

NSW Population Health and Services Research Ethics Committee (PHSREC) Terms of Reference

Cancer Institute NSW

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Definitions

Cancer Institute NSW	Cancer Institute NSW, as established under the Cancer Institute NSW Act 2003.
CCO/CEO	Chief Cancer Officer & Chief Executive Officer, Cancer Institute NSW or their delegate.
Chairperson	Chairperson, NSW Population & Health Services Research Ethics Committee.
Executive Director, OHMR	Executive Director, Office for Health and Medical Research, NSW Ministry of Health or their delegate.
Executive Officer:	Executive Officer, NSW Population & Health Services Research Ethics Committee.
HREC:	Human Research Ethics Committee, a committee constituted in accordance with the National Statement to review and where appropriate approve and monitor the ethical and scientific aspects of human research.
Lead HREC:	A Human Research Ethics Committee accredited by NSW Ministry of Health to conduct a single ethical and scientific review of multi- centre research projects.
NHMRC	National Health and Medical Research Council.
National Statement:	National Statement on Ethical Conduct in Human Research (2007) or replacement.
OHMR:	Office for Health and Medical Research.
PHSREC:	NSW Population & Health Services Research Ethics Committee.
Public Health Organisation:	As defined by Section 7 of the Health Services Act 1997(NSW): a Local Health District, a statutory health corporation or an affiliated health organisation in respect of its recognised establishments and recognised services.

1. OBJECTIVES

1.1. The objectives of the HREC are to:

- 1.1.1. Protect the rights, mental & physical wellbeing, dignity & safety of participants in research;
- 1.1.2. Promote ethical principles in human research;
- 1.1.3. Review research in accordance with the values and principles of ethical conduct outlined in the National Statement;
- 1.1.4. Facilitate ethical research in Australia through efficient and effective review processes;
- 1.1.5. Protect the privacy and confidentiality of participants and/or their personal health information, either directly or indirectly, in the proposals referred to it; and
- 1.1.6. Promote and endorse ethical standards of research and information privacy in proposals referred to it, by provision of guidance to researchers and others as appropriate.

2. FUNCTIONS

2.1. The functions of the HREC are to:

- 2.1.1. Provide independent, competent and timely review of research proposals submitted to it for approval, in respect of their ethical and scientific acceptability;
- 2.1.2. Act in accordance with NHMRC guidelines pertaining to HRECs, including the National Statement. The HREC will function as a properly constituted HREC in accordance with the National Statement;
- 2.1.3. Provide advice to the CCO/CEO and the Executive Director, OHMR on the ethical and scientific acceptability of research proposals submitted to it for approval;
- 2.1.4. Provide advice to the CCO/CEO and the Executive Director, OHMR on issues relating to the ethical conduct of research that might arise from time to time;
- 2.1.5. As a Lead HREC accredited in NSW for general research, provide a single ethical opinion on research projects which may be accepted by NSW Public Health Organisations; and
- 2.1.6. Provide assistance or advice to other HRECs regarding issues that within the specific expertise of the HREC.

3. SCOPE OF RESPONSIBILITY

Lead HREC in NSW for general research

3.1. The HREC may review multi-centre human research applications in the categories of population health and/or public health research, where the research will take place in any institutions governed by NSW Public Health Organisations, and where a component of the research meets the description in 3.2 below. “Population health research” includes, but is not limited to, epidemiological research, record linkage studies, and health services research. Population health and/or public health research does not include clinical trials.

General research in NSW and Australia

3.2. The HREC will review:

3.2.1. Population health research utilising and/or linking routinely collected health (and other) data, including but not limited to:

- Data collections owned or managed by NSW Ministry of Health (e.g. NSW Admitted Patient Data Collection; Perinatal Data Collection; NSW Emergency Department Data Collection; and New South Wales Population Health Surveys);
- Data collections owned or managed by the Cancer Institute NSW, (e.g. NSW Central Cancer Registry, NSW Pap Test Registry, BreastScreen NSW, and Quitline);
- Data collections being linked across jurisdictions participating in National Mutual Acceptance for multijurisdictional data linkage projects.

3.2.2. Applications from the NSW Ministry of Health and Cancer Institute NSW in relation to the conduct, management or modification of their data collections (referred to in 3.2.1 above).

Research proposals utilising population health data collections owned and/or managed by NSW Ministry of Health or the Cancer Institute NSW will be reviewed in accordance with NSW Ministry of Health Policy Directive PD2010_055 Research – Ethical and Scientific Review of Human Research in NSW Public Health Organisations or replacement.

