

Role and Purpose

It is a requirement for St Vincent's Health Australia (St Vincent's) to establish procedures for the ethical and governance review of human research. All research projects being conducted at, or recruiting participants from St. Vincent's facilities in Queensland, require ethics approval by the St. Vincent's Health and Aged Care Human Research Ethics Committee (SVHAC HREC).

The SVHAC HREC is registered with the National Health and Medical Research Council (NHMRC) (NHMRC Registration Number: EC00324). It is constituted in accordance with the *National Statement on Ethical Conduct in Human Research 2007* (National Statement).

SVHAC HREC members are appointed by the Divisional CEO, St Vincent's Aged and Shared Services, as a delegate of the SVHA Board. Membership is reviewed annually to ensure alignment with the National Statement's Composition of HRECs (Chapter 5.1).

Scope of Responsibilities

The SVHAC HREC is responsible for:

- reviewing and approving research submissions, ensuring compliance with the National Statement, Code of Ethical Standards for Catholic Health and Aged Care Services in Australia, St Vincent's processes and procedures and National and State legislative requirements;
- delegating the review of applications to experts when necessary;
- communicating decisions and findings to the Principal Investigator (PI) in a timely way via the Research, Ethics and Governance Officer;
- providing advice on ethical issues related to research;
- overseeing the monitoring of approved research; and
- Assess Quality Assurance activities for ethical review exemption (as requested).

Composition and Appointment

The SVHAC HREC Chairperson and Deputy Chairperson

The Chairperson is appointed by the Chief Executive Officer of St Vincent's Private Hospital Northside or delegate. In their absence, the Chairperson may appoint an Acting Chairperson prior to the HREC meeting.

SVHAC HREC Members

Prospective members of the HREC may be recruited by expressions of interest, direct approach, nomination or advertisement, and appointed in accordance with National Statement (Section 5.1.34 - 5.1.36).

The minimum membership of an HREC is eight according to the National Statement (Section 5.1.29). As far as possible:

- a) there should be equal numbers of men and women: and
- b) at least one third (1/3) of the members should be from outside the institution for which the HREC is reviewing research.



The membership of the SVHAC HREC is constituted according to the National Statement (Section 5.1.30). The composition of the minimum membership is:

- a) a Chairperson with suitable experience;
- b) at least two (2) lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
- c) at least one (1) person with knowledge of, and current experience in, the professional care, counselling or treatment of people; e.g. a nurse or allied health professional;
- d) at least one (1) person who performs a pastoral care role in a community, e.g. an Aboriginal Elder or a Minister of Religion;
- e) at least one (1) lawyer, where possible, who is not engaged to advise the institution; and
- f) at least two (2) people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

Where possible, one or more of the members should be experienced in reflecting on and analysing ethical decision-making.

Period of Appointment

Membership appointments to the SVHAC HREC will be considered for review every three years (National Statement 5.1.34). A member may be re-appointed for further three year periods.

Conditions of Appointment

Members are appointed as individuals for their knowledge, qualities, expertise and relevant experience, not as representatives of any organisation, group or opinion. This is a voluntary appointment.

- Before appointment, members acknowledge in writing their acceptance of the Terms of Reference of the SVHAC HREC and any requirements for confidentiality and conflict of interest required.
- Members will be provided a letter of appointment including the date of appointment, length of tenure, SVHAC HREC meeting attendance responsibilities and general responsibilities as a SVHAC HREC member.
- Members should inform the Chairperson if leave of absence is required. If unable to attend three or more consecutive meetings, members should consider their availability to remain on the Committee.

Parking and refreshments will be provided to facilitate members' attendance at meetings. Members agree to attend continuing education and training in research ethics (National Statement 5.2.3 (c)).

Induction, Mentoring and Training

New members are provided induction material and are given the opportunity to attend conferences and workshops, relevant to their roles and responsibility.

Confidentiality and Conflict of Interest

Members will be required to sign an agreement and declaration at the time of appointment and thereafter, every three (3) years, or earlier should their situation change, undertaking:

- any conflicts of interest which exist, or may arise during tenure on the SVHAC HREC, will be declared; and

- all matters of which they become aware of during the tenure will be kept confidential.
- Committee members use of SVHAC electronic devices (IPads) to review meeting documentation will adhere to SVHAC Information Technology Security Requirements. Committee Members have a responsibility to ensure that usernames and passwords are confidential, IPads are secured with a passcode, and IPads are kept in a safe and secure location (as would reasonably be expected).

SVHAC HREC support

The Research, Ethics and Governance Officer, SVHAC HREC is an employee of St Vincent's Health Australia and with assistance from the Chair:

- prepares the agenda for the SVHAC HREC meetings;
- attends the meeting and records the minutes;
- communicates with researchers on behalf of the SVHAC HREC;
- monitors all research submissions.
- reports all clinical trials to the St Vincent's insurer following ethics approval being granted;
- completes annual reports on behalf of the SVHAC HREC;
- maintains a local register of all research applications submitted to the SVHAC HREC, which includes details such as date of approval, monitoring and reporting requirements and protocol amendments;
- liaises with other HRECs in St Vincent's Health Australia and Catholic Health Australia research facilities and research personnel as required; and
- processes invoices from researchers.

