



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

Timelines for Ethical Review

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 an efficient and timely review of research.

Definitions

Nil

Procedure

The St Vincent's Hospital Human Research Ethics Committee (HREC) which reviews applications involving the use of drugs and/or devices, and applications which do not involve drugs or devices. There is also a Low Risk Research Sub-committee.

HREC

HREC will meet on the second Wednesday of each calendar month, excepting for January when only one meeting is held. If this day falls on a public holiday, the meeting will be rescheduled to the following day. All members are expected to attend at least one meeting per month, however if an apology is necessary all members are given the opportunity to provide written comments for discussion at the meeting.

All research applications submitted on or before the deadline for each month will be included on the agenda and reviewed at the meeting. The agenda and associated documents, including the Application Form, Participant Information and Consent Form, Clinical Trial Protocol, Investigators Brochure and any other study related documentation will be circulated to members electronically.

Distribution of the agenda will occur within 5 days of the agenda close date. This will ensure members are given a minimum of 7 days to consider the documentation.

If the agenda contains more protocols than time allows, a second meeting will be scheduled within 7 working days to ensure no undue delays are incurred.

Decisions will be recorded in the minutes which will be completed and circulated to the Chair and HREC for approval within 5 working days of the meeting. The investigator will also be notified in writing of the HREC decision within 2 working days of the meeting.

All additional documentation that is submitted for review and approval outside of session, including protocol amendments, annual review forms and other documentation must be actioned within 5 days of receipt.

Key performance indicators will be recorded monthly to assess the time periods from receipt to approval, which includes the handling time of both the Research Governance Unit and the Research Team. These KPI's will be reported to the HREC on a monthly basis.

Low Risk Research Subcommittee

The Low Risk Research Subcommittee facilitates the review of research using on-line mechanisms. There are no agenda close dates for the review of Low Risk Research applications. As a result these applications can be submitted for review as required.

On the day of receipt (or as close as possible), the application is posted on Basecamp, which is an electronic bulletin board. Two (professional spokesperson and a lay spokesperson) members of the Low Risk Research Subcommittee will be requested to perform a review of the application, within 7-10 working days of posting. A reminder will be sent after 7 days to ensure the target is met.

The investigator will be notified in writing of the Subcommittees decision within 5 working days at the completion of review.

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

Author: Dr Tam Nguyen, Deputy Director	
Date Issued: 2011	Next Review: 2023
Date Revised: 2020	Filepath: