

STANDARD OPERATING PROCEDURES

NSW POPULATION & HEALTH SERVICES RESEARCH ETHICS COMMITTEE

VERSION 1.0 – August 2006

PURPOSE & SCOPE

1. Under the *National Health and Medical Research Council Act 1992 (Cth)*, the Australian Human Research Ethics Committee (AHEC) was given statutory responsibility for the development of guidelines that governed the conduct of medical research involving humans. The primary guideline, the *National Statement on Ethical Conduct in Research Involving Humans* was developed in 1999, and is the principle guideline for all researchers wishing to conduct research with human participants.
2. The Standard Operating Procedures (SOPs) in the following document meet the Cancer Institute NSW obligations under Section 2.13 of the “*National Statement on Ethical Conduct in Research Involving Humans*” for the establishment of working procedures concerning the functions of Human Research Ethics Committees (HREC).
3. Under the *Cancer Institute NSW Act*, the Board of the Cancer Institute NSW has a statutory requirement to form a Human Research Ethics Committee to review research protocols relating to cancer research.
4. Further, the Board of the Cancer Institute NSW and the Director General, NSW Department of Health, has elected the Cancer Institute NSW to co-ordinate the development of operational systems for the Ethics Committee, including systems to aid researchers in complying with the regulations. This role includes the development of standard operating procedures for the Ethics Committee, the development of ‘*Researcher Guidelines for Submission*’, and the provision of operational advice and assistance.

IMPLEMENTATION

5. This version of the ‘*Cancer NSW Population & Health Services Research Ethics Committee Standard Operating Procedures*’ is due to come in to effect on August 1st 2006.
6. The Ethics Committee may, in consultation with the Cancer Institute NSW Board and the Director General, NSW Department of Health, develop additional operating procedures to deal with matters specific to the Ethics Committee.

TERMINOLOGY

7. A guide to the terminology used in the SOPs is set out in Section 1. The following should be noted:
 - 7.1. All reference to ‘the Chair’ of the Ethics Committee should be interpreted as referring also to the vice-chair when acting in place of the Chair; or, if neither is available, to the alternate vice-chair.

DEFINITIONS AND ACRONYMS

Board:	Cancer Institute NSW Board
Cancer Institute NSW:	Cancer Institute NSW, as constituted 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
Director-General:	Director-General, NSW Department of Health or his/her delegate
Ethics Committee:	NSW Population & Health Services Research Ethics Committee
Executive Officer:	Executive Officer, NSW Population & Health Services Research Ethics Committee
Chair:	Chairperson, NSW Population & Health Services Research Ethics Committee
Lead Committee:	A Human Research Ethics Committee accredited by NSW Health to conduct the single ethical and scientific review of multi-centre research projects
NSW Health Single Ethical Review Participants:	Those NSW Health bodies which have signed a Memorandum of Understanding to which the Cancer Institute 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
Research governance:	A framework through which research is effectively oversighted, such that it meets appropriate standards of quality, safety, privacy, risk management and financial management.

OBJECTIVES

1. The objectives of the Ethics Committee are to:
 - 1.1. Provide advice to the Director-General and the Board on the ethical acceptability of research proposals submitted to it for approval;
 - 1.2. Provide advice to the Director-General and the Board on issues related to the ethical conduct of research that might arise from time to time;
 - 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 Health Single Ethical Review Participants.
 - 1.4. Protect the rights, including mental & physical wellbeing, dignity & safety of participants of research;
 - 1.5. Facilitate ethical research through efficient and effective review processes;
 - 1.6. Promote ethical standards of human research;
 - 1.7. Review research in accordance with the National Statement;
 - 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;
 - 1.9. 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;

OVERALL FUNCTION

2. The overall functions of the Ethics Committee are to:
 - 2.1. Provide independent, competent and timely review of research proposals submitted to it for approval, in respect of their ethical acceptability;
 - 2.2. Act in accordance with NHMRC guidelines pertaining to HREC, including the National Statement.

SCOPE OF RESPONSIBILITY

3. Research proposals involving humans will be ethically assessed by the Ethics Committee where the research involves population health research which utilises population health data collections owned and/or managed by NSW Health or the Cancer Institute NSW.
4. This includes, but is not limited to, the area of cancer.
5. In relation to point 3.0, research proposals to be ethically assessed by the Ethics Committee may include:
 - 5.1. Population health research utilising data from the NSW Central Cancer Registry, the NSW Pap Test Registry, Breast Screen Registry, and other data and information collected, held and/or managed by the Cancer Institute NSW;
 - 5.2. Population health research utilising data from the NSW Health Inpatient Statistics Collection, the NSW Midwives Data Collection, the NSW Emergency Department Data Collection, and other data and information collected, held and/or managed by NSW Health;
 - 5.3. Research involving the linkage of a population health data collection owned and/or managed by NSW Health or the Cancer Institute NSW, with other data collections.
6. The Ethics Committee may, at its discretion, review research proposals to be undertaken by NSW Health or Cancer Institute NSW staff.
7. In addition, the Ethics Committee may, at its discretion, assess research proposals relating to the following areas, provided these are within the jurisdiction of one or more of the HREC of NSW Single Ethical Review Participants:
 - 7.1. Population health and health services research relating to cancer; and
 - 7.2. Population health and health services research generally.
8. The Ethics Committee may 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 both NSW Health and the Cancer Institute NSW prior to distribution.
9. 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 and the relevant privacy legislation that exist at both State and Federal level.
10. The Ethics Committee may provide assistance or advice to other HREC regarding issues that fall within the specific expertise of the Ethics Committee.
11. The Cancer Institute NSW will maintain the administrative responsibility for the Ethics Committee, and will liaise with the appropriate individuals at the NSW Department of Health as required.

COMPOSITION

12. The core membership of the Ethics Committee will be in accordance with the National Statement and any amendments to them as issued from time to time.
13. The core membership is to comprise of:
 - 13.1. A chairperson;
 - 13.2. At least two (2) members who are lay people, one man and one woman, who have no affiliation with the Cancer Institute NSW or NSW Health, and are not currently involved in medical, scientific or legal work;
 - 13.3. 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;
 - 13.4. At least one (1) member who persons a pastoral care role in a community, for example a minister of religion or an Aboriginal Elder;
 - 13.5. At least one (1) member who is a lawyer, but not a lawyer engaged or employed to advise the NSW Department of Health or the Cancer Institute NSW; and
 - 13.6. At least two (2) members with current research experience relevant to research proposal to be considered at the meetings they attend. These two members may be selected, according to need, from a pool of further members.
14. No member may be appointed in more than one of the above categories, but in each category alternating members may be appointed.
15. In addition to the membership outlined in point 13, wherever possible, membership will also include:
 - 15.1. A NSW Health Public Health Officer Trainee; and
 - 15.2. A nominee of the NSW Health Deputy Director-General, Population Health and Chief Health Officer.
16. Additional members may be appointment to ensure the Ethics 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. This may include the appointment of alternate members.
17. Where required, the Ethics Committee may seek advice and assistance from experts to assist with consideration of a project.
18. The Ethics Committee must, however, be satisfied that such experts have no conflicts of interest in relation to the project under consideration, arising from any personal involvement or participation in the project, any financial interest in the outcome of the project or any involvement in a competing project.

