



**RESEARCH GOVERNANCE UNIT**  
St. Vincent's Hospital (Melbourne)  
Caritas Christi Hospice  
St. George's Health Service  
Prague House  
Cambridge House  
DePaul House

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## Reporting and Accountability

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### **Statement of Intent and Outcomes**

The St Vincent's Hospital Human Research Ethics Committee is committed to fulfilling Section 5 of The National Statement on Ethical Conduct in Human Research (2007 – Updated 2018) 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.

### **Procedure**

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 (2007 – Updated 2018), and in particular, Section 5.7.

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);
- HREC's 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 St Vincent's Hospital Human Research Ethics Committee 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 St Vincent's Hospital (Melbourne) 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 5.1.3 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 St Vincent's Hospital 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 St Vincent's Hospital, 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 St Vincent's Hospital Human Research Ethics Committee 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 St Vincent's Hospital Human Research Ethics Committee also report operational activities to the NHMRC and National Institute of Health (NIH) on an annual basis, for confirmation of compliance.

**Associated Procedures/Instructions**

Nil

**Reference Documents**

- The National Statement on Ethical Conduct in Research Involving Humans in accordance with the NHMRC Act, 2007 – Updated 2018 (Cth)
- Australian Code for the Responsible Conduct of Research (2018)

Authorized by:



Dr Megan Robertson  
Director of Research

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