

Human Research Ethics Committees (HRECs) - Operations Manual for NSW Health

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Summary The purpose of this Operations Manual is to facilitate and support the ethical review of research and to achieve consistency and quality of that review. It is intended to assist Area Health Services and Human Research Ethics Committees in developing their own specific terms of reference and operating procedures.

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GUIDELINE

HUMAN RESEARCH ETHICS COMMITTEES (HRECs) OPERATIONS MANUAL FOR NSW HEALTH

Introduction:

This Guideline is intended to inform Area Health Services of this Operations Manual and provide guidance on its intended use and evaluation. This Operations Manual is consistent with the requirements of the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans* (National Statement) and all other State and Commonwealth requirements.

Background:

Area Health Services when establishing Human Research Ethics Committees (HRECs) are required to set out its terms of reference in accordance with the National Statement. Quality, consistent and timely ethical review of research relies on the existence of effective written terms of reference and operational practices.

Application:

NSW Health has developed this Operations Manual to facilitate and support the ethical review of research and to achieve consistency and quality of that ethical review. It is intended to assist Area Health Services and their HRECs in developing their own specific terms of reference and operating procedures. Matters of detail and precise procedure may be subject to particular local needs.

Area Health Services, in conjunction with their HRECs, are encouraged to utilise this Operations Manual and adapt their own terms of reference and operating practices so as to be consistent with it.

The Operations Manual will be reviewed and updated on a regular basis, to ensure its continued relevance and accuracy. NSW Health will evaluate its usefulness and implementation within six months of issuing this Guideline.

A copy of the Operations Manual is attached.

**Human Research Ethics Committees (HRECs) Operations
Manual for NSW Health**

Version 1, March 2005

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Preamble

NSW Health has produced this Operations Manual to facilitate and support ethical review in the NSW public health system. Its objective is to contribute to the effective functioning of Human Research Ethics Committees (HRECs) so that quality and consistency in ethical review is maintained.

It is intended that HRECs will use this Manual as a basis upon which to develop their own specific written procedures. Matters of detail and precise procedure may be subject to particular local needs.

This Operations Manual is consistent with the requirements of the NHMRC *National Statement on Ethical Conduct in Research Involving Humans* and all other State and Commonwealth requirements. The Manual has been developed with the assistance of many individuals, HRECs and institutions which are acknowledged overleaf.

The Terms of Reference set out the principles of practice and procedures and the Standard Operating Procedures detail the procedures and processes of the HREC.

The existence of clear and easily accessible written working practices and procedures is a requirement of the *National Statement* and goes a considerable way to evidencing that an HREC has acted reasonably in evaluating and reaching an opinion upon an application for ethical approval. In addition, some standardising of the Terms of Reference and operating procedures provides consistency for those making applications to HRECs, and helps to minimise duplication of effort by HREC Executive Officers and members.

Regular updates of this manual will be developed and circulated through the Executive Officers of HRECs.

Should you wish to make any comments about this Manual please contact:

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References

1. National Statement on Ethical Conduct in Research Involving Humans, National Health and Medical Research Council (NHMRC), 1999.
2. Governance Arrangements for NHS Research Ethics Committees, Central Office for Research Ethics Committees (COREC), Department of Health in England, 2001.
3. NHS Central Office for Research Ethics Committees (COREC) Standard Operating Procedures for Research Ethics Committees, Version 2.0 October 2004.
4. Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organisation, Geneva, 2000.
5. Manual for Research Ethics Committees, The Centre for Medical Law and Ethics, King's College, London (Fifth edition, 1997).
6. Guidelines and Recommendations for European Ethics Committees, European Forum for Good Clinical Practice, Revised edition 1997.
7. Joint NHMRC/AVCC Statement and Guidelines on Research Practice, Australian Vice-Chancellors' Committee, the Council of Australia's University Presidents, November 1997.
8. Human Research Ethics Committees and the Therapeutic Goods Legislation, Therapeutic Goods Administration, June 2001.
9. Access to Unapproved Therapeutic Goods via the Special Access Scheme, Therapeutic Goods Administration, October 2004.
10. Access to Unapproved Therapeutic Goods – Authorised Prescribers, Therapeutic Goods Administration, October 2004.
11. CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95).
12. The Terms of Reference of the following Human Research Ethics Committees were referred to in developing this document:
 - Cancer Council NSW Ethics Committee Terms of Reference
 - Central Coast Area Health Service Ethics Committee, Policies and Principles, 2003
 - Central Sydney Area Health Service Ethics Review Committee (RPAH Zone), Terms of Reference, 2004
 - Central Sydney Area Health Service HREC (Concord Repatriation General Hospital Zone), Terms of Reference, 2002
 - Corrections Health Human Research and Ethics Committee, Terms of Reference

- Greater Murray Area Health Service Ethics Committee, Terms of Reference 2004
- Hunter Area Health Service Research Ethics Committee, Terms of Reference 2001
- Macquarie & Far West Human Research Ethics Committee, Terms of Reference
- Mid North Coast Area Health Service Ethics and Research Committee, Terms of Reference 2001
- Northern Rivers Area Health Service Ethics and Research Committee Terms of Reference
- Northern Sydney Health Human Research Ethics Committee Terms of Reference, 2003
- NSW Department of Health Ethics Committee (DoHEC) Terms of Reference, 2001
- Royal Alexandra Hospital for Children HREC Terms of Reference, 2002
- Royal Rehabilitation Centre Sydney Ethics Committee Terms of Reference, 2004
- South Eastern Sydney Area Health Service – Eastern Section Research Ethics Committee, Terms of Reference, 2004
- South Western Sydney Area Health Service Ethics Committee, Terms of Reference, 2003
- St Vincent's Health Care Campus Human Research Ethics Committee, Terms of Reference, 2002
- University of Wollongong and Illawarra Area Health Service Human Research Ethics Committee, Terms of Reference, 2000
- Wentworth Area Health Service Ethics Committee, Terms of Reference

CHECKLIST FOR HREC TERMS OF REFERENCE

The following elements should be addressed in the Terms of Reference of all HRECs within the NSW public health system.

Subject matter	Issues to be considered
Purpose & function	*General principles about what the HREC aims to achieve and safeguard
Scope of responsibility	*The institutions, organisations and researchers for whom the HREC will provide ethical review *Reference should be made to the NSW Health Circular <i>Clinical Trials: Risk Management, Insurance and Indemnity</i> when considering this section of its Terms of Reference *Type of research to be reviewed
Status of the HREC within the Health Service	*Define under whose authority the HREC has been established *HRECs within the NSW public health system will normally be established under the authority of the Health Service Chief Executive *There should be clear documentation stating what authorities have been delegated to the HREC from the Chief Executive
Accountability of the HREC	*The reporting requirements to the Chief Executive, NHMRC, NSW Privacy Commissioner, NSW Health and any other state and/or commonwealth agencies *The Terms of Reference and SOPs should be available to the public
Membership	This should at least cover the following aspects of HREC membership: *Composition: including basic categories, quorum requirements including number of members and/or member categories, expert advice outside the HREC membership *Appointment: who appoints members, method of recruitment, procedure for selection, method of induction *Terms of appointment: duration of appointment, policy for renewal of appointment, disqualification procedure, resignation procedure, replacement procedure *Conditions of appointment: willingness to publicise name and profession, remuneration if any, confidentiality agreement, letter of appointment *Education and training for HREC members *Liability coverage for members
Conduct of business	Procedures: the HREC should operate according to written standard operating procedures Meetings: frequency, dates, conflicts of interest, decision making, elements of review, recording of decisions Submissions, notifications and approvals Expedited review: nature of applications, amendments and other considerations that will be eligible for expedited review, quorum requirements, status of decisions Multi-centre research: mechanism(s) for the streamlining of review of multi-centre applications Fees: if charged, under what circumstances Records: records and registers to be kept, security of data, retention and disposal of files

Post approval responsibilities	Monitoring: how often, mechanism, conditions of approval
Complaints and review	Concerning conduct of a project: who to notify, how the complaint will be handled, response to the complainant Concerning review process: who to notify, how the complaint will be handled, response to complainant Concerning rejection of application: who to notify, how the complaint will be handled, response to complainant
Amendment to Terms of Reference	Who, how and when amendments to the Terms of Reference can/should be made

SAMPLE TERMS OF REFERENCE

**[Insert name of Health Service]
HUMAN RESEARCH ETHICS COMMITTEE**

TERMS of REFERENCE **[Insert version number and date]**

OBJECTIVES

1. The HREC objectives are:
 - 1.1 Protect the mental and physical welfare, rights, dignity and safety of participants of research.
 - 1.2 Facilitate ethical research through efficient and effective review processes.
 - 1.3 Promote ethical standards of human research.
 - 1.4 To review research in accordance with the National Statement on Ethical Conduct in Research Involving Humans.

FUNCTIONS

2. The HREC functions are:
 - 2.1 To provide independent, competent and timely review of research projects involving humans in respect of their ethical acceptability.
 - 2.2 To provide ethical oversight, monitoring and advice for research projects involving humans.
 - 2.3 To prescribe the principles and procedures to govern research projects involving human subjects, human tissue and/or personal records.

SCOPE OF RESPONSIBILITY

3. Research proposals involving humans will be reviewed by the HREC where the research involves patients of [insert applicable option]:
 - any institutions governed by [insert name of Health Service]; or
 - the following institutions governed by [insert name of Health Service]

This term of reference does not prohibit the institution from accepting an ethical approval undertaken by another HREC as a sufficient ethical approval to allow the institution to approve the commencement of the project, provided that such other HREC is registered with the Australian Health Ethics Committee.

