



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

MAKING AND COMMUNICATING DECISIONS

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 that an efficient and transparent process is followed when making and communicating decisions.

Definitions

Nil

Procedure

Decisions about whether a research proposal meets the requirements of the National Statement must be informed by an exchange of opinions from each of those who constitute the minimum membership of the Committee. The minimum membership must be met in order to ensure a quorum is met. All exchanges of opinions should take place at a Committee meeting with all those members present.

When there is less than full attendance, the Chair must be satisfied, before a decision is reached, that the minimum membership have received all documentation and have had the opportunity to comment. All comments must be received in writing, and subsequently tabled at the meeting. This procedure complies with section 5.2.32 of The National Statement.

The Investigator and/or research team may also be invited to the meeting to promote efficient communication, and allow a comprehensive discussion of concerns. Investigators may also opt to request attendance during the discussion of their protocol to address any concerns; however, investigators must not be present during the decision making process.

Expert opinion may also be sought at any time, including from other HREC's who have reviewed the application in question.

The HREC will endeavour to reach decisions by general agreement; however this does not require unanimity. If the HREC encounters divided opinion, the Chair will call for a vote by the raising of hands both for, and against the decision in question. That with the greatest number of votes will be accepted as the formal decision. This will be minuted accordingly.

At each HREC meeting, detailed minutes must be recorded by an allocated administrative officer who is not a member of the committee.

The minutes must include a detailed account of the discussions that have occurred and any resulting decisions specific to the approval status (including unconditional approval, conditional approval, resubmission or rejection, and any delegation of authority to review

the response). Reference will also be made to the National Statement to justify the decision making process.

The Principal Investigator will be notified in writing of the outcome of ethical review. This must occur as soon as possible. Documentation must include the study title, the HREC reference number, the approval status, and a clear summary of required amendments (as required).

When a decision is delayed:

- The reasons will be recorded in the minutes and the investigator will be notified in writing of the reasons / queries
- Responses from the investigator/s must be in writing (responses may take the form of clarifications, agreement to protocol modifications, appeal against protocol modifications)

If the HREC is unable to review all applications listed on the agenda, a subsequent meeting may occur. Otherwise, excess applications may be deferred to the next monthly meeting.

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 review of amendments to approved protocols will also be delegated to the Chair/Spokesperson for out of session review. All decisions for the approval of amendments out of session must be tabled and ratified at the next available HREC meeting.

Annual reviews and other documents requiring approval will also be tabled and ratified at the next available HREC meeting.

The time taken to review and / or approve these documents is at the discretion of the Deputy Director, Chair/Spokesperson, but must remain timely.

For Sponsored research, all communication relating to ethical matters must be communicated through the site Study Coordinator. Direct contact between the Sponsor and the HREC or delegate must be of an administrative nature only.

Associated Procedures/Instructions

Procedure 5.7 – Documentation and Record Management

Procedure 5.10 – Expert Opinion

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

Author: Dr Tam Nguyen, Deputy Director of Research	
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