

Operations Manual: Human Research Ethics Committee Executive Officers

Summary This Guideline contains standard operating procedures to promote a consistent approach to the administration and management of Human Research Ethics Committee applications and approved projects across NSW Public Health Organisations.

Document type Guideline

Document number GL2010_014

Publication date 08 September 2010

Author branch Office for Health and Medical Research

Branch contact 9391 9920

Review date 30 March 2018

Policy manual Not applicable

File number 10/3562

Previous reference N/A

Status Review

Functional group Clinical/Patient Services - Research, Governance and Service Delivery

Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Affiliated Health Organisations - Declared, Public Health Units, Public Hospitals

Distributed to Public Health System, NSW Ambulance Service, Ministry of Health

Audience Research office staff

OPERATIONS MANUAL: HUMAN RESEARCH ETHICS COMMITTEE EXECUTIVE OFFICERS

PURPOSE

This document provides standard operating procedures for Executive Officers of NSW Health Human Research Ethics Committees (HRECs).

KEY PRINCIPLES

The standard operating procedures contained in this Guideline have been developed to promote a consistent approach to the administration and management of HREC applications and approved research projects across NSW Public Health Organisations.

Matters of detail and precise procedure may be subject to particular local needs.

Public Health Organisations may choose to adopt the standard operating procedures within this Guideline unchanged, or incorporate them into their existing standard operating procedures.

It is expected that, where a Public Health Organisation amends the standard operating procedures within this Guideline to reflect local practice and requirements, the amendment extends requirements.

USE OF THE GUIDELINE

NSW Public Health Organisations must establish structures and practices consistent with this Guideline in accordance with Policy Directive PD2010_055 *Ethical and scientific review of human research in NSW Public Health Organisations*.

REVISION HISTORY

Version	Approved by	Amendment notes
September 2010 (GL2010_014)	Deputy Director-General Population Health	New guideline

ATTACHMENTS

1. Operations Manual: Human Research Ethics Committee Executive Officers procedures

**Operations Manual: Human Research Ethics Committee
Executive Officers**

NSW HEALTH
PROCEDURES

Issue date: September 2010

GL2010_014

CONTENTS

BACKGROUND.....	1
1.1 About this document.....	1
1.2 Scope.....	1
1.3 Abbreviations	1
1.4 Key definitions.....	1
EO 001: HREC Executive Officer functions.....	6
EO 002: Australian Research Ethics Database (AU RED)	8
EO 003: Submission of new applications.....	9
EO 004: Full HREC review	10
EO 005: Expedited HREC review for low and negligible risk research	12
EO 006: Exemption from ethical and scientific review	15
EO 007: Withdrawal of applications.....	16
EO 008: Notification of HREC decisions	17
EO 009: Amendments to approved research projects	19
EO 010: Urgent safety-related measures.....	22
EO 011: Adverse event reporting.....	23
EO 012: Monitoring approved research projects.....	26
EO 013: Appeals on HREC decisions	29
EO 014: Complaints about the conduct of an approved research project	31
EO 015: Complaints about the conduct of HREC members.....	32
EO 016: Suspension or withdrawal of HREC approval.....	33
EO 017: Discontinuation of a research project by the investigator or sponsor	34
EO 018: Storage and retention of records.....	35
EO 019: Payment of fees	36
EO 020: Multi-centre research applications approved before July 2007.....	37
Appendix A: Summary of routes of obtaining Human Research Ethics Committee (HREC) approval and site authorisation for research taking place in NSW Public Health Organisations	38

BACKGROUND

1.1 About this document

This document provides standard operating procedures for Executive Officers of NSW Health Human Research Ethics Committees (HRECs).

The standard operating procedures have been developed to promote a consistent approach to the administration and management of HREC applications and approved research projects across NSW Public Health Organisations.

This Guideline should be read in conjunction with Guideline GL2010_013 *Operations Manual: Human Research Ethics Committees*.

1.2 Scope

The standard operating procedures apply to human research taking place in NSW Public Health Organisations, which means research:

- conducted at sites under the control of Public Health Organisations; and/or
- involving participants, tissue or data accessed through Public Health Organisations.

1.3 Abbreviations

AU RED	Australian Research Ethics Database
CTN	Clinical Trial Notification
CTX	Clinical Trial Exemption
HREC	Human Research Ethics Committee
NEAF	National Ethics Application Form
NHMRC	National Health and Medical Research Council
SAE	Serious adverse event
SUSAR	Suspected unexpected serious adverse reaction

1.4 Key definitions

Adverse event

For medicines, also referred to as **adverse experience**, any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign, symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

For devices, any undesirable clinical occurrence in a subject whether it is considered to be device related or not, that includes a clinical sign, symptom or condition and/or an observation of an unintended technical performance or performance outcome of the device.

[Ref: *Access to unapproved therapeutic goods via the Special Access Scheme* (2009)].

Approval conditions Part of the approval to be observed by the investigator in the conduct of the research. Approval conditions are issued by the HREC with the final letter confirming a favourable ethical opinion.

AU RED The Australian Research Ethics Database is an online system used by NSW Public Health Organisations for the management and administration of applications for ethical and scientific review and site authorisation.

Clinical trial means any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

[Ref: *Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95): Annotated with TGA comments*].

Co-ordinating Investigator is the individual who takes overall responsibility for the research project and submits the project for ethical and scientific review. They are responsible for ongoing communication with the HREC and passing on any outcomes from this to the Principal Investigators. For single centre research, Co-ordinating Investigator and Principal Investigator are synonymous.

Data & Safety Monitoring Board is an independent data monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy points, and to recommend to the sponsor whether to continue, modify, or stop a clinical trial.

[Ref: *Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95): Annotated with TGA comments*].

Department of Health is the NSW Department of Health as established under Section 6 of the *Health Administration Act 1982*.

Human research is research conducted with or about people, or their data or tissue as described in the *National Statement on Ethical Conduct in Human Research (2007)*.

Human Research Ethics Committee (HREC) is a committee constituted in accordance with the *National Statement on Ethical Conduct in Human Research (2007)* to review and where appropriate approve and monitor the ethical and scientific aspects of human research.

Investigator's brochure is a compilation of clinical and non-clinical data on the investigational product(s) relevant to the study of investigational product(s) in human subjects.

[Ref: *Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95): Annotated with TGA comments*].

Lead HREC is a local HREC accredited by the Director-General of the NSW Department of Health to conduct ethical and scientific review of human research on behalf of the NSW public health system in the categories of: (a) clinical trials/interventional clinical research; and/or (b) general research.

