

HREC Standard Operating Procedure

5.16 Reporting and accountability

Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to fulfilling Section 5.8 of the National Statement on Ethical Conduct in Human Research (2023) by ensuring appropriate operational accountability for the process of ethical review.

Definitions

Accountability is defined as the measures by which researchers, review bodies and institutions can demonstrate that their responsibilities have been, or are being fulfilled. Typical accountability measures involve reporting from one level of the hierarchy to a higher (or more general) level.

Procedures

To ensure operational accountability, all members of the St Vincent's Hospital Human Research Ethics Committee must be familiar with, and apply the principles of The National Statement on Ethical Conduct in Human Research (2023), and in particular, Section 5.8.

Responsibility for the ethical design, review and conduct of human research is exercised at different levels from the detail of research conduct to the more general oversight of review and funding.

Accordingly, responsibility is exercised at the different levels by:

- researchers (and where relevant their supervisors);
- HRECs and other ethical review bodies;
- institutions whose employees, resources or facilities are involved;
- funding organisations;
- agencies and governments

The line of accountability for these responsibilities runs:

- from researchers to review bodies and institutions;
- from review bodies and institutions to funders and other agencies;
- from agencies to government; and
- from government to the Australian public.

Typically, this accountability involves reporting from one level to the next.

The responsibilities of the HREC are to provide a transparent and efficient ethical review process.

Accountability

The SVHM HREC is accountable by:

- Ensuring qualified and experienced staff are appointed to the HREC
- Ensuring all members are formally inducted to ensure roles and responsibilities are understood, including those of the National Statement which govern the process of review.
- Ensuring the name of all members is published publically, by inclusion in the SVHM Annual Research Report.
- Ensuring key stake holders have access to a generic letter which confirms that the composition of the HREC complies with the requirements in Section 5.1.30 of the National Statement. This document will be made publically available via the St Vincent's Hospital Research Governance Unit website.
- Ensuring the Terms of Reference of the HREC is publically available via the SVHM Research Governance Unit website.
- Ensuring all HREC meetings are comprehensively minuted, including reference to the National Statement. Minutes must be ratified by the Chair and HREC both after the distribution of correspondence to Investigators, and formally at the next meeting. Minutes will be made available to the Chief Executive Officer of SVHM, the NHMRC or other such bodies as required.
- Ensuring Investigators have the opportunity to attend HREC meetings to provide background information and/or clarification relating to any submission upon which they are a listed Investigator. Attendance at meetings is restricted to the discussion regarding the introduction of the study on which they are listed; all investigators who attend in this capacity must not be present during subsequent discussion, or the HREC decision making process.
- Providing written notification to Investigators regarding the decisions of the HREC, and ensuring that Investigators have the opportunity to respond to any queries raised.
- Ensuring formal written notification is issued to the Principal Investigator in response to any decisions and/or submissions
- Ensuring electronic files containing all relevant documentation is kept securely within the Research Governance Unit for each study. As per the Freedom of Information Act (ref) Investigators can access this information by providing a reasonable justification. Access must be supervised, and no documentation can be removed by the Investigator at the time of file review. Review must also be documented within the file including the person's name, position, date of access, purpose of access, and confirmed authorisation by the Deputy Director of Research.

Reporting

As per the Organisational Chart, the SVHM HREC reports directly to the Director of Research, who reports to the Chief Executive Officer through the Chief Medical Officer.

Operationally, oversight is achieved through the ex-officio appointment of the Deputy Director of Research to the HREC. Furthermore, a copy of the ratified minutes is reported to the Deputy Director of Research on a monthly basis.


The ratified minutes of HREC meetings are also reported to the Chief Medical Officer and Chief Executive Officer on a monthly basis.

The SVHM HREC also report operational activities to the NHMRC on an annual basis, for confirmation of compliance.

Reference Documents

- The National Statement on Ethical Conduct in Human Research (2023)
- Australian Code for the Responsible Conduct of Research (2018)

Authorised by: Dr Megan Robertson, Director of Research



Megan ROBERTSON (Jul 1, 2024 09:56 GMT+10)

Author: Alexandra Braun, HREC Executive Officer

Date Issued: 2011

Date Revised: 2024

Next Review: 2027






5.16 Reporting and accountability

Final Audit Report

2024-06-30

| | |
|-----------------|--|
| Created: | 2024-06-30 |
| By: | Sue Ngeow (sue.ngeow@svha.org.au) |
| Status: | Signed |
| Transaction ID: | CBJCHBCAABAAHHL97nzDimDwGgM1Npa8LXSoYCTQgpQ_ |

"5.16 Reporting and accountability" History

-  Document created by Sue Ngeow (sue.ngeow@svha.org.au)
2024-06-30 - 11:55:41 PM GMT
-  Document emailed to Megan ROBERTSON (megan.robertson@svha.org.au) for signature
2024-06-30 - 11:56:22 PM GMT
-  Email viewed by Megan ROBERTSON (megan.robertson@svha.org.au)
2024-06-30 - 11:56:43 PM GMT
-  Document e-signed by Megan ROBERTSON (megan.robertson@svha.org.au)
Signature Date: 2024-06-30 - 11:56:50 PM GMT - Time Source: server
-  Agreement completed.
2024-06-30 - 11:56:50 PM GMT