with due process and natural justice.
  + The six-guiding trauma-informed principles of safety, trust, choice, collaboration, empowerment, and respect for diversity must be part of any approach to management of complaints. See [What is trauma-informed care? - Principles for effective support (nsw.gov.au)](https://www.health.nsw.gov.au/mentalhealth/psychosocial/principles/Pages/trauma-informed.aspx)
  + The principles/approaches outlined above, are to be applied to all complainants and researchers/investigators alike.
  + All actions taken to resolve the complaint must be recorded in the SRLS.
  + All responses from the complainant, including copies of emails or notes, must be recorded in the SRLS.
* **Resolution of the complaint/query**
  + If the query/complaint is unable to be resolved by the person responsible for follow up, refer the matter as outlined in the table above. When referring, provide full details of the action taken in attempting to resolve the complaint/query. **NB: these should have been captured in the SRLS** and readily available.
  + The Research Ethics Office must be kept informed.
  + The Research Ethics Office will, in consultation with the Chair(s) and Research Governance Office, seek advice on alternative approaches to resolving the complaint/query.
* **Timeliness – Performance Indicators**
  + Consistent with the Tasmanian Department of Health’s organisational complaints procedure and the Statewide Complaints Management Framework, queries/complaints must be dealt with promptly. The following times for addressing complaints/concerns are consistent with the DoH complaints management performance indicators and should be adhered to as closely as possible.

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| Acknowledge receipt of complaint/query | Within five (5) working days of receipt |
| Resolution | Within 35 working days of receipt. |
| Resolution not possible within 35 days | An email must be sent to the complainant with an apology for the delay and an update on the progress of their complaint/query.  See Appendix 1 for further details. |

* + Depending on the context of the complaint/query, more rapid resolution may be necessary.
* **When a complaint raises the possibility of research misconduct**
  + If a complainant alleges research misconduct, the Chair of the Ethics Committee must be advised, and any **research participant safety concerns must be addressed as an absolute priority**.
  + The **Deputy Chief Medical Officer** is nominated ‘Designated Person’ at the DoH to receive and follow up on serious breaches or allegations of research misconduct. Any allegation of research misconduct must be forwarded to the Deputy Chief Medical Officer for investigation.
  + Depending on the nature of the complaint/allegation/concern, the Chair or the Deputy Chief Medical Officer may escalate the complaint/allegation/concern to the SCMOU.
* **Confidentiality**
  + Confidentiality in the management of complaints should be maintained in accordance with the [Management of Personal Information Policy](https://cm.health.local/sdms/showdoc?recnum=P17/000101) and the *Personal Information Protection Act 2004.*
    - All information regarding complaints will be kept confidential amongst the staff concerned.
    - Refer to the DoH Policy (P21-39) for additional detail.
* **Complaints to support Quality Improvement**
  + Queries/complaints should be summarised for the LRR Ethics Committee’s review and used to ensure improvement to processes and prevention of occurrences.
  + In addition to all complaints relating to ethics review or implementation being thoroughly investigated, the resultant learnings are to be entered into SRLS and quality improvement activities implemented.
* **Reports to LRR Ethics Committee**
  + A report will be submitted to the Chair of the LRR Ethics Committee(s) and the Deputy Chief Medical Officer in June and December each year providing a summary of complaint/concern types, outcomes, and details of metrics related to performance against key performance indicators.

