

St Vincent's Hospital (Melbourne) Human Research Ethics Committee

TERMS OF REFERENCE

1. PURPOSE

To ensure that human research undertaken at St Vincent's Hospital and affiliated institutions conforms to the ethical standards demanded by the community at large, St Vincent's Hospital (Melbourne) and the [Code of Ethical Standards for Catholic Health and Aged Care Services \(2001\)](#).

To ensure that such research conforms with the statutory requirements of State and Federal legislation, and the guidelines of the National Health and Medical Research Council (NHMRC) such as the [National Statement on Ethical Conduct in Human Research 2007 \(Updated 2018\)](#), the [Australian Code for the Responsible Conduct of Research \(2018\)](#) and the [Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders \(2018\)](#).

2. TERMS OF REFERENCE

HREC shall:

- 2.1 Consider the ethical implications of all proposed clinical research and clinical trials in which drugs and/or devices are the major issue under examination and determine their acceptability on ethical grounds.
- 2.2 Have the authority to delegate low risk research proposals to a subcommittee (Low Risk Research Subcommittee) in order to expedite research that poses low or negligible risk to the participant. The HREC will remain responsible for activities and recommendations of any subcommittee.
- 2.3 Consider the scientific validity of research projects.
- 2.4 Monitor research projects to ensure they continue to conform to their conditions of approval.
- 2.5 Acknowledge and take into account any prior peer review which has judged that a project has research merit, when considering the project.
- 2.6 Ensure that unnecessary duplication of ethical review is minimized, including formal participation in the Department of Health Single Ethical Review Process (SERP) and single ethical review process/es initiated by the NHMRC.
- 2.7 Ensure that records are maintained of all proposed research projects including an identification number, a clinical trial registration number compliant with the International Committee of Medical Journal Editors requirements, principal investigator(s), date of ethical approval /non-approval, review date(s) and a copy of the project in its final approved form.

- 2.8 Maintain communication with the Australian Health Ethics Committee (AHEC) of the NHMRC and the Therapeutic Goods Administration (TGA) and provide access on request to information from HREC's records.
- 2.9 Maintain a professional secretariat.
- 2.10 Consider research proposals from non-affiliate researchers and institutions.
- 2.11 All members shall be required to declare any actual, apparent or potential conflict of interest. Once a conflict of interest is declared the member will not be involved in the decision making process.

3. KEY PERFORMANCE INDICATORS

Compliance with the *National Statement on Ethical Conduct in Research Involving Humans 2007* and subsequent updates (referred to as the *National Statement*); other NHMRC guidelines; Therapeutic Goods Administration (TGA) guidelines; Victorian Managed Insurance Authority guidelines; and State and National Privacy and other guidelines.

A maximum 'clock on' time of 60 days applies to all applications submitted for ethical review.

4. HREC APPOINTMENTS

The Chief Executive Officer of St Vincent's Hospital (Melbourne) will confirm the appointment of members to HREC.

5. MEMBERSHIP

- 5.1 HREC will maintain a minimum membership of at least eight members (of gender balance) as per the *National Statement*, including:

- A chair
- A lay man
- A lay woman
- A member of a community who performs a pastoral care role
- At least one lawyer, where possible one who is not engaged to advise the institution
- At least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.
- At least one person, with knowledge of, and current experience in, the professional care, counseling or treatment of people

In addition, St. Vincent's Hospital (Melbourne) has chosen to appoint a Deputy Chair from above list of members, to act in the capacity of Chair during periods of absence.

- 5.2 The Director of Research and Deputy Director of Research may also attend as Ex-Officio members. These members may contribute to discussions, but must remain non-voting at all times.
- 5.3 HREC may co-opt non-members to gather expertise as necessary, at any time during the process of review.
- 5.4 HREC may invite any person to attend a meeting, to either provide expertise/advice, or act as an observer.

6. TERM OF APPOINTMENT

All members of HREC shall be appointed for a period of twelve months. HREC members remain eligible for reappointment for subsequent term/s as applicable. No remuneration is provided as membership is voluntary.

7. QUORUM

To satisfactorily reach quorum, the minimum membership must reflect that prescribed in the National Statement. However, where there is less than full attendance of the minimum membership at a meeting, the Chair should be satisfied before a decision is reached that the views of those absent who belong to the minimum membership have been received and considered, as per section 5.2.30 of the National Statement.

8. FREQUENCY OF MEETINGS

HREC will meet twice per month, at least ten times per calendar year. A listing of all proposed meetings will be publicly displayed at all times.

9. ADMINISTRATIVE SUPPORT

Administrative support shall be provided by the Research Governance Unit, which shall be responsible for notifying each meeting; providing an agenda at least five working days before the meeting; recording the minutes; circulating the minutes within two weeks of the meeting; and providing written correspondence to applicants.

The Research Governance Unit will be responsible for the administrative management of administrative Standard Operating Procedures, Institutional Policies and Procedures, and any other administrative function required by the HREC and/or Institution.

10. REPORTING LINE

HREC shall report to the St Vincent's Health Australia Board of Management through the Chief Executive Officer of St Vincent's Hospital (Melbourne), through the compilation of an annual report.

11. REVISION DATE

The Terms of Reference will be reviewed every 12 months by the Deputy Director of Research and the Director of Research.

12. CONFIDENTIALITY

All matters and activities of HREC are to be treated as confidential at all times.

13. INDEMNIFICATION

Members of HREC, be they employees or volunteers, are covered under both the Public Liability and Professional Indemnity Policy of St Vincent's Hospital (Melbourne), in respect of liabilities that may arise in the course of the conduct of HREC members' duties.



Approved by:

Dr Megan Robertson
Director of Research
St Vincent's Hospital (Melbourne)