

SYDNEY ADVENTIST HOSPITAL GROUP HUMAN RESEARCH ETHICS COMMITTEE TERMS OF REFERENCE

COMMITTEE

Sydney Adventist Hospital Group Human Research Ethics Committee

APPOINTED BY

Sydney Adventist Hospital Ltd Board of Directors

RESPONSIBLE TO:

- Sydney Adventist Hospital Ltd Board of Directors
- Australian Health Ethics Committee (AHEC) in accordance with the requirements of the National Health and Medical Research Council (NHMRC)
- NSW Privacy Commissioner in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW)

PURPOSE

Sydney Adventist Hospital Group Human Research Ethics Committee is an Institutional Ethics Committee (IEC) established to:

- Protect the mental and physical welfare, rights, dignity and safety of participants in human research.
- Review research in accordance with the guidelines outlined in the *National Statement on Ethical Conduct in Human Research* in accordance with the National Health and Medical Research Council Act.
- Facilitate ethical research through efficient and effective review processes.
- Define the principles and procedures to govern research involving humans and promote ethical standards of human research.
- Facilitate the Group's research governance requirements.
- Monitor approved research during conduct of the study.

FREQUENCY AND CONDUCT OF MEETINGS

- Meetings are held bi-monthly, or at the call of the Research Governance & Ethics Officer, with an agenda and research submissions circulated to all members at least 7 days prior to the meeting.
- Meeting dates and submission closing dates are published on the Ethics Committee's website.
- Where there is less than full attendance at a meeting, the Chairperson must be satisfied that absent members have had an opportunity to contribute their views.
- Research submissions are fully considered in an independent, competent and timely manner and committee members must be satisfied that the welfare and rights of participants are protected.
- Members shall declare any conflict of interest that could influence a determination.
- Minutes of each meeting are circulated to all members, confirmed at the next meeting, signed by the Chairperson and filed.

MEMBERSHIP

Members:

Membership meets the minimum NHMRC requirements:

- Chairperson
- 1 Male lay person
- 1 Female lay person
- 2 Members with research experience
- 1 Member with current experience in the professional care, counselling or treatment of people
- 1 Minister of religion
- 1 Lawyer

Additional members may be appointed, upon the recommendation of the

Committee, to ensure the membership is equipped to address the relevant considerations arising from the categories of research conducted within the Group.

Additional member categories have been incorporated to meet the specific requirements of the committee as follows:

- An Accredited Medical Officer with knowledge of physically invasive procedures and/or medical interventions
- Vice-chairperson
- Research Governance & Ethics Officer
- Recording secretary
- Honorary Consultant

Appointment of Members:

- Members are appointed by the Board of Directors for a period of three years, renewable. A member may be invited to renew their tenure upon the recommendation of a sub-committee of the Ethics Committee comprising the Chairperson, Vice-Chairperson and Research Governance & Ethics Officer.
- The Research Governance & Ethics Officer of the Committee will liaise with the Secretary of the Board of Directors regarding the appointment and re-appointment of Committee members.
- Committee members act independently and not in a representative capacity.
- Formal notice of appointment will be provided which includes the date of appointment, length of tenure, meeting attendance responsibilities, general responsibilities as a Committee member and an assurance that insurance cover will be provided to members in respect of liabilities which may arise while carrying out their duties.
- Members are required to sign a statement undertaking that all matters associated with the Committee will be kept confidential during tenure and post-tenure; that any conflict of interest which exists or may arise during their tenure must be declared; and that they are not subject to any criminal conviction or disciplinary action which may prejudice their standing as a Committee member.
- A member may resign from the Committee upon giving written notice to the Chairperson.
- The Board of Directors may terminate the appointment of any Committee member if the Board is of the opinion that it is necessary for the proper and effective functioning of the Committee; if the person is not a fit and proper person to serve on the Committee; or if the person has failed to carry out their duties as a Committee member.
- Members who fail to attend three consecutive meetings of the Committee without cause may be asked to resign from the Committee.
- Upon appointment to the Committee, members are informed of their responsibilities and duties and provided ongoing training and support.
- Members must agree to their name and membership category being made available to the public including being published on the Ethics Committee's website.
- Members are not offered remuneration but will be reimbursed legitimate expenses incurred in attending Committee meetings or carrying out the business of the Committee.

