



**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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## DOCUMENTATION AND RECORD MANAGEMENT

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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 a high standard of documentation and record management.

### **Definitions**

Nil

### **Procedure**

All activities of the HREC, including the process and outcome of ethical review, must be documented and recorded appropriately.

The HREC may approve, request amendment of, or reject a research proposal on ethical grounds. Upon submission, it is the responsibility of the Investigator to submit all of the application documents including an Application Form (HREA), Participant Information and Consent Form, Clinical Protocol and / or Investigators Brochure (as applicable) and other material that depicts safety or that is used in recruiting potential research participants, including advertisements, letters of invitation etc. All documents must be approved by the Ethics Committee before use.

The Research Governance Unit must maintain a record of all research proposals received and reviewed, including at least the:

- Name/s of the institution/s to which the research approval is provided;
- Project identification number/s (including protocol number and HREC reference)
  - Name/s of principal researcher/s;
  - Title of the project;
  - Correspondence between the review body and the researcher about the review
  - Approval or rejection of any amendments to the project;
  - Proposed date of commencement and completion of the project;
  - Formal advice of approval status, including the period of approval;
  - Terms and conditions, if any, which apply to the approval of any project;
  - Duration of the approval;
  - Name of any other review body whose opinion was considered (including legal/privacy);
  - Mechanisms to be used to monitor the conduct of the research; and
  - Relevance, if any, of the Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information.

This will be performed using an electronic database.

Access to all files is restricted to staff of the Research Governance Unit, with supervised access granted only at the discretion of the Deputy Director of Research.

***Distribution to HREC members***

The agenda and application documents will be distributed to all members at least one week preceding each meeting, allowing a minimum reading time of 7 days. Where possible, distribution will occur electronically to reduce the requirement for paper copies.

At each HREC meeting, detailed minutes are taken by the HREC Secretary. These minutes are finalised as soon as possible after the meeting, and emailed to HREC members for ratification after the distribution of correspondence to researchers.

Once the minutes are ratified, a copy will be formally reported to the Chief Executive Officer of St Vincent's Hospital, and the Safety and Quality Unit.

A detailed record of decisions regarding approval, amendment or rejection of each protocol must be included within the written minutes, accompanied by a justification for each decision, linked to the relevant section/s of the National Statement.

The Principal Investigator (or delegated contact person) will be notified in writing of decisions within 2 days of the meeting.

When a decision is delayed the reasons will be recorded in the minutes and the investigator will be notified in writing of the reasons for the delay.

All responses to HREC queries from the investigator must be in writing (responses may take the form of clarifications, agreement to protocol modifications, or appeals against protocol modifications).

The HREC will provide a directive as to whether the investigator's response should be considered at the following meeting or whether authority will be delegated to the Chair/Spokesperson to consider the response. If the response is administrative or relates to governance issues only, delegation to review the response may also be given to the HREC Secretary. These decisions will be formally recorded in the Minutes.

If authority is delegated to the Chair/Spokesperson, approval may be issued upon receipt of an appropriate response. Alternatively it may be decided that the response should be considered at the next HREC meeting.

If authority is delegated and approval is issued out of session, such decisions must be tabled and ratified at the next available HREC meeting.

When a decision is made to terminate or suspend a previously approved protocol, the reasons will be recorded in the minutes and the investigator will be notified in writing of the reasons for the decision and actions that can be taken to discuss the situation further.

The Research Governance Unit will retain all study related documents on behalf of the HREC for a minimum 15 years (commencing the completion of the study), with all minutes and associated documents retained indefinitely.

All electronic documents are password protected, with access limited to staff of the Research Governance Unit and Information Technology (when requesting assistance only). No other member of staff will have access to electronic files without authorisation.

In the event an external opinion is sought, an expert opinion agreement and formal covering letter must be included reiterating the requirement to maintain confidentiality. A request for the return of all confidential documents must also be included.

Certain documentation will also be communicated via the website, to ensure documents are publicly available. This includes all application documentation, the composition of the committee, Terms of Reference, Standard Operating Procedures and minimum reporting requirements (including safety reporting).

**Associated Procedures/Instructions**

Procedure 5.10 – Expert Opinion

Procedure 5.16 – Reporting and Accountability

**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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<b>Author:</b> Dr Tam Nguyen, Deputy Director of Research	
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