The review of research proposals as described above will not incur any fee to the Cancer Institute NSW nor the NSW Ministry of Health.

3.3. The HREC may review research applications which meet the description in 3.1 and 3.2 above and which are being conducted at external institutions/organisations and investigators as approved by the CCO/CEO, in accordance with NSW Health policy directive PD 2008_046 or replacement. The review of such research will not incur a fee as the mandatory review of the research application described in SOP 1.9 is an appropriate reason for providing the services of the HREC to the External Entity free of charge.

3.4. The HREC may provide assistance or advice to other ethics committees regarding issues that fall within its specific areas of expertise.

3.5. The HREC will, in its assessment of proposals, examine the extent of the proposals' compliance with the NSW Ministry of Health's policy on information privacy and confidentiality, including the NSW Ministry of Health Privacy Manual and the relevant privacy legislation that exists at both State and Federal level.

Role of the Chairperson

3.6. The Chairperson is responsible for the conduct of HREC business and for ensuring that the HREC reaches decisions on all matters. Where the Chairperson is not available, the meeting will be chaired by a Deputy Chairperson, or their delegate.

3.7. The HREC has an Executive Committee comprising at least the HREC Chairperson (or their delegate) and the Executive Officer (or their delegate). The Deputy Chairperson or other Committee member may join the Executive Committee as required to manage the workload and/or provide expertise and advice.

Role of the Executive Committee

3.8. The HREC Executive Committee is delegated to undertake expedited review and approval of business that does not require full HREC review, including some or all of the following:

- Low and negligible risk research applications;
- Amendments to current HREC approved research projects;
- Responses to HREC queries, as approved by the full HREC for HREC Executive Committee review and approval;
- Responses to requests for further information for new projects;
- Data and/or Privacy Breaches
- Protocol deviations

Role of the Executive Officer

3.9. The Executive Officer is delegated to undertake expedited review and approval of administrative business that does not require full HREC review, including some or all of the following;

- Request for approval for change in personnel (but not change in Co-ordinating Principal Investigator)
- Minor administrative amendments to current projects and informed consent documents
- Responses to HREC queries, as approved by the full HREC or Executive Committee for Executive Officer review and approval
- Responses to requests for further information for new projects when delegated by the Chair;
- Annual progress reports and final reports;

3.10. The decisions of the HREC Executive Committee and the Executive Officer are noted at the next HREC meeting.

4. STATUS OF THE NSW POPULATION AND HEALTH SERVICES RESEARCH ETHICS COMMITTEE WITHIN THE NSW MINISTRY OF HEALTH

4.1. The HREC is established by, and is an advisory committee to, the CCO/CEO and the Executive Director, OHMR.

4.2. The HREC has the authority to:

- Grant ethical approval for research proposals;
- Request modification/s and/or clarification of research proposals;
- Reject research proposals on ethical grounds;
- Monitor ethically approved proposals;
- Approve protocol amendments;
- Suspend approved protocols;
- Withdraw ethical approval;
- Form appropriate subcommittees as required for expert advice; and
- Seek expert opinion as required.
- Provide advice on the ethical conduct of projects directed at supporting service

delivery, when requested by the relevant service.

- 4.3.** The CCO/CEO and the Executive Director, OHMR have no authority under the National Statement to give ethical approval. Only a HREC has that authority, which the CCO/CEO and the Executive Director, OHMR acknowledge.

5. ACCOUNTABILITY OF THE HREC

- 5.1.** The HREC is jointly accountable to the CCO/CEO and the Executive Director, OHMR in the conduct of all aspects of its business. The CCO/CEO and the Executive Director, OHMR will be informed of the decisions of the HREC on proposals submitted to it on a regular basis, either through the submission of the minutes of HREC meetings, or through the submission of an annual report.

- 5.2.** The HREC shall provide regular reports to the CCO/CEO and the Executive Director, OHMR and the reports will occur either through the submission of the minutes of HREC meetings, or through the submission of an annual report.

- 5.3.** The HREC will bring to the attention of the CCO/CEO and the Executive Director, OHMR any issues of significant concern regarding matters within its scope of responsibility.