TERMS OF REFERENCE

Scope:

- Research proposals involving humans will be reviewed by the Committee where research involves patients or clients of the Group.
- Research involving humans includes research on pharmaceuticals, medical devices, medication, radiation and imaging, surgical procedures, biological samples, medical records, as well as epidemiological, social and psychological investigations.
- The Committee may accept an ethical approval undertaken by another

Human Research Ethics Committee (HREC), a NSW Health Lead HREC, or an NHMRC Certified HREC as sufficient ethical approval to allow the commencement of the project within the Group provided the HREC is registered with the Australian Health Ethics Committee.

- The Committee may provide ethical review for research undertaken by affiliated institutions or organizations, where approval has been granted by the Group's Chief Executive Officer.
- The Hospital accepts legal responsibility for the Committee's decisions where research involves patients or clients of the Group.
- Legal responsibility for all aspects of the research project, where research does not involve patients or clients of the Group, remains with the researcher(s), the primary institution and the employing and/or sponsoring body.

Status:

- The Committee is an advisory committee of Sydney Adventist Hospital Ltd with responsibility for providing ethical review of human research which is to be carried out at by the Group and other approved institutions or organizations.
- The Board of Directors has delegated to the Committee the authority to:
 - Grant ethical approval to the conduct of research within the Group and other approved institutions or organizations.
 - Authorise commencement of research, which has been granted ethical approval and which complies with the Group's research governance requirements.
 - Approve amendments, on behalf of the Group, to research conducted within the Group.
 - Suspend or withdraw approval, on behalf of the Group, for the conduct of research within the Group.
 - The Group's Chief Executive Officer or delegate is responsible for endorsing research to be conducted within the Group, following ethical approval being granted by the Committee, by signing the Clinical Trial Notification (CTN) Form, Indemnity and Clinical Research Agreement.

Accountability:

- The Committee is accountable to the Board of Directors in the conduct of its business and shall provide an annual report at the end of each calendar year which will include information on membership, the number of submissions reviewed, status of research, a description of any complaints received and their outcome and general issues raised.
- The Committee may from time to time bring to the attention of the Board issues of significant concern.
- The Committee provides reports to the Australian Health Ethics Committee in accordance with the requirements of the NHMRC and to the NSW Privacy Commissioner in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW).
- The Committee's Terms of Reference, Standard Operating Procedures and membership will be available upon request to the general public.

Conduct of Business:

- The Committee performs its functions according to written operating procedures outlined in the *Human Research Ethics Committee Standard Operating Procedures*

Application:

- Researcher(s) are required to submit research proposals for ethical review in accordance with the Committee's Standard Operating Procedures and the Group's research governance requirements.
- All applications for ethical review must be submitted to the Research Governance & Ethics Officer by the relevant closing date.

- Researcher(s) may be invited to attend committee meetings to present their submissions for discussion.
- Specific procedures are used to manage multi-centre research and negligible risk research.
- Researcher(s) are formally advised of the terms and conditions of the Committee's determination.

Recording:

- The Committee maintains written records of all its activities.
- Research proposals are kept securely and confidentially in accordance with the requirements of the Health Records & Information Privacy Act 2002 (NSW).
- Records are retained for a minimum of 5 years from the date of completion, except in the case of clinical research where 15 years applies, and disposed of in a secure manner.
- The Committee maintains a register of all submissions received and reviewed.

Monitoring & Reporting:

- The Committee maintains records of research submissions and associated documentation and monitors progress of projects, in accordance with NHMRC requirements. At a minimum, researchers are required to submit an annual and final report.
- Researchers are required to immediately report anything which might warrant review of ethical approval of the research including proposed changes in the research protocol, unforeseen events that might affect continued ethical acceptability of the research, serious or unexpected adverse reactions and if the project is discontinued.
- The Committee may request further information of researchers, inspection of the site and/or records and withdraw or suspend approval.
- Specific reporting procedures are used for risk management purposes.

Complaints Mechanism:

- A complaints procedure is in place to facilitate the resolution of complaints by researcher(s), research participants and others.

Confidentiality:

- Committee members are required to maintain confidentiality regarding the content of research proposals and committee proceedings during tenure and post-tenure.

Fees:

- Fees for submitting a research proposal for ethical review and for research governance review are charged as outlined in the Committee's Schedule of Fees.
- Payment is made directly to the Group.
- Revenue raised is used to defray the operating costs of the Committee.

**AMENDMENT TO
TERMS OF
REFERENCE**

- These terms of reference will be reviewed every two years and amended as necessary.
- Amendments at other times may be made upon receipt of a written proposal from a Committee member or the Board of Directors. Following ratification at a meeting of the Committee amendments will be submitted to the Board of Directors for consideration.