



**CANCER INSTITUTE NSW
Clinical Research Ethics Committee**

**TERMS of REFERENCE
Version 1.0 (September 2006)**

DEFINITIONS

Board:	Cancer Institute NSW Board
Cancer Institute NSW:	Cancer Institute NSW, as established under the <i>Cancer Institute NSW Act 2003</i>
NSW Health:	New South Wales Department of Health
CCO:	Chief Cancer Officer & Chief Executive Officer, Cancer Institute NSW or his/her delegate
Ethics Committee:	Cancer Institute NSW Clinical Research Ethics Committee
Executive Officer:	Delegated member of the Cancer Institute NSW Clinical Research Ethics Committee Secretariat
Chair:	Chairperson Cancer Institute NSW Clinical Research Ethics Committee
Lead Committee:	A Human Research Ethics Committee accredited by NSW Health to conduct a single ethical and scientific review of multi-centre research projects
NSW Single Ethical Review Participants:	Those NSW bodies which have signed a Memorandum of Understanding to which the Cancer Institute NSW and NSW Health are a party, which governs the provision of a single ethical review of multi-centre research.
NHMRC:	National Health and Medical Research Council
National Statement:	<i>National Statement on Ethical Conduct in Research Involving Humans (1999)</i> or replacement
HREC:	Human Research Ethics Committee

1. OBJECTIVES

1.1. The objectives of the Ethics Committee are to:

- 1.1.1. Provide advice to the Board on the ethical acceptability of research proposals submitted to it for approval;
- 1.1.2. Provide advice to the Board on issues relating to the ethical conduct of research that might arise from time to time;
- 1.1.3. Upon future accreditation as a Lead Committee, provide a single ethical opinion on research projects submitted to it for approval which may be accepted by NSW Single Ethical Review Participants;
- 1.1.4. Protect the rights, including mental & physical wellbeing, dignity & safety of participants of research;
- 1.1.5. Facilitate ethical research through efficient and effective review processes;
- 1.1.6. Promote ethical standards of human research;
- 1.1.7. Review research in accordance with the National Statement;
- 1.1.8. Protect the privacy and confidentiality of participants and/or their personal health information, either directly or indirectly, in the proposals referred to it;
- 1.1.9. 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 Ethics Committee functions are to:

- 2.1.1. Provide independent, competent and timely review of research proposals submitted to it for approval, in respect of their ethical acceptability; and
- 2.1.2. Act in accordance with NHMRC guidelines pertaining to HREC, including the National Statement. The Committee will function as a properly constituted HREC in accordance with the National Statement.

3. SCOPE OF RESPONSIBILITY

3.1. Clinical cancer research proposals involving humans will be ethically assessed by the Ethics Committee. This will include, but not be limited to, cancer clinical trials involving:

- 3.1.1.1. Prevention;
- 3.1.1.2. Intervention;
- 3.1.1.3. Prophylactic;
- 3.1.1.4. Diagnostic;
- 3.1.1.5. Therapeutic;
- 3.1.1.6. Devices; or
- 3.1.1.7. Regime procedures.

3.2. The Executive Officer, at their discretion, may refer other types of cancer research to the Ethics Committee to that set out in 3.1.

3.3. The Ethics Committee may provide assistance or advice to other HREC regarding issues that fall within the specific expertise of the Ethics Committee.

3.4. The Ethics Committee will, in its assessment of proposals, examine the extent of the proposals compliance with the NSW Department of Health's policy on information privacy and confidentiality, including the *NSW Health Privacy Manual (2004)*, the Cancer Institute NSW's '*Functional Retention and Disposal Authority*' (DA204), and relevant privacy legislation that exist at both State and Federal level.

3.5. The Ethics Committee will produce written material which details how it will exercise its discretion in accepting research proposals for review as a Lead Committee. Any such documentation will be approved by the appropriate officers at the Cancer Institute NSW prior to distribution.