Local HREC is a NSW Health HREC established by a Public Health Organisation to provide ethical and scientific review of human research to be conducted at sites under its control.

Low risk research is research where the only foreseeable risk to the participant is one of discomfort. Discomforts may include minor side-effects of medication, discomforts related to measuring blood pressure or anxiety induced by an interview. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.

[Ref: *National Statement on Ethical Conduct in Human Research* (2007)].

Multi-centre research is research that is conducted at more than one site within the NSW public health system, where those sites are within the jurisdiction of more than one NSW Health HREC.

National Statement is the *National Statement on Ethical Conduct in Human Research* (2007).

Negligible risk research is research where there is no foreseeable risk of harm or discomfort and any foreseeable risk is not more than inconvenience to the participants. Inconvenience is the least form of harm that is possible for human participants in research. The most common examples of inconvenience in human research are filling in a form, participating in a survey or giving up time to participate in a research activity. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.

[Ref: *National Statement on Ethical Conduct in Human Research* (2007)].

NSW Health HREC is an HREC established by a Public Health Organisation and registered with the National Health and Medical Research Council.

Online Forms Website is an online system that enables users to electronically complete their applications for ethical and scientific review and site authorisation.

Principal Investigator is the individual who takes responsibility for the overall conduct, management, monitoring and reporting of research conducted at a site and submits the research project for site authorisation.

Public Health Organisation under the *Health Services Act 1997 (NSW)* is an Area Health Service, statutory health corporation or affiliated health organisation in respect of their recognised services.

Research is original investigation undertaken to gain knowledge, understanding and insight as described in the *Australian Code for the Responsible Conduct for Research* (2007).

Research Governance Officer is the individual appointed within the Public Health Organisation who is responsible for the management of applications for site authorisation and oversight of authorised research projects.

Research protocol is a document that details the objectives, design, methodology, statistical considerations and organisation of a research project.

Reviewing HREC is the HREC which undertook the ethical and scientific review and provided approval for the research project.

Serious adverse event (SAE):

For medicines, also referred to as **serious adverse drug reaction**, is any untoward medical occurrence that at any dose:

- results in death;
- is life-threatening;

- requires in-patient hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect; or
- is a medically important event or reaction.

NOTE: The term 'life-threatening' in the definition of 'serious' refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event/reaction which hypothetically might have caused death if it were more severe.

For devices is any adverse medical occurrence that:

- led to a death;
- led to a serious deterioration in health of a patient user or other. This would include:
 - a life threatening illness or injury;
 - a permanent impairment of body function or permanent damage to a body structure;
 - a condition requiring hospitalisation or increased length of existing hospitalisation;
 - a condition requiring unnecessary medical or surgical intervention; or
 - foetal distress, foetal death or a congenital abnormality/birth defect;
- might have led to death or a serious deterioration in health had suitable action or intervention not taken place. This includes:
 - a malfunction of a device such that it has to be modified or temporarily/permanently taken out of service; or
 - a factor (a deterioration in characteristics or performance) found on examination of the device.

[Ref: *Access to unapproved therapeutic goods via the Special Access Scheme* (2009)].

Serious unexpected suspected adverse reaction (SUSAR) is a serious adverse event for which there is some degree of probability that the event is an adverse reaction to the administered drug, and the adverse reaction is unexpected.

Single centre research is research that is conducted at one site only within the NSW public health system (i.e. single-site research) or at two or more sites under the jurisdiction of a single NSW Health HREC.

Site is a facility, location or service where the research is being conducted.

Site authorisation is the authorisation granted by the Chief Executive or delegate of the Public Health Organisation for the commencement of a research project.

Site-specific assessment is a mechanism used by Public Health Organisations to ensure that the proposed research project complies with minimum governance requirements, and to consider whether the research should be conducted and supported at the proposed site.

Sponsor of a clinical trial is the company, institution or organisation, body or individual that takes overall responsibility for the conduct of the trial and usually initiates, organises and supports the clinical trial.

Therapeutic good is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use (unless specifically excluded or included under Section 7 of the *Therapeutic Goods Act 1989*). Therapeutic use means use in or in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury;
- influencing inhibiting or modifying a physiological process;
- testing the susceptibility of persons to a disease or ailment;
- influencing, controlling or preventing conception;
- testing for pregnancy; or
- replacement or modification of parts of the anatomy.

[Ref: <http://tga.gov.au/docs/html/tga/tgaginfo.htm>, last accessed 10/08/2010].

EO 001: HREC Executive Officer functions

- 1.1. Each HREC will have an Executive Officer whose primary role is to manage the business of, and provide high level executive support to, the HREC, the HREC Executive Committee and any subcommittees.
- 1.2. The name and contact details of each Executive Officer will be made publicly available on the Public Health Organisation and Department of Health websites.
- 1.3. Responsibilities of Executive Officers will include, but not be limited to, the following:

Pre-approval

- a) Advising and assisting investigators in the submission of all applications to the HREC. This will necessitate a knowledge of state and national legislation, policies and guidelines related to human research.
- b) Managing all aspects of the application for ethical and scientific review of human research.
- c) Reviewing applications to the HREC to ensure all documentation is complete.
- d) Ensuring collection of appropriate fees for HREC review.

Post-approval

- a) Managing amendments to approved research projects.
- b) Managing appeals and complaints.
- c) Managing annual progress reports and final reports.
- d) Ensuring collection of appropriate fees for post-approval HREC review.

Other

- a) Managing the activities and records of the HREC, the HREC Executive Committee and subcommittees.
- b) Preparing reports to regulatory bodies, as required.
- c) Developing and implementing a continuing education program for the members of the HREC to ensure they are up to date with current legislation, policy directives, and guidelines pertaining to human research. This will also involve an assessment of external educational opportunities.
- d) Managing support personnel and participating in all aspects of their recruitment, selection, induction, continued mentoring, performance management and the assessment of educational opportunities.
- e) Maintaining records, including databases and filing systems.
- f) Developing and maintaining web-based information for investigators.
- g) Monitoring relevant regulatory and policy developments to ensure changes are incorporated into local HREC policies and procedures.
- h) Participating in the development and implementation of best practice policy, procedures and standardised systems within the Public Health Organisation and the NSW public health system.