19. Any person(s) consulted by the Ethics Committee shall be required to provide an undertaking of confidentiality and shall not be able to vote on any matter.
20. 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 Director-General and the Board. Members of any such sub-committee need not be members of the Ethics Committee.

APPOINTMENT OF MEMBERS

21. The Director General and the Board will appoint the founding members of the Ethics Committee. Thereafter, appointments will be made by the Director-General and the Board, in consultation with the Ethics Committee as deemed appropriate.
22. Prospective members will be recruited through appropriate means, such as spontaneous expressions of interest, objective nominations and externally advertised calls for expressions of interest.
23. A selection committee, constituted by two nominees of the Director-General and the Board shall review nominations and/or interview prospective applicants and make a recommendation regarding membership to the Director-General and the Board.
24. Thereafter, the selection committee shall follow the same process for appointment but shall also consult with the Ethics Committee.
25. Members are appointed as individuals for their knowledge, qualities and experience. They are not appointed as representatives of any organisation, community or opinion.
26. The Ethics Committee's secretariat will provide all members of the Ethics Committee with formal notice of appointment and an assurance of legal protection with respect to liabilities that may arise in the course of bona fide conduct of their duties as HREC members.
27. Founding members are appointed for an initial term of one (1) year. Thereafter, members shall be appointed for three year terms. Members may serve a maximum of two consecutive terms, unless otherwise approved by the Director-General and the Board.
28. Membership will lapse if a member fails, without reasonable excuse to attend (or provide comprehensive written comments) to three (3) consecutive meetings of the Ethics Committee, unless exceptional circumstances exist. The Chairperson will notify the member, in writing, of such a lapse of membership.
29. Members may seek a leave of absence from the Ethics Committee for extended periods.
30. 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 SOP003.

31. The Director-General and Board may agree to terminate the appointment of any member of the HREC if they are of the opinion that:
 - 31.1. It is necessary for the proper and effective functioning of the HREC;
 - 31.2. The person is not a fit and proper person to serve on an HREC;
 - 31.3. The person has failed to carry out their duties as an HREC member.
32. The Chairperson and Deputy Chairperson will be appointed by the Director-General and the Board conjointly. The Ethics Committee may nominate candidates for the position of Chairperson and Deputy Chairperson.
33. In the absence of the Chairperson, the Deputy Chairperson will perform the role and duties of the Chairperson.
34. 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.
35. The Chair of any such sub-committee will be appointed by the Director-General and the Board. Members of any such sub-committee need not be members of the Ethics Committee.

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**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedures**

Reference: SOP001 – Conditions of Membership of the Ethics Committee

Date: August 2006

Subject: To describe the conditions of membership to the Ethics Committee

REQUIRMENTS

1. Members will:
 - 1.1. Agree to their name and profession being made publicly available.
 - 1.2. Be required to sign the 'Code of Conduct for Committees of the Cancer Institute NSW' and a statement undertaking:
 - 1.3. Keep all matters of which he/she becomes aware during the course of his/her work on the Ethics Committee confidential;
 - 1.4. Declare any conflicts of interest, which exist or may arise during his/her tenure on the Ethics Committee; and
 - 1.5. Ensure 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.

REIMBURSEMENT

2. Members will not be offered remuneration.
3. Members will be reimbursed for legitimate expenses incurred in attending Ethics Committee meetings or in otherwise carrying out the business of the Ethics Committee.

EDUCATION

4. Newly appointed members shall be provided with adequate orientation, and be provided with a copy of the Members Reference Guide for their information.
5. Members will be asked to participate in relevant specialised working groups as required.
6. Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the Ethics Committee.
7. Expenses for these activities will be covered by the Cancer Institute and NSW Health at the discretion of the Ethics Manager, Cancer Institute NSW.

LIABILITY COVERAGE

8. The Cancer Institute and NSW Health, through the NSW Treasury Managed Fund (TMF) will provide indemnity for members of the Ethics Committee for any liabilities that arise as a result of the member exercising his or her duties as a member in good faith.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedures**

Reference: SOP002 – Reporting Requirements of the Ethics Committee

Date: August 2006

Subject: To describe the reporting requirements for the Ethics Committee

THE BOARD AND DIRECTOR GENERAL

1. The Director-General and the Board shall be informed of the decisions of the Ethics Committee on proposals submitted to it on a regular basis.
2. This will occur either through the submission of the minutes of Ethics Committee meetings, or through the submission of an annual report.
3. The Ethics Committee will report annually to the Director-General and the Board on its activities and its compliance with the reporting and monitoring requirements of the National Statement.
4. The report will include at least information on membership, meeting attendance, the number of proposals reviewed by the Ethics Committee, status of proposals, and a description of any complaints received and their outcome, and any other matters of an ethical nature as may have arisen.
5. The Ethics Committee will bring to the attention of the Director-General and the Board any issues of significant concern regarding matters within its scope of responsibility.

THE AUSTRALIAN HEALTH ETHICS COMMITTEE (AHEC)

6. The Ethics Committee will provide reports to the AHEC in accordance with the requirements of the NHMRC. This includes reporting annually about information relevant to the committees procedures such as:
 - 6.1. Membership/membership changes;
 - 6.2. Number of meetings;
 - 6.3. Confirmation of participation by required categories of members;
 - 6.4. The number of protocols presented, the number approved, and the number rejected;
 - 6.5. Monitoring procedures in place and any problems encountered; and
 - 6.6. Complaints procedures and number of complaints handled.

NSW PRIVACY COMMISSIONER

7. The Ethics Committee will provide reports to the NSW Privacy Commissioner in accordance with the requirements of the *Health Records and Information Act 2002 (NSW)*.

OTHER

8. The Ethics Committee will report on research projects involving humans in accordance with the NSW Health Circular 2001/66 'Responsibilities of Area Health Services regarding reporting on research activities'.
9. 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.
10. 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 and NSW Health websites.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedures**

Reference: SOP003 – Submission of applications for ethical review

Date: August 2006

Subject: To describe the procedure for submitting research applications to the Ethics Committee for ethical review

1. All applications for ethical review by the Ethics Committee must be submitted by close of business on the relevant closing date.
2. Procedures for submission are explained in the *'Guidelines for Submission to the NSW Population & Health Services Research Ethics Committee'*, available on request and from the Cancer Institute NSW website.
3. The closing dates for receipt of submissions for ethical consideration will be 21 working days prior to each Ethics Committee meeting.
4. Dates shall be available to prospective applicants on the Cancer Institute NSW and NSW Health websites.
5. All proposals for ethical assessment must be submitted using the National Health and Medical Research Council's 'National Ethics Application Form' (NEAF) accessible at www.neaf.gov.au
6. The applicant will be required to complete all sections of the application form and include all relevant documentations.
7. Prior to submitting a protocol to the Ethics Committee for review, chief investigators are to obtain the necessary approvals from the data custodian/s for the data items they wish to access.
8. Incomplete application forms will generally be returned to the applicant for completion. However, minor omissions may, at the discretion of the Ethics Committee's Executive Officer, be remedied by the applicant within a specified time frame.
9. The applicant will be required to submit as many copies of the application and supporting documentation as the Ethics Committee considers necessary to enable it to carry out a proper review.
10. The Executive Officer will undertake an administrative review of the application prior to acceptance onto the agenda, to ensure that the application has been completed and that there are no obvious omissions.
11. Inclusion of an application on the meeting agenda will be at the discretion of the Executive Officer, in consultation with the Chairperson.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedures**