4. STATUS OF THE ETHICS COMMITTEE WITHIN THE CANCER INSTITUTE NSW

- 4.1. The Ethics Committee is established under the *Cancer Institute NSW Act (2003)* by the Board with delegated authority to make decisions concerning the ethical acceptability of research involving humans and other matters referred to it from time to time.
- 4.2. The Board has delegated to the Ethics Committee the authority to:
 - 4.2.1. Grant ethical approval for research proposals;
 - 4.2.2. Request modification/s and/or clarification of research proposals;
 - 4.2.3. Reject research proposals on ethical grounds;
 - 4.2.4. Monitor ethically approved proposals;
 - 4.2.5. Approve protocol amendments;
 - 4.2.6. Suspend approved protocols;
 - 4.2.7. Withdraw ethical approval;
 - 4.2.8. Form appropriate sub-committees as required for expert advice; and
 - 4.2.9. Seek expert opinion as required.
- 4.3. The Board has no power under the National Statement to give ethical approval. Only a HREC has that authority, which the Board recognise.

5. ACCOUNTABILITY OF THE ETHICS COMMITTEE

- 5.1. The Ethics Committee is accountable to the Board in the conduct of its business. The Board shall be informed of the decisions of the Ethics Committee on proposals submitted to it on a regular basis through the submission of the minutes of Ethics Committee meetings.
- 5.2. The Ethics Committee shall provide an annual report to the Board at the end of each financial year, which will include information on membership, the number of proposals reviewed by the Ethics Committee, the status of proposals, a description of any complaints received and their outcome, general issues and other matters of an ethical nature as may have arisen.
- 5.3. The Ethics Committee will bring to the attention of the Board any issues of significant concern.

5.4. The Ethics Committee will provide reports:

5.4.1. To the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the NHMRC; and

5.4.2. To the NSW Privacy Commissioner in accordance with the requirements of the *Health Records and Information Privacy Act 2002 (NSW)*.

5.5. On research projects involving humans in accordance with the NSW Health Circular 2001/66 'Responsibilities of Area Health Services regarding reporting on research activities'. To meet this requirement the Cancer Institute NSW will report to the public on an annual basis through the Cancer Institute NSW Annual Report, available by request and on the Cancer Institute NSW website.

5.6. The Ethics Committee's Terms of Reference, Standard Operating Procedures and membership will be available upon request by the general public, and accessible on the Cancer Institute NSW website.

6. MEMBERSHIP

6.1. Composition

6.1.1. The composition of the Ethics Committee shall be in accordance with the National Statement, and include:

6.1.1.1. A chairperson;

6.1.1.2. At least two (2) members who are lay people, one man and one woman, who have no affiliation with the Cancer Institute NSW, and not currently involved in medical, scientific or legal work;

6.1.1.3. At least one (1) member with knowledge of, and current experience in, the professional care, counselling or treatment of people, for example a nurse, or a social worker;

6.1.1.4. At least one (1) member who persons a pastoral care role in a community, for example a minister of religion or an Aboriginal Elder;

6.1.1.5. At least one (1) member who is a lawyer, but not a lawyer engaged to advise the Cancer Institute NSW; and

6.1.1.6. At least two (2) members with current research experience relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from a pool of further members.

6.1.2. To ensure the membership will equip the Ethics Committee 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.

- 6.1.3. Additional members may be appointment to ensure the Committee has the expertise required to assess the proposals regularly submitted for its consideration. Such expertise will include, but not be limited to, experience in cancer care and/or cancer research.

6.2. Appointment

- 6.2.1. The Board will appoint the founding members of the Ethics Committee. Thereafter, appointments will be made by the Board in consultation with the Ethics Committee as deemed appropriate.
- 6.2.2. Prospective members of the Ethics Committee may be recruited by direct approach, nomination or by advertisement in the form of an Expression of Interest.
- 6.2.3. A selection committee, constituted by two nominees of the Board, shall review nominations and/or interview prospective applicants and make a recommendation regarding membership to the Board. Thereafter, the selection committee shall follow the same process for appointment but shall also consult with the Ethics Committee.
- 6.2.4. Appointments will allow for continuity, the development of expertise within the Ethics Committee, and the regular input of fresh ideas and approaches.