4. [insert this Point only if applicable] The HREC may grant ethical approval for research undertaken by the following external institutions/organisations and researchers:
 - [List each institution/organisation and/or researchers separately. Note: Approval must have been granted by the Chief Executive for the HREC to provide this service]

In such circumstances, an agreement shall exist between the Health Service and the external institution/organisation that defines the role of the HREC in providing ethical approval and ethical monitoring of the research and the role of the external institution/organisation in giving approval for the research to take place within its organisation. The agreement shall specify which party bears legal responsibility for the liabilities that arise from the ethical review conducted by the HREC, and shall also specify that the institution/organisation (not the Health Service) is responsible for liabilities arising from the conduct of the research.

5. Research involving humans includes research on pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures¹, biological samples, medical records, as well as epidemiological, social, and psychological investigations.

6. STATUS OF THE HREC WITHIN THE HEALTH SERVICE

- 6.1 The HREC is an advisory committee of the Health Service with responsibility for:
 - granting ethical approval;
 - withholding ethical approval; and
 - withdrawing ethical approval

for research to be carried out within the institutions noted in paragraph 3.

- 6.2 The Chief Executive or delegate is responsible for granting the Health Service's institutional approval for research to be conducted within its institution(s) giving due consideration to the advice of the HREC. (Note: The Chief Executive may not give approval for research to be conducted within the Health Service's institutions unless ethical approval has been granted by the HREC)

- 6.3 The Chief Executive has delegated to the HREC the authority to:
[Insert delegated authorities, which may for example include all or some of the following:
 - give approval on behalf of the Health Service to the conduct of ethically approved research in the institutions referred to in paragraph 3 of these Terms of Reference (except for the execution of CTN Forms which can only be signed by the Chief Executive or delegate);
 - approve amendments on behalf of the Health Service to research conducted at those institutions;
 - suspend approval on behalf of the Health Service for the conduct of research at those institutions;
 - withdraw approval on behalf of the Health Service for the conduct of research at those institutions.

ACCOUNTABILITY OF THE HREC

7. The HREC is accountable to the Chief Executive/ position of Chief Executive's nominee (delete whichever is not applicable) in the conduct of its business. The minutes of each HREC meeting shall be forwarded to the Chief Executive, following confirmation.

¹ NSW Health Circular No 2003/84 *Model Policy for the Safe Introduction of New Interventional Procedures into Clinical Practice*
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8. The HREC shall provide an annual report to the Chief Executive at the end of each [insert either financial or calendar] year, which will include information on membership, the number of proposals reviewed, status of proposals, a description of any complaints received and their outcome, and general issues raised.
9. The HREC may from time to time bring to the attention of the Chief Executive issues of significant concern.
10. The HREC will provide reports:
 - to the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the National Health and Medical Research Council (NHMRC);
 - to the NSW Privacy Commissioner in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW);
11. The HREC Terms of Reference, Standard Operating Procedures and membership will be available upon request to the general public and will be posted on the [insert name of Health Service] website.

MEMBERSHIP

12. Composition

- 12.1 The composition of the HREC shall be in accordance with the *National Statement* and shall include at least:
 - a chairperson;
 - at least two members who are lay people, one man and one woman, who have no affiliation with the Health Service, and are not currently involved in medical, scientific, or legal work;
 - a member with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC;
 - a member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
 - at least one member who is a minister of religion, or a person who performs a similar role in the community; and
 - at least one member who is a lawyer.
- 12.2 To ensure the membership will equip the HREC 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.
- 12.3 For the purposes of holding a meeting of the HREC, a quorum shall exist when a representative of each of the categories designated in the *National Statement* (and specified in paragraph 1.21) is present. In circumstances where such core members cannot be present, they may provide written comments in lieu of attendance. However, in those circumstances, there must be at least 5 members physically present to achieve quorum, including one of each of the following categories: Chair/Deputy Chair, lay person, researcher familiar with the types of proposals that are normally reviewed by the HREC.
- 12.4 The HREC shall be free to consult any person(s) considered by the HREC to be qualified to provide advice and assistance in the review of any research proposal submitted to it, subject to that person(s) having no conflict of interest and providing an undertaking of confidentiality. Such person(s) shall not be entitled to vote on any matter.

13. **Appointment**
- 13.1 The Chief Executive shall appoint members of the HREC, in consultation with the HREC and other senior Health Service officials, as deemed appropriate.
- 13.2 Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement.
- 13.3 A selection committee, consisting of the Chairperson, the Executive Officer and at least one other HREC member shall interview prospective applicants, consult with the HREC members and make a recommendation to the Chief Executive.
- 13.4 Appointments will allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.
14. **Terms of appointment**
- 14.1 Members are appointed for a period of three years and may serve two consecutive terms only unless otherwise approved by the Chief Executive. The Chairperson, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the Chief Executive.
- 14.2 Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the Chief Executive.
- 14.3 Membership will lapse if a member fails without reasonable excuse or without notifying the Chairperson to attend three consecutive meetings of the HREC, unless exceptional circumstances exist. The Chairperson in writing will notify the member of such lapse of membership. Steps shall be taken to fill the vacancy of the lapsed member.
- 14.4 A member may resign from the HREC at any time upon giving notice in writing to the Chairperson. Steps shall be taken to fill the vacancy of the former member.
- 14.5 The Chief Executive may terminate the appointment of any member of the HREC if the Chief Executive is of the opinion that:
- it is necessary for the proper and effective functioning of the HREC;
 - the person is not a fit and proper person to serve on an HREC;
 - the person has failed to carry out their duties as an HREC member.
- 14.6 Members will be provided with a letter of appointment which will include date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a HREC member, HREC meeting attendance responsibilities and general responsibilities as a HREC member.
15. **Conditions of appointment**
- 15.1 Members must agree to their name and profession being made available to the public, including being published on the [insert name of Health Service] website.
- 15.2 Members are not offered remuneration. However, members will be reimbursed for legitimate expenses incurred in attending HREC meetings or in otherwise carrying out the business of the HREC.

[Or: Payments made to HREC members may only be made in relation to the following items and at the following rates and on the following basis: (Criteria to be inserted)].

- 15.3 Members will be required to sign a statement undertaking:
- that all matters of which he/she becomes aware during the course of his/her work on the HREC will be kept confidential;
 - that any conflicts of interest, which exist or may arise during his/her tenure on the HREC will be declared; and
 - that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a HREC member.

16. Education for HREC members

16.1 Newly appointed members shall be provided with adequate orientation.

16.2 Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the HREC, at the expense of the Health Service.

17. Sub-committees

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

18. Liability coverage

18.1 The Health Service provides indemnity for members of the HREC for any liabilities that arise as a result of the member exercising his or her duties as a member in good faith. Such indemnity is provided through the NSW Treasury Managed Fund.

CONDUCT OF BUSINESS

19. Procedures

19.1 The HREC will perform its functions according to written standard operating procedures. These procedures shall be reviewed at least every two years and amended and updated as necessary. All HREC members shall have access to and/or be provided with copies of the procedures and shall be consulted with regard to changes thereto.

20. Submissions, notifications and approvals

20.1 All applications for ethical approval must be submitted to the Executive Officer of the HREC, by the relevant closing date, in writing in the format approved from time to time by the HREC and shall include such documentation as the HREC may specify.

20.2 Guidelines will be issued to assist applicants in their preparation of applications.

20.3 The HREC 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 HREC at which the application will be considered for the purpose of providing information to and answering questions from the HREC members.

20.4 The HREC will consider every correctly completed application which it receives at its next available meeting following receipt, provided that the

application is received by the relevant closing date. The Executive Office shall circulate the completed application and associated documents received with a meeting agenda to all members of the HREC at least 7 days prior to the next meeting.

- 20.5 The HREC may delegate consideration of certain scientific/technical matters to an HREC member or sub-committee of members. The HREC may also obtain expert scientific/technical advice, subject to paragraph 12.4.
- 20.6 The HREC may take into account the views or opinions of another HREC in relation to a research protocol.
- 20.7 The HREC will promptly notify the applicant in writing, advising whether the application, which it has considered, has received ethical approval and any conditions of that approval [The HREC may inform the applicant in writing that the research may commence: to be inserted where the HREC has delegated authority to approve research on behalf of the Health Service under paragraph 6].

21. **Expedited review**

- 21.1 The HREC may establish an Executive, consisting of at least the Chairperson and Executive Officer. Where provided by the Operating Procedures, the Executive may undertake expedited review of research proposals between scheduled meetings at the discretion of the Chairperson. The Executive may seek advice from other HREC members, as appropriate, before reaching a decision. If approval is granted, such approval shall be considered for ratification at the next HREC meeting.
- 21.2 The Executive may consider other items of business that are considered to be of minimal risk to participants such as appropriate adverse events, protocol reports, minor amendments and the like. The minutes of any such meetings will be tabled for ratification at the next HREC meeting.

22. **Multi-centre research**

- 22.1 To facilitate multi-centre research the HREC may:
 - communicate with any other HREC;
 - accept a scientific/technical and/or ethical assessment of the research by another HREC;
- 22.2 The HREC shall participate in the NSW Health Shared Scientific Assessment Scheme by requiring eligible protocols to be submitted to that Scheme.²

23. **Advocates and interpreters**

- 23.1 The HREC will consider whether an advocate for any participant or group of participants should be invited to the HREC meeting to ensure informed decision-making.
- 23.2 Where research involves the participation of persons unfamiliar with the English language, the HREC will ensure that the participant information sheet is translated into the participant's language and that an interpreter is present during the discussion on the project.

² At this time the SSAS is not compulsory, however NSW Health recommends that HRECs within the NSW public health system use the scheme
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24. **Meetings**

- 24.1 The HREC shall meet on a regular basis, which will normally be at [monthly/bimonthly] intervals.
- 24.2 Meeting dates and agenda closing dates will be published.
- 24.3 Any member of the HREC who has any interest, financial or otherwise, in a proposal or other related matter(s) considered by the HREC, should as soon as practicable declare such interest. If the member is present at a meeting at which the project is the subject of consideration, the member will withdraw from the meeting until the HREC's consideration of the relevant matter has been completed. 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 minuted³.
- 24.4 The HREC will endeavor 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 considered to 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.