### Roles and Responsibilities/Delegations

* The **Statewide Complaints Management Oversight Unit (SCMOU)** manages all Tier 1 complaints (see Attachment 1) and provides guidance to the Deputy Chief Medical Officer and Chair(s) of the LRR Ethics Committee(s) on matters that are serious, complex, or require organisational oversight.
* As the ‘designated person’ at the DoH to receive and follow up breaches or allegations of research misconduct, the **Deputy Chief Medical Officer** provides oversight and guidance in the management of complaints including:
  + Determination of whether a complaint or a concern is minor, a breach of The Code, or constitutes an allegation of serious research misconduct when the LRR Ethics Committee Chairs are uncertain.
  + Guidance on the response and management of complaints and/or concerns that are more than minor.
* The **Chair(s) of the LRR Ethics Committee(s)** are responsible for:
  + Determining whether a complaint is minor, a breach of The Code, or constitutes an allegation of serious research misconduct.
  + Seeking guidance from the Deputy Chief Medical Officer if determination in unclear.
  + Determining the most appropriate course of action in managing minor complaints.
  + Escalating processes in line with current DoH policies and procedures in the case of breaches of The Code or serious research misconduct.
  + Providing direction to the Research Ethics Office on all communications associated with any complaint including ensuring all persons relevant to the complaint are notified.
  + Ensure all communications related to any complaint and managed by the Research Ethics Office are reviewed prior to sending.
* **Chief Principal Investigators/Principal Investigators/Site Principal Investigators** will:
  + Respond to participant or potential participants queries.
  + Address minor complaints immediately, record the complaint in the SRLS, indicating how the complaint was assessed, investigated, managed/resolved, and what improvements were implemented (if applicable).
  + Include a note in the annual report.
  + Regardless of the level of complaint or severity of risk, support all participants or potential participants to make a complaint directly to the Research Ethics Office through the DoH Feedback form: [How to provide feedback | Tasmanian Department of Health](https://www.health.tas.gov.au/patients/your-rights-and-responsibilities/how-provide-feedback) if they wish to do so.
  + Inform the Research Ethics Office as soon as practicable about any complaint that cannot be addressed immediately.
* The **Research Ethics Office** will:
  + Receive complaints through the SRLS, email, letters, or phone calls.
  + Record details in the SRLS if the complaint was not entered through the system.
  + Advise the Chair(s) of complaints according to which LRR Ethics Committee reviewed the ethics application that is the subject of the complaint.
  + Provide advice to the Chair(s) on national and state legislation, the Statewide Complaints Management Framework and/or any other organisational policies and procedures relevant to the complaint.
  + Provide secretariat support during meetings and as required.
  + Ensure all communications related to the management of any complaint are reviewed by the Chair(s) prior to sending.

### Key Definitions

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| **CARE Values** | A unifying set of core values that guide the work done across the Department of Health to ensure CARE for the health and wellbeing of all in Tasmania. The values are: (1) Compassion, (2) Accountability, (3) Respect, and (4) Excellence. |
| **Complaint** | In accordance with AS/NZS 10002:2014, within the DoH/Tasmanian Health Service, the definition of a complaint is ‘expression of dissatisfaction made to or about an organisation, related to its products, services, staff or the handling of a complaint, where a response or resolution is explicitly or implicitly expected or legally required’. |
| **Complaint in the context of research** | A complaint in research is an expression of dissatisfaction regarding the provision of a service, decision or action by an Investigator/Researcher conducting research, including Quality Improvement (QI) and/or audit projects that were reviewed by the LRR Ethics Committee, which has personally affected an individual and which requires a response to address possible harm and/or promote resolution between the parties concerned. |
| **Complainant** | In this procedure, the term complainant refers to a person or persons who have made a complaint about the conduct of any research, QI, or audit project undertaken within the DoH. A complainant may be a research participant or their representative such as a family member, carer, or other substitute decision-maker. |
| **Concern** | Concerns may arise from any event, circumstance, act, or omission that may have occurred while a consumer is accessing, visiting, or receiving health services, or where a duty of care is owed. This may include something that does not ‘feel right’, to cause an uneasy or anxious feeling, may be a ‘gut feeling’ that something might be ‘off’, or something which may cause a consumer to worry about their experience or that of another person. |
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| **Natural Justice** | The minimum requirement in acting fairly, without bias and upholding the rights of all parties, which includes provision of a right of reply. |
| **Query** | A query is a question seeking additional information or advice related to the research project in which a person in considering participating, or in which they are already a participant, related to the conduct of any research, QI, or audit project undertaken in the DoH/ Tasmanian Health Service /AT. It may also include questions about specific elements of research, QI, or audit projects that might impact a participant’s engagement with such projects. |
| **Safety Reporting and Learning System (SRLS)** | The electronic information management system used by staff across the Tasmanian Health Service and DoH to report, manage and learn from safety concerns, consumer complaints and feedback - [Datix: Log in to Safety Reporting and Learning System (health.local)](https://srls.health.local/index.php?action=login) |
| **Substitute decision maker** | Action 2.5 of the Australian Commission on Safety and Quality in Health Care describe a ‘substitute decision maker as a nominated carer, a health attorney, or person nominated under an enduring power of attorney or guardianship arrangement’. |
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| **Vexatious complaints** | In line with regulatory and legal principles and precedent, a vexatious complaint is defined not by outcome or subject experience, but by a specific combination of basis and intent. That is, a vexatious complaint is a groundless (frivolous) complaint made with an adverse primary intent to cause distress, detriment, or harassment to the subject[[1]](#footnote-1). |