6.3. Terms of appointment

- 6.3.1. Founding members are appointed for an initial period of one year. Thereafter, members shall be appointed for three year terms. Members may serve a maximum of two consecutive terms, unless otherwise approved by the Board.
- 6.3.2. Membership will lapse if a member fails without reasonable excuse to attend three consecutive meetings of the Ethics Committee, 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 Ethics Committee at any time upon giving notice in writing to the Chairperson. The vacancy shall be filled pursuant to 6.2.
- 6.3.4. The Board may agree to terminate the appointment of any member of the HREC if they are of the opinion that:
 - 6.3.4.1. It is necessary for the proper and effective functioning of the HREC;
 - 6.3.4.2. The person is not a fit and proper person to serve on an HREC; or
 - 6.3.4.3. The person has failed to carry out their duties as an HREC member.

- 6.3.4.4. Members will be provided with a letter of appointment which will include:
- 6.3.4.5. Date of appointment;
- 6.3.4.6. Length of appointment;
- 6.3.4.7. 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 Ethics Committee member;
- 6.3.4.8. Meeting attendance responsibilities; and
- 6.3.4.9. General responsibilities as an Ethics Committee member.

6.4. Conditions of appointment

- 6.4.1. Members must agree to their name and profession being made publicly available.
- 6.4.2. Members will not be offered remuneration. However, members will be reimbursed for legitimate expenses incurred in attending Ethics Committee meetings or in otherwise carrying out the business of the Ethics Committee.
- 6.4.3. Members will be required to sign the 'Code of Conduct for Committees and Working Parties of the Cancer Institute NSW' and a statement undertaking:
 - 6.4.3.1. That all matters of which he/she becomes aware during the course of his/her work on the Ethics Committee will be kept confidential;
 - 6.4.3.2. That any conflicts of interest, which exist or may arise during his/her tenure on the Ethics Committee, will be declared; and
 - 6.4.3.3. That he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as an Ethics Committee member.

6.5. Education for Ethics Committee members

- 6.5.1. Newly appointed members will receive adequate orientation, and be provided with a copy of the '*Cancer Institute NSW Clinical Research Ethics Committee Members Reference Guide*', which will be updated from time to time.
- 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 Ethics Committee.

- 6.5.3. Expenses for these activities will be covered by the Cancer Institute NSW at the discretion of the Ethics Manager, Cancer Institute NSW.

6.6. Sub-committees

- 6.6.1. The Ethics Committee 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 Ethics Committee. The Chair of any such sub-committee will be appointed by the Board. Members of any such sub-committee need not be members of the Ethics Committee.

6.7. Liability coverage

- 6.7.1. The Cancer Institute NSW, through the NSW Treasury Managed Fund provides indemnity for members of the Ethics Committee for any liabilities that arise as a result of the member exercising his or duties as a member in good faith.

7. CONDUCT OF BUSINESS

7.1. Procedures

- 7.1.1. The Ethics Committee will perform its functions according to written standard operating procedures. These procedures shall be reviewed periodically and amended and updated as necessary.
- 7.1.2. All Ethics Committee members shall have access to and be provided with copies of the procedures and shall be consulted with regard to changes thereto.

7.2. Submissions, notifications and approvals

- 7.2.1. All applications for ethical review must be submitted to the Executive Officer of the Ethics Committee, by the relevant closing date. Applications are to be submitted electronically via the Cancer Institute NSW website, in the format approved from time to time by the Ethics Committee and shall include such documentation as the Ethics Committee may specify.
- 7.2.2. Applicants will be provided with access to the “*Guidelines for Submission*” either in hardcopy or via the website, to assist in the preparation of applications.
- 7.2.3. The Ethics Committee may request the applicant to supply any further information in relation to an application and/or request the applicant to attend a meeting of the Ethics Committee.
- 7.2.4. The Ethics Committee will consider completed applications received by the relevant closing date at the next Ethics Committee meeting.