5.4. The HREC will provide the following reports:

- 5.4.1. Significant changes to the ethical review processes and changes to the HREC membership will be proactively reported to the NHMRC as per Section 4.1.2 of the NHMRC Certification Handbook, November 2012;
- 5.4.2. Annual Report to the NHMRC as a registered HREC, and additional reporting to meet the NHMRC Certification requirements or replacement;
- 5.4.3. NSW Privacy Commissioner Report in accordance with the requirements of the *Health Records and Information Privacy Act 2002 (NSW)*.

- 5.5.** The HREC Terms of Reference, Standard Operating Procedures and membership will be available upon request by the general public, and accessible on the Cancer Institute NSW and NSW Ministry of Health websites.

6. MEMBERSHIP

6.1. Composition

6.1.1. The composition of the HREC shall be in accordance with the National Statement.

Minimum membership comprises eight members. As far as possible, men and women are represented in equal numbers and at least one third of the members are external to the institution for which the HREC is reviewing research. The membership comprises representatives from the following categories:

- A Chairperson with suitable experience whose other responsibilities will not impair the HREC capacity to carry out its obligations under the National Statement;
- At least two (2) members who are lay people, one man and one woman, who have no affiliation with the Cancer Institute NSW, have no affiliation with the Ministry of Health and are not currently involved in medical, scientific, legal or academic work;
- At least one (1) member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
- At least one (1) member who performs a pastoral care role in the community, for example a minister of religion or an Aboriginal Elder;
- At least one (1) member who is a lawyer, but not a lawyer engaged or employed to advise the Cancer Institute NSW or NSW Ministry of Health; and
- At least two (2) members with knowledge of and current research experience relevant to the applications to be considered at the meetings they attend.

6.1.2. In addition to the membership outlined at 6.1.1, wherever possible, membership will also include:

- A NSW Ministry of Health Public Health Officer Trainee and/or a NSW Ministry of Health Biostatistics Officer trainee; and
- A nominee of the NSW Ministry of Health Deputy Secretary, Population and Public Health and Chief Health Officer.

6.1.3. To ensure the HREC is equipped to address all the relevant considerations arising from the categories of research likely to be submitted, some or all of the above categories may be represented by more than one person.

6.1.4. No member is appointed in more than one of the membership categories.

6.1.5. The HREC is free to consult people considered by the HREC to be qualified to advise and assist in reviewing applications provided that there is no conflict of interest and an undertaking of confidentiality is given. Such people are not entitled to vote on any matter.

6.2. Appointment

6.2.1. Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement in the form of an Expression of Interest.

6.2.2. Prospective members may be invited to attend meetings as an observer, provided that an undertaking of confidentiality is given. Such people are not entitled to vote on any matter.

6.2.3. Prospective members are asked to provide a copy of their curriculum vitae to a selection committee. The selection committee will have a minimum composition of the Chairperson, the Executive Officer and another member of the HREC. The selection committee shall review nominations and/or interview prospective applicants and make a recommendation regarding membership to the CCO/CEO and the Executive Director, OHMR.

6.2.4. The CCO/CEO and the Executive Director, OHMR will appoint members of the HREC. The letter of appointment includes the date of appointment, length of tenure, information about indemnity and member responsibilities.

6.2.5. Appointments will allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.

6.3. Terms of appointment

6.3.1. Members are appointed for an initial period of one year. Thereafter members may be re-appointed for consecutive terms, the length of which is at the discretion of the Chair and Executive Officer. Members may serve a maximum of six years consecutively, unless otherwise approved by the CCO/CEO and the Executive Director, OHMR.

6.3.2. Membership will lapse if a member fails without reasonable excuse to attend

three consecutive meetings of the HREC, unless exceptional circumstances exist. The Chairperson will notify the member, in writing, of such lapse of membership. The vacancy shall be filled pursuant to 6.2.

6.3.3. A member may resign from the HREC at any time upon giving notice in writing to the Chairperson. The vacancy shall be filled pursuant to 6.2.

6.3.4. The CCO/CEO and the Executive Director, OHMR may agree to terminate the appointment of any member of the HREC if they are of the opinion that:

- It is necessary for the proper and effective functioning of the HREC;
- The person is not a fit and proper person to serve on an HREC; or
- The person has failed to carry out their duties as an HREC member.

6.3.5. Members will be provided with a letter of appointment which will include:

- Date of appointment;
- Length of appointment;
- Category of membership (as per 6.1) and any formally appointed roles;
- Assurance that legal protection will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as an HREC member;
- Meeting attendance responsibilities; and
- General responsibilities as an HREC member.

