

Research - Model for Single Ethical & Scientific Review of Multi-Centre Research

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Summary This Policy Directive sets out the operation of the NSW Health model for single ethical and scientific review of multi-centre research, under which every human research project is ethically and scientifically reviewed once only. The Policy Directive describes the August 2007 revisions and updates to the Standard Operating Procedures which support the model.

Replaces Doc. No. Research - Model for single ethical and scientific review of multi-centre research [PD2007_044]

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

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This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

NSW HEALTH MODEL FOR SINGLE ETHICAL AND SCIENTIFIC REVIEW OF MULTI-CENTRE RESEARCH

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Version: August 2007.

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1. INTRODUCTION

1.1 Purpose

This Policy Directive sets out the operation of the NSW Health model for single ethical and scientific review of multi-centre research (Single Review System). The system is one where lead Human Research Ethics Committees (HRECs) are accredited to undertake a single ethical and scientific review of human research to be conducted within the NSW public health system (outlined in Figure 1). The purpose of the Single Review System is to establish a mechanism whereby every research project is ethically and scientifically reviewed once only, with Public Health Organisations accepting the review undertaken by a lead HREC as a sufficient review for the purposes of the project being conducted at institutions under its control.

The aims of the Single Review System are as follows:

- To use the resources of the parties which are required to obtain and conduct ethical and scientific reviews more efficiently.
- To improve the quality and effectiveness of the ethical and scientific reviews obtained and conducted by the parties.
- To allow ethically and scientifically acceptable multi-centre research projects to commence in a more timely fashion.

Compliance with this policy is mandatory.

1.2 Background

In recognition of the need to streamline the review of multi-centre research, the Director-General convened the 'NSW Health Reference Group on Ethical Review of Multi-centre Research' in 2005. The purpose of this Reference Group was to inform the development of a streamlined system for the review of multi-centre research, and to provide advice on the implementation and evaluation of such a system within NSW Health.

The implementation of the Single Ethical Review System is in compliance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* which states that '...each institution has the further responsibility to adopt a review process that eliminates any unnecessary duplication of ethical review'.

The Single Review System is also supported by the NSW State Plan under Priority S2 "Improve survival rates and quality of life for people with potentially fatal or chronic illness through improvements in health care: undertaking research for better health outcomes".

1.3 Scope

This Policy Directive applies to all research involving humans to be conducted within the NSW public health system. The Directive establishes:

- the Standard Operating Procedures which must be complied with by Public Health Organisations when handling applications for multi-centre research to be conducted within institutions under their control, and by researchers when submitting their multi-centre research applications for review; and
- the Accreditation Standards which an HREC must comply with in order to be accredited by the Department as a lead HREC.

1.4 Implementation

This policy takes effect from **1 July 2007**. Public Health Organisations must implement the Single Review System in accordance with this Policy Directive and associated Standard Operating Procedures from 1 July 2007.

Enquiries regarding this policy should be directed to the NSW Health Research and Ethics Branch (02) 9391 9427.

1.5 Related Policy Directives

- PD2007_026 Human Research Ethics Committees: National Ethics Application Form – Application within NSW Health.
- PD2007_035 Human Research Ethics Committees: Standards for Scientific Review of Clinical Trials.
- PD2007_043 Authorisation of Proposals to Conduct Research on Humans within the NSW Public Health System

2. NSW HEALTH MODEL FOR THE SINGLE ETHICAL AND SCIENTIFIC REVIEW OF MULTI-CENTRE RESEARCH

- 2.1 As far as the Single Review System allows, each research project which is to be conducted in an institution under the control of a Public Health Organisation will be ethically and scientifically reviewed once only (single review).
- 2.2 Research projects which are to be conducted at more than one site and within the jurisdiction of more than one NSW Health HREC (multi-centre research), must be submitted to a lead HREC for single review.
- 2.3 Lead HRECs will be accredited by the Department of Health to provide a single review on behalf of all sites within the NSW public health system. The operations of a lead HREC and its manner of conducting its ethical and scientific review are a matter for it, provided that the Accreditation Standards (Appendix A), *NHMRC National Statement on Ethical Conduct*

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in Human Research (2007) and PD2007_035 Human Research Ethics Committees: Standards for Scientific Review of Clinical Trials are met.

- 2.4 A lead HREC will be accredited in one or both of the following categories of research: (i) clinical trials/interventional clinical research; (ii) general research (including epidemiological research, population health research, health services research, qualitative research, clinical research of a non-interventional nature and other general categories of research).
- 2.5 The selection of the lead HREC to undertake the single ethical and scientific review of a given research project is at the discretion of the applicant.
- 2.6 Information regarding lead HRECs will be publicly available on the Department's website.
- 2.7 Public Health Organisation's will accept the ethical and scientific review undertaken by a lead HREC as a sufficient review for the purposes of the project being conducted at institutions under its control, and will not require the project to be reviewed by any other HREC.
- 2.8 Public Health Organisation's will undertake a site specific assessment of all human research projects that are to be conducted at an institution under its control. The purpose of the site specific assessment is to enable the Public Health Organisation to assess the suitability of a research project to be conducted within its jurisdiction. The site specific assessment is a separate process to the ethical and scientific review undertaken by a lead HREC.
- 2.9 Public Health Organisations will co-operate with other parties involved in the Single Review System in accordance with the Memorandum of Understanding.
- 2.10 Certain research projects will require review by certain HRECs regardless of whether or not they have been, or are to be, reviewed by a lead HREC. These will be specified by the Department from time to time and include:
 - All research projects involving persons in custody require review by the HREC of NSW Justice Health.
 - Research projects coming within section 6.4 of the NSW Aboriginal Health Information Guidelines should be considered for review by the HREC of the Aboriginal Health and Medical Research Council.
 - Research projects requiring access to statewide data collections owned by NSW Health¹ will continue to require review by the NSW Population & Health Services Research Ethics Committee. However, this HREC is a lead HREC, and may conduct a single ethical and scientific review on behalf of NSW Health.

¹ This includes the following: NSW Central Cancer Registry; NSW Pap Test Register; NSW Inpatient Statistics Collection; NSW Emergency Department Data Collection; NSW Midwives Data Collection; etc.

- 2.11 Research involving agencies external to NSW Health may require approval from that agency and/or their HREC in accordance with that agency's requirements.
- 2.12 A web-based application tracking and management system known as Research Ethics Database (RED) will be used to support the Single Review System. Public Health Organisations must use RED for the management of all multi-centre research applications and all commercially sponsored single-site research applications. This does not prevent organisations from also using their own research application management systems.
- 2.13 A Quality Assurance Period will operate for a period of six months from the commencement of the operation of the Single Review System. During the Quality Assurance Period, a local HREC may, with the approval of its Chief Executive, re-review a project already reviewed by a lead HREC in order to examine whether its decision would have differed from that of a lead HREC. The duplicate review is to be undertaken for quality assurance purposes only and shall not result in either a formal approval or rejection of the project. The HREC undertaking the review for quality assurance purposes shall document the decision it would have made in respect of the research project had it been the lead HREC reviewing the project, and the reasons for that opinion. This outcome shall be submitted to the Public Health Organisation which requested the quality assurance review and the Department, in accordance with the Standard Operating Procedures.
- 2.14 A local HREC may only re-review projects during the Quality Assurance Period. A local HREC may only re-review projects that are to be conducted at one of its affiliated sites.
- 2.15 The Single Review System will apply to all types of research involving humans (both clinical and non-clinical research) which is to be conducted in the NSW public health system.
- 2.16 Fees charged for the review of multi-centre research applications must be in accordance with Departmental policy.
- 2.17 The operation of the Single Review System is set out in the accompanying Standard Operating Procedures (Appendix B). All users of the system must comply with these Standard Operating Procedures.

3 ACRONYMS AND DEFINITIONS

ACRONYMS

CTN: Clinical Trial Notification scheme

CTX: Clinical Trial Exemption scheme

HREC: Human Research Ethics Committee

ICH GCP: International Committee on Harmonisation. Good Clinical Practice

National Statement: NHMRC *National Statement on Ethical Conduct in Human Research, 2007* or any replacement of that document published by the National Health and Medical Research Council.

NEAF: National Ethics Application Form

NHMRC: National Health and Medical Research Council

RED: Research Ethics Database

TGA: Therapeutic Goods Administration

DEFINITIONS

Accreditation Standards: The standards which an HREC must meet in order to be accredited as a lead HREC within NSW Health. Available as Appendix A and also at: <http://www.health.nsw.gov.au/healthethics>

Authorisation of a research project: The approval granted by the Chief Executive (or delegate) for a research project to commence at a site. Authorisation to commence a research project may only be granted by the Chief Executive (or delegate) when a site-specific assessment is satisfactorily completed and a lead HREC has granted ethical approval.

Clinical trial: A study involving humans to find out whether an intervention, including treatments or diagnostic procedures, which it is believed may improve a person's health, actually does so.

Co-ordinating investigator: The investigator responsible for the submission of a new application for ethical review by a lead HREC and for the submission and communication of all subsequent requests and notifications for the approved research project to the lead HREC, including the distribution of all lead HREC approved documentation to local principal investigators (if applicable).

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

Expedited ethical review: An ethical review conducted outside a full ethics committee meeting by the HREC chair and/or delegated HREC members, in accordance with that HREC's standard operating procedures.

Epidemiological research: The study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems.

Final ethical opinion: The decision of the lead HREC to grant/not grant ethical approval for the research project.

Health services research: Research involving the integration of epidemiologic, sociologic, economic and other analytic sciences to study health services.

HREC reference number: The unique reference number assigned to the HREC application by RED.

ICH GCP: A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Local HREC: A NSW Health HREC associated with the site at which the project is to be conducted and responsible for the ethical and scientific review of single-site research.

Local Principal Investigator: Investigators who act as principal investigators at a study site/s in a multi-centre research project i.e. the investigator responsible for the overall conduct of the research project at an individual site.

Lead HREC: An HREC accredited by the Department to conduct a single ethical and scientific review of multi-centre research projects.

Multi-centre research: Research to be conducted at more than one site within NSW Health and within the jurisdiction of more than one local HREC.

NSW Health on-line forms website: The website which a researcher should use to complete the National Ethics Application Form and the Site Specific Assessment Form. Available at: <http://www.ethicsform.org/au>.

Population health research: Research directed towards preventing disease, prolonging life, and promoting health through the organised efforts of society.

Public Health Organisation: Under the *Health Services Act*, an area health service or a statutory health corporation, or an affiliated health organisation in respect of its recognised establishments and services.

Public health system: Under the *Health Services Act*, a public health system consists of all area health services, statutory health corporations and affiliated health organisations in respect of their recognised establishments and services.

Research governance: A framework through which research is effectively oversighted, such that it meets appropriate standards of quality, safety, privacy, risk management, financial management and ethical acceptability.

Research Governance Officer: The officer/s within a Public Health Organisation who is responsible for reviewing the Site Specific Assessment

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Form and making a recommendation to the Chief Executive/delegate as to whether a research project should be granted authorisation at that site.

Research misconduct: Deviation from the *Australian Code for the Responsible Conduct of Research*.

Serious Adverse Event (SAE): Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect (ICH GCP).

Single review: A research project being scientifically/technically and ethically reviewed once only.

Single-site research: Research to be conducted at one site only within the NSW public health system, or at two or more sites under the jurisdiction of a single NSW Health HREC.

Site: The location(s) where study-related activities are actually conducted (ICH GCP).

Site-specific assessment: The mechanism used by Public Health Organisations to determine the suitability of a research project to be conducted at a site, whether that project is multi-centre or single-site.