25. **Fees**

- 25.1 A fee will not be charged for applications submitted for assessment by the HREC.
[Or: A fee will be charged for applications submitted for assessment by the HREC in the following circumstances: (circumstances to be inserted)]

26. **Records**

- 26.1 The Executive Officer will prepare and maintain written records of the HREC's activities, including agendas and minutes of all meetings of the HREC.
- 26.2 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 HREC.
- 26.3 Files shall be kept securely and confidentially in accordance with the requirements of Health Records and Information Privacy Act 2002.
- 26.4 Records shall be held for sufficient time to allow for future reference. The minimum period for retention is at least 5 years from the date of completion of a project but for specific types of research, such as clinical research, 15 years shall apply^{4,5}.
- 26.5 The HREC will maintain a register of all the applications received and reviewed in accordance with the National Statement.

POST APPROVAL RESPONSIBILITIES

27. The HREC will monitor approved projects in terms of compliance with the HREC's ethical approval. In doing, the HREC so may request and discuss information on any

³ A discussion paper, prepared by the Health Ethics Branch, is currently in circulation

⁴ NSW Health General Retention and Disposal Authority – Public Health Services: Patient/Client Records (GDA 17)

⁵ Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)

relevant aspects of the project with the investigators at any time. In particular, the HREC will require applicants to provide a report at least annually, and at completion of the study.

28. The HREC will, as a condition of approval of each project, require that investigators immediately report anything which might warrant review of ethical approval of the project, including:
 - proposed changes in the research protocol or conduct;
 - unforeseen events that might affect continued ethical acceptability of the project;
 - serious or unexpected adverse events; and
 - if the project is abandoned for any reason.
29. The HREC may adopt any additional appropriate mechanism for monitoring, as deemed necessary.

COMPLAINTS AND REVIEW

30. Complaints concerning the conduct of a project

30.1 Any concern or complaint about the conduct of a project should be directed to the attention of the person nominated by the HREC. The person nominated by the HREC to receive complaints shall notify the Chairperson as soon as possible after a complaint is received. The Chairperson of the HREC will investigate the complaint and make a recommendation on the appropriate course of action. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Chief Executive or his/her nominee, or request the Chairperson to do so.

31. Complaints concerning the HREC's review process

31.1 Any concern or complaint about the HREC's review process should be directed to the attention of the Chairperson of the HREC, detailing it in writing. Complaints may also be made to the Chief Executive. The Chairperson will notify the Chief Executive of any complaints received by him/her, as soon as possible. The Chief Executive will inform the Chairperson of any complaints received by him/her as soon as possible.

The Chairperson will investigate the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Chief Executive, or his/her nominee, or request the Chairperson to do so. The Chairperson will provide to the Chief Executive all relevant information about the complaint/concern. The Chief Executive will determine whether there is to be a further investigation of the complaint. If it is decided there is to be a further investigation, then the Chief Executive will convene a suitable panel to review the complaint, ensuring that both the complainant and the HREC are afforded the opportunity to make submissions.

31.2 In conducting its review, the panel shall be concerned with ascertaining whether the HREC acted in accordance with the National Statement, its Terms of Reference, the Standard Operating Procedures, or otherwise acted in an unfair or unbiased manner.

32. Complaints concerning the HREC's rejection of an application

32.1 A person with a complaint about the HREC's rejection of their application should bring the complaint to the attention of the Chairperson of the HREC,

detailing the grounds of the complaint. Complaints may also be made to the Chief Executive. The Chairperson will notify the Chief Executive of the complaint as soon as possible. The Chief Executive will notify the Chairperson of any complaints received by him/her as soon as possible.

The Chairperson will investigate the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action. If the complainant is not satisfied with the action taken by the HREC, then he/she can refer the complaint to the Chief Executive, or his/her nominee, or request the Chairperson to do so. The Chairperson will provide to the Chief Executive all relevant information about the complaint. The Chief Executive will determine whether there is to be a further investigation of the complaint. If it is decided that there is a case to be investigated, then the Chief Executive will convene a suitable panel to review the complaint, ensuring that both the complainant and the HREC are afforded the opportunity to make submissions.

The outcomes of this process may include:

- The complaint/concern is dismissed.
- The complaint/concern is referred back to the HREC for consideration, bearing in mind the findings of the panel.

Should the HREC be requested to review its decision, then the outcome of this review by the HREC will be final. In accordance with point 6.2, the panel or Chief Executive cannot substitute its approval for the approval of the HREC.

AMENDMENT TO THE TERMS OF REFERENCE

33. These Terms of Reference may be amended by following the procedure below:

For those proposals made by a HREC member:

- The proposal must be in writing and circulated to all HREC members for their consideration.
- The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his or her views in writing.
- The proposal shall be ratified if two thirds of the members agree to the amendment.
- The Chairperson shall send the amendment to the Chief Executive for review and approval if appropriate.

For those proposals made by the Chief Executive:

- The Chief Executive will send the proposal to the HREC and seek the views of any relevant person.

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**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 001

Date: March 2005

Subject: HREC function

Purpose: To describe the function of the HREC

OVERALL FUNCTION

1. The primary objective of the HREC is to protect the mental and physical welfare, rights, dignity and safety of participants of research, to facilitate ethical research through efficient and effective review processes, to promote ethical standards of human research and to review research in accordance with the NHMRC *National Statement on Ethical conduct in Research Involving Humans (National Statement)*.

Scope of Responsibilities

1. The functions of the HREC are:
 - i. To provide independent, competent and timely review of research projects involving humans in respect of their ethical acceptability.
 - ii. To provide ethical oversight, monitoring and advice for research projects involving humans.
 - iii. To prescribe the principles and procedures to govern research projects involving human subjects, human tissue and/or personal records.
2. Research projects involving humans will be reviewed by the HREC where the research involves patients of [insert applicable option]:
 - any institutions governed by [insert name of Health Service]; or
 - the following institutions governed by [insert name of Health Service]

This operating procedure does not prohibit the institution from accepting an ethical approval undertaken by another HREC as a sufficient ethical approval to allow the institution to approve the commencement of the project, provided that such other HREC is registered with the Australian Health Ethics Committee.

3. Research projects may include, but is not limited to, research involving pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, biological samples, access to health information, as well as epidemiological, social, and psychological investigations.
4. The HREC will assess projects submitted to it for review in accordance with the *National Statement* (and any other legal requirements) in order to determine their ethical acceptability.
5. The HREC may review projects involving quality assurance when required. In determining whether or not quality assurance proposals require review, the HREC will refer to the NHMRC document '*When does quality assurance in health care require independent ethical review?*' and the '*Health Records and Information Privacy Act 2002: Statutory Guidelines on Management of Health Services*'. Note: NSW Health has drafted

guidelines on this issue titled *'Quality improvement and ethics review: a practice guide for NSW'*.

The HREC will/will not (delete whichever is not applicable) review human research proposals for external institutions/organisations as specified in the Terms of Reference. In such circumstances, an agreement shall exist between the Health Service and the external institution/organisation that defines the role of the HREC in providing ethical approval and ethical monitoring of the research and the role of the external institution/organisation in giving approval for the research to take place within its organisation. The agreement shall specify which party bears legal responsibility for the liabilities that arise from the ethical review conducted by the HREC, and shall also specify that the institution/organisation (not the Health Service) is responsible for liabilities arising from the conduct of the research.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 002

Date: March 2005

Subject: Membership composition

Purpose: To describe the membership composition of the HREC

1. The composition of the HREC shall be in accordance with the *National Statement*. Minimum membership shall comprise of seven members, being men and women, comprising:
 - a chairperson;
 - at least two members who are lay people, one man and one woman, who have no affiliation with the institution or organisation, and who are not currently involved in medical, scientific, or legal work.
 - at least one member with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC;
 - at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
 - at least one member who is a minister of religion, or a person who performs a similar role in the community;
 - at least one member who is a lawyer.
2. To ensure the membership will equip the HREC 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.
3. Where required, the HREC may seek advice and assistance from appropriate experts to assist with the review of a project. However, the HREC must 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 or any involvement in competing research. Such person(s) shall be required to provide an undertaking of confidentiality and shall not be entitled to vote on any matter.
4. Additional members may be appointed to ensure the HREC has the expertise required to assess the applications submitted to it for consideration. If additional members are appointed the composition of the HREC shall continue to reflect the diversity and balance of its members, including gender and the relative proportion of institutional and non-institutional members.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 003

Date: March 2005

Subject: Appointment of members

Purpose: To describe the procedure for the appointment of members to the HREC

1. Members are appointed as individuals rather than in a representative capacity.
2. Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement. Prospective members shall be asked to provide a copy of their Curriculum Vitae to the selection committee. Members must agree to their name and profession being made available to the public, including being published on the [insert name of Health Service] website.
3. A selection committee, consisting of the Chairperson, Executive Officer and at least one other HREC member shall interview the prospective applicant, consult with the HREC members and make a recommendation to the Chief Executive. Prospective members may be invited to attend a meeting of the HREC as an observer.
4. Members are appointed by the Chief Executive in consultation with the HREC and will receive a formal notice of appointment.
5. The Chairperson and Deputy Chairperson will be appointed by the Chief Executive. In the absence of the Chairperson, the Deputy Chairperson will perform the role and duties of the Chairperson.
6. The letter of appointment shall include the date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a HREC member, the circumstances whereby membership may be terminated and the conditions of their appointment.
7. Members will be required to sign a confidentiality undertaking upon appointment, stating that all matters of which he/she becomes aware during the course of his/her work on the HREC will be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the HREC will be declared; and that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a HREC member.
8. Upon appointment, members shall be provided with the following documentation:
 - HREC Terms of Reference;
 - HREC Standard Operating Procedures;
 - up-to-date list of members' names and contact information including that of the Executive Officer;
 - NHMRC National Statement on Ethical Conduct in Research Involving Humans;
 - NHMRC Human Research Ethics Handbook – Commentary on the National Statement, February 2002;
 - any previous reports on the HREC's activities; and
 - any other relevant information about the HREC's processes, procedures and protocols.