6.4. Conditions of appointment

6.4.1. Members must agree to their name and category of membership being made publicly available.

6.4.2. Members will not be offered remuneration. The exception to this are members of the Executive Committee (excluding the Executive Officer) who will be offered remuneration once formally appointed to the Executive Committee. The amount and frequency of remuneration will be approved by the CCO/CEO and the Executive Director, OHMR.

6.4.3. Members will be reimbursed for legitimate expenses incurred in attending HREC meetings or in otherwise carrying out the business of the HREC.

6.4.4. Members will be required to sign the 'Code of Conduct for Committees of the

Cancer Institute NSW' and a statement undertaking:

- That all matters of which the member becomes aware during the course of their work on the HREC will be kept confidential;
- That any conflicts of interest, which exist or may arise during their tenure on the HREC, will be declared; and
- That the member has not been subject to any criminal conviction or disciplinary action, which may prejudice their standing as an HREC member.

6.5. Orientation and training for HREC members

6.5.1. Newly appointed members shall be provided with adequate orientation.

6.5.2. Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the HREC.

6.5.3. Expenses for these activities will be covered by the Cancer Institute and NSW Ministry of Health at the discretion of the Director, Strategic Research Investment, Cancer Institute NSW.

6.5.4. Each member is:

- Expected to become familiar with the National Statement and consult other guidelines relevant to the review of specific research applications; and
- Encouraged to attend continuing education or professional development activities in research ethics once in each period of appointment.

6.6. Sub-committees

6.6.1. The HREC may appoint such sub-committees as it sees fit to carry out scientific or technical review of a research proposal, or ethical review of minimal risk research, submitted to the HREC. The Chair of any such sub-committee will be appointed by the CCO/CEO and the Executive Director, OHMR. Members of any such sub-committee need not be members of the HREC.

6.7. Liability coverage

6.7.1. The Cancer Institute NSW and NSW Ministry of Health, through the NSW Treasury Managed Fund provide indemnity for members of the HREC for any liabilities that arise as a result of the member exercising their duties as a member in good faith.

7. CONDUCT OF BUSINESS

7.1. Procedures

7.1.1. The HREC will perform its functions in accordance with written Terms of Reference and Standard Operating Procedures. These procedures shall be reviewed periodically and amended and updated as necessary.

7.1.2. The HREC Terms of Reference and Standard Operating Procedures are made publicly available.

7.1.3. Secretariat services will be provided by the Cancer Institute NSW.

7.2. Meetings

7.2.1. The HREC meets on a regular basis, which will normally be at monthly intervals.

7.2.2. Meeting dates and agenda closing dates will be made publicly available.

7.2.3. A quorum is required at each meeting for the HREC to reach a final decision on any agenda item. The quorum for meetings is the minimum membership as described in the National Statement Sections 5.1.28 – 5.1.31 attending in person or via telephone or videoconference.

7.2.4. Where there is less than a full attendance of the minimum membership at a meeting, the Chairperson must be satisfied “that the views of those absent who belong to the minimum membership have been received and considered”, for instance through prior submission of written comments (National Statement 5.2.30).

7.2.5. The Chairperson, in initial consultation with the Executive Officer, may cancel or postpone a scheduled meeting if a quorum cannot be achieved, with final approval from the CCO/CEO and Executive Director, OHMR.

7.3. Declaration of interest

7.3.1. An HREC member must declare to the HREC any conflicts of interest they have in relation to an application for ethical and scientific review or any other matter for

consideration at the meeting. Conflict of interest includes financial interests, personal, professional or institutional benefits or advantages that depend significantly on research outcomes.

7.3.2. An HREC member with a conflict of interest who is present at the meeting may be asked to withdraw from the meeting (by leaving the room) or may remain in the room at the HREC's discretion.

7.3.3. The HREC member with a conflict of interest will not participate in the discussions and will not be entitled to vote in the decision with respect to the matter.

7.3.4. The minutes will record the declaration of interest and the decision of the HREC on the procedures to be followed.

7.4. Confidentiality

7.4.1. HREC meetings are held in private. The agenda and minutes of meetings, applications, supporting documentation and correspondence are all treated confidentially.

7.5. Decision making

7.5.1. The HREC will endeavour to reach a decision concerning the ethical and scientific acceptability of a proposal by unanimous agreement. Where a unanimous decision is not reached, the Chairperson will need to facilitate the expression of opinion from all members, identify points of agreement and judge when a sufficient degree of general agreement has been reached. Any significant minority view (i.e. 2 or more members) is noted in the minutes.

