



# Women and Newborn Health Service Human Research Ethics Committee

## Terms of Reference

### 1. Name

The Committee will be known as the Women and Newborn Health Service Human Research Ethics Committee (“the Ethics Committee”).

### 2. Purpose

The purpose of the Ethics Committee is to ensure that all human research studies are conducted in accordance with the National Health and Medical Research Council (“NHMRC”) National Statement for Ethical Conduct in Human Research 2007 (“National Statement”) and the policies outlined in the WA Health Research Governance Framework.

### 3. Functions and Responsibilities

The functions and responsibilities of the Committee shall be to:

- a) Consider the ethical implications of all proposed research projects, as well as the scientific content and clinical implications, and to determine whether or not they are acceptable on ethical grounds.
- b) Provide for expeditious review of proposed research projects in extraordinary circumstances (see appendix 1).
- c) Maintain a record of all proposed research projects, so that the following items of information are readily available:
  - name of responsible institution
  - project identification number
  - principal investigator(s)
  - short title of project
  - ethical approval or non-approval with date
  - date(s) designated for review



- d) Preserve the protocols of research proposals in the form in which they are approved for a minimum period of seven (7) years from the approval or extension of the approval.
- e) Discuss and advise on:
  - Specific research ethical issues referred to the Ethics Committee by Women and Newborn Health Service (“WNHS”) Executive Committee; and
  - Specific research ethical issues the Ethics Committee considers of importance within the Hospital.
- f) Monitor the total impact of approved research projects on patients, families and hospital services.
- g) Provide a screening assessment of selected GEKO applications highlighted by the Performance, Review and Audit Coordinator to determine their suitability to remain within the GEKO pathway or to require a full HREC review.

#### **4. Accountability**

- a) The Committee is accountable to the Director Clinical Services in the conduct of its business.
- b) The minutes of each Ethics Committee meeting shall be forward to the Director Clinical Services following confirmation.
- c) The Ethics Committee may from time to time bring to the attention of the Director Clinical Services and/or the Clinical Governance Committee issues of concern to the Ethics Committee.
- d) The Ethics Committee will provide an annual report to the NHMRC in accordance with the requirements of the NHMRC and the National Statement, including information on membership, the number of proposals reviewed, status of proposals, a description of any complaints received and their outcome and general issues raised.
- e) The Terms of Reference shall be available upon written request and shall be posted upon the Women and Newborn Health Service (“WNHS”) website.

#### **5. Reporting**

The Ethics Committee will report annually to the WNHS Clinical Governance Committee and to the NHMRC.

## **6. Confidentiality**

The content of applications, discussions at meetings of the Ethics Committee and decisions of the Ethics Committee shall not be disclosed to unauthorised persons.

## **7. Education**

As per section 5.2.3 of the National Statement, HREC members are expected to attend education or training programs at least every three years. Where possible, WNHS should facilitate training for members annually and meet reasonable costs for members to attend regular training.

## **8. Sub-Committees and Working Parties**

The Ethics Committee may set up working parties and/or sub-committees to investigate and report on issues of relevance to the Ethics Committee and Hospital as the need arises.

The WNHS Scientific Advisory Sub-Committee (“SASC”) is a recognised sub-committee within these Terms of Reference.

## **9. Membership**

- a) The Ethics Committee shall consist of (total 11):
  - i. Chairperson (1)
  - ii. Laywoman not associated with the Hospital (1)
  - iii. Layman not associated with the Hospital (1)
  - iv. Minister of religion, or equivalent (1)
  - v. Lawyer (1)
  - vi. Members with knowledge of, and current experience in, the areas of research that are regularly considered by the Ethics Committee (2)
  - vii. Members with knowledge of, and current experience in, the professional care, counselling or treatment of people (1)
  - viii. Member of Health Service Executive Group (1)
  - ix. Member with experience in nursing and/or midwifery research (1)
  - x. Member with pharmaceutical knowledge (1)
- b) Categories (vi) and (vii) may include up to six additional members with the approval of the Ethics Committee and the Executive Director, Women and Newborn Health Service (“EDWNHS”)
- c) Each member is encouraged to nominate a delegate/proxy for confirmation by the Chairperson of the Ethics Committee.