- 1.4. The responsibilities of the HREC Executive Officer in relation to HREC meetings will include:
 - a) Publishing the schedule of HREC meetings;
 - b) Preparing the agenda;
 - c) Allocating lead reviewers (where this is the practice of the HREC);
 - d) Distributing agenda and papers;
 - e) Inviting the Co-ordinating Investigator and, where appropriate, supervisors/ student liaison officer or clinical supervisor to attend meetings and making necessary arrangements;
 - f) Preparing the venue;
 - g) Recording apologies for absence prior to the meeting;
 - h) Raising with the Chairperson any concern that a meeting may not be quorate;
 - i) Recording attendance by members for the discussion of each application for ethical and scientific review;
 - j) Advising the meeting as necessary on compliance with standard operating procedures;
 - k) Preparing the minutes of the meeting for review and approval;
 - l) Notifying investigators of decisions and taking other follow-up action as necessary; and
 - m) Identifying expert reviewers as required.
- 1.5. The Executive Officer will delegate tasks, as appropriate.
- 1.6. An orientation package, developed by the Public Health Organisation, will be provided to new Executive Officers.
- 1.7. Executive Officers will be encouraged to attend workshops, seminars and conferences related to their role. Examples include roundtable forums hosted by the Department of Health and training in the use of AU RED.

EO 002: Australian Research Ethics Database (AU RED)

- 2.1. The Australian Research Ethics Database (AU RED) is an online research application tracking and management system. AU RED is accessed from the website: <https://www.ethicsdatabase.org/au>
- 2.2. HREC Executive Officers will use AU RED for the management of applications submitted for full HREC review for research projects involving NSW Health sites.
- 2.3. From 01 January 2011, HREC Executive Officers will use AU RED for the management of all applications submitted to their HREC for review (i.e. those associated with full and expedited HREC review) for research projects involving NSW Health sites.
- 2.4. AU RED will be used by the Department of Health to monitor aspects of performance, including timelines for ethical review.

Users

- 2.5. Public Health Organisations will nominate prospective AU RED users to the Department of Health for authorisation and the issuing of user accounts. HREC members will not be granted access to AU RED, however access by the Chairperson and Deputy Chairperson may be considered on a needs basis.
- 2.6. Registered users of AU RED will sign a confidentiality undertaking (issued by the Department of Health) indicating that they will use the information contained in the system in a confidential manner.

Assistance

- 2.7. Instructions on how to use AU RED will be available from a user manual, available from the website: <https://www.ethicsdatabase.org/au>
- 2.8. A helpdesk will be available to provide technical support for AU RED users between the hours of 10:00 and 16:00 AEST, Monday to Friday:
Phone: (02) 9037 8404 | Email: helpdesk@infonetica.net

EO 003: Submission of new applications

- 3.1. In accordance with PD2010_055 *Ethical and scientific review of human research in NSW Public Health Organisations*, all human research that takes place in NSW Public Health Organisations must be reviewed and approved in accordance with the *National Statement*.
- 3.2. All applications for ethical and scientific review will be submitted to the HREC Executive Officer by the Co-ordinating Investigator using one of the following forms:
 - a) National Ethics Application Form (NEAF) for full HREC review; or
 - b) Application Form for Ethical and Scientific Review of Low and Negligible Risk Research for expedited HREC review.
- 3.3. The forms will be completed via the Online Forms Website:
<https://ethicsform.org/au/>
- 3.4. Investigators will create an account to access the Online Forms Website to generate an application.
- 3.5. The Online Forms Website provides guidance on how to complete the forms and on supporting documents required for making an application.
- 3.6. Applications for full HREC review will be submitted to the Executive Officer of the HREC by the published closing date. Each HREC will determine whether applications for expedited HREC review will be submitted by the published closing date, or at any time throughout the year.
- 3.7. The closing dates for applications for full HREC review will be no longer than 20 working days prior to each HREC meeting.
- 3.8. Each HREC will determine and make publicly available the format (electronic or hardcopy) and the number of copies of the application form and supporting documentation required to make an application.
- 3.9. Each Public Health Organisation will determine whether electronic signatures on the application form are acceptable.
- 3.10. A helpdesk will be available to provide technical support for Online Forms users between the hours of 10:00 and 16:00 AEST, Monday to Friday:
Phone: (02) 9037 8404 | Email: helpdesk@infonetica.net
- 3.11. Investigators will be able to access additional information by contacting the Research, Ethics and Public Health Training Branch:
Phone: (02) 9391 9427 | Email: healthethics@doh.health.nsw.gov.au.

EO 004: Full HREC review

- 4.1. In accordance with the *National Statement*, the following types of human research will be ethically and scientifically reviewed and approved by a full HREC before they take place in NSW Public Health Organisations.
- a) Research that involves more than low risk to participants.
 - b) Research that includes any of the following:
 - Interventions and therapies, including clinical and non-clinical trials and innovations or new treatment modalities;
 - Active concealment or planned deception of participants;
 - Exposure of illegal activities; and
 - Research specifically targeting Aboriginal or Torres Strait Islander peoples.
 - c) Research that includes any of the following, except where the project uses collections of non-identifiable data and involves only negligible risk to participants:
 - Human genetics;
 - Human stem cells;
 - Women who are pregnant and the human foetus;
 - People who are highly dependent on medical care who may be unable to give consent;
 - People with a cognitive impairment;
 - People with an intellectual disability or a mental illness; and
 - People who may be involved in illegal activities.
- 4.2. All applications for full HREC review by a NSW Health HREC will be made by the Co-ordinating Investigator using the National Ethics Application Form (NEAF), completed via the Online Forms Website.

Allocation of applications

- 4.3. The Executive Officer will determine, in consultation with the HREC Chairperson if required, the review requirements of an application prior to full review by the HREC (e.g. review by a scientific subcommittee, lead reviewer or external expert reviewer). Those HRECs which have a separate scientific subcommittee will forward all applications to the subcommittee for review prior to full HREC review.
- 4.4. The HREC will, at its discretion, cap the number of applications it reviews at each meeting to ensure the rigour of its review process.

Validation of applications

- 4.5. The Executive Officer will determine whether the application is valid and send an acknowledgement to the Co-ordinating Investigator, generally within 5 working days of receiving the application, by a written letter or email. If required, the Executive Officer will contact the Co-ordinating Investigator by telephone or email to request that they provide any missing information before issuing a formal

acknowledgement. The acknowledgement will include details of dates of the meeting(s) at which the application will be discussed and the HREC Reference Number.

4.6. An application will be accepted if it meets the following criteria:

- a) Documents relevant to the particular application are submitted in accordance with the HREC requirements;
- b) All sections and questions on the application form are completed;
- c) The application has been signed by the Co-ordinating Investigator and their head of department;
- d) Supporting documents are marked with version numbers and dates in the case of the research protocol, Participant Information Sheet and Consent Forms, letters to participants or others with an interest in the research, diaries, identification cards and any other documentation to be used in the research that is not already scientifically validated and referenced;
- e) All relevant scientific and technical assessments and reports (e.g. radiation, drug and biosafety committee reports) are included.