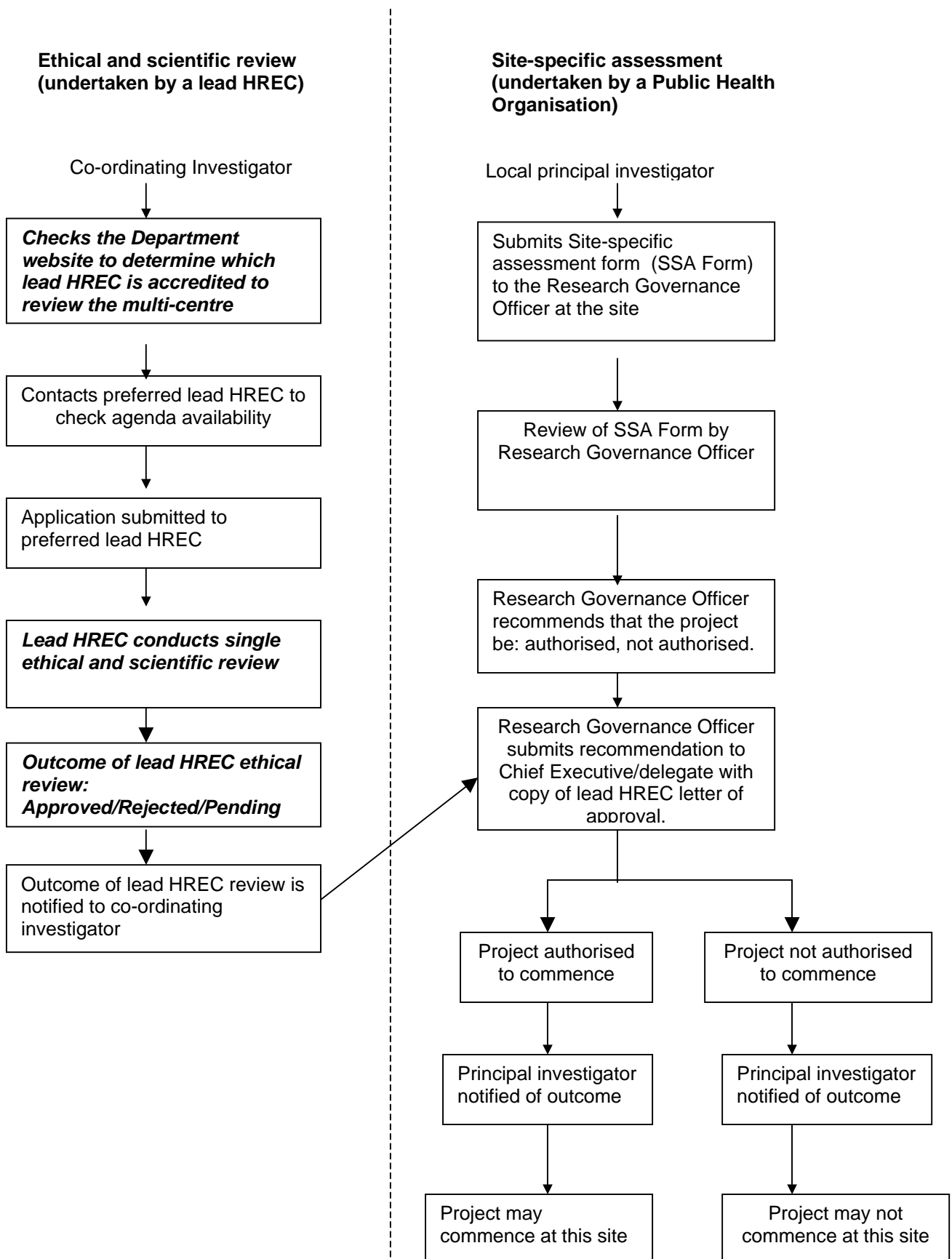
SSA reference number: The unique reference number assigned to the Site Specific Assessment by RED.

Standard Letters: The letters to be used by lead HRECs and Research Governance Officers for correspondence relating to multi-centre research projects.

Statutory health corporation: A corporation, listed in Schedule 2 of the *Health Services Act*, which provides certain health and health support services other than on an Area basis (including The Royal Alexandra Hospital for Children and Justice Health).

60 day clock: The maximum period of calendar days allowed from the cut-off date for submissions of a valid application to a lead HREC, to the date of written notification to the co-ordinating investigator (including CTN form/s signed by the HREC Chair where applicable) of the final ethical opinion on a multi-centre research application. This excludes the time during which a lead HREC is awaiting a response from a co-ordinating investigator to a request by that HREC for additional information. The 60 day clock will apply to the HREC review only and will not apply to the overall time taken for individual sites to grant authorisation for the commencement of research projects at their site.

Figure 1. Overview of the Single Review System



APPENDIX A

Accreditation Standards for lead HRECs operating under the NSW Health model for single ethical and scientific review of multi-centre research

March 2007

Background

These accreditation standards are based upon the legislation and guidelines surrounding the ethical review of research, including the requirements of the NHMRC National Statement on Ethical Conduct in Research Involving Humans and the HREC Operations Manual for NSW Health. The standards are designed to be implemented in two stages: the initial accreditation application and the accreditation review.

The initial accreditation application stage is when an HREC first applies for accreditation as a lead committee. At this stage, accreditation relies largely upon the provision of written information by the HREC itself. Within 12 to 18 months after initial accreditation, an accreditation review will be undertaken. At this stage, continuance of accreditation relies both on written material supplied by the HREC and the report of an independent peer review process. The independent peer review process is yet to be finalised, however Health Research and Ethics Branch will undertake consultation on this process at a later stage. Subsequent accreditation reviews will take place at specified periods.

Once accredited, a lead HREC remains accredited until its accreditation is revoked following an accreditation review. Generally, accreditation will only be revoked if there is a substantial and continuing failure to meet the accreditation standards. The particular process to be followed for the revocation of accreditation is yet to be finalised and will be included in the independent peer review process for consultation. However, the Health Research and Ethics Branch will endeavour to work with all accredited committees so that, as far as possible, lead HRECs can make any changes necessary to retain accreditation. All reasonable efforts will be made to facilitate continued accreditation before any lead HREC has its accreditation status revoked.

The accreditation standards are qualitative and quantitative in nature and relate to both the scientific and technical review mechanisms relied upon by the HREC, and the ethical review process.

Committees may be accredited in either or both of the following two categories:

- Clinical trials/interventional clinical research;
- General research (which includes epidemiological research, population health research, health services research, qualitative research, clinical research of a non-interventional nature and other general categories of research).

Further information on how to submit an application for accreditation is available from the document "Guidance for institutions and organisations nominating an HREC for accreditation under the NSW Health model for single scientific and ethical review", which can be located from the Health Research and Ethics Branch website: <http://www.health.nsw.gov.au/healthethics>. Enquiries may also be directed to Health Research and Ethics Branch on 9391 9427.

Lead HREC Accreditation Standards

1. Registration

- 1.1 The HREC is registered with the NHMRC and meets their annual reporting obligations.

Evidence

- *At initial accreditation application: copy of most recent NHMRC annual report acknowledgement letter.*
- *At accreditation review: copies of most recent reports.*

2. Timeliness

- 2.1 The HREC is able to review and provide a final ethical opinion on research proposals in a timely manner. That is, the time from the submission closing date to notification of the final ethical opinion on a multi-centre research proposal must be no more than 60 calendar days (excluding any time during which the HREC is awaiting a response from the investigator).

Evidence

- *At initial accreditation application: statement by the HREC Chair that, based on past experience of the HREC, the HREC is likely to be able to achieve a 60-day turnaround for most projects within the next 12 months.*
- *At accreditation review: report from the Research Ethics Database will indicate percentage of projects for which this was achieved.*

3. Executive support

- 3.1 The HREC has sufficient executive support to enable it to administer the number and type of applications that it is expected to receive, and to do so in a timely manner. This includes the provision of detailed and accurate advice to potential applicants.
- 3.2 A suitable percentage of the support officer's employment is dedicated to HREC work and is included in that officer's position description.

Evidence

- *At initial accreditation application: copy of position description of support officer(s) including estimate of the number of hours of administrative support provided to the HREC per week, record of number of applications received in the preceding calendar year and an estimate of the number of applications to be received in the coming year. Written confirmation by HREC Chair and Chief Executive that the executive support is sufficient for the effective operation of the committee.*
- *At accreditation review: report from peer-reviewer on level of executive support. Opinions from support officer(s) and HREC Chair.*

4. Resources

- 4.1 The HREC has sufficient resources to enable it to carry out its functions in an efficient and effective manner.

Evidence

- *At initial accreditation application: copy of HREC budget or statement by Director of Finance or equivalent as to the resources available for HREC operations. Written confirmation by the Chief Executive that fees received for ethical review remain in the HREC budget, in accordance with the Department's "Human Research Ethics Committees (HRECs) Fee Policy for Review of Clinical Trials within NSW Health" (PD 2005_628).*
- *At accreditation review: report from peer-reviewer on level of resources. Opinions from support officer(s) and HREC Chair.*

5. Membership

- 5.1 The HREC is able to meet the minimum membership requirements under the NHMRC National Statement. The HREC does not have any one member appointed to fill more than one category of membership.
- 5.2 The HREC members have sufficient experience in serving on an HREC (at least half of the members appointed in the minimum membership categories listed under the NHMRC National Statement, have two or more years of HREC membership experience).
- 5.3 Relevant details regarding HREC membership is made publicly available on request and on the HREC's website.
- 5.4 The HREC has a deputy chair who has the authority to carry out chair duties when the chair is unavailable.

Evidence

- *At initial accreditation application and accreditation review: record of membership composition of HREC, including dates of appointment and brief description of qualifications and experience of members (including that of scientific sub-committees where applicable). Relevant details from the HREC's website and other publications.*
- 5.5 There exist written methods of appointment of new members, and HREC members are appointed by the Chief Executive.

Evidence

- *At initial accreditation application and accreditation review: standard letters of appointment signed by Chief Executive (documenting the date of appointment, length of tenure, conditions of appointment, the circumstances whereby membership may be revoked and providing assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as an HREC member). If such appointment letters have not been provided to HREC members or are unavailable, the HREC will be requested to provide reasons why and how this will be rectified in the future.*

- 5.6 The members of the HREC understand their responsibilities under the NHMRC's National Statement on Ethical Conduct in Research Involving Humans and the NSW Health Records Information Privacy Act 2002 (including the statutory guidelines under this legislation) and apply the principles set out in these documents.

Evidence

- *At initial accreditation application: written confirmation by the HREC Chair that, based on experience, members are reasonably aware of the National Statement and the Health Records and Information Privacy Act and that copies of these documents are provided to new members.*
- *At accreditation review: peer-review of HREC meeting(s) to determine whether the relevant principles were applied to research projects.*

- 5.7 New members appointed to the HREC are provided with appropriate induction and receive copies of legislation and guidelines surrounding the ethical review of research including the NHMRC National Statement and Health Records and Information Privacy Act 2002.

Evidence

- *At initial accreditation application and accreditation review: written statement by HREC Chair as to the material supplied to new members.*

6. Meetings

- 6.1 The HREC must convene a sufficient number of meetings (not less than eight) per year at appropriate intervals. Such meetings should, where possible, not be cancelled or deferred in order to maintain capacity.

Evidence

- *At initial accreditation application and accreditation review: copy of proposed meeting schedule for the coming year and contingency arrangements should a core category member be unavailable to attend a meeting. Record of meetings held during the previous 12 months.*

- 6.2 Opportunity is given for investigators to meet with the HREC face-to-face if matters regarding their projects are questioned by the HREC.

Evidence

- *At initial accreditation application: written statement by the HREC Chair that the HREC considers holding face-to-face meetings with investigators to resolve issues which have been unresolved by written or telephone communication.*
- *At accreditation review: review of minutes of past meetings and discussions with the Chair to determine whether investigators have been given the opportunity to meet with the HREC where appropriate.*

- 6.3 Each member of the HREC has appropriate input into the deliberations of the committee.

Evidence

- *At initial accreditation application: written statement by the HREC Chair as to participation of members.*
- *At accreditation review: peer-review of HREC meeting(s) to assess member input.*

6.4 The HREC accepts applications for review submitted on the National Ethics Application Form (NEAF).

Evidence

- *At initial accreditation application and accreditation review: written statement by the HREC Chair that NEAF is accepted.*

6.5 The HREC considers characteristics of the local setting, both at which the research will be conducted and from which participants will be recruited, relevant to the ethical conduct of the research and seeks advice where appropriate.

Evidence

- *At initial accreditation application: written statement by the HREC Chair as to the operations of HREC in this regard.*
- *At accreditation review: peer-review of HREC meeting(s) and previous minutes.*

7. Expedited review of minimal risk research

7.1 The HREC has and implements a documented standard procedure for expedited review of minimal risk research proposals.

Evidence

- *At initial accreditation application and accreditation review: copy of documented procedure.*
- *At accreditation review: peer review of HREC minutes and documents to determine whether expedited review is undertaken in appropriate circumstances.*

7.2 For research proposals that have undergone expedited review, the HREC documents the determination made that the proposal involved minimal risk, the matters considered during the review, the decision taken by the HREC, the reasons for that decision and the ratification of the decision by the full committee.

Evidence

- *At initial accreditation application: written statement by the HREC Chair.*
- *At accreditation review: peer-review of HREC and Executive minutes.*

8. Recording of decisions

8.1 The HREC records the main ethical issues raised for each multi-centre research proposal and the decisions taken by the HREC.

- 8.2 The HREC records the manner in which scientific review was undertaken, by whom and the outcome of the scientific review, for each multi-centre research project.
- 8.3 The HREC records member's attendance and whether a quorum was achieved, including the minimum membership requirements under the National Statement.
- 8.4 The HREC records member's declaration of interests, including conflicts of interests, and the decision of the committee on the participation of the member concerned.
- 8.5 The HREC maintains records of all research proposals received and reviewed in an appropriate format and in accordance with the 'Joint NHMRC/AVCC Statement and Guidelines on Research Practice' and 'General Retention and Disposal Authority – Public Health Services: Administrative Records – GDA 21. IB2005_027'.
- 8.6 The HREC retains on file a complete copy of each research project and all associated documentation relating to its review by the HREC, including (where applicable) participant information sheets, consent forms and relevant correspondence, in the form in which they are approved.
- 8.7 The HREC notifies applicants promptly of the outcome of its review (no later than 10 working days from date of decision).
- 8.8 The HREC makes copies of its minutes available on request to peer-reviewers and the Chief Executive or delegate at sites at which the research is to be conducted (Chief Executives/delegates may only request sections of the minutes which are relevant to research projects being conducted within their site).

Evidence

- *At initial accreditation application: written statement by the HREC Chair as to these matters.*
- *At accreditation review: peer-review of HREC minutes and records.*

9. Handling of serious adverse events

- 9.1 The HREC has a documented and transparent procedure to manage notifications of serious adverse events, which is compliant with Departmental guidelines as may be issued from time to time².

