

HREC Standard Operating Procedure

5.8 Research Misconduct

Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to fulfilling Section 5 of the National Statement on Ethical Conduct in Human Research (2023) by ensuring awareness of the expected standards for the conduct of research, and to define the principals underlying the identification, investigation and management of research misconduct.

SVHM recognises that researchers have an obligation to act in the best interests of the institution, the community, funding bodies, sponsors, and other staff/researchers to maintain an environment that encourages intellectual honesty, integrity and scholarly and scientific rigour.

Researchers must ensure that they are familiar with, and act in accordance with the standards articulated within the National Statement on Ethical Conduct in Human Research (2023), the Code of Practice 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), including the principals underlying the identification, investigation and management of research misconduct.

Definitions

Research misconduct is defined as the deviation from standards and provisions of the Australian Code for the Responsible Conduct of Research 2018, and 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.

Research misconduct does not include differences in interpretation of or judgments about data.

Procedures

Upon receipt of a complaint, investigative processes will be conducted by the Research Governance Unit in collaboration with the Director of Research, and/or other senior members of the SVHM Executive (as appropriate). Other members of staff may be sought as required. Similarly, external/independent persons may also be sought.

The complaint must be reviewed by the aforementioned team, to determine the nature of the complaint, and whether a resolution can be attained at Departmental level, or whether a full investigation is required (either internal or external).

Internal Investigation

The Director of Research, the Deputy Director, a representative from Human Resources, the Head of Department (or delegate) in which the complaint concerns, and any other applicable members (as determined by the Director, Deputy Director, Human Resources Rep and Head of Department) will convene a formal meeting to consider the complaint. The procedure for investigation will be tailored to the nature of the complaint, and will be formally minuted during this meeting. Additional persons may be sought as the investigation proceeds.

Those investigating the complaint must consider the nature of the complainant and any associated evidence to decide whether the allegations can be dismissed before it is formally investigated, or whether a more detailed investigation is required. If there is to be a detailed investigation of the allegation, the staff member(s) concerned should be informed, initially in person and then in writing and given an opportunity to provide a written response. When establishing a group to consider the complaint, the Director of Research is required to ensure that the person who is the subject of the inquiry is granted a fair hearing under the legal principle of procedural fairness (also known as “natural justice”).

The group conducting the Internal Investigation will:

- Notify both the complainant and the person/s involved in the allegations, verbally in the first instance, and followed by a formal account in writing.
- If applicable, notify granting bodies such as the NHMRC, which have supported the research and involved researchers of the initiation of an investigation, within 10 days of the initial complaint or instigation of the internal investigation. This is a requirement of NHMRC Grant Agreements.
- Request as much data as necessary to adequately investigate the complaint. The process for securing such data must be supervised by a senior staff member who is independent of the allegation.
- Ensure a formal report is produced once the initial nature of the complaint has been reviewed. Both the complainant and those involved in the allegations will have the opportunity to comment on the report to ensure accuracy.
- Ensure that natural justice is accorded by providing all parties with every fair and reasonable opportunity and support to defend their reputations and work.
- Re-consider the complaint in light of responses received in relation to the initial written report
- Communicate findings and recommendations of appropriate actions to the researcher(s) involved and provide the researcher(s) the opportunity to respond.
- Make recommendations to the CEO and Director of Human Resources accordingly
- Communicate findings of the internal investigation to the granting body or other agencies notified at the outset of the internal investigation.
- Take any other necessary steps to ensure that the issue was completely investigated.
- After an initial investigation, make recommendations for further action, including whether or not an independent investigation is required.

Action on Completion of Internal Investigation - No case exists

If no case is found to exist, all concerned parties will be informed that there will be no further action taken.

If the complainant is a staff member and the complaint is considered improper Human Resources will be informed for further follow up. If the complainant is not a staff member then appropriate action should be taken which may include bringing the matter to the attention of the complainant's employer. If the charges were reasonably brought but found to be incorrect, the complainant should be informed of the outcome and given an opportunity to respond. It is important to ensure that the complainant is satisfied that the complaint has been properly considered and investigated and that the finding is valid. If the complainant is satisfied with the process and result all action on the case should cease.