Invalid applications

4.7. Where an application is not submitted on the correct application form and/or is missing the required supporting documents or significant sections of the form is incomplete, the Co-ordinating Investigator will be notified by letter explaining that the application will not be accepted for the current meeting and that further documentation/completion of the correct form is required prior to HREC review.

EO 005: Expedited HREC review for low and negligible risk research

- 5.1. NSW Health HRECs will provide an expedited review process for research projects that are considered to be low or negligible risk to participants as defined in the *National Statement*.
- 5.2. The *National Statement* describes research as “low risk” where the only foreseeable risk is one of discomfort. Discomforts may include minor side-effects of medication, discomforts related to measuring blood pressure or anxiety induced by an interview. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.
- 5.3. Research with “negligible risk” is described in the *National Statement* as where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience to the participants. Inconvenience is the least form of harm that is possible for human participants in research. The most common examples of inconvenience in human research are filling in a form, participating in a survey or giving up time to participate in a research activity. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.
- 5.4. The types of low and negligible risk research that may undergo expedited review include research where:
 - a) The threat to participants’ privacy and confidentiality is remote;
 - b) The project does not (or does not have the potential to) involve sensitive information about participants; and
 - c) The level of intrusiveness and disruption to participants is minimal.
- 5.5. Examples of research with low and negligible risk include, but are not limited to, the following:
 - a) Research involving only questionnaires and general surveys on non-controversial, non-personal issues that also include only basic demographic data and where, in all instances, respondents are not identified;
 - b) Research involving only the use and/or disclosure of information from existing data collections, where the identity of the person cannot reasonably be ascertained from the information to be disclosed to researchers;
 - c) Research involving human tissue where participant consent is not required because broad consent has been provided for use of the tissue in research and specific individuals cannot be identified from specimens used e.g. where specimens have never been labelled with individual identifiers or individual identifiers have been permanently removed; and
 - d) Research requiring access to individual medical records or to information stored electronically, through the site’s medical records department or other department/specialty, but where participant consent is not required because, in all instances, individuals cannot be identified from data extracted or provided.
- 5.6. Applications for expedited review of research with low and negligible risk to participants by a NSW Health HREC will be made by the Co-ordinating

Investigator using the Application Form for Ethical and Scientific Review of Low and Negligible Risk Research, accessed through the Online Forms Website.

- 5.7. The Co-ordinating Investigator will consult the HREC Executive Officer to determine if the research project can be classified as low or negligible risk research, before completing the form.
- 5.8. The Executive Officer will, at their discretion, request that the research project is submitted for a full review using NEAF if they consider the risk to participants to be greater than low risk.
- 5.9. The HREC will, at its discretion, request a full review using NEAF following assessment of the application for expedited review if it considers the risk to participants to be greater than low risk.

Validation of applications

- 5.10. The Executive Officer will decide whether the application is valid and send an acknowledgement to the Co-ordinating Investigator, generally within 5 working days of receiving the application, by a written letter or email. If required, the Executive Officer will contact the Co-ordinating Investigator by telephone or email to request that they provide any missing information before issuing a formal acknowledgement.
- 5.11. An application will be accepted if it meets the following criteria:
 - a) Documents relevant to the particular application are submitted in accordance with the HREC requirements;
 - b) All sections and questions in the application are completed; and
 - c) Supporting documents are marked with version numbers and dates.

Invalid applications

- 5.12. Where an application is not submitted on the correct application form and/or is missing the required supporting documents or significant sections of the form is incomplete, the Co-ordinating Investigator will be notified by letter explaining that the application will not be accepted and that further documentation/completion of the correct form is required prior to HREC review.

Review of applications

- 5.13. An application for expedited review of low and negligible risk research will be reviewed by the HREC Executive Committee comprising a minimum of two including the Chairperson or delegate and a member of the research office. This review will take place via face-to-face or telephone meeting or e-communication. The reviewers will have the opportunity to seek clarification from the investigator or from other HREC members, if required.
- 5.14. The HREC Executive Committee will be unanimous in its determination that the research qualifies as low and negligible risk and in its decision on the review. The HREC will note the decision of the HREC Executive Committee at the next available HREC meeting.

- 5.15. The HREC Executive Committee will minute the determination of the application as low and negligible risk, matters considered during the review, the decision taken with relevant experts if applicable, and the rationale for that decision.
- 5.16. Where the HREC Executive Committee is not unanimous in both the determination that the research qualifies as low and negligible risk and in its decision on the review, the application will be reviewed at a full meeting of the HREC.

EO 006: Exemption from ethical and scientific review

- 6.1. In accordance with the *National Statement*, Public Health Organisations will, at their discretion, exempt from ethical review research that:
 - a) is negligible risk research; and
 - b) involves the use of existing collections of data or records that contain only non-identifiable data about human beings.
- 6.2. Investigators with a research project that fulfils the above criteria will consult the HREC Executive Officer to ensure that the project is exempt from ethical and scientific review.
- 6.3. The HREC Executive Officer will remind investigators that academic journals often require evidence that a research project has been reviewed by an HREC or that it has been exempt from review by an HREC.

EO 007: Withdrawal of applications

- 7.1. The Co-ordinating Investigator will be able to withdraw an application at any time prior to receipt of the HREC review outcome.
- 7.2. Requests will be made in writing to the Executive Officer, who will acknowledge the request in writing.
- 7.3. If the withdrawn application is submitted to a new HREC, the Co-ordinating Investigator will include all previous documentation associated with the initial HREC review and reasons for withdrawal.
- 7.4. The new HREC will be able to request that the application is re-submitted to the original HREC for any reason.

EO 008: Notification of HREC decisions

- 8.1. The procedures outlined in this section apply to notification of the outcome of full and expedited HREC review.
- 8.2. Following confirmation of the minutes by the Chairperson, the Executive Officer will notify the Co-ordinating Investigator of the decision in writing within 10 working days of the meeting.

Requests for modification/further information

- 8.3. The following information will be included in the letter of notification:
 - a) The decision reached by the HREC or HREC Executive Committee;
 - b) Requests for modification of or further information for the research project with reference to the *National Statement* or relevant legislation where necessary and the process for approval of the modifications as agreed by the HREC or HREC Executive Committee; and
 - c) Notification that a response be provided within 3 months or two HREC meetings (whichever occurs sooner). After this time the application is considered withdrawn and the Co-ordinating Investigator will be required to submit a new application.