Reference: SOP004 – Executive Officer Responsibilities

Date: August 2006

Subject: To describe the responsibilities of the Executive Officer of the Ethics Committee

ON RECEIPT OF APPLICATIONS

1. On receipt of a completed submission for ethical review, the Executive Officer will:
 - 1.1. Ensure each application has been assigned a unique identification number, known as the Project Number.
 - 1.2. Open and maintain a confidential hard copy file for each application, including the original application and all subsequent information and correspondence relevant to the application. This hard copy file will be kept securely and confidentially at the Cancer Institute NSW.
 - 1.3. Provide applicants with correspondence confirming the receipt of their application, and provide details of the project number, and the date of the Ethics Committee meeting at which the proposal will be reviewed.
 - 1.4. Record the application on the a designated database housed at the Cancer Institute NSW; including NHMRC prescribed items of information: project identification number, the name of the responsible institution or organization, the name and qualifications of the Chief Investigator, title of the project and whether the project is multi-centred.

PRIOR TO ETHICS COMMITTEE MEETINGS

2. The Executive Officer will:
 - 2.1. Distribute to Ethics Committee members all relevant documentation relating to the research proposals received for review.
 - 2.2. Compile and distribute the meeting agenda to Ethics Committee members, as per SOP 008.
 - 2.3. The Executive Officer will refer the application to the Cancer Institute NSW Panel of Scientific Experts, in accordance with SOP 006.
 - 2.4. The Executive Officer may delegate consideration of certain scientific, technical or legal matters to a member or sub-committee of its members, or seek expert external advice as required.
 - 2.5. In accordance with SOP 007, research proposals may be referred to an executive Sub-Committee of the Ethics Committee for expedited review.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedures**

Reference: SOP005 – Data Governance Review

Date: August 2006

Subject: To describe the process of referring issues of data governance

INTRODUCTION

1. The Ethics Committee will be responsible for ethical review and oversight only. Matters of research governance, including responsibility for determining whether the resources, facilities and staff at the site at which the research is to be conducted are appropriate, are the responsibility of the individual institutions.
2. Research Governance issues include, but are not limited to, issues relating to contractual arrangements between the parties to the research, insurance and indemnity arrangements, regulatory and financial agreements and issues surrounding access of data.
3. The assessment of research governance within the Cancer Institute NSW will be undertaken by the Division of Registries and Population Health, and will assess the extent to which the proposed research protocol will impact on the registries.
4. Within NSW Health, this will be undertaken by the responsible Branch of the NSW Department of Health.

PROCESS OF REFERRAL

5. The referral of data governance issues will occur in parallel to the ethical assessment of the research protocol.
6. Investigators will be required, PRIOR to submitting an application for ethical review, to contact the relevant Data Custodian in order to begin the process of data governance review.
7. On receipt of a research proposal, the Executive Officer will undertake a review of the documentation to ensure that contact with the Data Custodian has been made by investigators.
8. If such contact has not been made, or is not evident in the provided documentation, the Executive Officer will contact the investigator and inform them that their proposal WILL NOT be reviewed until contact with the appropriate Data Custodian is made.
9. It should be noted that such contact does not constitute a review of data governance issues.
10. On confirmation of investigator contact with a Data Custodian, the Executive Officer will request the Data Custodian to undertake a formal data governance review of the research proposal.
11. This will occur within five (5) days upon submission of an application for ethical review.

12. Such review will occur according to the Cancer Institute NSW Data Governance Policy, available at the Cancer Institute NSW website.

FOLLOWING REVIEW

13. The Data Custodian will be required to complete an assessment of the data governance issues and submit this review to the Executive Officer within a specified timeframe.
14. A copy of this completed assessment will be stored in the confidential project file maintained at the Cancer Institute NSW.
15. Further information surrounding the procedures for this assessment can be found within the Cancer Institute NSW Data Governance Policy available from the Division of Cancer Information and Registries.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedures**

Reference: SOP006 – Referral for Scientific Review

Date: August 2006

Subject: To describe the process of referring an application for scientific review

ON RECEIPT OF APPLICATION

1. On receipt of a research proposal, the Executive Officer will:
 - 1.1. Within three (3) working days of receiving the application, identify and confirm the availability of a member of the scientific review panel.
 - 1.2. Refer the application to the nominated panel of Scientific Experts for scientific review. This referral will occur electronically.
 - 1.3. Prior to a formal report being forward to the Ethics Committee by the selected scientific reviewer, reviewers will be provided with the opportunity to convene a forum to allow reviewers the opportunity to access the views and/or opinions of follow reviewers prior to formally submitting a report. Such a forum is not mandatory.

ON RECEIPT OF SCIENTIFIC REVIEW

2. A formal scientific review will be forwarded to the Executive Officer, in accordance with the Cancer Institute NSW Policy on Scientific Review.
3. The Executive Officer will ensure the completed scientific review report is forwarded to members of the Ethics Committee prior to the Committee meeting at which the application will be discussed.
4. The spokesperson(s) delegated to discuss the application will also initiate discussion relating to the scientific review report.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedures**

Reference: SOP007 – Executive Sub-Committee of the Ethics Committee

Date: August 2006

Subject: To describe the process of referring items of business to the Executive Sub-Committee for expedited review

COMPOSITION

1. The Executive Sub-Committee of the Ethics Committee shall comprise of the:
 - 1.1. Chairperson;
 - 1.2. Executive Officer; and
 - 1.3. One other member of the Ethics Committee.

REFERRAL OF ITEMS OF BUSINESS

2. At the discretion of the Chairperson, expedited review of items of business that are considered to be of low risk may be considered by the Executive Sub-Committee between scheduled meetings. This may include some adverse events, some protocol reports, and minor amendments.
3. The minutes of Executive Sub-Committee meetings will be tabled for ratification at the next Ethics Committee meeting.
4. Research with the potential for physical or psychological harm should generally not be considered for expedited review. This includes research exploring sensitive personal or cultural issues.
5. Where the Chairperson considers that the research may involve a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the project must be considered by the full Ethics Committee and cannot be dealt with by expedited review.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedures**

Reference: SOP008– Agenda preparation

Date: August 2006

Subject: To describe the process and format of agenda for a meeting of the Ethics Committee.