7.5.2. The HREC shall be free to consult any person considered by the HREC to be qualified to provide advice and assistance in the review of any research proposal submitted to it, subject to that person providing an undertaking of confidentiality (or otherwise being subject to legislation requiring confidentiality) and provided that such person shall not be entitled to vote on any matter.

7.6. Records/Data Management

7.6.1. Written records of the HREC's activities will be prepared and maintained, including agendas and minutes of all meetings of the HREC.

7.6.2. Files shall be kept securely and confidentially in accordance with the requirements of the State Records Act 1998 and the Cancer Institute NSW Functional Retention and Disposal Authority.

7.6.3. The HREC will maintain a register of all the applications received and reviewed in accordance with the National Statement.

7.7. Monitoring research projects

7.7.1. The HREC will monitor approved research projects to ensure compliance with the conditions of approval and to protect the rights, safety and welfare of participants. This includes review of annual progress reports and final reports, safety reports and reports of protocol violations.

7.7.2. The HREC will, as a condition of approval of each project, require that investigators immediately report anything which might warrant review of ethical approval of the project, including:

- Proposed changes in the research protocol;
- Unforeseen events that might affect continued ethical acceptability of the project;
- The abandonment of the project for any reason.

7.7.3. The HREC may adopt at its discretion any additional appropriate mechanisms for monitoring, including:

- Discussion of relevant aspects of the project with investigators at any time;
- Random inspection of research sites, data or consent documentation;
- Interview with research participants or other forms of feedback from them.

7.7.4. The HREC also has the discretion to recommend in the letter of approval that the site co-ordinates onsite monitoring at recommended intervals or randomly throughout the project.

8. APPEALS AND COMPLAINTS

8.1. Complaints about the HREC's review process

8.1.1. A complaint about the HREC's review process will be directed to the attention of the Chairperson of the HREC, detailing the grounds of the complaint.

8.1.2. The Chairperson will investigate the complaint and its validity and recommend to the HREC an appropriate course of action. The HREC will notify the complainant of the course of action and determination in a timely manner.

8.1.3. If the complainant is not satisfied with the outcome, they will have the discretion to refer the complaint to the CCO/CEO and the Executive Director, OHMR or request that the Chairperson do so, in accordance with 8.5.

8.1.4. All complaints received will be reported by the Executive Officer to the CCO/CEO and the Executive Director, OHMR in an appropriate timeframe, depending on the seriousness of the complaint and the timeframe in which it is resolved. All complaints will at least be notified in the annual reports made pursuant to section 5.2.

8.2. Appeals regarding HREC rejection of an application

8.2.1. Where the HREC has rejected an application, the investigator will be able to:

- a) submit a new application to the HREC taking due account of the HREC's concerns. This will be processed and reviewed in the same way as any other new application; or
- b) lodge an appeal with the HREC Chairperson specifying the grounds of the appeal in writing. The Chairperson will investigate the appeal and its validity and recommend to the HREC an appropriate course of action in a timely manner. The HREC will notify the complainant of the course of action and determination in a timely manner.

8.2.2. If the appellant is not satisfied with the outcome, they will have the discretion to

refer the appeal to the CCO/CEO and the Executive Director, OHMR or request that the Chairperson do so, in accordance with 8.5.

8.2.3. All appeals received will be reported by the Executive Officer to the CCO/CEO and the Executive Director, OHMR in an appropriate timeframe, depending on the seriousness of the appeal and the timeframe in which it is resolved. All appeals will at least be notified in the annual reports made pursuant to section 5.2.

8.3. Appeals regarding HREC approval

8.3.1. Where the HREC has approved an application and:

- an ethical or scientific issue is subsequently identified by any party; or
- It has become apparent that the decision was based on inconsistent application of policy and guidelines

8.3.2. If the appellant is not satisfied with the outcome, they will have the discretion to refer the appeal to the CCO/CEO and the Executive Director, OHMR or request that the Chairperson do so, in accordance with 8.5.

8.3.3. All appeals received will be reported by the Executive Officer to the CCO/CEO and the Executive Director, OHMR in an appropriate timeframe, depending on the seriousness of the appeal and the timeframe in which it is resolved. All appeals will at least be notified in the annual reports made pursuant to section 5.2.