Approved research projects

- 8.4. Final approval for a research project will be given at:
 - a) the full HREC meeting where the application was initially considered; or
 - b) the full HREC meeting where the response to a request for modification/further information was considered; or
 - c) the HREC Executive Committee meeting where the low and negligible risk application was initially considered; or
 - d) the HREC Executive Committee meeting where the response to a request for modification/further information was considered.
- 8.5. The following information will be included in the approval letter:
 - a) The decision reached by the HREC or HREC Executive Committee;
 - b) A list of all approved documents including version numbers and dates;
 - c) A list of all sites for which the ethical and scientific approval applies;
 - d) Duration of ethical and scientific approval;
 - e) Confirmation that the HREC composition is in accordance with the *National Statement*; and
 - f) A statement to the effect that the project cannot commence at a NSW public health site until site authorisation is granted.
- 8.6. Additional approval conditions specified by the HREC or HREC Executive Committee for a particular application, for example a requirement for more frequent progress reports, will be included in the approval letter.

- 8.7. The opinion of the HREC or the HREC Executive Committee forms part of the recommendation to the Chief Executive or delegate to authorise the conduct of research at a NSW Public Health Organisation. The research will not commence until this authorisation has been granted.
- 8.8. Approved projects will be expected to commence within 12 months of the date on which a favourable ethical and scientific decision is given by an HREC. A project commences when any study procedure or any part of the protocol is implemented at a site.
- 8.9. Where the project does not commence within 12 months, the Co-ordinating Investigator will provide the HREC with an explanation in the annual progress report.

Rejected research projects

- 8.10. Where the research project is rejected, the following information will be included in the letter of notification:
 - a) The decision of the HREC or HREC Executive Committee;
 - b) Full explanation of reasons by reference to the *National Statement* or relevant legislation where necessary; and
 - c) Advice regarding available options for further review.

EO 009: Amendments to approved research projects

- 9.1. Investigators will obtain HREC approval before implementing amendments to a previously approved research project and documents which are likely to affect to a significant degree:
 - a) The rights, safety and welfare of the participants of the research;
 - b) The scientific value of the research;
 - c) The conduct or management of the research;
 - d) The monitoring requirements; or
 - e) The quality or safety of any investigational medicinal product/device used in the research.
- 9.2. Corrections to typographical errors or amendments to contact details which do not affect the version number or date of the study documents do not require HREC approval.
- 9.3. Amendments will be reviewed by the HREC Executive Committee in the first instance and a decision will be made as to whether the amendment should be referred to the full HREC.
- 9.4. The Co-ordinating Investigator will submit a signed request for amendment which includes:
 - a) A brief description of modifications and rationale including any summary of changes provided by the sponsor;
 - b) Implications for the ongoing conduct of the project; and
 - c) Any need to amend the protocol, Participant Information Sheet and Consent Form or any other documents.
- 9.5. Amendments to documents will:
 - a) Be provided in two versions: one version showing track changes and one with accepted track changes, with a cover page summarising the changes for large documents such as Investigator's Brochures or protocols;
 - b) Contain revised version numbers; and
 - c) Include version dates and page numbers on each page.
- 9.6. In reviewing the amendments, consideration will be given to:
 - a) Effects on the scientific value of the research;
 - b) Implications to the rights, safety and welfare of participants; and
 - c) Informed consent to participate in the research as amended.
- 9.7. If it is determined that modification/further information is required for the review of the amendment, the correspondence to the Co-ordinating Investigator will clearly articulate the reasons for this determination, and stipulate the information required. Requests for modification/further information will refer to the *National Statement* or relevant legislation where necessary.

- 9.8. Where a proposed amendment will fundamentally alter the nature of the research and the extent of the involvement of, or risk to, existing and/or potential participants, the HREC has the discretion to reject an amendment and request submission of a new application for full ethical review for example:
- a) A change in the primary purpose or objective of the research, such as the introduction of additional genetic studies;
 - b) A substantial change in research methodology;
 - c) Introduction of new classes of investigational product or other interventions (rather than simply re-scheduling or modifying those already approved);
 - d) Recruitment of a new type of participant (especially if these would be regarded as being from vulnerable groups); or
 - e) Extension of a drug trial into an open-label trial, i.e. all patients to receive trial drug.

Changes to research personnel

- 9.9. Where a new Co-ordinating Investigator is to be appointed, the HREC will be notified in writing by the departing Co-ordinating Investigator, the sponsor, or the incoming Co-ordinating Investigator.
- 9.10. Where a new Principal Investigator is to be appointed, the HREC will be notified in writing by the Co-ordinating Investigator.

Single centre research projects becoming multi-centre research projects

- 9.11. If the original application was reviewed by a lead HREC as a single centre application, the same HREC will review the additional site(s).
- 9.12. If the HREC which approved the original application is not a lead HREC, a new application will be submitted to a lead HREC and include copies of relevant correspondence from the original HREC. If approved, the lead HREC will be responsible for monitoring the research project, which includes review of amendments and adverse event reports.
- 9.13. Where the local HREC has approved the original application and it is transferred to a lead HREC, the following will occur:
- a) Approved projects which have commenced will continue operating at that site pending the decision of the lead HREC; and
 - b) Approved projects not yet commenced will commence at the site pending the decision of the lead HREC and site authorisation.
- 9.14. Where an application previously approved by the local HREC is rejected by the lead HREC, the following will occur:
- a) The Research Governance Officer at the site will be notified of the decision of the lead HREC by the Principal Investigator;
 - b) The Research Governance Officer will inform the Chief Executive or their delegate who authorised the original application that the lead HREC has rejected the application; and

- c) The Chief Executive will confer and determine whether the project requires suspension or withdrawal of previous ethical approval or site authorisation, or both. The Principal Investigator may appeal the final decision.

Adding a site to a multi-centre research project

- 9.15. The Co-ordinating Investigator will request approval to add sites to approved multi-centre research projects, in writing to the reviewing HREC, which approved the original application. Such requests will include a CTN or CTX form signed by the Principal Investigator if required.
- 9.16. The Principal Investigator at the additional site will submit an application for site authorisation to the Research Governance Officer.