1. The Executive Officer will prepare an agenda for each Ethics Committee meeting.
2. All completed applications and relevant documentation received by the Executive Officer by the closing date will be included on the agenda for the Committee's consideration at its next available meeting.
3. Correspondence and other documents received after the closing date may be included on the agenda at the discretion of the Chairperson/Executive Officer.
4. Under no circumstances shall new applications be tabled at the meeting.
5. The agenda format will include where appropriate the following items:
 - 5.1. Attendance / apologies;
 - 5.2. Potential Conflicts of Interest;
 - 5.3. Minutes of the previous meeting;
 - 5.4. Business arising from previous minutes;
 - 5.5. New proposals for ethical review;
 - 5.6. Amendments;
 - 5.7. Progress/Annual reports;
 - 5.8. Completed projects;
 - 5.9. Correspondence;
 - 5.10. Other business; and
 - 5.11. Next meeting.
6. The agenda, including a copy of each new application and relevant documents, will be distributed to all members of the Committee at least five (5) working days prior to the meeting. To ensure confidentiality, the agenda is to be distributed by courier or some form of registered mail.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedures**

Reference: SOP009 – Conducting a meeting of the Ethics Committee

Date: August 2006

Subject: To describe the format of meetings of the NSW Population & Health Services Research Ethics Committee

1. The Ethics Committee shall meet on a regular basis, which will be on a monthly cycle.
2. Meetings will be held in the Boardroom of the Cancer Institute NSW, Level 1, Biomedical Building, Australian Technology Park, Eveleigh, NSW 2015
3. Meeting dates and agenda closing dates will be readily available to the public and can be accessed from the Cancer Institute NSW and NSW Health websites.
4. Ethics Committee members may attend Ethics Committee meeting in person or via a telecommunication link, or a video link.
5. Members should negotiate with the Executive Officer if attendance in a manner other than in person is to be a regular occurrence.
6. Ethics Committee members who are unable to attend a meeting in any form may contribute to the meeting through a written submission to the Executive Officer or Chairperson.
7. The Chairperson, in consultation with the Executive Officer, may cancel a scheduled meeting if a quorum cannot be achieved.
8. The Ethics Committee will convene within 5 working days of the cancelled meeting to ensure all agenda items are considered (refer to point 8).
9. The Ethics Committee meetings will be conducted in private, to ensure confidentiality and open discussion. The Ethics Committee may however, agree to the presence of visitors or observers at the meeting.
10. A quorum shall exist when a representative of each of the categories outlined at SOP001 is present or has had the opportunity to contribute to the meeting's deliberations through the submission of written comments prior to the meeting.
11. In the event that a member of the core category is not in attendance at a meeting, an ethical determination cannot be made without either written comment from the absent member prior to the meeting, or by their ratification of the decisions of the Ethics Committee.
12. As per SOP 001, any member of the Ethics Committee who has any interest, financial or otherwise, in a proposal or other related matter considered by the Ethics Committee, should as soon as practicable declare such interest.

13. The Ethics Committee will determine if this results in a conflict of interest for the member and, if so, the member will withdraw from the meeting until the Ethics Committee's consideration of the relevant matters has been completed.
14. All declarations of interest and the absence of the member concerned will be minuted.
15. The Ethics Committee will endeavour to reach a decision concerning ethical acceptability of a proposal by unanimous agreement.
16. Where unanimous decisions cannot be reached, the decision will be considered to be carried by the majority of two-thirds of members who examined the proposal, provided that the majority includes at least one lay person.
17. Any significant minority view (i.e. two (2) or more members) will be noted in the minutes. A lesser minority view may also be noted, if such a request is made.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedure**

Reference: SOP010 – Consideration of research proposals requesting ethical review

Date: August 2006

Subject: To describe the process of the Ethic Committee's consideration of applications for ethical review

1. The Ethics Committee will consider a new application at its next available meeting provided that the application is received by the Executive Officer by the relevant closing date.
2. The application will be reviewed by all members of the Ethics Committee who are present at the meeting or have provided written comments in lieu of attendance.
3. The Ethics Committee will ethically assess each application in accordance with the National Statement. The Ethics Committee must ensure that it is sufficiently informed on all aspects of the research protocol, including its scientific validity, in order to make an ethical assessment.
4. Two members of the Ethics Committee will be designated as the 'spokespersons' for the project, for the purpose of initiating discussion of the project at the meeting.
5. In relation to Scientific Review, please refer to SOP 006.
6. The Ethics Committee's assessment of proposals involves consideration of each section of the application form, and the NSW Health Privacy Manual. Some of the issues considered include:
 - 6.1. How significant is the research/project?
 - 6.2. Is the design of the project valid?
 - 6.3. Will the project achieve its aims?
 - 6.4. Is it essential that identifiable or potentially identifiable data be used for the project?
 - 6.5. Does the investigator have the skills to successfully complete the project?
 - 6.6. Is the requested level of access to data the minimum required in order to achieve the project's objectives?
 - 6.7. Will informed consent be obtained from the subjects/participants?
 - 6.8. If informed consent will not be obtained, what justification is there for this?
 - 6.9. Does the public interest in the proposed project outweigh the public interest in the protection of privacy?
 - 6.10. How will the data be stored and protected?
7. In order to facilitate the Ethics Committee's consideration of an application, the Ethics Committee may request the applicant to attend a meeting, either in person or via telecommunications link.

8. 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.
9. The Ethics Committee may take into account the views or opinions on the research proposal held by another properly constituted HREC under the National Statement. The Ethics Committee may take into account the views or opinions of any scientific review of the research proposal undertaken by a recognised peer group.
10. Following consideration of a proposal, the Ethics Committee will make one of the following decisions:
 - 10.1. It will grant ethical approval of the project;
 - 10.2. It will grant ethical approval of the project subject to either the clarification of information, the provision of further information, or requested changes;
 - 10.3. It will defer making a decision on the project until the clarification of information, the provision of further information or requested changes are provided to the Ethics Committee;
 - 10.4. It will request a re-submission of the project; or
 - 10.5. It will reject the project, i.e. will not recommend ethical approval.
11. The Ethics Committee will endeavour to reach a decision concerning ethical acceptability of a proposal by unanimous agreement.
12. Where unanimous decisions cannot be reached, the decision will be considered to be carried by the majority of two-thirds of members who examined the proposal, provided that the majority includes at least one lay person.
13. Any significant minority view (i.e. two (2) or more members) will be noted in the minutes. A lesser minority view may also be noted, if such a request is made.
14. For proposals where the Ethics Committee has requested clarification, the provision of further information, or requested changes, the Ethics Committee may choose to delegate to the Chairperson or to an executive of nominated members the authority to approve proposals in between meetings.
15. Under the Cancer Institute NSW policy on single ethical review, applications must remain in the hands of the Ethics Committee for no more than 60 days.
16. This timeline will commence on the application closing date, and will be measured on a stop-clock basis. For example, the 60 day clock will stop when the application has been returned to the investigator by the Ethics Committee for amendments prior to ethical approval being granted.
17. In general, if ethical approval is granted, the ethical approval is granted for the stated duration of the project plus an additional year.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedures**

Reference: SOP011 – Minutes preparation

Date: August 2006

Subject: To describe the process and format for minutes of a meeting Ethics Committee.

1. The Executive Officer will prepare and maintain minutes of all meetings of the Ethics Committee.
2. The format of the minutes will include, where appropriate, the following items:
 - 2.1. Attendance / apologies;
 - 2.2. Potential Conflicts of Interest;
 - 2.3. Minutes of the previous meeting;
 - 2.4. Business arising from previous minutes;
 - 2.5. New proposals for ethical review;
 - 2.6. Amendments;
 - 2.7. Progress reports;
 - 2.8. Completed projects;
 - 2.9. Correspondence;
 - 2.10. Other business; and
 - 2.11. Next meeting.
3. The minutes should include the recording of decisions taken by the Ethics Committee as well as a summary of the proposal and the Ethics Committee's discussion. This includes reference to views expressed by absent members.
4. The minutes should include a detailed summary of the ethical issues that were discussed in relation to a new proposal or amendment and, where appropriate, reflection on the National Statement in considering the issues identified.
5. In recording a decision made by the Ethics Committee, any dissenting view will be noted in the minutes. A lesser minority view (i.e. 2 or more members) will be noted in the minutes. A lesser minority view may also be noted, if such a request is made.
6. To encourage free and open discussion and to emphasise the collegiate character of the Ethics Committee, particular views should not be attributed to particular individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections recorded.

