



PROCEDURE: COMPLAINTS

NHMRC National Statement

The RAH HREC is committed to fulfilling Section 5.6 of The National Statement on Ethical Conduct in Human Research [Ref 1] and ensuring that research is conducted according to the Australian Code for the Responsible Conduct of Research by ensuring all complaints are handled appropriately. All complaints must be handled promptly with due sensitivity and in recognition of principles of natural justice.

Scope

This policy outlines how the RAH HREC will efficiently, effectively and ethically deal with complaints made to the HREC irrespective of source of the complaint or the nature of the complaint.

Complaints received by HREC may concern:

- The HREC processes.
- The HREC decision.
- The nature or content of a HREC approved research study.
- The conduct of a researcher undertaking an HREC approved study.
- Other issues unrelated to the HREC.

Complaints received by HREC may be initiated by:

- Researchers.
- Participants in research or their relatives or other concerned parties.
- Researchers involved in the approved or other studies.
- Institutions, organisations or other individuals with a direct or indirect interest in the approved research.

Receiving complaints

Research participants, their families and other concerned parties have the right to communicate their concerns about any aspect of the services provided and are encouraged to do so. To facilitate this process the HREC will ensure that all Information Sheets for research participants contain the contact information for the HREC Executive Officer.

The HREC may receive the complaint in any form: in person, by telephone, by email or in writing. If the complaint is not received in writing the complainant will be encouraged to document the complaint in a letter or email to the Chairman of the HREC but, although desirable, this is not essential for the complaint to be investigated. Notes are taken by the person receiving the complaint (usually the Executive Officer) and a confidential memorandum is written to the Chairman of HREC. The complainant may be identified or anonymous.

If the complainant is identified a letter acknowledging the receipt of the complaint will be sent to the complainant irrespective of the nature of the complaint. This letter will be sent within 5 working days of receiving the complaint.

Details of the complaint are recorded in the HREC Complaints Database by the Executive Officer in the first instance and then updated by the Chairman or other delegated person in due course.

Investigating complaints

The Chairman of the HREC will make the initial determination about the seriousness of the complaint and the action required to deal with the complaint. This course of action may not finally be determined until other persons have been consulted. In all cases the course of

action will be consistent with the Royal Adelaide Hospital Research Code of Conduct [Ref 3], the SA Health Research Ethics Operational Policy Directive [Ref 4], the SA Health Research Governance Policy Directive [Ref 5] and the Australian Code for the Responsible Conduct of Research [Ref 2].

Complaints about the HREC

Complaints about HREC processes or decisions are appropriately managed by a third party. The SA Health Research Governance Policy Directive [Ref 5] includes a hierarchical approach to dealing with complaints about the Site Specific Assessment process. This has been adapted to deal with complaints about the ethics process as follows:

1. The Principal Investigator (PI) (also taken to include the Coordinating Principal Investigator (CPI) in the case of a process under the National Mutual Acceptance model) may appeal the final decision of the HREC, where a decision has been made to not approve an application, if he/she considers the decision has been made improperly or without due consideration of all relevant information.
2. The PI may also lodge a formal complaint about the HREC review process, where the PI considers the process has been unsatisfactory.
3. In both instances, the PI should outline their concerns in writing to the institutional Research Governance Officer (RGO, or equivalent).
4. The institutional Research Governance Officer will consult with the Chairman of the HREC on the substance of the complaint.
5. The PI may resubmit or amend their ethics application to meet any requirements outlined by the RGO. This application will be assessed according to the usual processes of the HREC and within a reasonable timeframe.
6. Where a complaint has been lodged, the RGO will notify the responsible Chief Executive Officer (CEO, or delegate) of any such complaints in a timely manner.
7. Following consideration and further investigation by the RGO, the Chairman of HREC and CEO/delegate (as required), the PI will be notified in writing of the outcome of the investigation including any further action to be taken to resolve the complaint.
8. If the PI remains dissatisfied with the outcomes of any further action by the RGO, the Chairman of HREC and/or CEO/delegate, this should be communicated in writing to the CEO/delegate. In these instances, the following process will be followed:
 - a) The CEO will determine if further investigation is necessary. If so, the CEO will establish a panel to consider the matter. The panel will include the following members:
 - i. The CEO/delegate;
 - ii. Two nominees of the CEO/delegate, including at least one independent nominee with expertise in research governance and ethics matters, including the requirements of the SA Health Research Governance Policy, the Australian Code for the Responsible Conduct of Research, and other applicable policy documents and guidelines.
 - b) The panel will allow the RGO, the Chairman of HREC, the local PI and the coordinating PI the opportunity to make submissions.
 - c) The CEO/delegate will notify the RGO, the Chairman of HREC, the PI and the CPI of the outcomes of the investigation.
9. Any recommendation or decision of the panel will be final.
10. The complaint and the outcome will be communicated to the Research Ethics Committee.
11. The complaint and the outcome will be recorded in the HREC Complaints database.

Complaints about the Research or Research Conduct

Complaints about the nature or conduct of a research study may take many forms and many different forms of resolution or response may be appropriate. In deciding upon the course of action the Chairman of HREC must take into account many factors including:

- Whether the alleged actions or processes have impacted or have the potential to impact on the health, safety or rights of research participants.
- Whether the researcher has deviated from the agreed research protocol.
- Whether the deviation has been deliberate or accidental.
- The confidentiality requested by the complainant and confidentiality due to researchers through the process of natural justice.