EO 010: Urgent safety-related measures

- 10.1. Where it is necessary to eliminate an immediate hazard to the research participants, modifications or changes to the research project will be implemented without prior HREC review.
- 10.2. The Co-ordinating Investigator will notify the HREC and Research Governance Officer of amendments arising from urgent safety-related events immediately and in writing (email is acceptable). The Co-ordinating Investigator will submit the implemented modification or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) to the HREC for review within 5 working days and the Principal Investigator will advise the Research Governance Officer of developments.
- 10.3. Review of amendments from urgent safety-related events will be expedited by the HREC Executive Committee.
- 10.4. Reports of urgent safety-related measures are in addition to adverse event reporting requirements.

EO 011: Adverse event reporting

Clinical trials involving therapeutic products

11.1. For clinical trials involving therapeutic products, adverse event reporting will meet the requirements of the National Health and Medical Research Council, Australian Health Ethics Committee (AHEC) Position Statement “*Monitoring and reporting of safety for clinical trials involving therapeutic products*” (May 2009), which can be found at:

http://www.nhmrc.gov.au/health_ethics/hrecs/reference_files/090609_nhmrc_position_statement.pdf

11.2. Table 1, adapted from the AHEC Position Statement, summarises the requirements for safety reporting to the reviewing NSW Health HREC for clinical trials involving therapeutic products.

11.3. For single centre research projects, the Co-ordinating Investigators will provide these reports to the reviewing HREC.

11.4. For multi-centre research projects, the Principal Investigator will report serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs), occurring at the site directly to the reviewing HREC. The Principal Investigator will provide a copy of these reports to the site Research Governance Officer and Co-ordinating Investigator. All other safety reports will be submitted to the reviewing HREC by the Co-ordinating Investigator.

11.5. Depending on the complexity, design and risk perceived, the reviewing HREC and/or the Public Health Organisation has the discretion to require that additional information be reported.

Other human research

11.6. For research other than clinical trials involving therapeutic products, the reviewing HREC will determine the minimum requirement for safety reporting, including adverse event reporting. Where the reviewing HREC requests reporting of SAEs and SUSARs, submission will be made in accordance with requirements outlined in Table 1.

11.7. Depending on the complexity, design and risk perceived, the Public Health Organisation has the discretion to require that additional information be reported.

Table 1: Safety reporting to the reviewing NSW Health HREC: for clinical trials involving therapeutic products.

Frequency	Items to be reported to HREC
In a prompt manner	<ul style="list-style-type: none"> • Serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs), with comment from the Co-ordinating Investigator. <ul style="list-style-type: none"> ○ Only from sites for which the HREC has given ethical and scientific approval. ○ Reporting within 72 hours of the event occurring, unless the Co-ordinating Investigator considers immediate notification is required. ○ Where there is only a local Data and Safety Monitoring Board for the project (e.g. investigator-initiated trial), notification within 24 hours of the event occurring. <p>(For multi-centre research projects the Principal Investigator, rather than the Co-ordinating Investigator, provides the above report.)</p> <ul style="list-style-type: none"> • Information which materially impacts the continued ethical acceptability of the trial. • Information that requires, or indicates the need for, a change to the trial protocol, including changed safety monitoring in the view of the Co-ordinating Investigator or sponsor.
At least 6-monthly	<ul style="list-style-type: none"> • Listing of all suspected unexpected serious adverse reactions, Australian and international, occurring with a compound or device including sponsor and Co-ordinating Investigator comment as to whether action is planned for the trial on the basis of the reports. <p>(European Union format is acceptable.)</p>
At least annually	<ul style="list-style-type: none"> • An updated Investigator Brochure (IB), or • A European Union Annual Safety Report (EU ASR) or similar format report, or • Current, approved product information (PI), if appropriate (e.g. in a study for a product approved in Australia or where an Investigator Brochure is no longer maintained). • Include sponsor and Co-ordinating Investigator comment as to whether action is planned for the trial on the basis of the report. • For trials that are investigator or collaborative group sponsored in which an IB, EU ASR or PI is not available, then a trial update may be submitted that provides appropriate review of safety information in the previous 12 months • Include Co-ordinating Investigator's own opinion in regard to potential impact on ethical acceptability and need for action. • Other reports consistent with section 5.5.5 of the <i>National Statement and Good Clinical Practice</i> adopted by the Therapeutic Goods Administration.

Review of safety reports by the HREC

- 11.8. Safety reports will be reviewed by an HREC subcommittee (such as a scientific review committee) or HREC Executive Committee to determine the appropriate course of action.
- 11.9. If the HREC subcommittee or HREC Executive Committee deems further information is required it will request this from:
 - a) an independent expert with expertise in the area; or
 - b) the Co-ordinating Investigator or Principal Investigator who submitted the report with a copy to the other.
- 11.10. For reported deaths the HREC will, at its discretion, request information such as autopsy reports and terminal medical records.
- 11.11. Following review, the HREC will take the appropriate course of action which will include, but not be limited to one or more of the following:
 - a) Including a notation on file of the safety-related occurrence;
 - b) Increasing monitoring of the research project;
 - c) Requesting an amendment to the project and/or Participant Information Sheet and Consent Form and any other study documents;
 - d) Suspending ethical approval; and
 - e) Withdrawing ethical approval.

Notification of HREC review outcome

- 11.12. The HREC will inform the Co-ordinating Investigator of the outcome of the review within 10 working days of the meeting, unless immediate notification is required for urgent safety reasons.
- 11.13. For multi-centre research projects, the Co-ordinating Investigator will provide a copy of the HREC review outcome to the Principal Investigators involved in the study. Each Principal Investigator will provide a copy of this HREC review outcome to the site Research Governance Officer.
- 11.14. The HREC has the discretion to notify the review outcome directly to the Principal Investigators and Research Governance Officers for safety reasons, in which case the Co-ordinating Investigator will be informed of this action.

EO 012: Monitoring approved research projects

- 12.1. The HREC will monitor approved research projects to ensure compliance with the conditions of approval and to protect the rights, safety and welfare of participants. This includes review of annual progress reports and final reports, safety reports and reports of protocol violations.
- 12.2. The HREC has the discretion to adopt other appropriate mechanisms for monitoring depending on the complexity, design and risk perceived, including:
 - a) Discussion of relevant aspects of the project with the investigators, at any time;
 - b) Random inspections of research sites, data, or consent documentation;
 - c) Interviews with research participants or other forms of feedback from them; and
 - d) Request and review reports from independent agencies such as a Data and Safety Monitoring Board.
- 12.3. The HREC will, at its discretion, recommend in the letter of approval that the site co-ordinates on-site monitoring at recommended intervals or randomly throughout the project.