7. Declarations of conflicts of interest by any member of the Ethics Committee and the absence of the member concerned during the Ethics Committee's consideration of the relevant application made in accordance with SOP 001 will be minuted.
8. The minutes should be produced as soon as practicable following the relevant meeting and should be checked by the Chairperson, Deputy Chairperson or an appropriate member of the Ethics Committee, for accuracy.
9. The minutes should be circulated to all members of the Ethics Committee as an agenda item for the next meeting. All members will be given the opportunity to seek amendments to the minutes prior to ratification of the minutes.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedure**

Reference: SOP012 – Notify investigators of the decision of the Ethics Committee

Date: August 2006

Subject: To describe the process of notifying investigators of the outcome of the NSW Population & Health Services Research Ethics Committee

1. The Ethics Committee upon making its decision, will, in writing, inform the nominated the Chief Investigator of the outcome of ethical review, be it approval or rejection, within five (5) working days of the meeting unless otherwise notified.
2. If the Ethics Committee determines that further information, clarification or modification is required for the consideration of the project, correspondence will be sent to the Chief Investigator which should articulate the reasons for the determination, and clearly set out the information that is required.
3. Where, possible, requests for additional information / clarification / modification should refer to the National Statement or other relevant guidelines and/or legislation.
4. If the requested information is not received by the Ethics Committee within three (3) months or three (3) meetings (whichever occurs sooner), the project will be dismissed and the applicant will need to re-submit the application for review at a later date.
5. The Ethics Committee shall endeavour to foster open communication with applications to resolve outstanding requests for information, clarification or modification of projects relating to ethical issues. The Ethics Committee may nominate one of its members to communicate directly with the applicant, or invite the applicant to attend the relevant Ethics Committee meeting.
6. Any notification of ethical approval must include reference to the following:
 - 6.1. The title of the project;
 - 6.2. Name of the Chief Investigator(s);
 - 6.3. The unique Ethics Committee project number;
 - 6.4. Specific reference to all documents reviewed by the Ethics Committee including the date of such documents;
 - 6.5. The date of the meeting during which the application was considered;
 - 6.6. The date of ethical approval by the Ethics Committee;
 - 6.7. The duration of the approval; and
 - 6.8. The requirement that the project should be conducted in accordance with the National Statement, the NSW Health Privacy Manual (2004), the *Health Records and Information Privacy Protection Act 2002* (NSW) and any other relevant guidelines and/or legislation;

- 6.9. The requirement that the project will be carried out as described in the application and in accordance with all subsequent correspondence;
 - 6.10. The Chief Investigator is to advise the Committee of any changes to the project or its conduct, if any unforeseen and/or adverse events take place that might affect continued ethical approval of the project, or if the project is abandoned for any reason. New ethical approval must be sought for substantially altered or revised research protocols;
 - 6.11. In order to fulfil the monitoring requirements of the Ethics Committee and the NHMRC, a report is required annually and at the completion of the study. Ethical approval may lapse unless the report is received; and
 - 6.12. Any other information the Ethics Committee deems necessary.
7. If the Ethics Committee deems the project to be ethically unacceptable, the notification of the Ethics Committee's decision should include the grounds for rejecting the project with reference to the National Statement and/or other relevant guidelines and/or legislation.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedures**

Reference: **SOP013 – Approving access to data owned or held by the Cancer Institute NSW**

Date: August 2006

Subject: To describe the process of approving an applicant's request to access data owned or held by the Cancer Institute NSW

1. Where an investigator is requesting access to data owned or held by the Cancer Institute, approvals must be obtained from the relevant data custodian prior to submitting an application to the Ethics Committee.
2. The Data Custodian will review the application as part of the Data Governance review, and develop documentation outlining the exact nature of the data requested by the applicant. This documentation will be known as Schedule 1.
3. The Executive Officer will notify the data custodian of decision of the Ethics Committee.
4. The CCO will, at the request of the Ethics Committee, write to the Director-General of NSW Health, within 7 working days of the meeting, advising of the Ethics Committee's decision, recommendations and any conditions imposed, and seeking the approval of the appropriate officer under the *Public Health Act* and regulations, and/or the *Health Administration Act* and regulations for this access to be given.
5. Any such letter will enclose a copy of Schedule 1, the ethics application form, and the research proposal.
6. Upon receipt of an approval to disclose the data from the appropriate officer, and resolution of any data governance issues, the Executive Officer will:
 - 6.1. Send correspondence to the Chief Investigator notifying them of the Ethics Committee's decision to give ethical approval.
 - 6.2. Include any conditions imposed by the Ethics Committee relating to both the ethical acceptability of the protocol, and any data governance issues in such correspondence.
 - 6.3. Enclose a copy of the approval to disclose the data from the appropriate officer, a copy of Schedule 1, as created by the data custodian, and a confidentiality undertaking which must be signed by the Chief Investigator prior to disclosure of the data.
7. A full copy of the application, including all correspondence, the Schedule 1 documentation, approvals to disclose and confidentiality undertaking letters will be provided to the data custodian for their own records.
8. For further information about the Cancer Institute NSW policy on the role of the Data Custodian, please refer to the Cancer Institute NSW Data Management Policy.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedure**

Reference: SOP013A – Approving access to data owned or held by NSW Health

Date: June 2006

Subject: To describe the process of approving an applicant's request to access data owned or held by NSW Health.

1. Where an investigator is requesting to access data owned or held by NSW Health, approvals must be obtained from the data custodian/s for the data items they wish to access prior to submitting an application to the Ethics Committee.
2. The Executive Officer will notify the data custodian once the request for access or linkage to the data has been approved by the Ethics Committee,
3. In accordance with SOP007, NSW Health will undertake a research governance assessment of the research proposal to assess the impact of releasing the data.
4. The data custodian will seek the approval of the appropriate officer under the Public Health Act and regulations, and the Health Administration Act and regulations.
5. Upon receipt of an approval to disclose from the appropriate officer, and an assessment, and resolution, of research governance issues, the Executive Officer will:
 - 5.1. Send correspondence to the Chief Investigator notifying them of the Ethics Committee's approval of the project, including any conditions imposed by the Ethics Committee.
6. Upon receipt of an approval to disclose from the appropriate officer, NSW Health will send a letter to the Chief Investigator enclosing a copy of the approval to disclose the data from the appropriate officer, and a confidentiality undertaking which must be signed by the Chief Investigator prior to disclosure of the data.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedures**

Reference: SOP014 – Submission of amendments and extensions to ethically approved projects

Date: August 2006

Subject: To describe the process of submitting applications for amendments of extensions of projects which already have ethical approval.

INTRODUCTION

1. Proposed changes to approved research projects, including conduct of the research and requests for extensions to the length of ethical approval, must be reported by the Chief Investigator to the Ethics Committee for approval.
2. Requests must outline the nature of the proposed changes and/or request for extension, reason/s for the request and an assessment of any ethical implications arising from the request on the conduct of the research.
3. All amended documents must have the changes highlighted and contain revised version numbers and dates.