- d) A quorum shall consist of at least one member from each of the categories (i) to (vii) above (“Minimum membership”).
- e) In the absence of a quorum at a meeting as referred to in clause 9 (d), a quorum will be deemed to be present if the Chairperson is satisfied at the commencement of the meeting that those who constitute the minimum membership have received the agenda and have had an opportunity to provide comments and to have those comments recorded and considered by the members present at the meeting.
- f) Terms of Members
  - i. The members of the Ethics Committee shall be appointed (or re-appointed) by the EDWNHS.
  - ii. The period of appointment to the Ethics Committee (other than for the Chairperson) shall be for a period of one year. External members may serve one or more terms by reappointment. Internal members may serve one or more terms by reappointment, up to a maximum of three years (excluding the Director of Research Ethics and Governance and the Director of Clinical Services).
  - iii. Vacancies, which occur within the term of appointment of the Ethics Committee, shall be filled for the unexpired period.

## 10. **Chairperson**

- a) The Chairperson shall be appointed by the EDWNHS from nominations received and shall hold office for a period of up to three years, but may serve one or more terms by reappointment as determined by the EDWNHS.
- b) The Chairperson shall appoint one of the members as Deputy Chairperson who shall hold office for the term of that appointment. In the Chairperson's absence, the Deputy Chairperson will be responsible for signing correspondence on behalf of the Ethics Committee and the review of Ethics Committee requested changes to applications, amendments, annual reports and Serious Adverse Events / Suspected Unexpected Serious Adverse Reactions reports. The Deputy Chairperson shall hold office at the Chairperson's discretion.
- c) In the temporary absence of the Chairperson, the Deputy Chairperson shall act for the Chairperson.
- d) In the absence of both the Chairperson and the Deputy Chairperson from a meeting of the Ethics Committee those present shall appoint one of the members present at the meeting as chairperson for that meeting of the Ethics Committee.

## 11. **Secretary to the Ethics Committee**

- a) The Research Ethics & Governance Office will provide secretarial support for the Ethics Committee.
- b) The secretary shall be the authorised channel of communication of all decisions of the Ethics Committee.
- c) The secretary will be responsible for receiving all applications for ethical approval and for keeping a register of all applications and approved protocols and for ensuring that all reporting, as required by and of the Ethics Committee, is complied with.

## 12. **Ethics Committee Operating Procedures**

### a) **Frequency of Meetings**

- i. The Ethics Committee shall meet monthly, except in the month of January.
- ii. Special meetings of the Ethics Committee may be called as required by the Chairperson.

### b) **Member Responsibilities**

Subject to the absence policy, each member must:

- i. Prepare for and attend scheduled meetings of the review body or, if unavailable, provide written comments or opinions about the ethical acceptability of research proposals in advance of any scheduled meeting; and
- ii. Attend a minimum of 6 meetings in a calendar year (Quota); and
- iii. Nominate a delegate/proxy to attend the meeting in their absence.

### c) **Absence Policy**

If a member is aware they will be unable to attend a monthly meeting they should notify the Chairperson in advance of the meeting. The member should liaise with their delegate/proxy as to their availability to attend the meeting in the member's absence. It is left to the Chairperson's discretion to decide what effect this absence shall have on the member's Quota.

### d) **Notice of Meetings**

Notices of meetings and supporting papers shall be despatched at least seven days in advance of the meeting date.

### e) **Conduct of Meetings**

Ethics Committee members shall act in accordance with the Department of Health and WA Health Code of Conduct at all times. Members' behaviour and meeting discussions shall uphold and reinforce the WNHS values of Excellence, Leadership, Integrity, Teamwork and Respect at all times.

### f) **Decision Making**



- i. The Ethics Committee will finalise decisions on the basis of consensus.
- ii. Decisions will either be unanimously resolved (all members support the decision), or approved by the majority of the Ethics Committee attending the meeting following a vote.

**g) Records / Minutes**

- i. Minutes of each meeting shall be prepared by the secretary and ratified by the Ethics Committee Chairperson. The ratified Minutes will be distributed promptly to each member of the Ethics Committee by the secretary.
- ii. Following ratification by the Ethics Committee Chairperson, letters of approval or otherwise for research projects considered by the Ethics Committee shall be forwarded promptly to researchers by the secretary.
- iii. The Minutes of each meeting shall be submitted to the next succeeding full meeting of the Ethics Committee for their certification by the Chairperson as a correct record of the proceedings.