Annual progress reports

- 12.4. Annual progress reports will be submitted to the reviewing HREC by the Co-ordinating Investigator. The first report will be submitted 12 months from the date of ethical approval.
- 12.5. For a multi-centre research project Principal Investigators, at sites for which the HREC has given ethical and scientific approval, will submit annual progress reports to the Co-ordinating Investigator using the reporting template stipulated by the HREC. A copy of the report will be provided to the site Research Governance Officer by the Principal Investigator.
- 12.6. The Co-ordinating Investigator will collate site annual progress reports for submission to the reviewing HREC with comments. The Co-ordinating Investigator will notify the relevant site Research Governance Officer if a Principal Investigator does not provide the required report for inclusion into the collated annual progress report.
- 12.7. The Executive Officer will send a reminder letter where a report is not received by the due date. If there is no response after 30 calendar days, a second reminder letter will be sent requesting the Co-ordinating Investigator to contact the Chairperson to discuss the report. If the report is still not received after a further period of 30 calendar days, the Chairperson will consider further action. Where suspension of HREC approval is proposed, the matter will be considered at a full HREC meeting.
- 12.8. Annual progress reports will be added to the agenda and reviewed by the HREC Executive Committee. The HREC will inform the Co-ordinating Investigator of the outcome of the review within 10 working days of the meeting, unless immediate notification is required.

- 12.9. For a multi-centre research project, the Co-ordinating Investigator will provide a copy of the HREC review outcome to the Principal Investigators involved in the project. Each Principal Investigator will provide a copy of this HREC correspondence to the site Research Governance Officer.
- 12.10. The HREC will have the discretion to notify the review outcome directly to the Principal Investigators and Research Governance Officers, in which case the Co-ordinating Investigator will be informed of this action.
- 12.11. The HREC will have the discretion to request more frequent progress reports, depending on the complexity, design and risk perceived.

Final reports

- 12.12. Final reports will be submitted to the reviewing HREC by the Co-ordinating Investigator, using the reporting template stipulated by the HREC, upon completion of the research project. Final reports will include a copy of the final results and publications if available. If project data and interpretation are fully addressed in a publication, a separate copy of final results will not be required.
- 12.13. For a multi-centre research project Principal Investigators, at sites for which the HREC has given ethical and scientific approval, will submit final site reports to the Co-ordinating Investigator using the reporting template stipulated by the HREC. A copy of the report will be provided to the site Research Governance Officer by the Principal Investigator.
- 12.14. The Co-ordinating Investigator will collate final site reports for submission to the reviewing HREC, upon completion of the project at all sites with comments. Final reports will include a copy of the final results from all sites for which the HREC has given ethical and scientific approval, and publications if available. If project data and interpretation are fully addressed in a publication, a separate copy of final results will not be required.
- 12.15. Final reports will be added to the agenda and reviewed by the HREC Executive Committee. The HREC file will be archived as an electronic and/or hard copy, according to the Public Health Organisation's archiving policy, once the final report is acknowledged.

Protocol deviation/violation reports

- 12.16. Protocol deviations are minor or administrative departures from HREC approved protocol procedures whereby data is unusable or not available, but which do not affect the scientific soundness of the research plan or the rights, safety, or welfare of research participants. Examples include: follow up visits that occurred outside the protocol required time frame because of the participant's schedule, or blood samples obtained at times close to but not precisely at the time points specified in the protocol.
- 12.17. At the discretion of the Co-ordinating Investigator (or Principal Investigator in the case of multi-centre research) a list of protocol deviations may be reported with the annual progress report, however this is not a requirement.
- 12.18. Protocol violations are instances where the protocol requirements and/or regulatory guidelines were not followed, and are generally more serious in nature than protocol deviations. Protocol violations are considered to potentially affect the scientific soundness of the research plan and/or the rights, safety, or welfare

of research participants. Examples include: failure to obtain participant consent and participant inclusion/exclusion violations.

- 12.19. Principal Investigators will provide to the HREC written reports of protocol violations in a timely manner. The Principal Investigator will provide a copy of the report and any responses from the HREC to the Research Governance Officer.

EO 013: Appeals on HREC decisions

Appeals regarding HREC rejection

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

- a) Submit a new application to the same HREC, taking due account of the HREC's concerns. This will be processed and reviewed in the same way as any other new application; or
- b) Lodge an appeal with the HREC Chairperson specifying the grounds of the appeal in writing. The Chairperson will investigate the appeal and its validity, and recommend to the HREC the appropriate course of action within 2 weeks from the time the appeal is lodged. The HREC will notify the appellant of the course of action and determination in a timely manner.

Appeals regarding HREC approval

13.2. Where the HREC has given a favourable decision on an application and

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

a written appeal will be lodged with the Chairperson in the first instance. The Chairperson will demonstrate due consideration by addressing each issue in writing.

Appeal to the Chief Executive

13.3. If the appellant considers that the HREC has failed to follow due process after making an appeal in line with 13.1 and 13.2 and remains unsatisfied with the outcome, they will have the discretion to lodge an appeal with the Chief Executive or request that the Chairperson do so.

13.4. The following process will be followed:

- a) The Chairperson will provide the Chief Executive with the following:
 - Details of the appeal;
 - Material reviewed; and
 - The results of the review.
- b) The Chief Executive will determine if further investigation of the appeal is necessary. If so, the Chief Executive will establish a panel to consider the appeal.
- c) The panel will include the following members:
 - The Chief Executive or their nominee as convenor;
 - Two nominees of the Chief Executive (not members of the HREC); and
 - Expert(s) in the discipline of research of the project under consideration.
- d) The panel will afford the HREC and the appellant the opportunity to make submissions.

e) The Chief Executive will notify the HREC and the appellant of the outcome of the investigation. The outcomes include:

- The appeal is dismissed; or
- The appeal is upheld and the panel makes recommendation to resolve the issues based on the findings of the panel.

13.5. If the panel or Chief Executive requests that the HREC re-review the application, the determination of the HREC will be final.

13.6. The panel or Chief Executive cannot reverse the final determination of the HREC.

EO 014: Complaints about the conduct of an approved research project

- 14.1. Each NSW Public Health Organisation will have a written procedure for handling complaints about the conduct of an authorised research project, which is made publicly available.
- 14.2. Complaints about the conduct of an authorised research project will be reported to the nominated contact of the reviewing HREC (e.g. Executive Officer) and/or the Public Health Organisation (e.g. Research Governance Officer). The complainant will receive an acknowledgement in writing where possible.
- 14.3. Where the complaint is submitted to the Public Health Organisation nominee, they will inform the Executive Officer of the reviewing HREC of the nature of the complaint if it is likely to have implications to the ongoing approval of the project by the reviewing HREC.
- 14.4. Where the complaint is submitted to the reviewing HREC nominee, they will inform the Research Governance Officer responsible for the site that is the subject of the complaint.
- 14.5. The Public Health Organisation will investigate the complaint and conduct an audit of the project if necessary. Where the complaint relates to suspected research misconduct, the matter will be dealt with in accordance with the *Australian Code for the Responsible Conduct for Research (2007)* by the National Health and Medical Research Council, Australian Research Council, and Universities Australia.
- 14.6. The Public Health Organisation will inform the following parties of the final outcome of any investigation/audit:
 - a) the complainant;
 - b) the Principal Investigator and/or other investigators to whom the complaint relates; and
 - c) the reviewing HREC (if it has been notified of the complaint).