9. Members are appointed for a period of three years and may serve two consecutive terms only unless otherwise approved by the Chief Executive. The Chair, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the Chief Executive. Members will be advised when his/her term has expired. Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the Chief Executive.
10. Appointments shall allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.
11. New members are expected to attend NSW Health and NHMRC education and training sessions as soon as practicable after their appointment. All members are expected to attend education and training sessions. Reasonable costs associated with attendance at training and education sessions will be met by the Health Service.
12. Member's shall/shall not [delete whichever is not applicable] be remunerated [If remunerated, insert rate of remuneration or who determines it eg. remunerated at rate determined by the Chief Executive from time to time]. Members will be reimbursed for legitimate expenses incurred in attending HREC meetings, such as travelling and parking expenses.
13. Members may seek a leave of absence from the HREC for extended periods. Steps shall be taken to fill the vacancy.
14. Membership will lapse if a member fails to attend three consecutive meetings of the HREC without reasonable excuse/apology, unless exceptional circumstances exist. The Chairperson will notify the member of such lapse of membership in writing. Steps shall be taken to fill the vacancy, which may arise.
15. Membership will lapse if a member fails to attend in full at least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.
16. Members will be expected to participate in relevant specialised working groups as required. The Chairperson will be expected to be available between meetings to participate in Executive meetings where required.
17. A member may resign from the HREC at any time upon giving notice in writing to the Chairperson. Steps shall be taken to fill the vacancy of the former member.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 004

Date: March 2005

Subject: Orientation of new members

Purpose: To describe the procedure for the orientation of new members

1. New HREC members must be provided with adequate orientation.
2. Orientation may involve all or some of the following:
 - Introduction to other HREC members prior to the HREC meeting.
 - Informal meeting with Chair and Executive Officer to explain their responsibilities as an HREC member, the HREC processes and procedures.
 - An opportunity to sit in on HREC meetings before their appointment takes effect.
 - 'Partnering' with another HREC member in the same category.
 - Priority given to participate in training sessions.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 005

Date: March 2005

Subject: Submission procedure for new applications

Purpose: To describe the procedure for the submission of new applications

1. All applications for ethical review must be submitted to the Executive Officer of the HREC, by close of business on the relevant closing date. The closing date for receipt of new applications onto the next HREC agenda shall be readily available to prospective applicants.
2. The closing dates for applications should normally be no earlier than 21 days and no later than 14 days prior to each HREC meeting. The closing dates for applications which have been reviewed by the NSW Health Shared Scientific Assessment Scheme (SSAS), shall normally be closer to the next HREC meeting than for those applications which have not been previously scientifically reviewed [*Note: This last sentence is relevant only for those HRECs with a separate scientific/technical sub-committee or who obtain an external scientific/technical opinion. In such circumstances where an application has been reviewed by the SSAS, additional scientific review by the HREC is not undertaken. There is no additional time required for the HREC to obtain scientific review, hence the shortened closing date*].
3. Applications must be submitted in the appropriate format as determined by the HREC, and shall include all documentation as required by the HREC. The procedures for application to the HREC and the application format shall be readily available to applicants. [*Note: the National Application Form is currently under development by the National Health and Medical Research Council and should be utilised by the HREC when approved by the Department*].
4. Guidelines shall be issued by the HREC to assist applicants in the preparation of their applications, including guidance on how to determine whether application to the HREC is necessary.
5. A fee will not be charged for applications submitted for assessment by the HREC [or: A fee will be charged for applications submitted for assessment by the HREC in the circumstances outlined in the HREC's Fee Policy. The fee policy shall be made available to applicants prior to submission of an application to the HREC]. *Note: The NSW Health document 'Report on NSW Health Human Research Ethics Committees Fee Policies, Nov 2001' is currently under revision.*

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 006

Date: March 2005

Subject: Processing of applications for review

Purpose: To describe the procedure for the processing of new applications

1. Applications will be checked for their completeness by the Executive Officer prior to their acceptance onto the agenda. Incomplete applications will be returned to the applicant.
2. The Executive Officer will determine whether or not the application has been submitted to the Shared Scientific Assessment Scheme for review.
3. Where the application has been submitted to the Shared Scientific Assessment Scheme, the scientific review of the Shared Scientific Assessment Committee will replace the HREC's own scientific review mechanism in accordance with the '*Shared Scientific Assessment Scheme Manual, version November 2004*'.
4. Once a completed application has been accepted for ethical review, the Executive Officer shall assign a unique project identification number to the project (Refer to SOP 020 for appropriate record keeping procedures). The project will be added to the HREC's register of received and reviewed applications.
5. The Executive Officer will acknowledge acceptance of the application for ethical review by issuing an acknowledgement letter to the principal investigator within 7 days of receipt of the application. The acknowledgement letter shall include the date of the meeting at which the application will be reviewed, as well as the unique project identification number given by the HREC to the project.
6. The application will be included on the agenda for the next available HREC meeting, provided it is received by the relevant closing date and is complete [*Note: Those HRECs which receive a substantial number of applications may need to defer some applications to the following HREC meeting. If this occurs, priority should be given to those applications which were received first and/or urgent applications at the discretion of the Chairperson*].

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 007

Date: March 2005

Subject: Preparation of agenda

Purpose: To describe the process and format of agenda for an HREC meeting.

1. The Executive Officer will prepare an agenda for each HREC meeting.
2. All completed applications and relevant documents received by the Executive Officer will be included on the agenda for HREC consideration at its next available meeting.
3. The meeting agenda and associated documents will be prepared by the Executive Officer and circulated to all HREC members at least 7 days prior to the next meeting.
4. Documentation received after the closing date will be included on the agenda and/or tabled at the meeting at the discretion of the Chairperson. Under no circumstances shall new applications for research be tabled at the meeting.
5. Agenda items will include at least the following items:
 - i. apologies;
 - ii. minutes of the previous meeting;
 - iii. business arising from the previous minutes;
 - iv. conflicts of interest;
 - v. new applications;
 - vi. amendments to approved protocols;
 - vii. correspondence;
 - viii. other business;
 - ix. close and next meeting.
6. The agenda and all documentation shall remain confidential.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 008

Date: March 2005

Subject: Conduct of meetings

Purpose: To describe the format of meetings of the HREC.

1. The HREC shall meet on a regular basis, which will normally be at [monthly/bimonthly] intervals. Meeting dates and agenda closing dates shall be publicly available.
2. Members may attend HREC meetings in person or via teleconference or video link.
3. The Chairperson may cancel a scheduled meeting if a quorum cannot be achieved (refer to Point 7). Should this occur, the HREC will convene within 5 working days of the cancelled meeting to ensure all agenda items are considered.
4. Meetings will be scheduled for an allocated time. If the business has not been completed within the allocated time, then the HREC may either continue the meeting until all agenda items have been considered or schedule an additional meeting. If an additional meeting is called for, then the meeting should be held within 5 working days.
5. The HREC meeting will be conducted in private, to ensure confidentiality and open discussion. Members will be advised of the meeting room details in the meeting agenda.
6. Notwithstanding paragraph 5, the HREC may agree to the presence of visitors or observers to a meeting.
7. Members who are unable to attend a meeting should contribute prior to the meeting through written submissions to the Executive Officer or Chairperson. These should normally be received at least 3 working days prior to the meeting so that copies may be made available in advance to members. The minutes should record the submission of written comments.
8. A quorum must be present in order for the HREC to reach a final decision on any agenda item. A quorum shall exist when a representative of each of the following categories is present:
 - a chairperson;
 - at least two members who are lay people, one man and one woman, who have no affiliation with the institution or organisation, and who are not currently involved in medical, scientific, or legal work;
 - at least one member with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC;
 - at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
 - at least one member who is a minister of religion, or a person who performs a similar role in the community;
 - at least one member who is a lawyer.

In circumstances where such core members cannot be present, they may provide written comments in lieu of attendance. However, in those circumstances, there must be at least 5 members physically present to achieve quorum, including one of each of

the following categories: Chairperson/Deputy Chairperson, lay person, researcher familiar with the types of proposals that are normally reviewed by the HREC.

9. If the meeting does not achieve quorum, the Chairperson shall decide it can proceed only in exceptional circumstances. In such circumstances, decisions made by the HREC must be ratified by at least one representative from those membership categories not present.
10. Any member of the HREC who has any interest, financial or otherwise, in a project or other related matter(s) considered by the HREC, should declare such interest. This will be dealt with in accordance with SOP 023.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 009

Date: March 2005

Subject: Consideration of applications for ethical review by the HREC

Purpose: To describe the process of the HREC's consideration of applications for ethical assessment

1. The HREC will consider a new application at its next available meeting provided that the application is received by the relevant closing date.
2. The application will be reviewed by all members of the HREC present at the meeting or providing written comments in lieu of attendance.
3. The HREC will deal with multi-centre research applications in accordance with SOP019.
4. The HREC will ethically assess each application in accordance with the NHMRC *National Statement on Ethical Conduct in Research Involving Humans*. The HREC must ensure that it is sufficiently informed on all aspects of a research protocol, including its scientific validity, in order to make an ethical assessment.
5. The HREC will consider whether an advocate for any participant or group of participants should be invited to the HREC meeting to ensure informed decision-making.
6. Where research involves the targeted recruitment of persons unfamiliar with the English language, the HREC will ensure that the participant information sheet is translated into the participant's language and that an interpreter is present during the discussion on the project.
7. The HREC, after consideration of an application at a meeting will make one of the following decisions:
 - It will approve the project as being ethically acceptable, with or without conditions.
 - It will defer making a decision on the project until the clarification of information or the provision of further information to the HREC.
 - It will request modification of the project.
 - It will reject the project.
8. The HREC will endeavour to reach a decision concerning the ethical acceptability of a project by unanimous agreement. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of two-thirds of members who examined the project, 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.
9. In order to facilitate consideration of an application, the HREC may invite the applicant to be present at the relevant meeting for its discussion and to answer questions.
10. For projects where the HREC has requested clarification, the provision of further information, or modification of the project, the HREC may choose to delegate the authority to review that information and approve the project between meetings to one of the following:
 - chairperson alone; or

- chairperson, in oral or written consultation with one or more named members that were present at the meeting or who submitted written comments on the application; or
- a sub-committee of the HREC.