Evidence

- *At initial accreditation application and accreditation review: copy of procedure.*

² The Department is currently developing a standard procedure for the handling of notifications of serious adverse events. In the interim, HRECs must demonstrate that they have a standard operating procedure with regards to serious adverse event reporting.

10. Terms of reference

10.1 The HREC terms of reference are made available upon request to the general public and posted on the HREC's website.

10.2 The terms of reference have been approved by the Chief Executive/delegate.

Evidence

- *At initial accreditation application and accreditation review: copy of dated HREC Terms of Reference including evidence of approval by Chief Executive or delegate.*

11. Standard operating procedures

11.1 The standard operating procedures of the HREC are commensurate with the Department's "HREC Operations Manual for NSW Health" (GL2005_059) and the "Standard Operating Procedures for users of the NSW Health model for single review of multi-centre research".

11.2 The standard operating procedures are made available upon request to the general public and posted on the Area Health Service's website.

Evidence

- *At initial accreditation application and accreditation review: copy of dated Standard Operating Procedures. Written confirmation by the HREC Chair that the Standard Operating Procedures will be amended to incorporate the procedures under the NSW Health model for single review of multi-centre research.*

12. Complaints procedures

12.1 The HREC has written procedures for receiving and handling complaints from research participants about the conduct of an authorised research project which it has reviewed.

12.2 The HREC has nominated a person to whom complaints from research participants, researchers or other persons, may be made in the first instance.

12.3 The HREC has written procedures for receiving and handling appeals from researchers about the review process.

Evidence

- *At initial accreditation application: copy of written procedures.*
- *At accreditation review: peer review of complaints (if any) dealt with.*

13. Reporting

13.1 The HREC has a designated senior officer within the Public Health Organisation to whom it reports on decisions about ethical review of research proposals, on administrative and staffing matters, and on budgetary/resource matters.

13.2 The HREC must provide regular (at least annual) written reports to the Chief Executive on matters including membership, number of proposals reviewed, status of proposals, description of any complaints received and their outcome and other general issues (such as administrative, staffing matters and budgetary matters).

Evidence

- *At initial accreditation application and accreditation review: copy of most recent HREC report to Chief Executive or delegate.*

14. Training and education

14.1 The HREC members and support staff have attended relevant training and continuing education opportunities conducted by the NHMRC, NSW Health or other relevant body.

14.2 HREC members are given an equal opportunity to attend training and continuing education opportunities.

Evidence

- *At initial accreditation application and accreditation review: record of number of attendances by HREC members and support staff at training and education sessions.*

15. Conflicts of interest

15.1 The HREC has a standard procedure for identifying and handling potential conflicts of interest for HREC members and experts, which is transparent.

Evidence

- *At initial accreditation application: copy of documented procedure..*
- *At accreditation review: peer-review of HREC minutes.*

16. Additional standards for HRECs accredited to review clinical trials and interventional clinical research

16.1 The HREC must have in place a means of obtaining a timely scientific review by relevant experts in a broad range of clinical areas without regular reliance on the NSW Health Shared Scientific Assessment Committee³. That is, the scientific review relied upon by the HREC must be able to be completed within a sufficient timeframe so as to enable the HREC to provide a final ethical opinion on the proposal within a maximum of 60 calendar days.

Evidence

- *At initial accreditation application: written statement from HREC Chair setting out arrangements for scientific review and access to relevant expertise, including the areas of expertise available and the circumstances, if any, in which the HREC may need to rely on the Shared Scientific Assessment Committee. Copy of terms of reference of scientific/technical sub-committee if applicable.*

³ This does not preclude use of the Shared Scientific Assessment Committee for unusually complex research, or occasional first-time-in-human and first-time-in patient clinical trials.

- *At accreditation review: peer-review of HREC minutes/scientific sub-committee minutes and/or expert reports.*

16.2 Understanding of Therapeutic Goods Legislation as it relates to clinical trials and the Note For Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA Comments.

Evidence

- *At initial accreditation application: written statement by the HREC Chair that, based on experience, members are aware of the Therapeutic Goods Legislation and the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA Comments and that copies of these documents are provided to new members.*
- *At accreditation review: peer-review of HREC minutes/scientific sub-committee minutes and/or expert reports.*

16.3 The HREC has demonstrated experience in reviewing clinical research, including clinical trials. In addition, the HREC must review a sufficient⁴ number of clinical research projects per year in order to maintain capacity.

Evidence

- *At initial accreditation application and accreditation review: number of clinical research projects (including clinical trials) reviewed in the previous 12 months.*

17. Additional Standards for HRECs accredited to review general research (including population health, health services and epidemiological research, non-interventional clinical research and other general research)

It is acknowledged that the degree to which these categories of general research require scientific or technical review is highly variable, depending on the nature and extent of the research project, the degree to which it has been previously reviewed and its risk profile. Generally, research projects in this category that have undergone peer review through an external funding process (for example, NHMRC review) do not require further scientific or technical review. However, scientific/technical review may be required for experimental studies involving interventions other than invasive clinical treatments (including randomised control trials of such interventions) as well as observational studies, including cohort studies, case-controlled studies, cross-sectional studies, large surveys and qualitative studies. Lead HRECs should be able to apply expertise to the review of these studies where required and this may include expertise or experience in general research techniques, epidemiology, public health research and health services research. Expertise in biostatistics, health economics and qualitative research may also be relevant. This expertise may not necessarily be vested in the HREC's membership, but may be available through obtaining external reviews where necessary.

17.1 The HREC must have in place a mechanism (either through its membership or through accessing relevant individuals with expertise/experience) that is

⁴ The Department has not set a threshold with regards to the number of research projects which must be reviewed in order to meet this standard. Rather, this standard will be reviewed as part of the overall assessment of the HREC's ability to meet the accreditation standards.

sufficient to adequately review the scientific/technical aspects of general research, health services research, population health research and epidemiological studies, within a sufficient timeframe so as to ensure the HREC is able to provide a final ethical opinion on the proposal within a maximum of 60 calendar days.

Evidence

- *At initial accreditation application: written statement from HREC Chair setting out arrangements for scientific and technical review and access to relevant expertise, including the areas of expertise available.*
- *At accreditation review: peer-review of HREC minutes and other relevant documents.*

17.2 The HREC has demonstrated experience in reviewing population health, health services and epidemiological research. In addition, the HREC must review a sufficient number of these types of research per year in order to maintain capacity.

Evidence

- *At initial accreditation application and accreditation review: number non-clinical research reviewed in the previous 12 months.*
-

APPENDIX B

Standard Operating Procedures under the NSW Health model for single ethical and scientific review of multi-centre research

August 2007

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Summary of August 2007 amendments to the Standard Operating Procedures

This summary describes revisions and updates to the Standard Operating Procedures which support the NSW Health model for the single ethical and scientific review of multi-centre research. One new Standard Operating Procedure has been introduced: SOP 035 titled "Single-site research projects progressing to multi-centre research projects". Revisions have also been made to the following SOPs: SOP 015 "Clinical trials conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) Schemes"; SOP 023 "Reporting and review of serious and unexpected adverse events"; and SOP 033 "Multi-centre research projects approved prior to implementation of single review".

AMENDED STANDARD OPERATING PROCEDURES:

SOP 015: Clinical trials conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) Schemes

- This amended SOP removes the requirement that local principal investigators must sign the CTN/CTX Form prior to submission to the lead HREC.

SOP 023: Reporting and review of serious and unexpected adverse events

- This amended SOP makes changes to paragraph 23.3 by removing the requirement that local principal investigators must report suspected unexpected serious adverse reactions (SUSARS) occurring at a site within the NSW public health system directly to the lead HREC. Co-ordinating investigators will be responsible for this, as per the requirements of paragraph 23.2.
- Serious adverse events occurring at a site within the NSW public health system (and which are reportable to the lead HREC under the NHMRC HREC Alert No1, 18 April 2007) must continue to be submitted to the lead HREC by the local principal investigator at that site.

SOP 033: Multi-centre research projects approved prior to implementation of single review

- This amended SOP clarifies the procedure to follow for research projects which were approved by a NSW Health HREC prior to 1 July 2007 and which are to be extended to an additional site(s). Paragraph 33.5 introduces the provision for such research projects to be submitted to a lead HREC:
 - If the project is to be extended to one additional site only and the additional site is not within the jurisdiction of the local HREC which originally approved the project, the project may be submitted to the local HREC associated with the additional site for review or it may be submitted to a lead HREC;
 - If the project is to be extended to two or more additional sites within the NSW public health system, such that it would be within the jurisdiction of two or more local HRECs, the project must be submitted to a lead HREC for review. This is regardless of whether or not the local HREC which originally reviewed the project has become a lead HREC.

NEW STANDARD OPERATING PROCEDURE:

SOP 035: *Single-site research projects progressing to multi-centre research projects*

- This new SOP clarifies the procedure to follow for single-site research projects which were approved by a NSW Health HREC after 1 July 2007 and which are to be extended to an additional site(s).

SOP 001: Scope of the NSW Health model for single review.

Function: To describe the scope of the NSW Health model for single ethical and scientific review of multi-centre research.

Version: 1.0

- 1.1 Every research project which is to be conducted at a site under the control of a NSW Public Health Organisation will be ethically and scientifically reviewed once only (single review), except where stated under paragraphs 1.7 through to 1.10.
- 1.2 The system of single review will apply to ALL types of research involving humans. This includes, but is not limited to:
 - Clinical trials;
 - Clinical research;
 - Health services research;
 - Population health research;
 - Epidemiological research;
 - Tissue banking;
 - Release of data and data linkage; and
 - Qualitative research.
- 1.3 Multi-centre research means research to be conducted at more than one site within NSW Health and within the jurisdiction of more than one local HREC.
- 1.4 Single ethical and scientific review will be undertaken only by a lead HREC accredited by the Department of Health.
- 1.5 Every research project must undergo a research governance review at each site where the research is to be conducted (this is known as a site-specific assessment).
- 1.6 A multi-centre research project must not commence at a site within a NSW Public Health Organisation unless the following has been documented:
 - The project has received ethical approval from a lead HREC;
 - A site-specific assessment has been undertaken at the site where the research is to be conducted; and
 - The Chief Executive or delegate has sighted the lead HREC approval, considered the site-specific assessment and authorised commencement of the project.
- 1.7 Research involving persons in custody will continue to require review by the Justice Health HREC, even if reviewed by a lead HREC.
- 1.8 Research projects coming within section 6.4 of the NSW Aboriginal Health Information Guidelines should be considered for review by the HREC of the Aboriginal Health and Medical Research Council, even if reviewed by a lead HREC.
- 1.9 Research involving access to statewide data collections owned or managed by NSW Health will continue to require review by the NSW Population & Health Services Research Ethics Committee, even if reviewed by a lead HREC. However, the NSW Population & Health Services Research Ethics Committee is

a lead HREC. Projects reviewed by this HREC do not require review by another HREC, except as set out in paragraphs 1.7 and 1.8.

- 1.10 Research involving agencies external to NSW Health may require approval from that agency and/or their HREC in accordance with that agency's requirements.

SOP 002: Lead HREC function and accountability

Function: To describe the role and function of lead HRECs operating under the single review model.

Version: 1.0

- 2.1 A lead HREC is an HREC which has been accredited by the Department of Health to undertake the single ethical and scientific review of multi-centre research projects conducted within the NSW public health system. Only a lead HREC may conduct the single review of multi-centre research projects on behalf of all NSW Public Health Organisations.
- 2.2 Lead HRECs have been accredited by the Department to review multi-centre research applications in one or both of the following areas:
- Clinical trials/interventional clinical research;
 - General research (which includes epidemiological research, population health research, health services research, clinical research of a non-interventional nature and other general categories of research).
- 2.3 A lead HREC may only undertake reviews of multi-centre research proposals in the research area for which it has been accredited (SOP 2.2). For example, a lead HREC accredited to review multi-centre research proposals in the area of general research, may not review multi-centre clinical drug trials.
- 2.4 Lead HRECs accredited to undertake reviews of multi-centre research projects in the area of general research, must not review multi-centre research proposals in the following research categories (unless they have also been accredited to review multi-centre research in the area of clinical trials/interventional clinical research):
- Clinical trials being conducted under the CTN/CTX Schemes;
 - Research requiring review by Gene and Related Therapies Research Advisory Panel (GTRAP);
 - Research involving radiation safety, drugs, surgery;

Where a Lead HREC is only accredited in the general research category, it should exercise caution in determining whether any multi-centre projects submitted to it are within its area of expertise, or whether they should be referred to a clinical trials/interventional clinical research lead HREC. In this respect, it is the nature of the intervention upon participants that is of importance, rather than whether the research strictly comes within the definition of “clinical trial”. Some research that may legitimately be reviewed by an HREC accredited in general research may come within the strict definition of “clinical trial”, because it involves the randomisation of subjects. An example may be a randomised controlled trial (RCT) to evaluate different models of non-interventional health service provision, or of behavioural therapy. However, a RCT which falls into any of the above categories, or involves evaluation of a drug or an invasive clinical intervention upon a participant would certainly need to be dealt with by an HREC accredited in the category of clinical trials/interventional clinical research.

- 2.5 A Public Health Organisation must only accept a single review for a multi-centre research project from a suitably accredited lead HREC. Non-lead HRECs may

continue to conduct ethical and scientific reviews for research being conducted only at sites within the jurisdiction of their HREC (i.e. single-site research).