The Chair, also an employee of St Vincent's Health Australia, coordinates governance requirements including obtaining site approval.

Mechanisms of Reporting

The SVHAC HREC submits an annual report to the:

- Facility CEO (St Vincent's Private Hospital Northside, St Vincent's Private Hospital Brisbane, St Vincent's Private Hospital Toowoomba; and
- NHMRC (Annual Compliance Report).

Indemnity

St Vincent's Health Australia indemnifies the decisions made and advice given by the SVHAC HREC.

Applications

The SVHAC HREC is committed to the timely review of research submissions. To assist this process, researchers must ensure documents are submitted electronically to the Research, Ethics and Governance Officer.

A list of documents required by the SVHAC HREC can be found on the St Vincent's Health Australia Queensland facilities' websites.

Submissions are emailed to svhac.hrec@svha.org.au

Levels of ethical review

Once the submission has been received, it will be reviewed and categorised as either low/negligible risk or high risk research. Low/negligible risk research may qualify for expedited review outside of the scheduled HREC meeting times. Expedited review may also be possible for studies that have gained ethics approval from another HREC. Amendments may also be reviewed and approved by expedited review.

Any research that is determined to be more than low risk will require full ethics review. The SVHAC HREC conducts full ethics review at its bi-monthly meeting. The review of Quality Assurance projects will be undertaken as requested as a function of the SVHAC HREC.

Full SVHAC HREC Meetings

Meetings will be held bi-monthly.

- A timetable for meetings will be provided to members.
- Notice of meeting will be given at least two (2) weeks before the HREC meeting.
- An electronic copy of the agenda will be forwarded to members approximately two (2) weeks before the meeting.
- The SVHAC HREC Chairperson may reschedule a meeting to consider urgent matters.

Quorum

Decisions by the Committee about whether the research project meets the requirements of the National Statement must be informed by the exchange of opinions from each of the members of the SVHAC HREC. Questions or issues raised should be linked by members to the relevant section of the National Statement.

Where there is less than full attendance of the minimum membership at a meeting, the Chairperson must be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have received all papers and have had an opportunity to contribute their views and that these have been recorded and considered. Members who are unable to attend a meeting will be encouraged to contribute and advise their opinion via electronic submission to the Chairperson or Coordinator prior to the meeting.

Meetings will normally be held at St Vincent's Private Hospital Northside. Teleconference linkage to individual members unable to be present in person will be acceptable. The Principal Investigator or a representative for the investigator may be invited to attend the relevant meeting to discuss an application but would be required to leave before a decision is made on the outcome.

- Draft minutes will be forwarded to the Chairperson within five working days of the meeting.
- To assist with the preparation of minutes, the proceedings of HREC meetings may be recorded.
- SVHAC HREC recommendations will be forwarded by email to researchers within 10 days of the SVHAC HREC meeting or notification should be sent advising of a delay.
- Advice to applicants regarding the ethical consideration and approval of applications will include details of reporting requirements and monitoring processes.

Monitoring (National Statement Chapter 5.5)



On ethics approval being granted, the PI must agree to:

- keep adequate records regarding the research and provide access to the SVHAC HREC when requested;
- provide collated progress reports at intervals specified by the SVHAC HREC and at completion of any research;
- notify the SVHAC HREC of significant events, side effects or complications occurring at any time during the research including the course of action taken;
- notify the SVHAC HREC of any complaints received from participants, staff, observers or the community;
- provide advice on any proposed changes to be made to the protocol and awaiting SVHAC HREC approval of these prior to implementation;
- notify the SVHAC HREC if the research is to be discontinued before the expected date of completion; and
- provide a copy of published results and presentations at conferences etc. to the SVHAC HREC.

With respect to information provided during monitoring, the SVHAC HREC may:

- request an interview with the researchers if required;
- request access to research data and records if required; and
- request the opinion of external experts if considered necessary.

Handling Complaints (National Statement Chapter 5.6)

Participant Information Sheets must include the SVHAC HREC contact details to enable complaints to be made.

- All Research Ethics complaints should be forwarded to the SVHAC HREC Chairperson via the Research, Ethics and Governance Officer.
- The Chairperson will consider the complaint and determine a course of action.
- The complaint and the proposed action will be reported to the next meeting of the SVHAC HREC.
- All complaints will be acknowledged by the SVHAC HREC office as per the St Vincent's Health and Aged Care Complaints Management Policy and Procedures.
- Complaints about any decisions of the HREC that cannot be resolved by the Chair and Research Ethics Manager will be referred to the Facility CEOs (St Vincent's Private Hospital Northside, St Vincent's Private Hospital Brisbane, St Vincent's Private Hospital Toowoomba) for further consideration.

Reference Material

National Health and Medical Research Council National Statement on Ethical Conduct in Human Research 2007 (updated July 2017)