### Related Documents/Legislation

**INTERNAL DOCUMENTS**

* [DoH Complaint and Feedback Management Statewide Policy](https://cm.health.local/sdms/showdoc?recnum=P22/328)
* [Datix: Log in to Safety Reporting and Learning System (health.local)](https://srls.health.local/index.php?action=login).
* [General Enquiries Form | Tasmanian Department of Health](https://www.health.tas.gov.au/contact-us/general-enquiries)
* [Low Risk Research Procedure](https://cm.health.local/sdms/showdoc?recnum=P22/332)
* [Management of Personal Information Statewide Policy](https://cm.health.local/pandp/showdoc.aspx?recnum=P17/000101)
* [Reporting Concerns of Inappropriate Behaviour Form (health.tas.gov.au)](https://forms.health.tas.gov.au/221008315290040)
* [Research Governance Policy Framework](https://cm.health.local/sdms/showdoc?recnum=P20/299)

* [Statewide Complaints Management Framework (health.tas.gov.au)](https://doh.health.tas.gov.au/intranet/ots/complaints/Statewide_Complaints_Management_Framework_-_Final.pdf)
* Terms of Reference: Low Risk Ethics Committee

**EXTERNAL DOCUMENTS**

* [*Australian Open Disclosure Framework: Better communication, a better way to care* (2013)](https://www.safetyandquality.gov.au/sites/default/files/migrated/Australian-Open-Disclosure-Framework-Feb-2014.pdf)
* [Open Disclosure Statewide Protocol](https://cm.health.local/sdms/showdoc?recnum=P19/000385)
* [NHMRC *National Statement on Ethical Conduct in Human Research* (2023, and updates)](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)
* [NHMRC *Australian Code for the Responsible Conduct of Research* (2018 and updates)](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018)
* [*Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018)*](https://www.nhmrc.gov.au/sites/default/files/documents/reports/guide-managing-investigating-potential-breaches.pdf)
* NHMRC [*Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods (2018)*](https://www.australianclinicaltrials.gov.au/sites/default/files/content/For%20researchers/Guidance%20on%20the%20Reporting%20of%20Serious%20Breaches%20of%20GCP.pdf)
* NHMRC *Guidelines approved under Section 95A of the* Privacy Act 1988 (2014): [guidelines-s95a-privacy-act-pr2 (1).pdf](file:///C:\Users\bkameniar\Downloads\guidelines-s95a-privacy-act-pr2%20(1).pdf)
* NHMRC *Flowchart determining whether the s95A guidelines apply:* [Flowchart-s95a-Guidelines (1).pdf](file:///C:\Users\bkameniar\Downloads\Flowchart-s95a-Guidelines%20(1).pdf)
* *Personal Information Protection Act* 2004 [PERSONAL INFORMATION PROTECTION ACT 2004 (austlii.edu.au)](http://www6.austlii.edu.au/cgi-bin/viewdb/au/legis/tas/consol_act/pipa2004361/)
* *THS Open Disclosure* [Course: THS Open Disclosure (dhhs.tas.gov.au)](https://theo.dhhs.tas.gov.au/course/view.php?id=1062)

### Attachments

1. Table 1: Summarised DoH Complaint Management Model
2. Overview of the Recommended approach for managing and investigating a potential breach of the Code (*Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research* 2018, pg. 3).