In such circumstances, the HREC shall be informed at the next available meeting, of the final decision taken on its behalf, including the applicant's response and the reason for the decision taken.

11. Exceptionally, the HREC may decide that the information should be considered at a further meeting of the HREC.

12. The HREC may conduct expedited review of projects in accordance with SOP011.

[Insert name of Health Service] Human Research Ethics Committee

Standard Operating Procedures

Reference Number: SOP 010

Date: March 2005

Subject: Preparation of minutes

Purpose: To describe the process and format for minutes of a meeting of the HREC.

1. The HREC Executive Officer will prepare and maintain minutes of all meetings of the HREC.
2. The format of the minutes will include at least the following items:
 - i. apologies;
 - ii. attendance;
 - iii. minutes of the previous meeting;
 - iv. business arising from the previous minutes;
 - v. conflicts of interest;
 - vi. new applications;
 - vii. amendments to approved projects
 - viii. correspondence;
 - ix. other business;
 - x. close and next meeting.
3. The minutes should include the recording of decisions taken by the HREC as well as a summary of relevant discussion. This includes reference to views expressed by absent members.
4. In relation to the review of new applications or amendments, the minutes shall record a summary of the main ethical issues considered, including any requests for additional information, clarification or modification of the project.
5. In recording a decision made by the HREC, any significant minority view (i.e. 2 or more members) will be noted in the minutes.
6. To encourage free and open discussion and to emphasize the collegiate character of the HREC, 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 HREC and the absence of the member concerned during the HREC consideration of the relevant application will be minuted (refer to SOP023 regarding a members declaration of a conflict of interest).
8. The minutes will be produced as soon as practicable following the relevant meeting and should be checked by either the Chairperson and/or the Deputy Chairperson, for accuracy.
9. The minutes will be circulated to all members of the HREC as an agenda item for the next meeting. All members will be given the opportunity to seek amendments to the

minutes prior to their ratification. The minutes will be formally ratified at the next HREC meeting.

10. The original copy of each meeting's minutes will be retained in a confidential 'Minutes' file.
11. The minutes of each Committee meeting shall be forwarded to the Chief Executive.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 011

Date: March 2005

Subject: Expedited review

Purpose: To describe the procedure for the expedited review of research by the HREC.

1. The HREC may establish an Executive, consisting of at least the Chairperson and the Executive Officer. The Executive may undertake expedited review of research projects in the following circumstances:

[insert relevant classes of minimal risk research, such as:

- questionnaires on non-controversial, non-personal issues
- research which is being conducted primarily at another institution/Health Service and has been approved by another HREC, but which involves a minimal risk component at this Health Service. For example, research involving the recruitment and treatment of patients at Health Service A, with tissue samples being sent to Health Service B for testing. In this instance, it would be acceptable for Health Service B to expedite the review of the project provided it has been reviewed and approved by the HREC of Health Service A or another HREC whose review the institution is willing to accept.]

Expedited review of research projects may be undertaken between scheduled meetings at the discretion of the Chairperson. The Executive may seek advice from other HREC members or suitably qualified experts, as appropriate, before reaching a decision. The decision of this review must be tabled for ratification at the next HREC meeting.

The Executive may consider other items of business that are considered to be of minimal risk to participants such as appropriate adverse events, project reports, minor amendments and the like.

2. The minutes of Executive meetings will be tabled for ratification at the next HREC meeting.
3. Research with the potential for physical or psychological harm should generally not be considered for expedited review. This includes clinical trials, research involving invasive physical procedures and research exploring sensitive personal or cultural issues.
4. Where the Chairperson considers that research may involve a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the protocol must be considered by the full HREC and cannot be dealt with by expedited review.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 012

Date: March 2005

Subject: Notification of decisions of the HREC for new applications

Purpose: To describe the procedure for the notification of decisions of the HREC concerning the review of new applications.

1. The HREC will report in writing to the principal investigator, advising whether the application has received ethical approval (including any conditions of approval), within 5 working days of the meeting, unless otherwise notified.
2. If the HREC determines that further information, clarification or modification is required for the consideration of a project, the correspondence to the principal investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information/clarification/modification should refer to the NHMRC *National Statement on Ethical Conduct in Research Involving Humans* or other relevant pieces of legislation.
3. If the requested information is not received from the applicant within 3 months or 2 meetings (whichever occurs sooner), the project will be dismissed and the applicant will be required to re-submit the project at a later date.
4. The HREC shall endeavour to openly communicate with applicants to resolve outstanding requests for further information, clarification or modification of projects relating to ethical issues. The HREC may nominate one of its members to communicate directly with the applicant or by inviting the applicant to attend the relevant HREC meeting.
5. The HREC will notify the applicant of the ethical approval of a project only when all outstanding requests for further information, clarification or modification have been satisfactorily resolved. Notification of ethical approval will be in writing, and will contain the following information:
 - title of project;
 - name of the principal investigator(s);
 - unique HREC project identification number;
 - the version number and date of all documentation reviewed and approved by the HREC including Clinical Protocols, Patient Information Sheets, Consent Forms, advertisements, questionnaires etc;
 - date of HREC meeting at which the project was first considered;
 - date of HREC approval;
 - duration of HREC approval; and
 - conditions of HREC approval, if any.

[For HRECs with delegated authority to approve research projects on behalf of the Health Service the HREC may inform the applicant in writing that the research may commence]

A standard response will be issued, in the format set out in Attachment A [Note: the HREC should attach a copy of its standard response letter to these Standard Operating

Procedures]. Research projects may not commence until written notification which confirms this has been received.

6. If the HREC determines that a project is ethically unacceptable, the notification of the HREC's decision will include the grounds for rejecting the project with reference to the *National Statement* or other relevant pieces of legislation.
7. The status of the project shall be updated on the HREC's register of received and reviewed applications.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 013

Date: March 2005

Subject: Submission of amendments and extensions to approved projects

Purpose: To describe the procedure for the submission and HREC review of requests for amendments and extensions to approved protocols.

1. Proposed changes to approved research projects, conduct of the research, or requests for extensions to the length of HREC approval, are required to be reported by the principal investigator to the HREC for review.
2. Requests shall 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. All amended documents must have the changes highlighted and contain revised version numbers and dates.
3. Expedited review of requests for minor amendments and extensions may be undertaken by the HREC Executive between scheduled meetings at the discretion of the Chairperson and in accordance with SOP 011, on the condition that it be ratified at the next HREC meeting. Where an urgent protocol amendment is required for safety reasons, the Chairperson may review and approve the request. In such circumstances, the HREC will review the decision at its next available meeting.
4. All other requests for amendments shall be reviewed by the HREC at its next available meeting, provided the request has been received by the Executive Officer by the agenda closing date.
5. The HREC will report in writing to the principal investigator, advising of the ethical approval of the proposed amendment and/or request for extension, within 5 working days of the meeting at which the request was considered (this may be the full HREC meeting or the Executive meeting). [For HRECs with delegated authority to approve research projects on behalf of the Health Service the HREC may inform the applicant in writing that the amended research may commence].
6. A standard response will be issued, in the format set out in Attachment B [*Note: the HREC should attach a copy of its standard response letter to these Standard Operating Procedures*].
7. If the HREC determines that further information, clarification or modification is required for the consideration of the request for amendment or extension, the correspondence to the investigator should clearly articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information/clarification/modification should refer to the *National Statement* or relevant pieces of legislation.
8. All reviewed and approved requests for amendments and extensions shall be recorded, and the status of the project shall be updated on the HREC's register of received and reviewed applications.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 014

Date: March 2005

Subject: Handling of adverse events

Purpose: To describe the procedure for the reporting and handling of adverse events

1. The HREC shall require, as a condition of approval of each project, that researchers immediately report serious or unexpected adverse events to the HREC, including those that have occurred at other institutions participating in the study.
2. Notifications of adverse events must be submitted in the appropriate format as determined by the HREC (Refer to Appendix F), and shall include all documentation as required by the HREC. This documentation shall include as a minimum:
 - Advice from the principal investigator as to whether, in his/her opinion, the adverse event was related to the protocol or in the case of a drug/device trial, whether the adverse event was related to the study drug/device.
 - Advice from the principal investigator as to whether, in his/her opinion, the adverse event necessitates an amendment to the project and/or the Patient Information Sheet/Consent Form.
 - Advice from the principal investigator regarding the frequency of the event in relation to the total number of participants, for the trial in which the event occurred.
 - Advice from the principal investigator as to whether the event has been notified to the Independent Safety and Data Monitoring Board (if one exists).
3. The procedures and format for notification of adverse events to the HREC shall be readily available to investigators.
4. Adverse events may be reviewed by an Executive or Subcommittee of the HREC, which shall determine the appropriate course of action. This may include:
 - notation on file of the occurrence;
 - increased monitoring of the project;
 - request for an amendment to the protocol and/or Patient Information Sheet/Consent Form;
 - suspension of ethical approval; or
 - termination of ethical approval.

Any such adverse events shall be reported to the HREC at the next available meeting.

5. The Chairperson may take the appropriate course of action for those adverse events deemed serious and requiring immediate attention. This may include:
 - Referral to the scientific/technical subcommittee;
 - Immediate request for additional information;
 - Immediate suspension of ethical approval;
 - Immediate termination of ethical approval.