The complaint and the outcome must be recorded on the RGU complaints register.

Action on Completion of Internal Investigation – A case is proven to exist

If the internal investigation committee finds that research misconduct has occurred, Human Resources will be informed, for further follow up (including potential disciplinary actions such as counseling, educational measures, suspension or termination of employment). The extent of the disciplinary actions will take into account the available sanctions under any industrial instrument and/or employment contract, the nature of information uncovered during the internal investigation and the degree to which final conclusions and actions are dependent on an independent investigation. The staff member(s) under investigation will be notified in writing of the conclusions and recommendations of the internal investigation and will have the opportunity to comment on the conclusions.

If a conclusion cannot be drawn, or if additional expertise is required, an independent investigation may be recommended to the Chief Executive Officer. This may occur at any stage during review.

Following consultation, the CEO may then authorize an independent investigation if the internal investigation indicates that significant deviation from the Code may have taken place, or if it is in the best interests of the institution.

Independent Investigation

The independent investigation group will be nominated by the CEO of St Vincent's Hospital (Melbourne).

The independent investigation committee will:

- Review the findings of the internal investigation.
- Consider if the scope of the investigation was adequate or if it should be broadened. For example, if the internal investigation makes findings that cast any doubt on the validity of one or more research publications produced by a staff member, it may be necessary for the independent investigation committee to investigate the person's past research.
- Draw conclusions about the extent of the problem.
- Make recommendations about possible actions against the involved individuals.

In addition, the findings of the independent investigation should be considered by the CEO in the context of any other allegations of a non-research nature, such as whether the research unit requires specific action, either of a supportive, counseling or remedial nature.

In order to assure the scientific community that the investigative process has been rigorous and appropriate, the independent investigation group shall observe the following conditions:

- The group must have a minimum membership of three (3) people.



- At least one (1) member must have knowledge and research experience in the relevant field of research, and be without direct affiliation to St Vincent's Hospital, and without a conflict of interest.
- One (1) member should be a lawyer and without direct affiliation to St Vincent's Hospital, and without a conflict of interest.
- The person facing the allegations is entitled to legal representation.
- The group is not bound by the rules of evidence but its procedures must be consistent with the principles of natural justice and due process.
- Any findings must relate only to transgressions of the provisions of the Code.
- The group may seek legal advice from Corporate Counsel at St Vincent's Hospital
- The group will have the powers to seek evidence as required
- The group must formally report the conclusion of the investigation to the CEO, who will take appropriate actions in line with St Vincent's Hospital Policy.
- The CEO (in conjunction in full or part, with the Director of Research) must inform all relevant parties to the findings of the committee, as well as actions taken by St Vincent's Hospital. Relevant parties may include (but are not limited to affected staff, research collaborators, including those at other institutions, all funders of the research, sponsors and supporters of the research, journal editors and professional registration bodies.

Protection of Interested Parties

Allegations of research misconduct must be handled with care. An association with misconduct has the potential to damage the reputations of those including the accused, the complainant, others associated with the work, the host laboratory and the institution.

All investigations will be conducted in a manner which protects the rights of those involved, whilst rigorously investigating the issue at hand. Those who make allegations must also be treated fairly and, if appropriate, according to the legislative provisions for "whistleblowers" before, during and after the investigation/s of the allegation/s.

Individuals involved in an issue of research misconduct, either by being directly under investigation or indirectly through association with the work, should be personally advised in the first instance by the Director of Research, followed by a written account of what to expect from the pending investigation process. It is highly desirable that individual/s under investigation have an independent advisor who has a good understanding of the issues involved and can provide support during the investigation/s.

However, where a disclosure is assessed as not being a protected disclosure (in accordance with Part 2 of the Whistleblowers Protection Act 2001) and/or as being malicious or vexatious, the matter will either be dealt with in accordance with the SVHM Complaints Handling Policy (with appropriate support, advice and guidance). All such disclosures will be dealt with in a fair, timely and transparent manner.

Confidentiality must also be maintained at all times, as far as is reasonably possible.


Associated Procedures/Instructions

5.14 – Complaints management

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)

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5.8 Research Misconduct

Final Audit Report

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