8.4. Complaints about the conduct of an approved research project

8.4.1. Complaints about the conduct of an approved research project will be reported to the Executive Officer of the HREC. Where the research is being conducted in a Public Health Organisation, the complaint may also be made to the Research Governance Officer of the Public Health Organisation. The complainant will receive an acknowledgement in writing where possible.

8.4.2. Where the complaint is submitted to the Research Governance Officer, they will inform the Executive Officer of the HREC of the nature of the complaint if it is likely to have implications for the ongoing approval of the project by the HREC.

8.4.3. Where the complaint is submitted to the Executive Officer, they will inform the Research Governance Officer responsible at the site that is the subject of the complaint.

8.4.4. Where the complaint involves an allegation of research misconduct, the complaint will be managed in accordance with the local complaint handling procedures of the organisation at which the researcher is located.

For complaints to be investigated by the HREC:

8.4.5. The Executive Officer in conjunction with the Chairperson of the HREC will investigate the complaint and make a recommendation to the HREC on the appropriate course of action. The HREC will notify the complainant of the course of action and determination in a timely manner.

8.4.6. If the complainant is not satisfied with the outcome, they will have the discretion to refer the complaint to the CCO/CEO and the Executive Director, OHMR or request that the Chairperson do so, in accordance with 8.5.

8.4.7. All complaints received will be reported by the Executive Officer to the CCO/CEO and the Executive Director, OHMR in an appropriate timeframe, depending on the seriousness of the complaint and the timeframe in which it is resolved. All complaints will at least be notified in the annual reports made pursuant to section 5.2.

8.5. Referral of appeals or complaints to the CCO/CEO and the Director, OHMR

8.5.1. If a complainant or appellant considers that the HREC has failed to follow due process after making an appeal or complaint in line with 8.1, 8.2, 8.3 or 8.4 and remains unsatisfied with the outcome, they may refer the appeal or complaint to the CCO/CEO and the Executive Director, OHMR, or may ask the Chairperson to do so. The CCO/CEO and the Executive Director, OHMR will jointly determine if the complaint warrants further investigation.

8.5.2. If it is determined that the complaint does warrant further investigation then the CCO/CEO and the Executive Director, OHMR will convene a suitable panel to review the complaint, ensuring that both the complainant and the HREC are afforded due process.

8.6. Complaints about the conduct of HREC members

8.6.1. Complaints about the conduct of an HREC member are managed by the CCO/CEO and the Executive Director, OHMR who will inform the Chairperson of the complaint.

9. AMENDMENT TO THE TERMS OF REFERENCE

9.1. These Terms of Reference will be reviewed every three years and will be amended by the procedure outlined in 9.2 below:

9.2. In respect of proposals for amendment to the Terms of Reference brought forward by HREC members:

9.2.1. The proposal must be in writing and circulated to all HREC members for their consideration;

9.2.2. The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register their views in writing;

9.2.3. The proposal brought forward shall be referred to the CCO/CEO and the Executive Director, OHMR for review and agreement, where two thirds of the HREC members agree to the amendment;

9.2.4. The CCO/CEO and the Executive Director, OHMR will consider the proposal and notify the HREC of the outcome of their consideration. If the CCO/CEO and the Executive Director, OHMR agree to the amendment, the Terms of Reference will be so amended by the Executive Officer and the amendment will be ratified at the next HREC meeting, and will take effect from that date.

9.3. In respect of proposals for amendment brought forward by either the CCO/CEO or the Executive Director, OHMR:

9.3.1. The CCO/CEO and the Executive Director, OHMR may put forward a proposal for amendment to the Terms of Reference. Such proposals must be in writing and must first be agreed by both the CCO/CEO and the Executive Director, OHMR. The proposal shall then be circulated to all HREC members for their consideration;

9.3.2. The proposal will be tabled at the next scheduled HREC meeting;

9.3.3. The HREC will provide its advice on the proposal to the CCO/CEO and the Executive Director, OHMR as soon as practicable after the meeting at which it was considered;

9.3.4. The CCO/CEO and the Executive Director, OHMR shall consider the advice of the HREC, and if both agree to proceed with the amendment, the Terms of Reference will be so amended by the Executive Officer. The amendment will be tabled at the next HREC meeting, and will take effect from that date.

10. TERMINATION OF HREC RESPONSIBILITY

10.1. Where the HREC is to be merged, closed or has ceased to function, the Cancer Institute NSW and/or the NSW Ministry of Health will notify the NHMRC and determine the appropriate course of action, such as the status of its registration and or status as a certified institution with the NHMRC and the monitoring of previously approved research.