6. The HREC shall provide notice to the investigator that it has received notification of the serious or unexpected adverse event, and the course of action it has deemed necessary to take.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 015

Date: March 2005

Subject: Monitoring of approved research projects

Purpose: To describe the procedure for monitoring research projects approved by the HREC to ensure compliance with ethical approval.

1. The HREC will monitor approved projects to ensure compliance with its ethical approval. In doing so it may request and discuss information on any relevant aspects of the project with the investigators at any time. In particular, the HREC will require applicants to provide a report at least annually, and at completion of the study. Continuing approval of the research will be subject to the principal investigator submitting an annual report.
2. The HREC shall require the following information in the annual report:
 - progress to date or outcome in the case of completed research;
 - maintenance and security of records;
 - compliance with the approved protocol; and
 - compliance with any conditions of approval.
3. The HREC may adopt any additional appropriate mechanism/s for monitoring, as deemed necessary, such as:
 - random inspections of research sites, data and signed consent forms;
 - interview, with their prior consent, of research participants.
4. The HREC shall require, as a condition of approval of each project, that investigators immediately report anything which might warrant review of ethical approval of the protocol, including:
 - proposed changes in the protocol;
 - any unforeseen events that might affect continued ethical acceptability of the project; and
 - new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial, or which may indicate the need for amendments to the trial protocol.
5. The HREC shall require, as a condition of approval of each project, that investigators inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion.
6. Where the HREC is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved project, the HREC may withdraw approval. In such circumstances, the HREC shall inform the principal investigator and the institution of such withdrawal of approval in writing, and recommend to the institution that the research project be discontinued, suspended, or that other necessary steps be taken.
7. In determining the frequency and type of monitoring required for approved projects, the HREC will give consideration to the degree of risk to participants in the research project.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 016

Date: March 2005

Subject: Complaints about the conduct of a research project

Purpose: To describe the mechanism for receiving, handling and responding to complaints concerning the conduct of a project approved by the HREC

1. The HREC shall nominate a person to whom complaints from research participants, researchers, or other interested persons about the conduct of approved research projects, may be made in the first instance. The name and/or position and contact details of the person nominated by the HREC to receive complaints must be included in the Patient Information Sheet and/or Consent Form for each project.
2. Any concern or complaint received about the conduct of a research project approved by the HREC should be directed to the attention of the person nominated by the HREC. That nominated person is responsible for obtaining in writing the grounds of the concern or complaint and shall notify the Chairperson as soon as possible after a complaint is received.
3. The Chairperson will bring the complaint to the attention of the Chief Executive as soon as possible. The Chairperson will send a letter of acknowledgement to the complainant and a letter of notification to the principal investigator, outlining the complaint and the mechanism for investigating the complaint, as set out below.
4. Where the complaint concerns a serious matter within the jurisdiction of the Health Care Complaints Commission, the Chief Executive 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*'.
5. The Chairperson will instigate an investigation of the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action. This investigation shall take no longer than 2 weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist. If the complaint is substantiated, action may include:
 - the requirement for amendments to the project, including increased monitoring by the HREC;
 - suspension of the project;
 - termination of the project; or
 - other action to resolve the complaint.

The complainant shall be informed of the outcome of the Chairperson's investigation.

6. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Chief Executive, or his/her nominee, or request the Chairperson to do so.
7. The Chairperson of the HREC will provide the Chief Executive or his/her nominee with all relevant information about the complaint/concern, including:
 - the complaint;

- material reviewed in the Chairperson's investigation;
 - the results of the Chairperson's investigation; and
 - any other relevant documentation.
8. The Chief Executive will determine whether there is to be a further investigation of the complaint. Where no further investigation, the Chief Executive will inform the complainant and the Chairperson of this.
9. If the Chief Executive determines there is to be a further investigation, then he/she will establish a panel to consider the complaint.
10. The panel will include, at least, the following members:
- the Chief Executive or his/her nominee as convenor of the panel;
 - two nominees of the Chief Executive (not members of the HREC); and
 - the HREC Executive Officer.
11. The panel will afford the HREC and 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 an opportunity to make submissions.
12. The panel may access any documents relating to the project. The panel may interview other parties, and seek internal and external expert advice, as it sees fit.
13. The Chief Executive will notify the complainant and the Chairperson of the outcome of the investigation, and the investigator if an allegation against them. The outcomes may include:
- The complaint/concern is dismissed.
 - The Chief Executive directs appropriate action to be taken to resolve the complaint.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 017

Date: March 2005

Subject: Complaints concerning the HREC's review process

Purpose: To describe the procedure for receiving and handling concerns or complaints from investigators about the HREC's review process.

1. Any concern or complaint about the HREC's review process should be directed to the attention of the Chairperson of the HREC, detailing in writing the grounds of the concern or complaint. Complaints may also be made to the Chief Executive.
2. The Chairperson will inform the Chief Executive as soon as possible of any complaints received by him/her. The Chief Executive will inform the Chairperson as soon as possible of any complaints received by him/her. The Chief Executive will send a letter of acknowledgement to the complainant, outlining the following mechanism.
3. The Chairperson will instigate an investigation of the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action. This investigation shall take no longer than 2 weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist.
4. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Chief Executive, or his/her nominee, or request the Chairperson to do so.
5. The Chairperson of the HREC will provide the Chief Executive with all relevant information about the complaint/concern, including:
 - the complaint;
 - material reviewed in the Chairperson's investigation;
 - the results of the Chairperson's investigation; and
 - any other relevant documentation.
6. The Chief Executive will determine whether there is to be a further investigation of the complaint.
7. If the Chief Executive determines there is to be a further investigation, then he/she will establish a panel to consider the complaint/concern. Where there is to be no further investigation, the Chief Executive will inform the application and the Chairperson of this.
8. The panel will include, at least, the following members:
 - The Chief Executive or his/her nominee as Convenor of the panel.
 - Two nominees of the Chief Executive (not members of the HREC).
9. The panel will afford the HREC and the complainant the opportunity to make submissions.
10. The panel may access any documents relating to the project. The panel may interview other parties, including internal and external expert advice. In conducting its review, the

panel shall be concerned with ascertaining whether the HREC acted in accordance with the NHMRC National Statement on Research Ethical Conduct in Research Involving Humans, its Terms of Reference, Standard Operating Procedures, or otherwise acted in an unfair or unbiased manner.

11. The Chief Executive will notify the complainant and the HREC of the outcome of the investigation. The outcomes of this process may include:
 - The complaint/concern is dismissed.
 - The complaint/concern is referred back to the HREC for consideration, bearing in mind the findings of the panel.

12. The panel may also make recommendations about the operation of the HREC including such actions as:
 - Review Terms of Reference and Standard Operating Procedures;
 - Review committee membership;
 - Take other such action as appropriate.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 018

Date: March 2005

Subject: Complaints concerning the HREC's rejection of an application

Purpose: To describe the procedure for receiving and handling complaints from investigators about the HREC's rejection of an application

1. A person with a concern or complaint about the HREC's rejection of their application should detail the grounds of the concern or complaint in writing and bring it to the attention of the Chairperson of the HREC. Complaints may also be made to the Chief Executive.
2. The Chairperson will bring to the attention of the Chief Executive as soon as possible any complaints received by him/her. The Chief Executive will inform the Chairperson as soon as possible of any complaints received by him/her. The Chief Executive will send a letter of acknowledgement to the complainant, outlining the following mechanism.
3. The Chairperson will instigate an investigation of the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action. This investigation shall take no longer than 2 weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist.
4. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Chief Executive or his/her nominee, or request the Chairperson to do so.
5. The Chairperson of the HREC will provide the Chief Executive with all relevant information about the complaint, including:
 - the complaint;
 - material reviewed in the Chairperson's investigation;
 - the results of the Chairperson's investigation; and
 - any other relevant documentation.
6. The Chief Executive will determine whether there is to be a further investigation of the complaint.
7. If the Chief Executive determines there is a case to be investigated, then he/she will establish a panel to consider the complaint.
8. The panel will include, at least, the following members:
 - The Chief Executive or his/her nominee as convenor of the panel
 - Two nominees of the Chief Executive (not members of the HREC)
 - An expert/s in the discipline of research of the project under consideration
9. The panel will afford the HREC and the complainant the opportunity to make submissions.

10. The panel may access any documents relating to the project. The panel may interview other parties, and seek any other internal and/or external expert advice.
11. The Chief Executive will notify the complainant and the HREC of the outcome of the investigation. The outcomes of this process may include:
 - The complaint/concern is dismissed.
 - The complaint/concern is referred back to the HREC for consideration, bearing in mind the findings of the panel.
12. Should the HREC be requested to review its decision, then the outcome of this review by the HREC will be final.
13. The panel or Chief Executive cannot substitute its approval for the approval of the HREC.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 019

Date: March 2005

Subject: Handling of multi-centre research

Purpose: To describe the procedure for the handling by the HREC of multi-centre research, including applications submitted to the NSW Health Shared Scientific Assessment Scheme.

1. To facilitate the review of multi-centre research the HREC may:
 - communicate with any other HREC;
 - accept a scientific/technical and/or ethical assessment of the research by another HREC;
 - share its scientific/technical and/or ethical assessment of the research with another HREC.
2. The HREC shall participate in the NSW Health Shared Scientific Assessment Scheme (SSAS) by requiring clinical drug trials *yet to be reviewed* by 2 or more HRECs within NSW Health, to be submitted to the SSAS.
3. Where it is determined that an application is eligible for review by the SSAS (that is, it is a clinical drug trial *yet to be reviewed* by 2 or more HRECs within NSW Health) but that it has not been submitted to the SSAS for review, the HREC may take the following course of action:
 - accept the application for HREC review, but inform the applicant that it will not be considered until the application has been reviewed by the SSAS;
 - at the discretion of the Executive Officer and Chairperson, accept the application for HREC review and not require the applicant to submit the application to the SSAS [*Note: At this stage the SSAS is not mandatory. It is therefore a matter for the Chairperson and Executive Officer as to whether it is a requirement for eligible applications to be submitted to the SSAS*].