With due regard to the issues of the complaint the Chairman may decide that the complaint can be investigated by a number of methods including:

- An internal investigation conducted by the Chairman of HREC.
- An internal investigation conducted by the Chairman of HREC and designated committee members.
- An internal investigation conducted by a third party such as the Research Governance Officer and/or members of the RAH research community.
- An external investigation conducted by a third party such as another SA Health HREC or SA Health researchers external to the RAH.
- An external investigation conducted by a third party from another state.

In each case the Chairman will ensure that the method of investigation is consistent with the processes described in the Australian Code for the Responsible Conduct of Research [Ref 2].

Following Investigation of the complaint the HREC Chairman or other appropriate person, depending on the type of investigation, will communicate the result of the investigation to the complainant. This communication may be verbal or written depending upon the seriousness of the complaint and the method of investigation.

Where the content of the complaint is substantiated and the outcome may create risk for the institution, the HREC Chairman or other appropriate person, will communicate the outcome of the investigation to the Research Governance Officer and the Executive Director of Medical Services. This communication will be in writing.

Where the content of the complaint is substantiated the HREC Chairman will report on the complaint to the HREC Committee.

Complaint Resolution

Before any action is taken against a researcher as a result of a complaint the HREC Chairman will consult with the Research Governance Officer and the Executive Director of Medical Services. Consensus will be reached about the action required.

Actions to be taken in response to a substantiated complaint are varied but must be commensurate with the seriousness of the complaint and must take into account the wilfulness or otherwise of the actions which triggered the complaint. Actions may range from counselling through to termination of the research study and suspension of research privileges. Any discussion, counselling or sanction conducted as part of complaint resolution will be documented in a Memorandum and/or in the HREC Complaints Database.

In each case the Chairman will ensure that the resulting sanctions are consistent with the processes suggested in the Australian Code for the Responsible Conduct of Research [Ref 2]. Breaches of the Code will in general require less serious sanctions than research misconduct.

Where the researcher or research project is affiliated with a University or other institution the HREC Chairman, Research Governance Officer or the Executive Director of Medical Services will communicate the outcome of the investigation and the sanctions applied to the appropriate person, for example, the Deputy Vice Chancellor of Research. This communication will be in writing.

Appeals

Where a complainant considers that the process of dealing with the complaint has not been appropriate or that the outcome is unsatisfactory they may seek to review the outcome of the complaint through similar processes to those above:

1. If the complainant is dissatisfied with the outcomes of the complaint investigation this should be communicated in writing to the CEO/delegate. In these instances, the following process will be followed:
 - a) The CEO will determine if further investigation is necessary. If so, the CEO will establish a panel to consider the matter. The panel will include the following members:
 - iii. The CEO/delegate;
 - iv. Two nominees of the CEO/delegate, including at least one independent nominee with expertise in research governance and ethics matters, including the requirements of the SA Health Research Governance Policy, the Australian Code for the Responsible Conduct of Research, and other applicable policy documents and guidelines.
 - b) The panel will allow the complainant, the Chairman of HREC, the RGO and the person who is the subject of the complaint the opportunity to make submissions.
 - c) The CEO/delegate will notify the complainant, the Chairman of HREC, the RGO and the person who is the subject of the complaint of the outcomes of the review.
2. Any recommendation or decision of the panel will be final.
3. The complaint and the outcome will be communicated to the Research Ethics Committee.
4. The complaint and the outcome will be recorded in the HREC Complaints database.

References

- [1] National Statement on Ethical Conduct in Human Research. NHMRC 2007 as updated from time to time.
- [2] Australian Code for the Responsible Conduct of Research jointly issued by the National Health and Medical Research Council, the Australian Research Council and Universities Australia. (2007) Available at <http://www.nhmrc.gov.au/guidelines/publications/r39>.
- [3] Royal Adelaide Hospital Research Code of Conduct. Instruction Number OWI-02238. Available on the RAH website at eCentrRAHI.
- [4] SA Health Research Ethics Operational Policy Directive. Available at: <http://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/About+us/Health+and+medical+research/Research+ethics/Research+ethics>
- [5] SA Health Research Governance Policy Directive. Available at: <http://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/About+us/Health+and+medical+research/Research+ethics/Research+governance>

Revision history

Version 1.0 A Thornton 1 August 2014

Appendix 1 Definitions

Research is defined as that which:

“includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction.”¹

Complaint is defined as:

A verbal or written expression of dissatisfaction which requires a response.²

Research Misconduct is defined as

“Research misconduct 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.

Misconduct includes avoidable failure to follow an approved research protocol, 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 honest differences in judgement in the management of the research project, and may not include honest errors that are minor or unintentional.”³

The term misconduct is used for serious or deliberate deviations from the Code for the Responsible Conduct of Research.

Breach of the Code is defined as

The term breach is used for less serious deviations from this Code that are appropriately remedied within the institution.

¹ From Research Assessment Exercise for Universities in the United Kingdom as cited in Australian Code for the Responsible Conduct of Research jointly issued by the National Health and Medical Research Council, the Australian Research Council and Universities Australia. (2007)

² Adapted from the MacMillan Dictionary.

³ Australian Code for the Responsible Conduct of Research jointly issued by the National Health and Medical Research Council, the Australian Research Council and Universities Australia. (2007) Available at <http://www.nhmrc.gov.au/guidelines/publications/r39>