PROCESS OF REVIEWING ADMENMENT REQUESTS

4. Request for amendments shall be reviewed by the Ethics Committee at the next available meeting, provided that the request has been received by the Executive Officer by the relevant closing date.
5. If the amendments are deemed suitable for expedited review, this shall occur as per SOP007.
6. Any discussion of these amendments and/or requests for extension should be minuted.
7. Where an urgent protocol amendment is required for safety reasons, the Chairperson will seek a process to expedite review.
8. The Ethics Committee will report in writing to the Chief Investigator of the ethical approval of the proposed amendment and/or request for extension, within five (5) working days of the meeting at which the request was discussed.
9. If the Ethics Committee determines that further information, clarification or modification is required for consideration of the request for amendment or extension, the correspondence to the Chief Investigator should clearly articulate the reasons fro this determination, and clearly set out the information that is required.
10. Where possible, requests for additional information/clarification/modification should refer to the National Statement or relevant guidelines or legislation.

NSW Population & Health Services Research Ethics Committee

Standard Operating Procedure

Reference: SOP015 – Reporting and Handling Adverse Events

Date: August 2006

Subject: To describe the process of reporting and handling adverse events

INTRODUCTION

An adverse event is a term defined in the *National Statement on Ethical Conduct in Research Involving Humans*, 1999, that relates specifically to human participants in a research project. It refers to an unfavourable occurrence relating to a person participating in a project and which may or may not have a causal relationship to the project.

“Adverse events include physical reactions to drugs or any other interventional procedure, but also emotional and/or psychological distress e.g. due to the nature of questions in a questionnaire, complaints against privacy etc.”

INVESTIGATOR RESPONSIBILITY

1. It is a condition of ethical approval that Chief Investigators advise the Ethics Committee of any adverse events that take place.
2. Chief Investigators should immediately report all adverse events to the Committee.
3. Reporting should be made in writing and directed to the Chairperson of the Ethics Committee. The reporting should include comment from the investigator on whether, in his/her opinion, the adverse event was related to the project.

CONSIDERATION BY THE ETHICS COMMITTEE

4. In general, adverse events will be considered by the Ethics Committee at its next scheduled meeting, at which the Committee will determine the appropriate course of action. This could include:
 - 4.1. Notation on file of the occurrence;
 - 4.2. Increased monitoring of the project;
 - 4.3. Suspension of ethical approval;
 - 4.4. Termination of ethical approval; or
 - 4.5. Request for an amendment to the project.
5. For adverse events deemed by the Chairperson as serious and requiring immediate attention, the Chairperson will take such action as considered necessary. In these circumstances, discussion will be brought to the Ethics Committee for ratification.
6. The Ethics Committee shall inform the investigator of its intention to take any action.

NSW Population & Health Services Research Ethics Committee

Standard Operating Procedure

Reference: SOP016 – Monitoring of ethically approved projects

Date: June 2006

Subject: To describe the process of monitoring studies/project already given ethical approval by the Ethics Committee

1. The Ethics Committee will monitor the progress of all proposals for which it has granted ethical approval to ensure it is complying with the guidelines set down in its proposal and those contained in the National Statement.
2. The Ethics Committee may request and discuss information on any relevant aspects of the project with the investigators at any time.
3. In particular, the Ethics Committee will require applicants to provide an annual report, and a final report at the project's completion. Continuing approval of the research will be subject to the Chief Investigator's completion of annual reports.
4. The Ethics Committee shall required the following information to be provided in the annual report:
 - 4.1. Progress to date or outcome in relation to a completed project;
 - 4.2. Maintenance and security of research documentation and data;
 - 4.3. Compliance with the approved protocol; and
 - 4.4. Compliance with the conditions of approval.
5. Report Forms will be readily available from the Ethics Committee's Executive Officer, and the Cancer Institute NSW and NSW Health web sites.
6. To ensure a project is monitored annually, reports should be received in time for consideration by the Ethics Committee at the meeting preceding the 12 month anniversary of the date of the ethical approval letter. Example: For a project granted ethical approval late April 2005, the annual report should be received by the closing date for the meeting preceding the end of April 2006.
7. The Ethics Committee may at any stage, adopt addition appropriate mechanisms for monitoring, as deemed necessary, such as:
 - 7.1. Random inspections of research sites;
 - 7.2. Random inspections of data and signed consent forms; or
 - 7.3. Interviews, with prior consent, of research participants.

8. The Ethics Committee shall require as a condition of ongoing approval of a project, that investigators immediately report anything which may warrant review of ethical approval of the protocol including:
 - 8.1. Proposed changes in the protocol;
 - 8.2. Any unforeseen events that might effect continued ethical acceptability of the project; and
 - 8.3. New information from published or unpublished studies which may have an impact on the continued ethical acceptability of the research, or which may indicate the need for amendments to the research protocol.
9. The Ethics Committee shall require, as a condition of approval of each project, that investigators inform the Ethics Committee, giving reasons, if the research project is discontinued before the expected date of completion.
10. Where the Ethics Committee is satisfied that the circumstances have arisen such that a research project is not being, or cannot be conducted in accordance with the approved project, the Ethics Committee may withdraw approval in accordance with SOP018.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedure**

Reference: SOP017 – Withdrawal or Suspension of ethical Approval

Date: August 2006

Subject: To describe the process of withdrawing or suspending ethical approval for research protocols already given ethical approval by the Ethics Committee

1. The Ethics Committee may suspend or withdraw ethical approval if a project is not being, or cannot be, conducted in accordance with the approved protocol.
2. Ethical approval of a project may be suspended or withdrawn in the following circumstances:
 - 2.1. If serious misconduct by an investigator is reasonably suspected or proven;
 - 2.2. If the wellbeing of participants is jeopardised; or
 - 2.3. If an investigator has failed to comply with any conditions imposed by the Ethics Committee, including monitoring requirements.
3. The Ethics Committee will advise the Board, and the Director-General, of the withdrawal of ethical approval of any project.
4. The CCO / Director-General will, on the advice of the Ethics Committee, inform in writing the Chief Investigator and the relevant institution or organisation of such withdrawal, and recommend to the institution or organisation that the project be discontinued, suspended, or that other necessary steps be taken.
5. If a project has not commenced within 1 year from the date of ethical approval, then ethical approval will lapse. If the investigator is still planning to undertake the project then a new submission to the Ethics Committee is required.
6. In relation to the deletion of data accessed by the registry prior to withdrawing ethical approval, please refer to the *Cancer Institute NSW Data Management Policy*, accessible from the Division of Registries and Population Health.