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 020

Date: March 2005

Subject: Record keeping

Purpose: To describe the procedure for the preparation and maintenance of records of the HREC's activities.

1. The Executive Officer will prepare and maintain written records of the HREC's activities, including agendas and minutes of all meetings of the HREC.
2. The Executive Officer will prepare and maintain a confidential electronic and/or paper record for each application received and reviewed and shall record the following information:
 - unique project identification number;
 - the principal investigator(s);
 - the name of the responsible institution or organisation;
 - title of the project;
 - ethical approval or non-approval with date;
 - Health Service approval for commencement of research with date [insert if HREC does not have delegated authority to approve the commencement of research on behalf of the Health Service];
 - approval or non-approval of any changes to the project;
 - the terms and conditions, if any, of approval of the project;
 - whether approval was by expedited review; and
 - action taken by the HREC to monitor the conduct of the research.

The paper file shall contain a hard copy of the application, including signatures, and any relevant correspondence including that between the applicant and the HREC, all approved documents and other material used to inform potential research participants.

3. All relevant records of the HREC, 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, all documents provided to HREC members, which are no longer, required, are to be disposed of in a secure manner, such as shredding or placed in confidential bins. Members who do not have access to secure disposal should leave their documents with the Executive Officer for disposal.
5. Data pertaining to research projects shall be held for sufficient time to allow for future reference. The minimum period for retention for non-clinical research is at least 5 years after the date of publication or completion of the research or termination of the study. For clinical research, 15 years shall apply. Retention periods shall comply with NSW Health '*Information Bulletin 2004/20 General Retention and Disposal Authority – Public Health Services: Patient/Client Records (GDA 17)*'.
6. A register of all the applications received and reviewed shall be maintained in accordance with the NHMRC *National Statement on Ethical Conduct in Research Involving Humans*.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 021

Date: March 2005

Subject: Special Access Scheme applications

Purpose: To describe the procedure for the review and approval of access to unapproved therapeutic goods via the Special Access Scheme

1. When seeking approval to supply unapproved therapeutic goods to a single patient, medical practitioners may make an application to the nominated 'external delegate' within the organisation (Note: Refer to *Human Research Ethics Committees and the Therapeutic Goods Legislation, June 2001*).
2. The HREC may establish an Executive of members, consisting of the Chairperson, the Executive Officer and one other member to consider the granting of approvals under section 19(1)(a) of the Therapeutic Goods Act by 'external delegates'. In accordance with Regulation 47A(6)(b) of the Act, all-special access scheme applications approved by an external delegate must be approved by an HREC.
3. All decisions made by the Executive shall be tabled for ratification at the next HREC meeting.
4. When considering the granting of approvals by external delegates, the HREC shall be provided with the following information, in accordance with the *Therapeutic Goods Act 1989* and associated regulations*:
 - the product for which approval is sought;
 - whether that unapproved product is included on the list of products which can be approved by the practitioner;
 - details about the product to be prescribed, including an assessment of the efficacy and safety of the product;
 - the medical condition for which approval is being sought;
 - an assessment of the seriousness of the condition being treated;
 - the intended mode of use/treatment regimen and whether this conforms to the treatment protocol; and
 - the clinical justification for use of the unapproved product, including the nature and availability of alternative treatments.
5. For HREC purposes, the procedure outlined in point 4 for reviewing access to unapproved therapeutic goods via the Special Access Scheme is the same for Category A and Category B patients.

*Refer to the *Therapeutic Goods Administration Access to Unapproved Therapeutic Goods via the Special Access Scheme, October 2004*

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 022

Date: March 2005

Subject: Authorised Prescriber applications

Purpose: To describe the procedure for the review and approval of access to unapproved therapeutic goods via Authorised Prescribers.

1. The HREC may establish an Executive of members, consisting of the Chairperson, the Executive Officer and one other member to consider authorised prescriber applications. The HREC may also seek advice from its scientific/technical sub-committee or drug sub-committee [if available], when considering the issues outlined in Point 3.
2. All decisions made by the Executive shall be tabled for ratification at the next HREC meeting.
3. When considering a proposal by a medical practitioner to become an Authorised Prescriber, the ethics committee shall undertake an assessment of the following, in accordance with the *Therapeutic Goods Act 1989* and associated regulations*:
 - the safety of the product in relation to its proposed use;
 - the suitability of the medical practitioner; and
 - information to be given to the patient about the product and the informed consent form.
4. If endorsed, the HREC shall provide a letter of endorsement to the applicant in the format suggested by the Therapeutic Goods Administration [Note: Refer to *Access to Unapproved Therapeutic Goods – Authorised Prescribers, October 2004*]. The HREC may impose any conditions on the endorsement such as:
 - a requirement that regular reports be provided to the HREC containing such information as the number of patients for whom the unapproved product has been prescribed;
 - requirements for reporting of any adverse events.
5. The HREC shall review its endorsement of the Authorised Prescriber if it becomes aware of:
 - inappropriate use of the product by the Authorised Prescriber;
 - a concern about the safety of the product;
 - failure of the Authorised Prescriber to comply with conditions imposed by the HREC; or
 - failure of the Authorised Prescriber to comply with State/Territory legislation
6. The HREC may withdraw its endorsement of the Authorised Prescriber if it is satisfied that the welfare and/or rights of patients are not or will not be protected. The HREC shall advise the medical practitioner and the Chief Executive of its concerns in the first instance. The Chief Executive and the Chairperson of the HREC shall jointly determine whether to contact the Therapeutic Goods Association.

*Refer to the Therapeutic Goods Administration *Access to Unapproved Therapeutic Goods – Authorised Prescribers, October 2004*.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 023

Date: March 2005

Subject: Handling of conflicts of interest

Purpose: To describe the procedure for the handling of conflicts of interest of HREC members

1. A HREC member shall, as soon as practicable during the HREC meeting, inform the Chairperson if he/she has a conflict of interest, financial or otherwise, in a project or other related matter(s) considered by the HREC.
2. The HREC 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 HREC's consideration of the relevant matter has been completed. The member shall not be permitted to adjudicate on the research.
3. All declarations of conflict of interest and the absence of the member concerned will be minuted.

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 024

Date: March 2005

Subject: HREC reporting requirements

Purpose: To describe the reporting requirements of the HREC

1. The minutes of each HREC meeting will be forwarded to the Chief Executive, following confirmation.
2. The HREC shall provide an annual report to the Chief Executive at the end of each [financial/calendar] year on its progress, including:
 - membership/membership changes;
 - number of meetings;
 - number of projects reviewed, approved and rejected*;
 - monitoring procedures for ethical aspects of research in progress and any problems encountered by the HREC in undertaking its monitoring role;
 - description of any complaints received and their outcome;
 - description of any research where ethical approval has been withdrawn and the reasons for withdrawal of approval; and
 - general issues raised.
3. The HREC will provide reports to the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the NHMRC.
4. The HREC will provide reports to the NSW Privacy Commissioner in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW).
5. The HREC Terms of Reference, Standard Operating Procedures and membership will be available upon request to the general public, and will be posted on the Health Service website.

**Note: The Report of the Review of the Role and Functioning of Institutional Ethics Committees (March 1996) suggests that in order to ensure the breadth and experience of committee members is maintained, those HRECs with a small workload should consider amalgamation with another HREC.*

**[Insert name of Health Service] Human Research Ethics Committee
Standard Operating Procedures**

Reference Number: SOP 025

Date: March 2005

Subject: Review of Standard Operating Procedures and Terms of Reference

Purpose: To describe the procedure for the approval of amendments to the HREC Standard Operating Procedures and Terms of Reference

1. The Standard Operating Procedures and Terms of Reference shall be reviewed at least every two years and amended as necessary.
2. The Standard Operating Procedures and Terms of Reference may be amended by following the procedure below:

For those proposals made by a HREC member:

- The proposal must be in writing and circulated to all HREC members for their consideration.
- The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his or her views in writing.
- The proposal shall be ratified if two thirds of the members agree to the amendment.
- The Chairperson shall send the amendment to the Chief Executive for review and approval if appropriate.

For those proposals made by the Chief Executive:

- The Chief Executive will send the proposal to the HREC and seek the views of any relevant person.

[insert name of Area Health Service] HREC Membership

Name	Category
	Chairperson
	Lay woman
	Lay man
	Member with knowledge of, and current experience in the areas of research regularly considered by the HREC
	Member with knowledge of, and current experience in, the professional care, counselling or treatment of people
	Minister of religion, or person who performs similar role in the community
	Lawyer
	Other appropriate member(s)

Attachment A

Standard Letter for HREC Approval of New Application

This should include at least the following pieces of information:

- title of project;
- name of the principal investigator(s);
- unique HREC project identification number;
- the version number and date of all documentation reviewed and approved by the HREC including Clinical Protocols, Patient Information Sheets, Consent Forms, advertisements, questionnaires etc;
- date of HREC meeting at which the project was first considered;
- date of HREC approval;
- duration of HREC approval;
- conditions of HREC approval, if any; and
- if the research is being conducted by an external organisation (if it is in the HREC's TOR to provide ethical review for that external organisation) a statement that approval of this project does not have the effect of conferring any insurance or indemnity coverage on the external organisation by the Health Service in relation to the project, and responsibility for any liabilities arising from the conduct of the project remains entirely with the external organisation.

[Example only, HREC to insert own version]

[name of principal investigator]
[address]

[Date of letter]

Dear [insert name of principal investigator]

[insert unique HREC project ID number, full title of study]

Thank you for submitting the above project which was first considered by the [insert name of HREC] at its meeting held on [insert date]. This HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that the Committee has granted ethical approval of the above project .