- 2.6 The operations of a lead HREC are a matter for it, provided that the Accreditation Standards, *National Statement* and Policy Directive PD2007_035 *Human Research Ethics Committees: Standards for Scientific Review of Clinical Trials* are met. Lead HRECs must use the Research Ethics Database and the Standard Letters appended at Appendix C of this Policy Directive.
- 2.7 Public Health Organisations must ensure that the following information about its lead HREC/s is made publicly available on its website:
 - HREC contact details;
 - Submission closing dates for HREC meetings (and scientific/technical sub-committees if applicable);
 - HREC meeting dates;
 - The specific research area for which that HREC is accredited as a lead HREC (i.e. clinical research, general research or both research areas).
- 2.8 Lead HRECs are directly accountable to the Public Health Organisation that constituted it for their day-to-day operations.
- 2.9 Lead HRECs and their auspicing organisations must ensure the HREC's continued compliance with the Department's Accreditation Standards.

SOP 003: Selection and role of the co-ordinating investigator.

Function: To describe the process for selection of the co-ordinating investigator and to describe their role.

Version: 1.0

- 3.1 The co-ordinating investigator for a multi-centre research project is responsible for the submission of an application to a lead HREC and for the submission and communication of all subsequent requests and notifications for the authorised research project to the lead HREC, including the distribution of all lead HREC approved documentation to site investigators (if applicable). It is not the responsibility of the lead HREC to ensure that local principal investigators have copies on file of the correspondence between the lead HREC and the co-ordinating investigator.
- 3.2 For research projects involving only one investigator, that investigator will be the co-ordinating investigator for that project. For research projects involving more than one investigator, one investigator must be appointed as the co-ordinating investigator for that project.
- 3.3 Appointment of the co-ordinating investigator is the responsibility of the project investigators, in communication with the research sponsor (if applicable). The co-ordinating investigator need not reside within the NSW public health system.
- 3.4 The position of co-ordinating investigator must be determined prior to submission of an application to a lead HREC.
- 3.5 The co-ordinating investigator may nominate a second investigator through which the lead HREC may communicate if the co-ordinating investigator is unavailable.

SOP 004: The Research Ethics Database (RED).

Function: To describe the role and function of RED.

Version: 1.0

- 4.1 Research Ethics Database (RED) is a web-based research application tracking and management system available to all NSW Health HREC Executive Officers and Research Governance Officers. RED can be accessed from the Health Research and Ethics Branch website: <http://www.health.nsw.gov.au/healthethics>.
- 4.2 Lead HREC Executive Officers must use RED for the management of multi-centre research projects submitted to their HREC for single review, including the recording of the decisions taken by the lead HREC on proposals submitted to it for single review.
- 4.3 Research Governance Officers must use RED for the management of multi-centre research projects submitted for site-specific assessment, including the recording of decisions taken by the Chief Executive/delegate on research proposals submitted for authorisation.
- 4.4 Local and lead HREC Executive Officers must use RED for the management of single-site commercially sponsored applications. Local and lead HREC Executive Officers may choose to also use RED for the management of all other single-site research applications submitted to their HREC for review.

Research Governance Officers must use RED for the management of single-site commercially sponsored applications. Research Governance Officers may choose to also use RED for the management of all other single-site research applications submitted for site-specific assessment (this will only be possible however, in circumstances where the local HREC has also chosen to use RED for the management of the corresponding single-site HREC application).
- 4.5 Public Health Organisations must nominate prospective RED users to the Department of Health for authorisation and the issuing of user accounts. HREC members will not be granted access to RED, however access by Chairs and Deputy Chairs may be considered on a needs basis.
- 4.6 Registered users of RED must sign a confidentiality agreement (issued by the Department of Health) indicating they will use the information contained in the system in a confidential manner.
- 4.7 The Standard Letters used to support the single review model will be automatically generated by RED and may be saved and edited by the user. These letters may be updated by the Department from time to time.
- 4.8 RED will be used by the Department to monitor certain aspects of the system's performance, such as meeting the 60 day clock for HREC review, lead HREC workload and distribution of work.
- 4.9 Instructions on how to use RED are available from the user manual, available from the Health Research and Ethics Branch website.
- 4.10 A help desk will be available to assist users of RED. The help desk number is available from the Health Research and Ethics Branch website.

SOP 005: The NSW Health on-line forms website.

Function: To describe the role and function of the on-line forms website.

Version: 1.0

- 5.1 The on-line forms website allows investigators to complete and submit their applications to the lead HREC and the Research Governance Officer electronically (using NEAF and the Site Specific Assessment Form respectively). The on-line forms website should be used for all multi-centre research projects.
- 5.2 The on-line forms website enables investigators to receive status updates on the progress of their submissions.
- 5.3 To access the on-line forms website, investigators must register. For more information, visit the on-line forms website:
<http://www.ethicsform.org/au>.
- 5.4 A help desk will be available to assist users of the on-line forms website with any technical problems. The help desk number is available from the Health Research and Ethics Branch website.

SOP 006: Submission of a new multi-centre research proposal for review by a lead HREC.

Function: To describe the process for submission of a new application to a lead HREC for single review, including the completion of the HREC application.

Version: 1.0

6.1 Only those research projects which are to be conducted at more than one site within the NSW public health system and within the jurisdiction of more than one local HREC, are eligible to be submitted to a lead HREC for single review.

Note: The local HREC may or may not be a lead HREC.

6.2 Co-ordinating investigators may choose to which lead HREC to submit their research proposals, provided that the HREC is accredited in the research area of that project (for example, clinical trials must be submitted to a lead HREC accredited in clinical trials/interventional clinical research). In determining to which preferred lead HREC to submit a multi-centre research project, it is the responsibility of the co-ordinating investigator to ascertain, prior to submission, which lead HREC has been accredited to review that area of research. This information will be available from the Health Research and Ethics Branch website.

6.3 An application for single review must be submitted to one lead HREC only, in relation to any multi-centre research project to be conducted within the NSW public health system. Co-ordinating investigators cannot submit an application for single review to more than one lead HREC.

6.4 The lead HREC chosen to conduct the single review need not be associated with one of the sites at which the research is to be conducted. Generally however, co-ordinating investigators will be expected to submit their applications to a lead HREC associated with a site at which the research is to be conducted.

6.5 The co-ordinating investigator is strongly encouraged to communicate with the Executive Officer of the preferred lead HREC prior to submission of an application, thereby signalling an intention to submit to that lead HREC.

6.6 Applications to a lead HREC must be submitted on the NHMRC's National Ethics Application Form (NEAF) located on the NSW Health on-line form website: <http://www.ethicsform.org/au>. Applications which are not completed using NEAF, will not be accepted by the lead HREC.

6.7 When completing the submission to the lead HREC, the co-ordinating investigator should bear in mind that the submission relates to the proposed ethical conduct of the research at all sites within the NSW public health system, not just the site at which the co-ordinating investigator is conducting the research.

6.8 The co-ordinating investigator must specify in the submission to the lead HREC, all sites within the public health system at which the research project is to be conducted.

- 6.9 The co-ordinating investigator must record their name and contact details on the on-line form as the “Applicant”. Where the co-ordinating investigator is also a principal investigator at a site within NSW Health, their name and contact details should also be recorded on the on-line form as a “Principal Researcher” (to enable data from this section to populate the corresponding section in the SSA Form). The co-ordinating investigator must also, if applicable, record on the on-line form the name and contact details of the principal investigator at each site.
- 6.10 The co-ordinating investigator must indicate in the submission to the lead HREC, whether:
- any member of the research team has any business, financial or other similar affiliation with the provider(s) of funding/support or supplier of a drug/device;
 - any member of the research team has a financial interest in the outcome of the research; or
 - any other possible conflicts of interest.
- 6.11 It will not be necessary for the Heads of Departments/schools/research organisation to sign off on the co-ordinating investigator’s submission to the lead HREC, as this is a requirement of the site-specific assessment.
- 6.12 Upon completion of the on-line form, the co-ordinating investigator must lock the application. Applications submitted without a lock code will not be accepted. The co-ordinating investigator must sign the declaration at the end of the form and submit the required number of copies (including relevant supporting documentation) to the lead HREC, as is deemed necessary by that HREC.
- 6.13 It will not be necessary for the principal investigator at each site to sign the on-line form which is submitted by the co-ordinating investigator to the lead HREC. However, the principal investigator should ensure that they sign a copy of this form and maintain it on their file for audit purposes.
- 6.14 Should a research project require assessment by an Institutional Biosafety Committee (IBC), evidence of IBC approval must be provided to the lead HREC.
- 6.15 Should a research project involve ionizing radiation, the Australian Radiation Protection and Nuclear Safety Agency Code of Practice *Exposure of Humans to Ionizing Radiation for Research Purposes* May 2005, may need to be complied with, including the requirement that an independent assessment or verification by a medical physicist is obtained (paragraph 2.1.6 of the Code of Practice) and a submission be prepared to the HREC in accordance with the HREC’s requirements (paragraph 2.1.7 of the Code of Practice).
- 6.16 Should a research project require assessment by the NHMRC’s Gene and Related Therapies Research Advisory Panel (GTRAP), this assessment must be provided to the lead HREC.
- 6.17 Multi-centre research submissions to lead HRECs may only be made by the co-ordinating investigator for that project. Submissions may not be made by a sponsor or contract research organisation on behalf of the co-ordinating investigator.
- 6.18 Fees charged for submission of a multi-centre research project to a lead HREC for single review, must be in accordance with Departmental policy.

SOP 007: Acceptance of a multi-centre research proposal by a lead HREC.

Function: To describe the process for acceptance or non-acceptance of a multi-centre research proposal submitted to a lead HREC.

Version: 1.0

- 7.1 Lead HRECs must only accept multi-centre research proposals which have been completed on NEAF.
- 7.2 A lead HREC must only accept a multi-centre research application for single review if it has been accredited by the Department to undertake single reviews for the research area of the submitted project (refer to SOP 002). A lead HREC must decline to accept a multi-centre research application for single review if it has not been accredited by the Department to undertake single reviews for the research area of the submitted project.
- 7.3 In some circumstances (other than clinical trials), a lead HREC may decline to accept a multi-centre research application for single review if it is of the opinion that it does not have the requisite scientific/technical expertise to adequately review the proposal. In such circumstances, the lead HREC should advise the co-ordinating investigator that it does not have the relevant expertise to review a particular project and suggest another, more appropriate HREC. Where the lead HREC is uncertain as to whether it has the requisite expertise to scientifically/technically review the project, it may seek advice from another lead HREC or the Department.
- 7.4 Lead HRECs may cap the number of multi-centre research applications they are able to accept at any particular meeting. This decision may be made on a per-meeting basis and is at the discretion of the lead HREC. A lead HREC may decline to accept a multi-centre research application for single review if it has reached its meeting capacity for the review of multi-centre research.
- 7.5 If the Executive Officer advises that the HREC cannot accept the application for its next scheduled meeting because it has reached its capacity for that meeting, the co-ordinating investigator may choose to either submit the application for the next available meeting of that lead HREC, or withdraw the application (if it has already been submitted to the lead HREC) and contact another lead HREC. Refer to SOP 008, 8.3 for further information on the 60 day clock.
- 7.6 Upon receipt of an application for single review of a multi-centre research project, the Executive Officer of the lead HREC will perform a search in RED to confirm that the application has not already been allocated to another lead HREC. If the research project has already been submitted to a lead HREC, the Executive Officer must decline to accept the application as a multi-centre research project may be submitted to one lead HREC only.
- 7.7 If an application is unable to be accepted for review by a lead HREC, it will be returned to the co-ordinating investigator or disposed of in a confidential manner.
- 7.8 If the application has not already been submitted to another lead HREC, the Executive Officer will register the application in RED by entering the application's lock code. The unique HREC reference number automatically generated by RED will be used thereafter to uniquely identify that multi-centre research project within NSW Health.

- 7.9 The Executive Officer will check all eligible applications to determine their validity. A valid application is one which is deemed to be complete and accurate by the Executive Officer (including the provision of all relevant signatures and supporting documentation).
- 7.10 Should the application be invalid, the co-ordinating investigator will be requested to supply the additional information. The Executive Officer will update RED accordingly and generate Standard Letter 002. The 60 day clock will not commence until a valid application has been received (refer to SOP 008).
- 7.11 If the application is valid, the Executive Officer will inform the co-ordinating investigator in writing of the HREC meeting at which the project is to be considered. The Executive Officer must also inform the co-ordinating investigator in writing, of the requirement to apply separately to each site at which the research project is to be conducted for a site-specific assessment to be undertaken. Standard Letter 001 must be used.
- 7.12 In some exceptional circumstances, a lead HREC may choose to accept a valid application after the submission closing date if there is space available on its agenda. If an application is accepted after the submission closing date, the 60 day clock will commence on the submission closing date. The decision to accept an application after the submission closing date is at the discretion of the Executive Officer and the lead HREC Chair.

For example, if an invalid application has been received by the submission closing date, but the missing documentation/information is only minor in nature, the lead HREC may accept this application provided the application can be validated (that is, all necessary documentation is provided by the co-ordinating investigator) prior to the agenda papers being distributed to HREC members.

SOP 008: The 60 day clock.

Function: To describe the purpose and function of the 60-day clock for the single ethical and scientific review of multi-centre research proposals.