NSW Population & Health Services Research Ethics Committee

Standard Operating Procedure

Reference: SOP018 – Handling of Complaints/Concerns about the Conduct of a research project

Date: August 2006

Subject: To describe the process of handling complaints brought forward about the conduct of a research project ethically approved by the Ethics Committee

1. For the purposes of handling complaints regarding the conduct of a research project, the Executive Officer shall be nominated as the contact person.
2. The name and contact details of the Executive Officer should be included in the Patient Information Sheet and/or Consent Form for each project.
3. Any person, being a project participant, researcher or other interested person, with a complaint about the conduct of a project, should bring the complaint to the attention of the Executive Officer of the Ethics Committee in the first instance.
4. The Executive Officer will document in writing, the grounds of the concern or complaint.
5. The Executive Officer will notify the Chairperson as soon as possible after a complaint is received.
6. The Chairperson will bring the complaint to the attention of the Director-General and the Board in an appropriate timeframe, depending on the seriousness of the conduct and the timeframe in which it is resolved. All complaints will at least be notified in the annual reports made pursuant to SOP004.
7. The Chairperson will send a letter of acknowledgement to the complainant and a letter of notification to the Chief Investigator, outlining the complaint and the mechanism for investigating the complaint, as listed below.
8. Where a complain concerns a serious matter within the jurisdiction of the Health Care Complaints Commission, the CCO/Director-General shall consider referral of the complaint to that body in accordance with NSW Health's 'Guideline on the Management of a Complaint or Concern about a Clinician, November 2001'.
9. The Chairperson, in conjunction with the Executive Officer will instigate an investigation of the complaint and its validity, and make a recommendation to the Ethics Committee on the appropriate course of action.
10. This investigation shall take no longer than two (2) weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist.

11. If the complaint is substantiated, action may include:
 - 11.1. The requirement for amendments to the project, including increased monitoring by the Ethics Committee;
 - 11.2. Suspension of ethical approval for the project;
 - 11.3. Termination of ethical approval for the project; or
 - 11.4. Other action to resolve the complaint.
12. The complainant shall be informed, in writing, of the outcome of the Chairperson's investigation.
13. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Director-General or CCO or request the Chairperson to do so.
14. The Chairperson will provide the Director-General/CCO with all relevant information about the complaint/concern, including:
 - 14.1. The complaint;
 - 14.2. The material reviewed in the Chairperson's investigation;
 - 14.3. The results of the investigation; and
 - 14.4. Any other relevant documentation.
15. The Director-General/CCO will determine in their discretion whether there is to be further investigation of the complaint. Where no further investigation is to occur, the Director-General/CCO will inform the complainant and the Chairperson of this decision.
16. If the CCO/Director-General determines that further investigation is warranted, then the CCO/Director-General will establish a panel to consider the complaint.
17. The panel will include, at least, the following members:
 - 17.1. The Director-General/CCO as convenor of the panel;
 - 17.2. Two nominees of the Director General/CCO who are not members of the Ethics Committee; and
 - 17.3. The Ethics Committee's Executive Officer.
18. The panel will afford the Ethics Committee and the complainant the opportunity to make submissions. Where the complaint concerns the conduct of an investigator or any staff member, the panel shall also provide that person with the opportunity to make submissions.
19. The panel may access any documentation relating to the project. The panel may interview other parties, and obtain internal and external expert advice, as it sees necessary.

20. The Director-General/CCO will notify the complainant and the Chairperson of the decision of the panel, and any other relevant parties if an allegation is made against them. The outcomes may include:

20.1. The complaint/concern is dismissed; or

20.2. The Director-General/CCO directs appropriate action to be taken to resolve the complaint which may include, but is not limited to referring the matter back to the Ethics Committee to consider suspension or termination of ethical approval.

NSW Population & Health Services Research Ethics Committee

Standard Operating Procedure

Reference: SOP019 – Handling of Complaints/Concerns about the ethical review process

Date: August 2006

Subject: To describe the process of handling complaints brought forward about the conduct of the Ethics Committee's review process

1. A person with a concern or complaint about the Ethics Committee's review process will be directed to the attention of the Chairperson of the Ethics Committee, detailing, in writing, the grounds of the concern or complaint.
2. All complaints received will be reported to the Director-General and 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 SOPXXX.
3. The CCO/Director-General will send a letter to the complainant acknowledging receipt of their complaint, and outlining the mechanism by which the complaint will be investigated.
4. The Chairperson in conjunction with the Executive Officer will instigate an investigation of the complaint, and make a recommendation to the Ethics Committee on the appropriate course of action. This investigation should take no longer than two (2) weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist.
5. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she may refer the complaint to the Director-General or the CCO or request the Chairperson to do so.
6. The Chairperson of the Ethics Committee will provide the /Director-General or the CCO with all the relevant information about the complaint/concern, including:
 - 6.1. The complaint;
 - 6.2. Material reviewed in the Chairperson's investigation;
 - 6.3. The results of the Chairperson's investigations; and
 - 6.4. Any other relevant documentation.
7. The/Director-General and/or the CCO will then determine in their discretion, if the complaint/concern warrants investigation. If he/she believes there is to be no further investigation, they are to inform the Chairperson and the complainant. If it is determined that the complaint/concern does warrant further investigation then a panel to review the complaint will be convened.

8. The panel will include, at least, the following members:
 - 8.1. The CCO/Director-General as Convenor of the panel;
 - 8.2. Two nominees of the CCO/Director-General who are not members of the Ethics Committee; and
 - 8.3. The Ethics Committee Executive Officer.
9. The panel will afford the Ethics Committee and the complainant the opportunity to make submissions.
10. The panel may access any documents relating to the project.
11. The panel may interview other parties, and obtain internal and external expert advice as it sees necessary.
12. In conducting its review, the panel shall be concerned with ascertaining whether the Ethics Committee acted in accordance with:
 - 12.1. The National Statement;
 - 12.2. Its Terms of Reference;
 - 12.3. Its Standard Operating Procedures;
 - 12.4. Otherwise acted in an unfair or biased manner.
13. The CCO/Director-General will notify the complainant and the Ethics Committee of the outcome of the panel's investigation. The outcomes of this process may include:
 - 13.1. The complaint/concern is dismissed;
 - 13.2. The complaint/concern is referred back to the Ethics Committee for consideration, bearing in mind the findings of the panel.
14. The panel may also make recommendations about the operation of the Ethics Committee including such actions as:
 - 14.1. Review of the Terms of Reference;
 - 14.2. Review of Ethics Committee membership;
 - 14.3. Other actions as appropriate.

NSW Population & Health Services Research Ethics Committee

Standard Operating Procedures

Reference:	SOP020 – Handling of appeals concerning the Ethics Committee’s rejection of an application
Date:	August 2006
Subject:	To describe the process of receiving and handling appeals from Investigators about the Ethics Committee’s rejection of an application

1. A person with a concern or complaint regarding the Ethics Committee’s rejection of their application will be directed to the attention of the Chairperson of the Ethics Committee, detailing, in writing, the grounds of the concern or complaint.
2. All complaints received will be reported to the Director-General and 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 SOP004.
3. The CCO/Director-General will send a letter of acknowledgement to the complainant, acknowledging receipt of their complaint, and outlining the mechanism by which the complaint will be investigated.
4. The Chairperson in conjunction with the Executive Officer will instigate an investigation of the complaint, and make a recommendation to the Ethics Committee on the appropriate course of action. This investigation should take no longer than two (2) weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist.
5. If the complainant is not satisfied with the outcome of the Chairperson’s investigation, then he/she may refer the complaint to the Director-General or the CCO or request the Chairperson to do so.
6. The Chairperson of the Ethics Committee will provide the Director-General/CCO with all the relevant information about the complaint/concern, including:
 - 6.1. The complaint;
 - 6.2. Material reviewed in the Chairperson’s investigation;
 - 6.3. The results of the Chairperson’s investigations; and
 - 6.4. Any other relevant documentation.
7. The/Director-General and/or the CCO will then determine in their discretion, if the complaint/concern warrants investigation. If he/she believes there is to be no further investigation, they are to inform the Chairperson and the complainant. If it is determined that the complaint/concern does warrant further investigation then a panel to review the complaint will be convened.

