

**HUMAN RESEARCH ETHICS COMMITTEE****TERMS OF REFERENCE****1. Purpose**

**1.1.** The South West Healthcare (SWH) has a Human Research Ethics Committee (HREC) registered with National Health and Medical Research Council (NHMRC). The purpose of this registered HREC committee is to carry out the functions of an institutional ethics committee consistent with values and principles set out in the [National Statement on Ethical Conduct in Human Research](#) (the National Statement 2007, updated 2018) and any revisions made to it.

The Committee shall ensure that human research undertaken at SWH and affiliated institutions conforms with the guidelines of the [National Health and Medical Research Council \(NHMRC\)](#), the [Australian Code for Responsible Conduct of Research](#) (the Code), and the statutory requirements of State and Federal legislation. Any human research involving non-standard care - including interventional drug and device clinical trials must be reviewed by a NHMRC certified HREC.

**1.2.** The Committee shall:

- 1.2.1 Review research proposals involving human participants to ensure that they are ethically acceptable and in accordance with the National Statement;
- 1.2.2 Consider the scientific validity and merit of research proposals to ensure that research risks to participants are reasonable in relation to anticipated benefits;
- 1.2.3 Protect the rights, dignity, safety and well-being of research participants by reviewing all documents to be used for recruiting potential participants, including: advertisements, letters of invitation, information sheets, and consent forms;
- 1.2.4 Uphold the reputation of SWH and affiliated institutes by approving research that meets relevant ethical and scholarly standards;
- 1.2.5 Ensure that those conducting human research are either adequately experienced and qualified, or appropriately supervised;
- 1.2.6 Acknowledge and consider any prior peer review of research proposals;
- 1.2.7 Adhere to the NHMRC [National Mutual Acceptance \(NMA\)](#) process and accept ethical approval by certified HRECs for multi-site studies;
- 1.2.8 In line with 1.2.7 the [site specific assessments \(SSA\)](#) and [research governance](#) applications shall be reviewed by the SWH Research Governance Office for completion and submitted to Executive for endorsement; this may occur out-of-session in line with SWH committee practice;
- 1.2.9 Monitor approved research projects to ensure continued compliance with the conditions of approval;
- 1.2.10 Maintain communication with Australian Health Ethics Committee (AHEC) of NHMRC and address any inquiry from them about the SWH HREC records;

- 1.2.11 Consider research proposals from non-affiliate institutions for ethics review for sites for which we have approving rights for.

## **2. Function**

### **2.1.** The Committee shall:

- 2.1.1 Conduct ethical review of human research proposals in accordance with the National Statement.
- 2.1.2 Provide transparent and consistent decisions to researchers, and:
  - 2.1.2.1 Approve ethically acceptable human research proposals;
  - 2.1.2.2 Request amendments for human research proposals that are either incomplete or require further development;
  - 2.1.2.3 Reject human research proposals which do not meet required ethical standards;
  - 2.1.2.4 Grant extensions of ethics approval based on satisfactory interim progress reports;
  - 2.1.2.5 Withdraw ethics approval due to research misconduct.
- 2.1.3 Monitor the conduct of approved research proposals by reviewing/noting:
  - 2.1.3.1 Annual progress reports, or outcome in final completion reports;
  - 2.1.3.2 Safety reports, adverse event reports, amendment request forms, protocol deviations or violation reports; and
  - 2.1.3.3 Cessation of relevant research projects/activity.
- 2.1.4 Maintain appropriate confidentiality of the content of both applications and the deliberation of reviewers.

## **3 Reporting**

### **3.1** The Committee shall:

- 3.1.1 Provide reports and /or minutes to the SWH Chief Executive Officer through the relevant SWH Committee for review;
- 3.1.2 Self-report to NHMRC on their activities over the previous calendar year.

## **4 Administration**

### **4.1 Membership**

- 4.1.1 The Committee shall be constituted in accordance with the National Statement and shall maintain a minimum membership of at least eight members. As far as possible:
  - 4.1.1.1 There should be equal numbers of men and women;
  - 4.1.1.2 At least one third of the members should not be directly employed by SWH;
- 4.1.2 This minimum membership is:
  - 4.1.2.1 A Chair, with suitable experience;

- 4.1.2.2 At least two lay people (community representatives), one man and one woman, who have no affiliation with the SWH and do not currently engage in medical, scientific, legal or academic work;
  - 4.1.2.3 At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people;
  - 4.1.2.4 At least one person who performs a pastoral care role in a community;
  - 4.1.2.5 At least one lawyer, where possible one who is not engaged to advise SWH; and
  - 4.1.2.6 At least two people with current research experience relevant to research proposals to be considered at the meetings.
- 4.1.3 The Committee may seek advice from other expert(s), with relevant expertise related to a particular proposal, subject to disclosure and management of any conflict of interest and their undertaking of confidentiality as required by HREC members.
- 4.1.4 There will be in attendance at least one of the following:
- 4.1.4.1 Manager of Research;
  - 4.1.4.2 Research Governance Officer.