Version: 1.0

- 8.1 Written notification of the final ethical opinion of the lead HREC (with CTN/CTX forms signed by a member of the HREC [not the Authorising Authority] if applicable, refer to SOP 015) should be provided to the co-ordinating investigator within a maximum of 60 calendar days. This is known as the “60 day clock”.
- 8.2 The 60 day clock will apply to the lead HREC review only and will not apply to the overall time taken for individual sites to grant authorisation for the commencement of research projects at their site.
- 8.3 The 60 day clock will commence on the submission closing date for the meeting at which the application is to be first considered, assuming the submission is accepted as per SOP 007. Where a lead HREC has reached its capacity and a co-ordinating investigator has chosen to wait for the project to be reviewed at the next available meeting of that HREC (rather than submit to another lead HREC that may be available to review the project sooner), the 60 day clock will commence from the submission closing date for the meeting at which the application is to be first considered.
- 8.4 The 60 day clock will stop while awaiting a response from the co-ordinating investigator to a request by the lead HREC. The date at which the clock stops will be the date on which the request for further information was sent to the co-ordinating investigator (not the date the decision was made by the HREC). The clock will commence again when a complete response, addressing the issues raised by the HREC, has been received by the Executive Officer.

Where responses are not date stamped on receipt by the Executive Officer, the date of receipt should be presumed to be the working day after the day of posting (Express Post) or the third working day after posting (regular post). This applies whether or not the Executive Officer is present to receive the response. Where the response arrives piecemeal, the date upon which the clock will recommence is the date on which the final part of the response is received.
- 8.5 The 60 day clock applies to valid multi-centre research applications only.
- 8.6 The 60 day clock is a measure of performance only. Expiration of the 60 day clock does not entitle the investigator to any remedies, such as immediate provision of a decision regarding ethical approval, or the return of application fees.

SOP 009: Ethical and scientific/technical review of new research proposals submitted for consideration by a lead HREC.

Function: To describe the process of ethical and scientific review conducted by a lead HREC.

Version: 1.0

9.1 The manner in which the lead HREC conducts its ethical review of a multi-centre research project is at the discretion of that HREC, provided the Department's Accreditation Standards and the requirements of the *National Statement* are met.

9.2 The manner in which the lead HREC obtains a scientific/technical review of a multi-centre research project is at the discretion of that HREC, provided the Department's Accreditation Standards, the *National Statement* and Policy Directive PD2007_035 *Human Research Ethics Committees: Standards for Scientific Review of Clinical Trials* is complied with.

A lead HREC may, for unusually complex clinical trials and occasional first-time-in-human/first-time-in-patient clinical trials, refer the scientific review to the Shared Scientific Assessment Scheme (for clinical drug trials) or refer the clinical trial to the Therapeutic Goods Administration Clinical Trials Exemption Scheme. Refer to Policy Directive PD2007_035.

9.3 The lead HREC in conducting its review of a multi-centre research project will consider ethical issues only, not site-specific matters of research governance. Matters of research governance are to be considered by the site as part of its site-specific assessment process (refer to SOP 017).

9.4 The lead HREC will not be required to review the Site Specific Assessment Form or the recommendation made by a Research Governance Officer, prior to reaching its final ethical opinion.

9.5 The lead HREC, after consideration of an application will make one of the following decisions:

- Approve the project as being ethically acceptable, with or without conditions.
- Request the provision of further information or modification of the project .
- Not approve the project.

The decision taken by the lead HREC will be recorded in RED.

9.6 For ethically approved projects, the HREC should consider the proposed duration of the project as specified in the HREC application, when determining the duration of its approval.

9.7 Where the lead HREC has requested the provision of further information and/or modification/s to the project, the lead HREC must establish a procedure for considering interim correspondence received from the co-ordinating investigator. This procedure should be included in the lead HREC's Standard Operating Procedures and may include the following:

- Delegation of the authority to review the interim correspondence and approve the project between meetings at the discretion of the Chair alone;

- Delegation of the authority to review the interim correspondence and approve the project between meetings at the discretion of an Executive of the HREC, comprising of one or more HREC members;
 - Delegation of the authority to review the interim correspondence and approve the project between meetings at the discretion of a sub-committee of the HREC;
 - Consideration of the interim correspondence at a further meeting of the HREC (in exceptional circumstances or where those delegated authorisation to review interim correspondence recommend reference back to a further meeting of the HREC).
- 9.8 To provide suitable oversight of this delegated authority to review the interim correspondence and approve the project between meetings, the lead HREC must be informed at the next available meeting of the final decision taken on its behalf, including the investigator's response and the reason for the decision taken.
- 9.9 Co-ordinating investigators may submit responses to lead HREC requests in either electronic format or hard copy, depending upon the requirements of the lead HREC.
- 9.10 For the review and approval of informed consent documents, refer to SOP 010.
- 9.11 The lead HREC may, at its discretion, discuss aspects of a multi-centre research project with the relevant Research Governance Officer.

SOP 010: Review of informed consent documentation.

Function: To describe the process for the review and approval of informed consent documentation.

Version: 1.0

10.1 The informed consent documentation to be used throughout the research project (including Participant Information Sheets and Informed Consent Forms) will be reviewed by the lead HREC.

10.2 Where the informed consent documentation to be used at each site is identical (except for local contact information), the co-ordinating investigator may submit a master version only to the lead HREC (Master Consent Document). It will not be necessary for the lead HREC to review and approve the individual informed consent documentation to be used at each site (Site Specific Consent Document).

Note: if one of the proposed sites is St Vincent's Hospital, the standard wording used by this institution which relates to the use of contraception, must be included in the informed consent documentation to be used at that site. In these circumstances, the co-ordinating investigator may submit to the lead HREC (which may or may not be St Vincent's Hospital) either:

- A Master Consent Document which contains the standard St Vincent's Hospital wording (with or without alternate wording for all other sites); or
- A Master Consent Document without the standard St Vincent's Hospital wording AND a Site Specific Consent Document with the standard St Vincent's Hospital wording.

For more information on the standard wording related to the use of contraception, visit the St Vincent's Hospital website at:

<http://wwwsvh.stvincents.com.au/researchoffice/ReschOffice/forms%20&%20templates.html>

10.3 If the informed consent documentation is approved, the lead HREC will ensure the approval letter for that project documents if it is a Master Consent Document and/or a Site Specific Consent Document as well as the version number and date for each document.

10.4 The proposed Site Specific Consent Document (based on the Master Consent Document submitted to the lead HREC) must be attached to the SSA Form and submitted by the local principal investigator to the relevant Research Governance Officer (refer to SOP 019).

This Site Specific Consent Document must contain:

- the name of the site from which recruitment is to occur (this may be on the relevant institutional letterhead);
- the relevant site specific contact details (such as the local principal investigator, who to contact if injury is sustained, the contact details of the person identified by the institution to receive complaints, etc.);
- the name and contact details of the lead HREC which ethically approved the project;

- the Master Consent Document version number & date (on which the Site Specific Document is based); and
- the Site Specific Consent Document version number & date.

The site name, protocol number (if applicable) and Site Specific Consent Document version number & date must appear on a footer on each page of the document. A statement such as “Based on the *[protocol number or, if not applicable, the project title]* Master Consent Document Version #, Date dd/mm/yyyy”, must appear on the front page of the Site Specific Document.

Unless the Site Specific Consent Document has specific lead HREC review and approval (which should only occur in very exceptional cases), the Site Specific Consent Document must be identical to the Master Consent Document except for the above additions.

The local principal investigator must also submit the Master Consent Document approved by the lead HREC (if applicable) to the Research Governance Officer when available.

- 10.5 When conducting the site-specific assessment, the site will conduct an administrative review of the Site Specific Consent Document to ensure it contains local institutional letterhead and local contact information. Sites must not re-examine ethical issues dealt with by the lead HREC or require review of informed consent documents by their local HREC.
- 10.6 Where the lead HREC requires changes to the Master Consent Document as a condition of approval of the study, the local principal investigator must also update the Site Specific Consent Document (ensuring all conditions of paragraph 10.4 are met). This updated Site Specific Consent Document should be submitted to the relevant Research Governance Officer along with the lead HREC approval letter for the study. The same procedure should be adopted for amendments to the Master Consent Document made after the study has commenced (refer to SOP 022).

SOP 011: Expedited review of new research proposals submitted to a lead HREC.

Function: To describe the procedure for expediting new research proposals involving no more than low risk, which are submitted to a lead HREC for single review.

Version: 1.0

- 11.1 A multi-centre research project which involves no more than low risk may undergo expedited HREC review at the discretion of the lead HREC and in accordance with the *National Statement*. Research with the potential for physical or psychological harm should generally not be considered for expedited review. This includes clinical drug trials, research involving invasive physical procedures and research exploring sensitive personal or cultural issues.
- 11.2 Lead HRECs must have a documented Standard Operating Procedure for the expedited review of the multi-centre research applications described in paragraph 11.1. This procedure must include who will initially consider the proposal to determine whether it is suitable to be expedited (eg. The Chair and Executive Officer or sub-group of the HREC etc). The lead HREC must be informed at the next available meeting of the decision taken on its behalf.
- 11.3 For research proposals that have undergone expedited review, the HREC should document the determination made that the proposal involved minimal risk, the matters considered during the review, the decision taken by the HREC, the reasons for that decision and the ratification of the decision by the full committee.
- 11.4 Multi-centre research projects to be conducted in the area of clinical research, are not permitted to undergo expedited ethical review by a lead HREC.

SOP 012: Preparation of minutes of lead HREC meetings.

Function: To describe the procedure for preparing minutes of lead HREC meetings.

Version: 1.0

- 12.1 The minutes of the lead HREC should record those applications for which single review was provided.
- 12.2 The minutes of the lead HREC should also record the following for each multi-centre research project for which single review was provided:
- The main ethical issues discussed by the HREC and the decision/s taken by the HREC.
 - The scientific/technical review (if any) that was obtained, from whom, and the outcome of that review.
 - HREC member's attendance and whether a quorum was achieved, including the minimum membership requirements under the *National Statement*.
 - HREC member's declaration of interests, including conflicts of interests, and the decision of the committee on the participation of the member concerned.
- 12.3 On request, extracts from the minutes of lead HREC meetings and the relevant scientific review (or Assessment Checklist for clinical trials) should be made available to the Chief Executive/delegate and Research Governance Officer at sites at which the research is to be conducted. Chief Executives/delegates and Research Governance Officers may only request sections of the lead HREC minutes and scientific review which are relevant to research projects being conducted at sites within their jurisdiction.

SOP 013: Notification of the outcome of review by a lead HREC.

Function: To describe the process for notifying the co-ordinating investigator of the outcome of the lead HREC's review of a new multi-centre research project.

Version: 1.0

13.1 The Executive Officer of the lead HREC must promptly notify the co-ordinating investigator of the outcome of the lead HREC's review. This must be in writing and, where possible, be no later than 10 working days from the date of the meeting at which the decision was made. Executive Officers are not required to copy this correspondence to local principal investigators. It is the responsibility of the co-ordinating investigator to determine the manner in which lead HREC correspondence will be disseminated.

Note: The 60 day clock will stop on the date on which the correspondence is sent to the co-ordinating investigator, not the date upon which the HREC decision was made.

13.2 When notifying the co-ordinating investigator of the outcome of the lead HREC's review, the corresponding Standard Letter must be used (refer to Appendix A). The standard letter must specify all documents reviewed by the HREC including their version numbers and dates.

13.3 Where applicable, the TGA's CTN/CTX form (signed by a member of the lead HREC) must accompany the final HREC approval letter to the co-ordinating investigator. The signed CTN/CTX forms must include all trial sites for which the HREC is providing approval (refer to SOP 15).

13.4 The Executive Officer will record the decision of the lead HREC (including any conditions of ethical approval or reasons for rejection) and the date of the decision in RED as soon as practicable (and no later than within 5 working days) from the date of the meeting at which the decision was made. The date of the decision is the date on which the correspondence is sent to the co-ordinating investigator (this may be via email or in hard copy).

13.5 Ethical approval granted by the lead HREC does not imply that authorisation to commence the research project will be granted by the Chief Executive (or delegate) at the site at which the research is to be conducted. This is a matter for the site (refer to SOP 021).

13.6 Where the lead HREC has rejected a project, the lead HREC must notify all Research Governance Officers that have received applications for site-specific assessment (this information will be available from RED). Any site-specific assessment which is underway should be discontinued.

SOP 014: Consideration of interim correspondence for new applications

Function: To describe the procedure for considering interim correspondence from co-ordinating investigators relating to new multi-centre research projects.

Version: 1.0

- 14.1 Responses to requests for further information, modification or clarification by a lead HREC, will be considered by that HREC in accordance with the decision taken at the meeting at which the project was considered (refer to SOP 009).
- 14.2 The Executive Officer of the lead HREC must enter the date of receipt of the interim correspondence in RED so as to re-start the 60 day clock (see SOP 008).
- 14.3 The Executive Officer of the lead HREC must promptly notify the co-ordinating investigator of the outcome of the lead HREC's review of the interim correspondence, using the relevant Standard Letter.
- 14.4 The decision taken by the lead HREC will be updated in RED as soon as practicable (and no later than within 5 working days) from the date on which the decision was made.
- 14.5 For the consideration of correspondence relating to amendments to authorised research projects, refer to SOP 022.

SOP 015: Clinical trials conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) Schemes.

Function: To describe the additional requirements for clinical trials being conducted under the CTN or CTX Schemes.