Summarised DoH Complaint Management Model with **Research Examples**

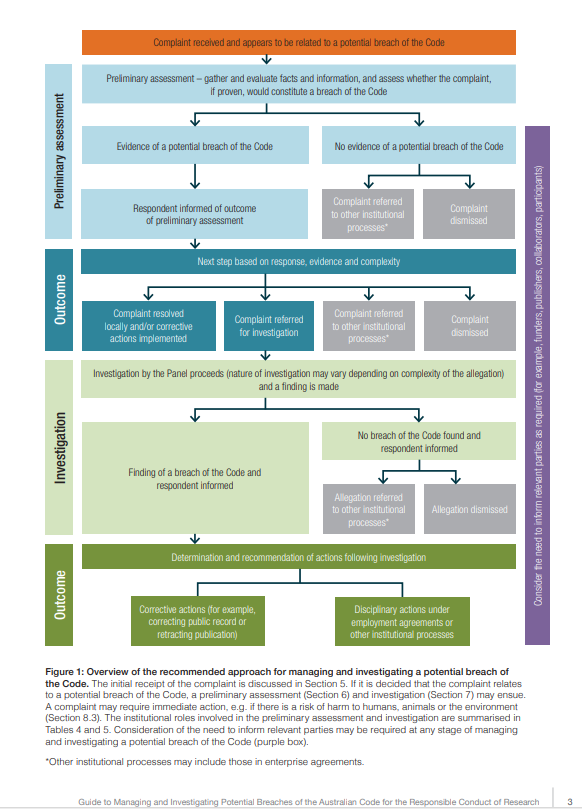
**Attachment 1**

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| Complaint Tier | Possible Complaint Triggers1 | Complaint Resolution2 4 |
| **Tier 1 – SCMOU complaints management** | * A research related event resulting in significant consumer or staff harm or death * Alleged assault * Complaints referred from third party organisations (e.g., Integrity Commission) | * SCMOU leads coordination/management of the complaint * SCMOU assesses and triages all child safeguarding concerns or complaints * Aim to resolve within six (6) months3 |
| **Tier 2 – Local complaints resolution** | * A research related event which caused harm e.g., it may have required hospitalisation or referrals * Staff behaviour considerations * Withdrawal of trial treatment * Closure of trial prior to publicised end date * Research Data Breach * Serious Privacy or Confidentiality Breaches * Breach of The Code/serious research misconduct * Any major ethics concern | * Tier 2 responses may take longer given the complexity and/or severity of the complaint * Resolved by local complaint management units within ninety (90) working days * For **research ethics and research governance matters**, the local complaint management unit is led by the **Deputy Chief Medical Officer (DCMO)** |
| **Tier 3 – Local complaints resolution** | * Communication issues   + Wording of questionnaires   + Consent procedure   + Information provided in PICF * Any aspect of the research that may cause discomfort or burden | * Resolved by local complaint management units within thirty-five (35) working days * For **research ethics and research governance matters** complaints can be managed through the **Research Ethics and Governance Unit** in consultation with the **Chair**(s) of the LRR Ethics Committee (when appropriate) and the **DCMO** |
| **Tier 4 – Point of service resolution** | * Inconvenience * Minor burdens * General concerns | * Resolved at point of service by frontline staff/**researchers** (i.e., at time of complaint receipt), unless escalated. |

Notes:

1. Staff training will support the consistent application of Complaint Response Tiers
2. Further details regarding response timeframes are included in the Statewide Complaint Management Policy and throughout P007 Managing Queries and Complaints
3. Timeframe dependent on specific circumstances (e.g., conduct matter referred to HR and court proceedings may involve significant timelines beyond the anticipated six month resolution)
4. Complaint resolution may require consultation/with/input from relevant Supporting Functions (see Diagram 1 in [Statewide Complaints Management Framework (health.tas.gov.au)](https://doh.health.tas.gov.au/intranet/ots/complaints/Statewide_Complaints_Management_Framework_-_Final.pdf))

**Attachment 2**



1. [Morris, J et al. (2017). Reducing, identifying, and managing vexatious complaints. Centre for Health Policy.](C://Users/acruwys/Downloads/AHPRA---Report---Reducing--identifying-and-managing-vexatious-complaints---Centre-for-Health-Policy.PDF) [↑](#footnote-ref-1)