8. The panel will include, at least, the following members:
 - 8.1. The CCO/Director-General as Convenor of the panel;
 - 8.2. Two nominees of the Chief Executive/Director General who are not members of the Ethics Committee;
 - 8.3. The Ethics Committee Executive Officer; and
 - 8.4. An expert(s) in the discipline of research of the project under consideration
9. The panel will afford the Ethics Committee and the complainant the opportunity to make submissions.
10. The panel may access any documents relating to the project.
11. The panel may interview other parties, and obtain internal and/or external expert advice as it sees necessary.
12. In conducting its review, the panel shall be concerned with ascertaining whether the Ethics Committee acted in accordance with:
 - 12.1. The National Statement;
 - 12.2. Its Terms of Reference;
 - 12.3. Its Standard Operating Procedures; or
 - 12.4. Otherwise acted in an unfair or biased manner.
13. The Chief Cancer Officer/Director-General will notify the complainant and the Ethics Committee of the outcome of the panel's investigation. The outcomes of this process may include:
 - 13.1. The complaint/concern is dismissed;
 - 13.2. The complaint/concern is referred back to the Ethics Committee for consideration, bearing in mind the findings of the panel.
14. Should the Ethics Committee be requested to review its decision, then the outcome of that review by the Ethics Committee will be final.
15. Neither the panel nor the Director-General nor the CCO can substitute its approval for the approval of the Ethics Committee.

NSW Population & Health Services Research Ethics Committee

Standard Operating Procedures

Reference: SOP021 – Confidentiality and Security of Applications and Proceedings

Date: August 2006

Subject: To describe the process of ensuring confidentiality and security of the applications and proceedings of the NSW Population & Health Services Research Ethics Committee

1. Members of the Ethics Committee will treat as, and keep, confidential, all information and documents which relate to proposals considered by the Ethics Committee.
2. Members are required to sign a confidentiality agreement upon joining the Ethics Committee.
3. All relevant records of the Ethics Committee, including applications, membership, minutes and correspondence, will be kept as confidential files in accordance with the requirements of the *Health Records and Information Privacy Act 2002* (HRIPA) and the *State Records Act 1998*.
4. To ensure confidentiality, meeting papers, including applications, will be distributed to the members of the Ethics Committee by courier, or registered post, for those external to the Cancer Institute NSW, and by hand for those internal to the Cancer Institute NSW.
5. All documents are to be disposed of in a secure manner, such as shredding or placed in confidential bins. Ethics Committee members who do not have access to secure disposal should leave their documents with the Executive Officer for disposal.

**NSW Population & Health Services Research Ethics Committee
Standard Operating Procedures**

Reference: SOP022 – Record Keeping

Date: August 2006

Subject: To describe the procedure for the preparation and maintenance of records of the NSW Population & Health Services Research Ethics Committee

1. The Executive Officer will:
 - 1.1. Prepare and maintain written records of the Ethics Committee's activities, including agendas and minutes of all meetings of the Ethics Committee.
 - 1.2. Prepare and maintain a confidential electronic and/or paper record for each application received and reviewed, and shall record the following information:
 - 1.2.1. Unique project identification number;
 - 1.2.2. The principal investigator(s);
 - 1.2.3. The name of the responsible institution or organisation;
 - 1.2.4. The title of the project;
 - 1.2.5. Ethical approval or non-approval with date;
 - 1.2.6. Approval or non-approval of any changes to the project;
 - 1.2.7. The terms and conditions, if any, of approval of the project;
 - 1.2.8. Whether approval was by expedited review; and
 - 1.2.9. Action taken by the Ethics Committee to monitor the conduct of the research.
2. Paper files shall contain a hard copy of the application, including signatures, and any relevant correspondence including that between the applicant and the Ethics Committee, all approved documents and other material used to inform potential research participants.
3. All relevant records of the Ethics Committee, including applications, memberships, minutes and correspondence, will be kept as a confidential file in accordance with the requirements of the *Health Records and Information Privacy Act 2002 (NSW)* and the *State Records Act 1998 (NSW)*.
4. Data pertaining to research projects shall be held for sufficient time to allow for future reference. Retention of data pertaining to research projects will comply with the NSW Health '*Information Bulletin 2004/20 General Retention and Disposal Authority – Public Health Services: Patient/Client Records (GDA 17)*'.
5. In general, files for proposals ethically considered by the Ethics Committee will be stored for 10 years after action is completed and then state archived. A register of all the applications received and reviewed shall be maintained in accordance with the National Statement.

NSW Population & Health Services Research Ethics Committee

Standard Operating Procedures

Reference: SOP023 – Conflict of Interest

Date: August 2006

Subject: To describe the procedure for handling conflicts of interest amongst the Ethics Committee.

1. Any member of the Ethics Committee who has any interest, financial or otherwise, in a proposal or other related matter considered by the Ethics Committee, should as soon as practicable declare such interest.
2. The Ethics Committee will determine if this results in a conflict of interest for the member and, if so, the member will withdraw from the meeting until the Committee's consideration of the relevant matters has been completed. The member shall not be permitted to adjudicate on the research.
3. Withdrawal from the meeting will be only for the period during which the particular protocol from which the conflict arises. Such withdrawal may be either being physically absent from the meeting, or providing no comment, or no opinion during the member discussion.
4. All declarations of interest and the absence of the member concerned will be minuted.

NSW Population & Health Services Research Ethics Committee

Standard Operating Procedures

Reference: SOP024 – Amendment to the Standard Operating Procedures

Date: August 2006

Subject: To describe the procedure for amending the Standard Operating Procedures of the NSW Population & Health Services Research Ethics Committee.

These Standard Operating Procedures may be amended by the procedure outlined below:

ETHICS COMMITTEE MEMBER PROPOSALS

1. The proposal must be in writing and circulated to all Ethics Committee members for their consideration;
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;
3. The proposal brought forward shall be referred to the Director-General and the Board for review and agreement, where two thirds of the Ethics Committee members agree to the amendment;
4. The Director-General and the Board will consider the proposal and notify the Ethics Committee of the outcome of their consideration. If the Director-General and the Board agree to the amendment, the Standard Operating Procedures 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.

DIRECTOR – GENERAL / BOARD PROPOSALS

5. The Director-General or the Board may put forward a proposal for amendment to the Standard Operating Procedures;
6. Such proposals must be in writing and must first be agreed by both the Director-General and the Board. The proposal shall then be circulated to all Ethics Committee Members for their consideration;
7. The proposal will be tabled at the next scheduled Ethics Committee meeting;
8. The Ethics Committee will provide its advice on the proposal to the Director-General and the Board as soon as practicable after the meeting at which it was considered;
 - 8.1. The Director-General and the Board shall consider the advice of the Ethics Committee, and if both agree to proceed with the amendment, the Standard Operating Procedures 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.