**h) Conflict of Interest**

- i. A member of the Ethics Committee, who has duties or interests in conflict with their duties or interests on the Ethics Committee, whether direct, indirect, financial, material or otherwise, must withdraw or declare a possible conflict of interest to the Chairperson.
- ii. The member shall withdraw from the Ethics Committee by leaving the meeting room for the duration of the deliberation in question, prior to any discussion or decisions on the matter being taken unless the Ethics Committee determines the conflict is trivial or unlikely.
- iii. Where the Chairperson has excused a person from the Ethics Committee for that matter it may co-opt an alternative person to sit on the Ethics Committee for the purpose and duration of the period during which such matter is under.

**13. Reports and Committee Outcomes Evaluation**

The Ethics Committee has three key performance indicators:

- a) Submission of an annual report of the Ethics Committee's activities, key performance indicators and outcomes is to be presented to the WNHS Clinical Governance Committee.
- b) Review of the Terms of Reference:
  - i. In the first year of operation or following a significant change;

- ii. Thereafter at least once every two years, and that includes a review of the nominated Chairperson.

#### **14. Scientific Advisory Subcommittee (SASC)**

- a) The Ethics Committee will appoint a Scientific Advisory Sub-committee (SASC) in accordance with the SASC Terms of Reference below.
- b) The SASC will:
  - i. Meet monthly, except in the month of January;
  - ii. Assess the scientific validity, methodology and significance of the proposed research and recommend applications move forward for review by the Ethics Committee as appropriate;
  - iii. Assess the impact of the proposed research on WNHS services;
  - iv. Monitor the surveillance reports of approved research projects;
  - v. Review and assess adverse events;
  - vi. Provide a report and comments to the Ethics Committee regarding surveillance and adverse event reports; and
  - vii. Seek external review of proposed research if SASC considers additional expertise is required to assess the scientific validity, significance and impact of the proposed research.

#### **15. Adoptions and amendment of terms of reference**

Variations to these Terms of Reference may be made by the WNHS Executive Group and must be consistent with current NHMRC Guidelines, the Guidelines of the Australian Health Ethics Committee (AHEC) and policies outlined in the WA Health Research Governance Framework (<http://www.health.wa.gov.au/circularsnew/Research.cfm>).

**First formulated:** July 1995

**Revised:** May 1998, Feb 2001, June 2003, June 2007, Sept 2009, Sept 2010, Jan 2012, Jan 2014, Sept 2016, Sept 2017, Oct 2018, March 2021, July 2021 (*ad hoc*), Feb 2022

**Next Review** Feb 2024



## EXPEDITIOUS REVIEW OF RESEARCH PROPOSALS AND AMENDMENTS

1. In extraordinary circumstances a proposal for a research project may receive provisional approval outside an ordinary meeting of the Ethics Committee (the Ethics Committee). If, in the opinion of the Chairperson of the Ethics Committee, a proposal warrants such review the procedure outlined below will be followed:
  - i. The proposal will be sent by the most convenient means (electronically or otherwise) to all members of the Ethics Committee, including the SASC;
  - ii. Written or verbal comments/approval from members of the Ethics Committee will be requested to be given to the Ethics Committee Secretary by a date and time stipulated by the Chairperson;
  - iii. As soon as practicable after the stipulated date and time the Chairperson will confirm the decision of the Ethics Committee to the Secretary who shall as soon as practicable thereafter inform the Executive Director of the Women and Newborn Health Service and the researchers of that decision;
  - iv. The proposal will be put before the Ethics Committee at its next meeting for ratification of the decision made.
2. In some instances it may not be possible, due to the comments received from the Ethics Committee members, for the proposal to be approved outside a meeting. In such cases the proposal will form part of the agenda at the next meeting of the Ethics Committee.
3. Submission of applications for simple amendments and extensions where there are no ethical or governance implications (e.g. minor corrections of wording, updating of personnel details, reformatting of documents etc.) may be assessed and provisionally approved by the administrative staff of the Research Ethics & Governance Office to enable expedited approval, prior to formal consideration and approval by the Ethics Committee at the next scheduled meeting.



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