- 7.2.5. The Executive Officer shall circulate the completed application and associated documents received with a meeting agenda to all members of the Ethics Committee at least five (5) working days before the next meeting.
- 7.2.6. The Ethics Committee will delegate certain scientific, technical or legal matters to a member or sub-committee of its members, or seek expert external advice as required.
- 7.2.7. The Ethics Committee may take into account the views or opinions on the protocol held by another properly constituted HREC under the National Statement. The Ethics Committee may take into account the views or opinion of any scientific review of the research proposal undertaken by a recognised peer group.
- 7.2.8. The Executive Officer will promptly notify the applicant in writing, advising whether the Ethics Committee has approved the application, and of any conditions which the Ethics Committee considers should be applicable to the ethical conduct of the research.

7.3. Expedited review

- 7.3.1. The Ethics Committee will establish an executive sub-committee of members, consisting of the Chairperson, the Executive Officer and one other member to consider items of business that are considered to be of low risk. Such items may include some adverse events, some protocol reports, minor amendments and the like. The minutes of any such meetings will be tabled at the next Ethics Committee meeting for ratification.
- 7.3.2. Where expedited review is appropriate, as defined in 7.3.1, such review may be undertaken between scheduled meetings at the discretion of the Chairperson. He/she may seek advice from other Ethics Committee members, as appropriate, before reaching a decision. Where approval is granted, minutes will be tabled at the next Ethics Committee meeting for ratification.

7.4. Multi-centre research

- 7.4.1. The Ethics Committee will act as a 'lead' human research ethics committee within NSW Health's program of 'Single Ethical Review for Multi-centre Research'.
- 7.4.2. To facilitate the ethical assessment of multi-centre research the Ethics Committee may:
 - 7.4.2.1. Communicate with Clinical Research Regulatory Officers, responsible at the institutional/facility level for streamlining research governance administration;
 - 7.4.2.2. Accept a scientific/technical assessment of the research by another appropriate body;

7.5. Advocates and interpreters

- 7.5.1. The Ethics Committee will consider whether an advocate for any participant or group of participants should be invited to the Ethics Committee meeting to ensure informed decision-making.
- 7.5.2. Where research involves the participation of persons unfamiliar with the English language, the Ethics Committee will ensure that the participant information sheet is translated into the participant's language and that an interpreter is present during the informed consent process.

7.6. Meetings

- 7.6.1. The Ethics Committee shall meet on a regular basis, which will normally be at monthly intervals.
- 7.6.2. Meeting dates and agenda closing dates shall be published and available on the Cancer Institute NSW website.
- 7.6.3. Any member of the Ethics Committee who has any interest, financial or otherwise, in a proposal or other related matter(s) considered by the Ethics Committee, should as soon as practicable declare such interest.
- 7.6.4. If the member is present at a meeting at which the project is the subject of consideration, the member will withdraw from the meeting (by leaving the room) until the Ethics Committee's consideration of the relevant matter has been completed.
- 7.6.5. The member will not participate in the discussions and will not be entitled to vote in the decision with respect to the matter. All declarations of interest and absence of the member concerned will be minuted.
- 7.6.6. A quorum shall exist when a representative of each of the categories outlined at 6.1.1 is present or has had the opportunity to contribute to the meeting's deliberations through the submission of written comments prior to the meeting.
- 7.6.7. The Ethics Committee will endeavour to reach a decision concerning the ethical acceptability of a proposal by unanimous agreement. Where a unanimous decision is not reached, the decision will be carried by a majority of two-thirds of members who examined the proposal, provided that the majority includes at least one layperson. Any significant minority view (i.e. 2 or more members) shall be noted in the minutes. A lesser minority view may also be noted, if such request is made.
- 7.6.8. The Ethics Committee shall be free to consult any person(s) considered by the Ethics Committee to be qualified to provide advice and assistance in the review of any research proposal submitted to it, subject to that person(s) providing an undertaking of confidentiality and provided that such person(s) shall not be entitled to vote on any matter.