EO 015: Complaints about the conduct of HREC members

15.1. Complaints about the conduct of an HREC member will be managed using the following process:

- a) A complaint will be submitted in writing to the Chief Executive. The Chief Executive will inform the Chairperson of the complaint received. The Chief Executive will acknowledge the complaint in writing.
- b) The Chief Executive will investigate the complaint by establishing a panel.
- c) The panel will include the following members:
 - The Chief Executive or their nominee as convenor; and
 - Two nominees of the Chief Executive (not members of the HREC).
- d) The panel will afford the subject HREC member and the complainant the opportunity to make submissions.
- e) The Chief Executive will notify the subject HREC member and the complainant of the outcome of the investigation. The possible outcomes include:
 - The complaint is dismissed; or
 - The complaint upheld and the panel make recommendation to resolve the issues based on the findings of the panel.

EO 016: Suspension or withdrawal of HREC approval

- 16.1. The HREC will suspend ethical and scientific approval if satisfied that a research project is not, or cannot be, conducted in accordance with the approval or that the rights, safety or welfare of participants may be compromised. Suspension can relate to some or all project activities. Certain aspects of the protocol will continue to ensure participant safety even if a project is suspended, for example; collection of safety data, administration of study drug or study procedures that are not related to the grounds for suspension. At a minimum suspension will involve cessation of participant recruitment. The HREC will specify what aspects of the project will cease and when activities can recommence.
- 16.2. Where the HREC suspends ethical approval, the Co-ordinating Investigator and Research Governance Officer at each relevant site will be notified in writing within 3 working days of the decision to suspend, unless immediate notification is required for urgent safety reasons.
- 16.3. Upon suspension, the HREC Chairperson with the support of the Executive Officer and other nominated members of the HREC will investigate the conduct of the project and compile a report for consideration by the full HREC and the Co-ordinating investigator.
- 16.4. The Co-ordinating Investigator will be requested to respond to the report.
- 16.5. The full HREC will consider the response of the Co-ordinating Investigator to the report and decide on the conditions for reinstatement of approval or whether approval will be withdrawn.
- 16.6. The HREC will notify the Co-ordinating Investigator of its decision.
- 16.7. An investigator will discontinue research following suspension or withdrawal of ethical and scientific approval and will comply with the special conditions imposed by the HREC.

EO 017: Discontinuation of a research project by the investigator or sponsor

- 17.1. The Co-ordinating Investigator will inform the HREC of a research project at any site which is:
- a) abandoned – has never commenced;
 - b) prematurely terminated – commenced at one or more sites but is terminated on ethical, safety, financial or other grounds; or
 - c) suspended – commenced and temporarily stopped for any reason. The suspension applies to certain aspects of the project such as recruitment or the entire project.
- 17.2. Where the project is prematurely terminated or suspended the Principal Investigator will notify the research participants in writing.
- 17.3. Where a project is abandoned, prematurely terminated or suspended by the Co-ordinating Investigator or the Principal Investigator, the HREC will be promptly informed and provided with a comprehensive written explanation of the circumstances, having regard to the safety and welfare of research participants.
- 17.4. The Principal Investigator will demonstrate that the issues relating to suspension have been adequately addressed, and have obtained approval from the reviewing HREC and authorisation from the site before recommencing the suspended procedure.
- 17.5. A final report will be submitted if a project is abandoned or terminated.

EO 018: Storage and retention of records

- 18.1. The Executive Officer will maintain a confidential electronic and paper record of HREC meetings, including agendas and minutes.
- 18.2. The Executive Officer will maintain a confidential electronic and paper record for each application received and reviewed and will record the following information:
- a) Unique project identification number;
 - b) The Co-ordinating Investigator;
 - c) The name of the responsible institution or organisation;
 - d) Title of the application;
 - e) Date of the final ethical and scientific decision; and
 - f) Approval or rejection of amendments to the project.
- 18.3. Paper files will contain a copy of the signed application and review documents, correspondence, approved documents and other material used to inform potential research participants.
- 18.4. HREC records will be kept as confidential files in accordance with the *State Records Act 1998*. The following documents issued by the State Record Authority of NSW, which regulates record keeping in NSW Health, contain a section on research management:
- a) *General Retention and Disposal Authority: Public Health Services: Patient/Client Records (GDA17)*
 - b) *General Retention and Disposal Authority: Public Health Services: Administrative Records (GDA 21)*
- 18.5. A register of all the applications received and reviewed will be maintained in accordance with the *National Statement*.
- 18.6. Documents provided to the HREC which are no longer required will be disposed of in a secure manner. Members without access to secure disposal systems will leave their documents with the Executive Officer for disposal.

EO 019: Payment of fees

- 19.1. Review of applications and amendments by the HREC will be subject to a fee.
- 19.2. The fees structure is outlined in PD2008_030 *HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research*
- 19.3. The Co-ordinating Investigator will provide the HREC with details of the sponsor organisation to which the invoice will be sent.
- 19.4. The HRECs will determine whether the invoices will be paid at the time of application.
- 19.5. The HREC will determine whether to withhold a letter of approval until the fee is received.

EO 020: Multi-centre research applications approved before July 2007

- 20.1. Applications approved by a NSW Health HREC prior to implementation of the NSW Health model for single ethical and scientific review of multi-centre research will continue to operate in accordance with previous arrangements for HREC review.
- 20.2. Where a research project approved before July 2007 is to be conducted at one or more new sites within the NSW public health system, the process described under “Single centre research projects becoming multi-centre research projects” in EO 009 will apply.
- 20.3. Amendments and extensions of projects approved before July 2007 will be submitted to the original HREC, unless the project has been transferred to a lead HREC in accordance with EO 009, 9.13.

Appendix A: Summary of routes of obtaining Human Research Ethics Committee (HREC) approval and site authorisation for research taking place in NSW Public Health Organisations