Version: 1.1

- 15.1 Applications to lead HRECs for clinical trials which are to be conducted under the CTN Scheme, should be accompanied by a separate *'Notification of Intent to Supply Unapproved Therapeutic Goods under the Clinical Trial Notification (CTN) Scheme'* form (obtained from the Therapeutic Goods Administration) for each site participating in the study.

CTN forms should generally be provided to the lead HREC at the time of submission of a new application.

Note: As an alternative, the co-ordinating investigators may choose to submit one CTN/CTX form only to the lead HREC (with a separate section 1.5 "trial site details" for each site at which the research is to be conducted), rather than multiple forms. In this case, the lead HREC will sign the CTN/CTX form at section 3 and return it to the co-ordinating investigator.

- 15.2 Applications to lead HRECs for clinical trials which are to be conducted under the CTX Scheme, should be accompanied by a separate *'Notification of the Conduct of a Trial under the CTX Scheme'* form (obtained from the Therapeutic Goods Administration) for each site participating in the study.

CTX forms should generally be provided to the lead HREC at the time of submission of a new application.

- 15.3 The local principal investigator at each site is not required to sign Section 2 of the CTN or CTX Form prior to submission of the Form to the lead HREC by the co-ordinating investigator.

- 15.4 For ethically approved research projects conducted under either the CTN or CTX Schemes, a member of the lead HREC should sign the relevant Form/s at Section 3. The local principal investigator at each site is not required to sign Section 2 of the CTN or CTX Form prior to the lead HREC signing and returning the Form to the co-ordinating investigator.

The lead HREC should return the signed Form/s to the co-ordinating investigator along with the HREC approval letter, for dissemination to local principal investigators. The local principal investigator should then sign Section 2 of the Form and submit the signed Form to the Research Governance Officer at the site at which the research is to be conducted (refer to SOP 019).

- 15.5 For additional trial sites, which have not been included in the originally signed CTN or CTX forms, an additional Trial Site Details page should be submitted by the co-ordinating investigator to the lead HREC for its signature (also refer to SOPs 027 and 035 for information regarding the addition of trial sites).

SOP 016: Withdrawal and re-submission of an application for lead HREC review.

Function: To describe the process for withdrawal and re-submission of an application for lead HREC review.

Version: 1.0

- 16.1 The co-ordinating investigator may withdraw an application which has been submitted to a lead HREC for review, at any time. The Executive Officer of the lead HREC will be required to enter the reasons for the withdrawal of the project into RED, and the stages through which the application had progressed prior to its withdrawal.
- 16.2 Should the co-ordinating investigator wish to resubmit the application for HREC review, the application should be resubmitted to the lead HREC to whom the original application was submitted, unless there are extenuating circumstances (for example, if the lead HREC to which the application was first submitted had reached its meeting capacity for the review of multi-centre research applications and was unable to review the application at that meeting. Refer to SOP 7.5).
- 16.3 On re-submission, the co-ordinating investigator must declare the original HREC reference number previously assigned to the project by the lead HREC. The 60 day clock will commence from the submission closing date for the meeting at which the resubmitted application is to be considered.
- 16.4 Should the application be re-submitted to a lead HREC which did not review the original application, the co-ordinating investigator must include in the re-submission all previous documentation associated with the initial HREC review. A lead HREC will be able to identify whether a project has been withdrawn from another lead HREC, and will consider an application for a re-submitted project to be incomplete unless this previous documentation is provided.
- 16.5 The HREC to whom the project is re-submitted may for any reason, if it did not review the original submission, request that the co-ordinating investigator re-submit the project to the lead HREC to whom the original application was submitted.

SOP 017: The site-specific assessment.

Function: To describe the role and purpose of the site-specific assessment.

Version: 1.0

- 17.1 The site specific assessment is the mechanism used by Public Health Organisations to assess the suitability of a research project to be conducted at a particular site, whether that project is multi-centre or single-site. The site-specific assessment is a separate process to the ethical and scientific/technical review undertaken by the lead HREC. It is not a second ethical review undertaken by the local site and does not involve consideration of the project by the local HREC (unless that HREC is the lead HREC for that particular project). Further information on the site specific assessment is available from the Health Research and Ethics Branch website: <http://www.health.nsw.gov.au/healthethics>.
- 17.2 Each site at which the multi-centre research project is to be conducted must undertake a site specific assessment of the research project. The site specific assessment involves consideration of the following matters:
- Whether the facilities and resources required for the research to proceed at the site have been identified, are appropriate and available.
 - Whether the researchers involved in the project at the site have the necessary skills, experience, training and expertise to carry out their role in the research project.
 - Whether, in all the circumstances, the Public Health Organisation wishes the research to be conducted at its site.
- 17.3 The site specific assessment may occur in parallel to the lead HREC's review.
- 17.4 It is a matter for each Public Health Organisation to determine the sites within its jurisdiction which require separate site specific assessment of research projects. This information will be made available on the Public Health Organisation's and the Department's website.

SOP 018: The Research Governance Officer.

Function: To describe the role and function of the Research Governance Officer.

Version: 1.0

- 18.1 The Research Governance Officer is the person/s responsible within a Public Health Organisation for reviewing the Site Specific Assessment Form (refer to SOP 019) and for making a recommendation to the Chief Executive/delegate as to whether or not the research project should proceed at that site.
- 18.2 It is a matter for the Public Health Organisation to determine who will be the Research Governance Officer/s at each separate site within the organisation. Research Governance Officers must be notified to the Department by the Public Health Organisation.
- 18.3 The name and contact details of each Research Governance Officer must be made publicly available on the Public Health Organisation's and Department's website.

Further information on the role of the Research Governance Officer is available from the Health Research and Ethics Branch website.

SOP 019: Submission of applications for site-specific assessment.

Function: To describe the procedure for submission of an application for site-specific assessment by the local principal investigator.

Version: 1.0

- 19.1 Applications for site specific assessment must be made using the Department's standard Site Specific Assessment Form (the SSA Form), available from the on-line forms website. The SSA Form may be amended by the Department from time to time.
- 19.2 A separate SSA Form must be completed and submitted for each separate research project and for each site requiring separate site-specific assessment (it is a matter for the Public Health Organisation to determine the sites within their jurisdiction which require separate site specific assessment).
- 19.3 The standard SSA Form will be generated by the co-ordinating investigator on the on-line forms website. The co-ordinating investigator must transfer a separate SSA Form (some data fields will have been already populated from the HREC application) to the principal investigator at each site for completion. The principal investigator will receive an email, notifying him/her that an SSA Form is awaiting completion on the on-line forms website.
- 19.4 The principal investigator responsible for the overall conduct of the research project at the site, should complete the SSA Form using the on-line forms website. This may or may not be the co-ordinating investigator. For multi-centre projects involving only one investigator (the co-ordinating investigator), that investigator will be responsible for completing the SSA Form for all sites.
- 19.5 The local principal investigator is responsible for ensuring all sections of the SSA Form are completed correctly, including the checklist, and that all requested supporting documentation is provided, including relevant signatures.
- 19.6 The principal investigator must ensure that the HREC reference number allocated to that project by the lead HREC is included on the SSA Form (the HREC reference number will automatically populate into the SSA Form when using the on-line forms website).
- 19.7 Once the SSA Form has been completed using the on-line form website, the SSA Form should be locked and a lock code obtained. The SSA Form should then be submitted (with its lock code) to the relevant Research Governance Officer, accompanied by one copy of the following documentation (where applicable):
 - CTN/CTX form signed by a member of the lead HREC (when available);
 - Final research protocol;
 - Investigator's brochure;
 - HREC application;
 - Site Specific Consent Document/s (refer to SOP 010);
 - Master Consent Document/s approved by the lead HREC (refer to SOP 010);
 - Advertisement/s;
 - Questionnaire/s; and
 - Any other documentation submitted to the lead HREC for review.

- 19.8 One copy of the lead HREC approval letter must be submitted to the Research Governance Officer when available. Should the lead HREC not grant approval for the research project, this must also be notified to the Research Governance Officer.
- 19.9 Where new or modified documentation has been submitted to the lead HREC for review (due to, for example, a request by the lead HREC), this must also be submitted by the principal investigator to the relevant Research Governance Officer.

Note: for the review and approval of amendments to authorised research projects, refer to SOP 022.

- 19.10 Applications for site-specific assessment may be made at any time, provided the local principal investigator has completed the standard Site Specific Assessment Form and obtained both the lock code and HREC reference number.

SOP 020: Consideration of applications for site-specific assessment.

Function: To describe the site-specific assessment undertaken by a Public Health Organisation.

Version: 1.0

20.1 Upon receipt of an application for site specific assessment, the Research Governance Officer will enter the application's lock code into RED and generate an SSA Reference Number.

Note: The HREC application must have already been entered into RED before a Research Governance Officer can register a related SSA Form on RED.

20.2 Applications for site specific assessment which are submitted without a lock code or HREC reference number, will not be accepted by the Research Governance Officer. Applications for site specific assessment which are not submitted on the Standard Site Specific Assessment Form will not be accepted.

20.3 The Research Governance Officer will check the application to determine whether it is a valid application. A valid application for site specific assessment is one which is deemed to be complete by the Research Governance Officer (including the provision of all relevant signatures and supporting documentation).

20.4 Should an invalid Site Specific Assessment Form be received by the research governance officer, the local principal investigator will be requested to supply the missing information.

20.5 The Research Governance Officer will review all valid applications for site specific assessment. In conducting this review, advice may be sought from other Public Health Organisation personnel as is deemed necessary (for example, the Research Governance Officer may request advice from risk management officers in relation to insurance and indemnity issues). The Research Governance Officer may also, at his/her discretion, discuss aspects of the research project with the lead HREC.

20.6 Research Governance Officers will consider only those matters concerning the site suitability of the research project.

20.7 When review of the SSA Form is completed, the Research Governance Officer will complete section e) of the Form ("Recommendation by the Research Governance Office") by indicating whether authorisation is recommended, not recommended or requires Chief Executive/delegate consideration. Where the Research Governance Officer has recommended that authorisation is not granted, a reason/s should be provided. Once completed, the Research Governance Officer should submit the Form to the Chief Executive/delegate, accompanied by one copy of the lead HREC approval letter.

20.8 It is expected that the site specific assessment will be conducted in an efficient and timely manner. However, at this stage, the 60 day clock does not apply to the site specific assessment.

20.9 Where the local principal investigator decides not to proceed with conducting the research project at that site, the SSA Form should be withdrawn. Requests to withdraw the research project from SSA, must be made in writing (this may be

via email) to the relevant Research Governance Officer. The Research Governance Officer should update RED accordingly.

- 20.10 Should a principal investigator wish to re-submit an application for site specific assessment which has previously been withdrawn, the Research Governance Officer may request that a new SSA Form be completed.

SOP 021: Authorisation of a research project.

Function: To describe the process for gaining authorisation to commence a research project at a site.

Version: 1.0

- 21.1 Authorisation of a research project is the approval granted by the Chief Executive (or delegate) for a research project to commence at a site. Only the Chief Executive (or delegate) has the authority to grant/not grant authorisation for a research project to commence within, or in association with, their health facilities. This responsibility cannot be delegated to the Public Health Organisation's HREC.
- 21.2 Authorisation to commence a research project may only be granted by the Chief Executive (or delegate) when a site-specific assessment is satisfactorily completed and a lead HREC has granted ethical approval. A research project cannot commence at a site until it has received approval from a lead HREC and authorisation from the Chief Executive (or delegate).
- 21.3 The Chief Executive (or delegate) may choose to not grant authorisation for a research project, notwithstanding that lead HREC approval has been granted. However, a Chief Executive (or delegate) cannot grant authorisation for a research project that has not received lead HREC approval.
- 21.4 In making the determination to either grant or not grant authorisation, the Chief Executive (or delegate) will review the completed Site Specific Assessment Form and lead HREC approval letter, submitted by the Research Governance Officer.
- 21.5 The Chief Executive (or delegate) will sign section (f) of the SSA Form ("Authorisation by Chief Executive") and return the Form and any other accompanying documentation to the Research Governance Officer.
- 21.6 For clinical trials conducted under the CTN or CTX Schemes, the Chief Executive (or delegate) will also be required to sign the CTN or CTX form at Section 4 and return this to the Research Governance Officer.
- 21.7 The Research Governance Officer is responsible for notifying the local principal investigator of the Chief Executive (or delegate's) decision. This must be in writing and in the form of Standard Letter 012 or 013, accompanied by the signed CTN/CTX forms (if applicable).
- Only when the principal investigator has been notified in writing of the decision by the Chief Executive/delegate to authorise the research project, can the project commence at that site.
- 21.8 The Research Governance Officer must enter the decision of the Chief Executive (or delegate) in RED (that is, whether or not the project has been authorised to commence at the site), including the date upon which the outcome was notified to the local principal investigator.
- 21.9 All documentation relating to the site-specific assessment for each research project (including evidence of final ethical opinion from the lead HREC, HREC application form, protocol, copy of CTN form etc.) must be kept on file in a secure and confidential manner by the relevant Public Health Organisation.

21.10 Neither the Research Governance Officer nor the local principal investigator will be required to notify the lead HREC of the outcome of the site specific assessment (as lead HREC Executive Officers shall be able to access this information from RED).

SOP 022: Amendments to an authorised research project.

Function: To describe the procedure for making an amendment to a research project which has been granted authorisation by a Chief Executive (or delegate).