## **4.2 Chair**

- 4.2.1 A chair and deputy with suitable experience shall be recommended by the committee and approved by the SWH Chief Executive Officer.

## **4.3 Quorum**

- 4.3.1 As far as possible, each HREC meeting should have least one member in each category in attendance (see 4.1.2.1 to 4.1.2.6);
- 4.3.2 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.

## **4.4 Terms of Appointment**

- 4.4.1 SWH shall appoint the Chair and members to the committee. Members shall be appointed for a term of three years and remain eligible for reappointment for subsequent term/s as applicable:
  - 4.4.1.1 Appointments will be conducted in a fair and transparent manner. Recruitment of members may occur through direct approach and/ or advertisement as required;
  - 4.4.1.2 Members are requested to provide reasonable notice (preferably at the prior meeting, or at least two weeks earlier than the forthcoming meeting) prior to non-attendance at a meeting. Should this not be possible, members should expect to receive all the relevant meeting papers and take the opportunity to contribute their views so that these can be recorded and considered;

- 4.4.1.3 Committee members are required to adhere to the organisational standards on privacy and confidentiality;
- 4.4.1.4 Appropriate induction, training and information resources shall be provided to new committee members. Members will be updated at least annually on significant changes relevant to the responsibilities of the HREC;
- 4.4.1.5 All committee members shall be provided continuing education / training in accordance with the National Statement.

#### **4.5 Indemnification**

- 4.5.1 Members of HREC are covered under the Public Liability Policy of SWH for liabilities that may arise in the course of bona fide conduct of their duties in this capacity.

### **5 Operating Procedures**

#### **5.1 Frequency of meetings**

- 5.1.1 The Committee will meet once every second month, but to a minimum of at least five times per calendar year;
- 5.1.2 Based on the workload, additional Low/Negligible Risk subcommittee meetings will be convened at the discretion of the Chair of the Committee;
- 5.1.3 A listing of all meetings and submission closing dates for application will be publicly available on the SWH website.

#### **5.2 Decision making**

- 5.2.1 The National Statement does not require unanimity in decision-making and recommends that the Committee shall endeavor to reach decision by general agreement;
- 5.2.2 The Committee may request researchers to present their research projects;
- 5.2.3 The researchers may request an opportunity to attend a meeting to speak for their proposal and the committee may invite researchers to do so;
- 5.2.4 A maximum time for decision of 60 days applies to all applications submitted for ethical review.

#### **5.3 Member responsibilities**

- 5.3.1 Each member of the committee is responsible for deciding whether a research proposal under review meets the requirements of the National Statement and is ethically acceptable;
- 5.3.2 To fulfil their responsibilities, each member of the committee should:
  - 5.3.2.1 Become familiar with National statement;
  - 5.3.2.2 Be prepared, read agenda and research proposals or, if unavailable, communicate concerns and opinions before meetings;
  - 5.3.2.3 Provide written comments on items assigned for review;

- 5.3.2.4 Attend continuing education or training programs in research ethics at least every three years;
- 5.3.2.5 Disclose any actual or potential conflict of interest, including any financial or other interest or affiliation that may affect conduct of the ethics review or research.

#### **5.4 Absences**

- 5.4.1 Committee members are expected to attend at least 75% of committee meetings held during the year. If a member is absent for three consecutive meetings without notice to the Chair or justifiable reason, the Committee Chair will review their membership.

#### **5.5 Agenda**

- 5.5.1 Agenda and papers will be sent out no less than five business days prior to the next meeting.

#### **5.6 Minutes**

- 5.6.1 The proceedings of the Committee shall be recorded in minutes and will be circulated within two weeks of the meeting.

#### **5.7 Administrative Support**

- 5.7.1 The SWH Research Governance Office shall be responsible for providing administrative support, including:
  - 5.7.1.1 Notifying meetings and submission closing dates;
  - 5.7.1.2 Circulating agenda to the committee members;
  - 5.7.1.3 Recording and circulating the minutes;
  - 5.7.1.4 Providing written correspondence to the applicants;
  - 5.7.1.5 Maintaining all meeting and project records;
  - 5.7.1.6 Providing reports to relevant SWH Committee and NHMRC;
  - 5.7.1.7 Upholding the legal requirements where relevant;
  - 5.7.1.8 Establishing, implementing and documenting its working procedures;
  - 5.7.1.9 Any other administrative function required by the HREC and/or SWH.
- 5.7.2 The SWH Research Governance Office is responsible for Research Governance functions as defined by the [National Statement](#) (2007, updated 2018) and the [National Clinical Trials Governance Framework](#).