The following documentation has been reviewed and approved by the HREC:

- [insert the version number and date of all documentation reviewed and approved by the HREC including Clinical Protocols, Patient Information Sheets, Consent Forms, advertisements, questionnaires etc.]

Please note the following conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
 - any serious or unexpected adverse events; and
 - unforeseen events that might affect continued ethical acceptability of the project.
2. The Principal Investigator will report proposed changes to the research protocol, conduct of the research, or length of HREC approval to the HREC in the specified format, for review.
3. The Principal Investigator will inform the HREC, giving reasons, if the project is discontinued before the expected date of completion.
4. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
5. [insert any other conditions imposed by the HREC]

HREC approval is valid for [insert length of HREC approval] from the date of this letter.

The HREC also has delegated authority to approve the commencement of this research on behalf of [insert name of Health Service]. This research may therefore commence. [Insert only where the HREC has such delegated authority and where the research is taking place within the Health Service]

[insert if research is being conducted within an external organisation]. Although it is within this HREC's Terms of Reference to review research which takes place within [insert name of external organisation] we note that [external organisation] is not part of [insert name of Health Service]. This approval does not have the effect of conferring any insurance or indemnity coverage on the external organisation by the [name of Health Service] in relation to this project, and any liabilities arising from the conduct of the project are entirely the responsibility of [name of external organisation].

Should you have any queries about your project please contact [insert name and contact details of HREC Executive Officer or Chairperson]. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the [insert name of Health Service] website:

[insert website URL]

Please quote [insert unique HREC project ID number] in all correspondence.

The HREC wishes you every success in your research

Yours faithfully

[insert name of HREC Chair]
[insert HREC address]

Attachment B

Standard Letter for HREC Approval of Amendment

This should include at least the following pieces of information:

- title of project;
 - name of the principal investigator(s);
 - unique HREC project identification number;
 - the version number and date of all documentation reviewed and approved by the HREC including Clinical Protocols, Patient Information Sheets, Consent Forms, advertisements, questionnaires etc;
 - date of HREC meeting (or Executive Meeting) at which the amendment and/or request for extension was first considered;
 - date of HREC approval; and
 - conditions of HREC approval, if any.
-

[Example only, HREC to insert own version]

[name of principal investigator]
[address]

[Date of letter]

Dear [insert name of principal investigator]

[insert unique HREC project ID number, full title of study]

Thank you for submitting a request for an amendment to the above project. This was first considered by the [insert name of HREC] at its meeting/Executive meeting [delete whichever is not applicable] held on [insert date]. This HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that the Committee has granted ethical approval for the following amendment request

- [insert summary of amendment request including the version number and date of all documentation reviewed and approved by the HREC including Clinical Protocols, Patient Information Sheets, Consent Forms, advertisements, questionnaires etc.]

Please note the following conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:

- any serious or unexpected adverse events; and
 - unforeseen events that might affect continued ethical acceptability of the project.
2. The Principal Investigator will report proposed changes to the research protocol, conduct of the research, or length of HREC approval to the HREC in the specified format, for review.
 3. The Principal Investigator will inform the HREC, giving reasons, if the project is discontinued before the expected date of completion.
 4. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
 5. [insert any other conditions imposed by the HREC]

The HREC has delegated authority to approve the commencement of this amendment on behalf of [insert name of Health Service]. This amended research may therefore commence [Insert only where HREC has such delegated authority and research is taking place within the Health Service]

[Insert if research is being conducted within an external organisation]. Although it is within this HREC's Terms of Reference to review research which takes place within [insert name of external organisation] we note that [external organisation] is not part of [insert name of Health Service]. This approval does not have the effect of conferring any insurance or indemnity coverage on the external organisation by the [name of Health Service] in relation to this project, and any liabilities arising from the conduct of the project are entirely the responsibility of [name of external organisation].

Should you have any queries about your project please contact [insert name and contact details of HREC Executive Officer or Chairperson]. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the [insert name of Health Service] website:

[insert website URL]

Please quote [insert unique HREC project ID number] in all correspondence.

Yours faithfully

[insert name of HREC Chair]
[insert HREC address]

Attachment C
Standard Response Letter for HREC Request for Additional Information

[Example only, HREC to insert own version]

[name of principal investigator]
[address]

[Date of letter]

Dear [insert name of principal investigator]

[insert unique HREC project ID number, full title of study]

Thank you for submitting the above project/amendment [delete whichever is not applicable] which was first considered by the [insert name of HREC] at its meeting held on [insert date]. This HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans (National Statement)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

In order to make a determination of the ethical acceptability of your project, please respond to the following request for additional information/clarification or modification [delete whichever is not applicable]:

1. [List each request separately. Each request must clearly articulate the reasons for this determination and clearly set out the information that is required, relying on the relevant paragraphs of the National Statement, relevant legislation or other applicable guidelines].

Please refer to paragraph [insert relevant paragraph/s of the *National Statement*, relevant legislation or other applicable guidelines].

In order to facilitate the Committee's consideration of your project, please provide the requested information as soon as possible. Your response may be emailed to the Executive Officer [insert email address] however this should be accompanied by a hard copy.

Please note that if the requested information is not received within 3 months or two meetings (whichever occurs sooner), the project will be dismissed and you will be required to re-submit the project at a later date.

Should you have any queries about your project please contact [insert name and contact details of HREC Executive Officer or Chairperson].

Please quote [insert unique HREC project ID number] in all correspondence.

Yours sincerely

[insert name of HREC Chair]
[insert HREC address]

Attachment D
Standard Response Letter for HREC Rejection of New Application
[Example only, HREC to insert own version]

[name of principal investigator]
[address]

[Date of letter]

Dear [insert name of principal investigator]

[insert unique HREC project ID number, full title of study]

Thank you for submitting the above project which was first considered by the [insert name of HREC] at its meeting held on [insert date]. This HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans (National Statement)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

The HREC has decided not to approve your project for the following reasons:

1. [List each reason separately. Each reason must refer to the relevant paragraph/s of the *National Statement*, relevant legislation or other applicable guidelines].

Should you wish to discuss the HREC's review of your project, please contact [insert name and contact details of HREC Executive Officer or Chairperson].

Yours sincerely

[insert name of HREC Chair]
[insert HREC address]

Attachment E
Standard Letter for Expedited HREC Approval of New Application
[Example only, HREC to insert own version]

[name of principal investigator]
[address]

[Date of letter]

Dear [insert name of principal investigator]

[insert unique HREC project ID number, full title of study]

Thank you for submitting the above project which was first considered by an Executive of the [insert name of HREC] for expedited review. This HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans (National Statement)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that the Executive has granted ethical approval of the above project.

The following documentation has been reviewed and approved by the HREC:

- [insert the version number and date of all documentation reviewed and approved by the HREC including Clinical Protocols, Patient Information Sheets, Consent Forms, advertisements, questionnaires etc.]

Please note the following conditions of approval:

1. This approval requires ratification by the HREC at its next available HREC meeting.
2. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
 - any serious or unexpected adverse events; and
 - unforeseen events that might affect continued ethical acceptability of the project.
3. The Principal Investigator will report proposed changes to the research protocol, conduct of the research, or length of HREC approval to the HREC in the specified format, for review.
4. The Principal Investigator will inform the HREC, giving reasons, if the project is discontinued before the expected date of completion.
5. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.

6. [insert any other conditions imposed by the HREC]

HREC approval is valid for [insert length of HREC approval] from the date of this letter.

The HREC also has delegated authority to approve the commencement of this research on behalf of [insert name of Health Service]. This research may therefore commence. [Insert only where the HREC has such delegated authority]

[insert if research is being conducted within an external organisation]. Although it is within this HREC's Terms of Reference to review research which takes place within [insert name of external organisation] we note that [external organisation] is not part of [insert name of Health Service]. This approval does not have the effect of conferring any insurance or indemnity coverage on the external organisation by the [name of Health Service] in relation to this project, and any liabilities arising from the conduct of the project are entirely the responsibility of [name of external organisation].

Should you have any queries about your project please contact [insert name and contact details of HREC Executive Officer or Chairperson]. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the [insert name of Health Service] website:

[insert website URL]

Please quote [insert unique HREC project ID number] in all correspondence.

The HREC wishes you every success in your research

Yours faithfully

[insert name of HREC Chair]
[insert HREC address]

Attachment F

Standard Requirements for Reporting of Serious and Unexpected Adverse Events

[Example only, HREC to insert own version]

HREC Project No:

Full title of study:

Sponsor Protocol No: (if applicable)

Name of Principal Investigator:

Report No. and Date	Description of Event	Frequency of event in relation to total number of participants	Indicate if event occurred within [insert AHS]	Relationship of the event to the study drug/device (Unlikely/possible/probable/definite/unknown)	Ethical implications of the event on the conduct of the trial/investigator comment (if applicable)

Please indicate if any of the above adverse event/s necessitates an amendment to the project and/or the Patient Information Sheet/Consent Form.

Signature of Principal Investigator:.....

The above serious adverse event/s will be noted/reviewed [delete whichever is not applicable] by the [name of HREC] at its meeting on the:

Signature of HREC Secretariat/Chair.....

Date.....

*Note: The standard forms of the following NSW Health HRECs were referred to when developing Attachment F:

- Central Coast AHS HREC
- Children's Hospital Westmead HREC
- Concord Hospital HREC
- North Coast AHS HREC
- Northern Sydney Health HREC
- South Eastern Sydney AHS – Eastern Section HREC
- South Eastern Sydney AHS – Southern Section HREC
- South Western Sydney AHS HREC
- St Vincent's Hospital HREC
- Sydney South West AHS Ethics Review Committee (RPA Zone)
- Sydney West AHS HREC, Nepean Campus
- Sydney West AHS HREC, Westmead Hospital