Version: 1.0

Note: the term “amendment” is used here to describe changes made to the research project after that project has been granted authorisation.

22.1 As a condition of ethical approval, the lead HREC shall require the co-ordinating investigator to request its approval for proposed amendments to the research project which may affect its ongoing ethical and/or scientific acceptability, including amendments to the protocol that:

- are proposed or undertaken in order to eliminate immediate risks to participants;
- may increase the risks to participants; or
- significantly affect the conduct of the research project.

Only those amendments which may affect the ethical and/or scientific acceptability of the multi-centre research project require submission to, and review by, the lead HREC which originally considered the project.

22.2 Requests for lead HREC approval of amendments must be submitted, in writing, to the lead HREC which originally considered the project and in the format specified by that lead HREC. The HREC reference number must be quoted in the submission.

22.3 Amendment requests which apply to more than one site should be submitted to the lead HREC by the co-ordinating investigator. If the amendment request applies to a single site only, the local principal investigator at that site may submit the request directly to the lead HREC.

22.4 Upon receipt of the amendment request, the HREC Executive Officer will update RED. The lead HREC will review the amendment request according to its established standard operating procedures which will include one of the following:

- Review by the Chair alone;
- Review by an Executive of the HREC, comprising of one or more HREC members;
- Review by a sub-committee of the HREC; or
- Review by the full HREC.

The HREC Executive Officer will notify the co-ordinating investigator (or local site investigator for single site amendments) of the outcome of the lead HREC’s decision and update RED accordingly.

The lead HREC must keep on file all documentation pertaining to requests for amendments to research projects which have been submitted to it for review.

22.5 A copy of the request submitted to the lead HREC and the outcome of the lead HREC's review, must also be sent to the relevant Research Governance Officer by the local principal investigator (for single-site amendments) or the co-ordinating investigator (for amendments relating to more than one site).

22.6 Upon receipt of the amendment request, the Research Governance Officer will review the documentation and inform the local principal investigator as to whether or not site authorisation is necessary for the amendment to be implemented at that site.

Where the Research Governance Officer has determined that site authorisation is necessary, the research governance officer will follow the procedure outlined under SOP 22.10. The amendment may not be implemented at that site until the lead HREC has granted approval AND the site has granted authorisation.

Where the Research Governance Officer has determined that site authorisation is not required, the Research Governance Officer will notify the local principal investigator in writing (this may be by email). The local principal investigator may implement the amendment upon approval being granted by the lead HREC.

22.7 When in doubt as to whether the proposed amendment may affect the ethical/scientific acceptability of the project and would therefore necessitate review by the lead HREC, the investigator should communicate with the lead HREC to ascertain whether an amendment request to the HREC is required.

22.8 Deviations from, or changes to the research project, may be implemented without prior review and documented approval from the lead HREC and the site, where it is necessary to eliminate an immediate hazard(s) to the research participants. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) must be submitted to the lead HREC and research governance officer.

22.9 Amendments to the research project which may impact upon the site-specific assessment, must be submitted to the Research Governance Officer for that site. Where the investigator is of the opinion that the amendment does not impact upon the ethical and/or scientific acceptability of the project, the lead HREC is not required to be notified. Examples of amendments to the site-specific assessment which may require review by the site (and not the lead HREC), include changes to the following:

- Use of departmental facilities
- Contractual arrangements
- Insurance and indemnity arrangements.

When in doubt as to whether the proposed amendment may affect the site-specific assessment of the project, the investigator should communicate with the Research Governance Officer to ascertain whether an amendment request should be submitted.

22.10 Upon receipt of the request for amendment to the site-specific assessment, the research governance officer will determine whether Chief Executive (or

delegate) authorisation is required for the amendment to be implemented at that site.

Should the Research Governance Officer be of the opinion that authorisation from the Chief Executive (or delegate) is not required due to the minimal impact of the proposed amendment on the suitability of the site, the Research Governance Officer will notify the local principal investigator in writing, that authorisation is granted for the amendment to be implemented at the site. The Research Governance Officer will record this decision in RED.

Should the Research Governance Officer be of the opinion that authorisation from the Chief Executive (or delegate) is required (for example, if the amendment is substantial and significantly impacts upon the use of institutional facilities, resources or staff), the Research Governance Officer will forward the investigator's request to the Chief Executive (or delegate) for consideration as to whether, in all the circumstances, it is reasonable for the amendment to be implemented at that site. The Research Governance Officer will then notify the local principal investigator as to whether or not authorisation has been granted by the Chief Executive (or delegate) for the amendment to be implemented at that site. The Research Governance Officer will record this decision in RED.

- 22.11 When determining whether or not authorisation is required from the Chief Executive (or delegate) for implementation of the amendment request, the following matters should be considered:
- whether or not the amendment request involve significant additional resources;
 - whether or not the amendment request involve a significant impact upon the use of institutional facilities;
 - whether or not the amendment request involve a significant impact upon the workload of staff.

This determination will need to be made on a per project basis. Appropriate advice may be sought from personnel within the Public Health Organisation as is considered necessary.

- 22.12 The local principal investigator may implement the amendment to the site-specific assessment at the site when written confirmation has been received that the amendment has been authorised by the site (amendments which affect the ethical and/or scientific acceptability of a research project must also be approved by the lead HREC prior to implementation).
- 22.13 If, in the course of reviewing an amendment request, the Research Governance Officer is of the opinion that it may impact on the ongoing ethical/scientific acceptability of the project (for example, amendments to the recruitment process), and an amendment request has not been submitted to the lead HREC, the Research Governance Officer will notify the local principal investigator that lead HREC review of the amendment may be required before the proposed amendment can be authorised and therefore implemented at the site.
- 22.14 All documentation relating to amendment requests for each research project must be kept on file in a secure and confidential manner, by the relevant Public Health Organisation.

SOP 023: Reporting and review of serious and unexpected adverse events.

Function: To describe the procedure for the notification and review of adverse events for authorised research projects.

Version: 1.1

23.1 The lead HREC shall require, as a condition of ethical approval of each research project, that the lead HREC be notified of anything which might warrant review of the ethical approval of the project, including serious and unexpected adverse events.

23.2 For multi-centre clinical trials, the reporting of serious adverse events or serious adverse reactions to the lead HREC must meet the requirements of the National Health and Medical Research Council's "*HREC Alert No 1, 18 April 2007. Advice for HRECs on Adverse Event Reporting in Australia in Clinical Trials*" available at: <http://www.nhmrc.gov.au/ethics/human/hreca/alerts.htm>.

This document sets out the minimum reporting requirements for adverse events occurring in clinical trials. A lead HREC may impose additional reporting requirements reflecting the degree of risk of the research to participants.

It is the responsibility of the co-ordinating investigator to provide such reports to the lead HREC.

23.3 For serious adverse events occurring at a site within the NSW public health system (and which are reportable to the lead HREC under the NHMRC HREC Alert No1, 18 April 2007), such reports must be provided to the lead HREC by the local principal investigator at that site. A copy of the report must also be provided to the Research Governance Officer at the site at which the event occurred and to the co-ordinating investigator (as it may impact on the continuation of the study).

23.4 Such events must be reported to the lead HREC in the format specified by the lead HREC.

23.5 For clinical research where the event has occurred at a site within NSW Health, the incident may also be reportable under the clinical governance policy of the Public Health Organisation, including the incident management process outlined under Policy Directive PD 2006_030 *Incident Management Policy*. This requirement is additional to the reporting to the lead HREC.

23.6 The co-ordinating investigator must inform the lead HREC of any significant findings and recommendations made by an independent Data Safety and Monitoring Board (DSMB) established for the research project (if applicable).

23.7 Upon receipt of a report of an adverse event, the lead HREC will, according to its documented standard operating procedures, review the report and take the appropriate course of action which may include:

- Acknowledging receipt of the report;
- Noting of the event;
- Referral to the lead HREC's scientific sub-committee/scientific expertise for advice;

- Immediate request for additional information from the co-ordinating investigator or local principal investigator;
- Immediate suspension of ethical approval;
- Immediate discontinuation of ethical approval;
- Other action as recommended by the HREC.

23.8 Where the lead HREC considers it appropriate that the report requires the immediate suspension or discontinuation of the ethical approval of the research project, the lead HREC must immediately notify the co-ordinating investigator, local principal investigators and the Research Governance Officer at all other sites at which the project is being conducted. This must be followed by notice in writing, within 3 working days.

SOP 024: Monitoring of ethically approved research projects.

Function: To describe the responsibilities for monitoring the ethical conduct of an authorised research project.

Version: 1.0

24.1 The frequency and type of monitoring shall reflect the degree of risk to research participants, and may include:

- Reports from researchers (refer to SOP 24.3);
- Reports from independent agencies (such as a data and safety monitoring board);
- Random inspections of research sites, data, or consent documentation; and
- Interviews with research participants or other forms of feedback from them.

24.2 Public Health Organisations must comply with the reasonable requirements of the lead HREC in relation to the monitoring of research taking place within their institutions.

24.3 At regular periods (reflecting the degree of risk, and at least annually and at the completion of the project), co-ordinating investigators must, for each site at which the research is being undertaken, provide reports to the approving lead HREC on matters including:

- Progress to date, or outcome in the case of completed research;
- Maintenance and security of records;
- Compliance with the approved research proposal; and
- Compliance with any conditions of approval.

24.4 It is not necessary for each site to submit individual reports to the lead HREC, unless this is a condition of lead HREC approval. Rather, the co-ordinating investigator will be required to report on the ethical conduct of the trial undertaken at all sites.

Note: In practice, the co-ordinating investigator may collate individual reports provided from each site and send this directly to the lead HREC or he/she may prepare a single summary report.

24.5 The local principal investigator is not required to submit progress reports on the local conduct of the research project to Research Governance Officers, unless this is a condition of authorisation. The site may request a copy of the progress reports from the lead HREC at any time.

24.6 Progress and annual reports must be submitted in the format specified by the lead HREC. These will be reviewed according to the lead HREC's standard operating procedures.

SOP 025: Suspension or withdrawal of ethical approval for a research project.

Function: To describe the procedure for the suspension or withdrawal of ethical approval by a lead HREC.

Version: 1.0

- 25.1 Where a lead HREC finds reason to believe that continuance of a research project will compromise participants' welfare, or that the research project is not being conducted in accordance with its ethical approval, it should immediately seek to establish whether ethical approval for the project should be suspended or withdrawn. This process should ensure that researchers and others involved in the project are treated fairly and with respect.
- 25.2 In such circumstances, the lead HREC must immediately notify the co-ordinating investigator, local principal investigators and Research Governance Officers at each site of the decision taken by the HREC. This notification must be confirmed in writing within three working days.
- 25.3 Only the lead HREC may suspend or withdraw ethical approval for a project it has previously approved. However, sites retain control over the governance of research and may withdraw authorisation for the conduct of the research at the site, notwithstanding that ethical approval has not been withdrawn (refer to SOP 026).
- 25.4 An investigator cannot continue with the research if ethical approval has been suspended or withdrawn and must comply with any special conditions imposed by the lead HREC. The research may not be resumed unless either:
- The investigator subsequently establishes that continuance will not compromise participants' welfare; or
 - The research is modified to provide sufficient protection for participants, the modification is ethically reviewed, and the modified research is approved by the lead HREC.
- 25.5 It is the responsibility of the Executive Officer of the lead HREC to update RED accordingly.

SOP 026: Suspension or withdrawal of authorisation by the site at which the research is being conducted.

Function: To describe the procedure for the suspension or withdrawal of authorisation by the site at which the research is being conducted.

Version: 1.0

- 26.1 Where a Chief Executive (or delegate) is satisfied that circumstances have arisen such that it is no longer appropriate to conduct a research project at a site within their jurisdiction, it should immediately seek to establish whether authorisation for the project should be suspended or withdrawn. This process should ensure that researchers and others involved in the project are treated fairly and with respect.
- 26.2 In such circumstances, the Research Governance Officer must immediately notify the local principal investigator and the lead HREC of its decision.
- 26.3 An investigator cannot continue with the research at a site if the Chief Executive (or delegate) has suspended or withdrawn authorisation for the research to be conducted at that site.
- 26.4 It is the responsibility of the Research Governance Officer to update RED accordingly.

SOP 027: Extension of a multi-centre research project to additional sites.

Function: To describe the procedure for the inclusion of additional sites in a research project which has been granted ethical approval by a lead HREC.

Version: 1.0

- 27.1 Where, following the granting of lead HREC approval to commence a multi-centre research project, that project is to be extended to an additional site, the local principal investigator responsible for the conduct of the project at the additional site must submit a Site Specific Assessment Form to the relevant Research Governance Officer (with the notification of original ethical approval by the lead HREC and all other necessary attachments and signatures), as per SOP 019. The Site Specific Assessment Form must contain the HREC reference number and the lock code.
- 27.2 Upon receipt of the SSA Form, the Research Governance Officer will enter the locked code into RED and generate the SSA reference number. The SSA Form will be dealt with as per SOP 020.
- 27.3 The research will not be able to proceed at that site until the Public Health Organisation's Chief Executive (or delegate) has granted authorisation.
- 27.4 Co-ordinating investigators must also inform the lead HREC that an additional site/s has been added. Where the conduct of the project at the additional site will vary from the conduct of the project described in the original protocol/application approved by the lead HREC (in a way which may affect the ethical and/or scientific acceptability of that project), an amendment request must also be submitted to the lead HREC. Instances where this may occur include:
- Extension of project to include a sub-study which is to be conducted at an additional site¹.
 - Extension of project to include testing of participants which is to be conducted solely at an additional site.