7.7. Records/Data Management

- 7.7.1. The Executive Officer will prepare and maintain written records of the Ethics Committee's activities, including agendas and minutes of all meetings of the Ethics Committee.
- 7.7.2. The Executive Officer will prepare and maintain a file for each application received including a copy of the application, and any relevant correspondence including that between the applicant and the Ethics Committee.
- 7.7.3. Files shall be kept securely and confidentially in accordance with the requirements of *Health Records Information Privacy Act (2002) NSW*, the NSW Health 'General Retention and Disposal Authority – Public Health Services: Administrative Resources – GDA21', the Cancer Institute NSW's 'Functional Retention and Disposal Authority' (DA204) or any replacement thereof.
- 7.7.4. Files shall be held for sufficient time to allow reference. The minimum period for retention is at least 5 years from the date of completion of a proposal¹ but for specific types of research, such as clinical research, 15 years shall apply². Files may be kept indefinitely, at the discretion of the Ethics Committee, subject to the agreement of the Cancer Institute NSW.
- 7.7.5. The Ethics Committee will maintain a register/database of all the applications received and reviewed in accordance with NHMRC guidelines.

7.8. Post approval responsibilities

- 7.8.1. The Ethics Committee will monitor approved projects and in doing so may request and discuss information on any relevant aspects of the project with the investigators at any time. In particular, the Committee will require applicants to provide a progress report at least annually, and at completion of the study.
- 7.8.2. The Ethics Committee 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:
 - 7.8.2.1. Proposed changes in the research protocol or conduct;
 - 7.8.2.2. Unforeseen events that might affect continued ethical acceptability of the project;
 - 7.8.2.3. Serious or unexpected adverse events; or
 - 7.8.2.4. The abandonment of the project for any reason.

¹ Joint NHMRC/AV-CC Statement & Guidelines of Research Practice

² Note for Guidance on Good Clinical Practice Guidelines

- 7.8.3. The Ethics Committee may adopt any additional appropriate mechanism, such as site inspections, for monitoring, as deemed necessary.

8. COMPLAINTS & REVIEW

8.1. Complaints concerning the conduct of a project

- 8.1.1. A person with a complaint about the conduct of a project should bring the complaint to the attention of the Executive Officer in the first instance, detailing the grounds of the complaint. The Executive Officer in conjunction with the Chairperson of the Ethics Committee will investigate the complaint and make a recommendation on the appropriate course of action.
- 8.1.2. All complaints received will be reported to the Board in an appropriate timeframe, depending on the seriousness of the complaint and the timeframe in which it is resolved. All complaints will be at least notified in annual reports made pursuant to section 4.5.2
- 8.1.3. If the complainant is not satisfied with the outcome of the Ethics Committee's investigation, then he/she can refer the complaint to the CCO or his/her nominee. All complaints received will be reported to the Board on their receipt.

8.2. Complaints concerning the Ethics Committee's review process

- 8.2.1. A complaint about the Ethics Committee's review process will be directed to the attention of the Chairperson of the Ethics Committee, detailing the grounds of the complaint.
- 8.2.2. All complaints received will be reported to the Board in an appropriate timeframe depending on the seriousness of the complaint and the timeframe in which it is resolved. All complaints will be at least notified in the annual reports made pursuant to section 4.5.2.
- 8.2.3. The Chairperson will investigate the complaint, and make a recommendation to the Ethics Committee on the appropriate course of action. If the complainant is not satisfied with the outcome of the preliminary investigation, then he/she can refer the complaint to the CCO or his/her nominee. The Chairperson will provide to the CCO all relevant information about the allegation(s).
- 8.2.4. The CCO will then determine if the complaint warrants investigation. If it is decided that the complaint does warrant investigation, then a suitable panel to review the complaint will be convened, ensuring that both the complainant and the Ethics Committee are afforded due process.
- 8.2.5. In conducting its review, the panel shall be concerned with ascertaining whether the Ethics Committee acted in accordance with the National Statement, its Terms of Reference, the Standard Operating Procedures, or otherwise acted in an unfair or biased manner.

- 8.2.6. The Ethics Committee will only consider review of an ethical decision where, upon investigation, a complaint about its ethical review process in making that decision is substantiated.

8.3. Complaints concerning the Committee's rejection of an application

- 8.3.1. A person with a complaint about the Ethics Committee's rejection of their proposal should bring the complaint to the attention of the Chairperson of the Ethics Committee, detailing the grounds of the complaint.
- 8.3.2. All complaints received will be reported to the Board 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 4.5.2.
- 8.3.3. The Chairperson will investigate the complaint and make a recommendation to the Ethics Committee on the appropriate course of action. If the complainant is not satisfied with the outcome of the preliminary investigation, then he/she can refer the complaint to the CCO or his/her nominee. The Chairperson will provide to the CCO all relevant information about the allegation(s). The CCO will then decide if the complaint warrants investigation.
- 8.3.4. If it is determined that the complaint does warrant investigation, then the CCO will convene a suitable panel to review the complaint, ensuring that both the complainant and the Ethics Committee are afforded due process.
- 8.3.5. The Chief Cancer Officer may:
- 8.3.5.1. Dismiss the complaint;
 - 8.3.5.2. Refer the complaint back to the Ethics Committee for consideration, bearing in mind the findings of the panel.
- 8.4. Should the Ethics Committee be requested to review its decision then the outcomes of the review of the Ethics Committee will be final. The Panel or the CCO cannot substitute approval for the application.

8.5. Alleged misconduct of a researcher

- 8.5.1. A person with a complaint about the alleged misconduct of a researcher involved in a proposal approved by the Ethics Committee should bring the matter to the attention of the Executive Officer in the first instance, detailing the grounds of the allegations. The Executive Officer in conjunction with the Chairperson of the Ethics Committee will investigate the allegations and make a recommendation on the appropriate course of action.

- 8.5.2. If the complainant is not satisfied with the outcome of the Committee's investigation, then he/she can refer the complaint to the CCO or his/her nominee. All complaints received will be reported to the Board on their receipt.

9. AMENDMENT TO THE TERMS OF REFERENCE

9.1. These Terms of Reference may be amended by the procedure outlined below:

9.1.1. In respect of proposals brought forward by Ethics Committee members:

- 9.1.1.1. The proposal must be in writing and circulated to all Ethics Committee members for their consideration;
- 9.1.1.2. The views of the members should be discussed at the next scheduled meeting of the Ethics Committee, and a vote taken at that meeting. Any member unable to attend such a meeting may register his or her views in writing;
- 9.1.1.3. The proposal brought forward shall be referred to the Board for review and agreement, where two thirds of the Ethics Committee members agree to the amendment;
- 9.1.1.4. The Board will consider the proposal and notify the Ethics Committee of the outcome of their consideration. If the Board 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 Ethics Committee meeting, and will take effect from that date.

9.1.2. Proposals brought forward by the Board:

- 9.1.2.1. The Board may put forward a proposal for amendment to the Terms of Reference;
- 9.1.2.2. Such proposals must be in writing and must first be agreed by the Board. The proposal shall then be circulated to all Ethics Committee Members for their consideration;
- 9.1.2.3. The proposal will be tabled at the next scheduled Ethics Committee meeting;
- 9.1.2.4. The Ethics Committee will provide its advice on the proposal to the Board as soon as practicable after the meeting at which it was considered;
- 9.1.2.5. The Board shall consider the advice of the Ethics Committee, 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 Ethics Committee meeting, and will take effect from that date.

10. REVIEW OF TERMS OF REFERENCE

10.1. These Terms of Reference will be initially reviewed at the end of twelve (12) months from their commencement, and thereafter at least every three years.

11. APPLICATION FEES

11.1. At its inception, fees will not be charged to investigators for applications submitted for review by the Ethics Committee (or, a fee will be charged).