Such amendments will be dealt with in the manner set out in SOP 022.

- 27.5 Multi-centre research projects which are to be conducted under either the CTN or CTX Schemes will be required to submit additional information to the lead HREC, as per SOP 015, because of the need for a member of that HREC to sign the CTN/CTX documentation.

¹ The lead HREC may request that the sub-study be submitted as a new application.

SOP 028: Study closure at a site.

Function: To describe the procedure for notification of study closure status.

Version: 1.0

- 28.1 Where an authorised research project is to be closed at one or more sites, the co-ordinating investigator must notify the lead HREC in writing. The local principal investigator at each site must also notify the Research Governance Officer in writing.
- 28.2 RED will be updated accordingly by the Research Governance Officer.
- 28.3 Where a research project is terminated or suspended by the co-ordinating investigator or local principal investigator before the expected date of completion, the lead HREC and research governance officer must be promptly informed and provided with a detailed written explanation of the circumstances and reasons why.

SOP 029: Appointment of a new co-ordinating or site investigator.

Function: To describe the procedure for appointment of a new co-ordinating or site investigator.

Version: 1.0

29.1 Where a new co-ordinating investigator is to be appointed, the lead HREC must be notified in writing by either the departing co-ordinating investigator, the sponsor or the new co-ordinating investigator. The new co-ordinating investigator will be required to sign the declaration on NEAF and submit this to the lead HREC.

29.2 Where the new co-ordinating investigator is also a new principal investigator at a site, he/she must also notify the relevant Research Governance Officer and sign the relevant declaration on the Site Specific Assessment Form. A curriculum vitae should also be submitted should the Research Governance Officer not already have one on record.

SOP 030: Complaints concerning the lead HREC's review of a multi-centre research project.

Function: To describe the procedure whereby a co-ordinating investigator may seek a review of the decision taken by a lead HREC on a multi-centre research proposal.

Version: 1.0

- 30.1 A co-ordinating investigator may seek a review of the decision made by a lead HREC. This request must be in writing and may be directed to the attention of the lead HREC Chair and/or the Chief Executive/delegate to whom the lead HREC is accountable. The Chair will notify the Chief Executive/delegate of any complaints received as soon as possible. The Chief Executive/delegate will notify the Chair of any complaints received as soon as possible.
- 30.2 The review will be dealt with according to the lead HREC's documented standard operating procedures. If the investigator is not satisfied with the outcome of the lead HREC's review of the matter, the investigator may refer the complaint to the Chief Executive/delegate or request the Chair to do so. The Chair shall provide to the Chief Executive/delegate all relevant information about the review.
- 30.3 The Chief Executive/delegate will consider the complaint, ensuring that both the investigator and the HREC are afforded the opportunity to make submissions. The Chief Executive/delegate may convene a suitable panel to assist him/her reviewing the complaint. The panel should consist of persons with expertise relevant to the substance of the complaint.
- 30.4 The Chief Executive/delegate 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 lead HREC for consideration, bearing in mind the findings of the Chief Executive/delegate's review.
- 30.5 If the complaint is referred back to the lead HREC for review, the lead HREC shall re-consider the complaint, taking due account of the findings of the Chief Executive/delegate, including any advice from him/her or from any panel constituted to assist him/her in conducting the review. The lead HREC will notify the co-ordinating investigator of the outcome of this re-review.
- 30.6 If the co-ordinating investigator is still not satisfied with the decision of the lead HREC, the investigator may refer the complaint to the Department of Health.
- 30.7 The Department of Health will convene a panel to review the complaint. The lead HREC and the Chief Executive/delegate will provide the panel with all material related to the original complaint, the review by the Chief Executive and the re-review by the lead HREC. The investigator and the HREC will have the opportunity to put submissions before the panel. The panel will consider this material in reviewing the complaint. The panel may, in its discretion:
- Request further information from the investigator, lead HREC or Chief Executive/delegate;
 - Seek the advice of any relevant experts;

- Consider any other material relevant to the complaint.

The panel's power on review will be restricted to dismissing the complaint or returning the decision to the lead HREC for re-review. The panel will not be empowered to grant ethical approval in substitution for the approval of the lead HREC (as this is not permitted under the *National Statement*). Should the lead HREC be requested to review its decision, the outcome of this review by the lead HREC will be final. The project may not be submitted to another lead HREC for a second opinion.

- 30.8 The Public Health Organisation responsible for the site at which the research project is to be conducted may not appeal the final outcome of the lead HREC's review. However, it is a matter for the Public Health Organisation to determine whether the research project should be conducted at sites under its control (refer to SOP 026).
- 30.9 All complaints will be recorded in RED.

SOP 031: Review of a Public Health Organisation's decision to not authorise a multi-centre research project.

Function: To describe the procedure whereby a principal investigator may seek a review of the Public Health Organisation's decision to not authorise a multi-centre research project.

Version: 1.0

31.1 Local principal investigators may seek a review of a decision by a site not to authorise a project. It is a matter for the Chief Executive to determine the manner in which such reviews will be handled.

SOP 032: Complaints about the conduct of an authorised research project.

Function: To describe the procedure for handling complaints about the conduct of an authorised research project.

Version: 1.0

- 32.1 Institutions and their HRECs must have a written policy regarding the procedure for handling complaints about the conduct of an authorised research project, which is in accordance with the *National Statement*.
- 32.2 All concerns, allegations or complaints must be reported to the person nominated by the institution to handle such complaints (for example, the Research Governance Officer or hospital patient representative). Upon receipt of a complaint, the person nominated by the institution shall, as soon as possible, notify the lead HREC which approved the project and the Research Governance Officer at the site from which the complaint arose. Should the complaint be reported directly to the lead HREC, the lead HREC must, as soon as possible, notify the Research Governance Officer at the site from which the complaint arose. The institution and the lead HREC shall co-operate with each other in determining how to handle the complaint.
- 32.3 Where the complaint relates to research misconduct, the matter should be dealt with in accordance with the Public Health Organisation's policy and the *Australian code for the responsible conduct of research*.
- 32.4 The institution must consider whether the complaint should be handled according to the Department's Policy Directive PD2006_007 *Complaint or Concern about a Clinician – Principles for Action*.
- 32.5 The complaint may also need to be registered in the Incident Information Management System (IIMS), in accordance with the Department's Policy Directive PD2006_073 *Complaint Management Policy*.
- 32.6 Individual sites will have access to information about complaints concerning the conduct of an approved research project by accessing RED. Information relating to the complainant will be de-identified. Refer to SOP 004 for further requirements regarding confidentiality of this information.
- 32.7 All complaints will be recorded in a de-identified manner in RED by the Research Governance Officer.

SOP 033: Multi-centre research projects approved prior to implementation of single review.

Function: To describe the procedure for the ongoing ethical and scientific/technical review of multi-centre projects approved by a NSW Health HREC prior to implementation of the model for single review.

Version: 1.1

- 33.1 Research projects which were approved by a NSW Health HREC prior to implementation of the Department of Health model for single review of multi-centre research, will continue to operate in accordance with previous arrangements for HREC review (refer to paragraph 33.5 for the procedures to follow where the project is to be extended to more than one site within the NSW public health system).
- 33.2 Paragraph 33.1 applies even if the NSW Health HREC that approved the project prior to the implementation of the model subsequently became a lead HREC. That is, no approval from a NSW Health HREC is considered to be an approval from a lead HREC unless the approval was given after the 1st July 2007.
- 33.3 Amendment requests for multi-centre research projects which were approved by one or more NSW Health HRECs prior to the introduction of the single review model, will continue to require approval from each HREC which provided original ethical approval (except under the conditions described in 33.5 (ii)).
- 33.4 Reports of serious and unexpected adverse events for multi-centre projects which were approved by one or more NSW Health HRECs prior to the introduction of the single review model, will continue to be reported to each HREC which provided original ethical approval (except under the conditions described in 33.5 (ii)).
- 33.5 Where the research project is to be extended to additional site(s) within the NSW public health system, the following procedures shall apply:
- (i) If the project is to be extended to one additional site only and the additional site is not within the jurisdiction of the local HREC which originally approved the project, the project may be submitted to the local HREC associated with the additional site for review or it may be submitted to a lead HREC (in which case 33.5 (ii) applies). A site specific assessment form must be submitted to the Research Governance Officer associated with the site.
 - (ii) If the project is to be extended to two or more additional sites within the NSW public health system, such that it would be within the jurisdiction of two or more local HRECs, the project must be submitted to a lead HREC for review. This is regardless of whether or not the local HREC which originally reviewed the project has become a lead HREC (see 33.2). A site specific assessment form must be submitted to the Research Governance Officer at each site.

The lead HREC to whom the project is submitted will undertake a review of the project and, if the project is approved, will become responsible for the ongoing review functions for that project.

Where the local HREC/s has/have approved the project for commencement at its/their site/s prior to 1 July 2007 and the lead HREC subsequently also approves the project, but with modifications or conditions, then the modifications and conditions apply to the project at the local sites.

The same procedures outlined in SOP 35.8 shall be followed where the local HREC/s has/have approved the project for commencement at its site prior to 1 July 2007 and the lead HREC subsequently rejects the project.

The same procedures outlined in SOP 35.9 shall be followed where the local HREC/s has/have rejected a project prior to 1 July 2007 that is subsequently approved by a lead HREC.

SOP 034: Re-review for quality assurance in the quality assurance period

Function: To describe the process whereby a local HREC may choose to re-review a project that has already been reviewed by a lead HREC for quality assurance purposes during the quality assurance period.

Version: 1.0

- 34.1 A quality assurance period will be in force for six months from the date of commencement of the single review system. During the quality assurance period, a local HREC may re-review a project already reviewed by a lead HREC in order to examine whether its decision would have differed from that of the lead HREC.
- 34.2 A local HREC may only re-review projects during the quality assurance period.
- 34.3 A local HREC may only-review projects that are to be conducted at one of its affiliated sites.
- 34.4 A local HREC may only re-review projects with the approval of its Chief Executive.
- 34.5 A local HREC may re-review all projects, or a selection of projects, that have already been reviewed by a lead HREC.
- 34.6 The Chief Executive must notify the Health Research and Ethics Branch if its HREC intends to undertake re-reviews during the quality assurance period.
- 34.7 The research governance officer for the local HREC's affiliated site shall be informed of the Chief Executive's approval to re-review projects during the quality assurance period. The research governance officer shall provide copies of the documents related to the research project to the Executive Officer of the local HREC, who shall list them on the appropriate HREC agenda under the heading "quality assurance reviews for single review system".
- 34.8 The local HREC may contact the lead HREC for information regarding their review of the project that is not available from the Research Governance Officer. However, the local HREC is not to contact either the principal investigator or co-ordinating investigator in relation to the project.
- 34.9 Subject to 34.8, the method of re-reviewing the project shall be at the discretion of the local HREC, but should, as far as practical, mirror the process the local HREC would have used to review the project if the local HREC had been the lead HREC for that project.
- 34.10 A local HREC that undertakes a re-review of a project in the quality assurance period must complete the "Quality Assurance Review Form" (Appendix D of this Policy Directive) in respect of that re-review.
- 34.11 At the conclusion of the quality assurance period, the local HREC shall forward all Quality Assurance Review Forms to the Health Research and Ethics Branch, along with a "Quality Assurance Summary Report" (Appendix D). The HREC shall also forward a copy of the "Quality Assurance Summary Report" to its Chief Executive.

- 34.12 Re-reviews of projects in the quality assurance period do not impact on the lead HREC's decision or on the project's commencement at any sites.
- 34.13 If, after conducting a re-review, the local HREC has serious concerns regarding the project that, in its opinion, should prevent the commencement or continued operation of the project at its affiliated site or any other site, or require substantial amendments to the project, it shall contact the Health Research and Ethics Branch. The Health Research and Ethics Branch shall facilitate consultation between the Chair and Executive Officer of the lead HREC that reviewed the project, the Chair and Executive Officer of the local HREC that re-reviewed the project and a representative of Health Research and Ethics Branch, to determine an appropriate course of action. If, however, the concern relates to the safety of any project participant, such that the project should, in the opinion of the local HREC that re-reviewed the project, be immediately suspended, the Chair of the local HREC shall immediately contact the Chair of the lead HREC and explain the reasons why the project should be suspended. The lead HREC shall then take appropriate action to suspend ethical approval for the project. The lead HREC shall also contact the Research Governance Officer at all sites, to inform him or her of its opinion on the need to suspend the trial.

SOP 035: Single-site research projects progressing to multi-centre research projects.

Function: To describe the procedure for the handling of single-site research projects which progress to multi-centre research projects.

Version: 1.0

- 35.1 Single-site research projects (research which is conducted at one site only within the NSW public health system, or at two or more sites under the jurisdiction of a single NSW Health HREC) must be submitted to the local HREC for review, regardless of whether or not the local HREC is a lead HREC accredited by the Department to undertake single reviews of multi-centre research.
- 35.2 Where a single-site research project is to be extended to an additional site within the NSW public health system, and where the following criteria applies, the project must be submitted to a lead HREC for review notwithstanding that it has already been reviewed by a local HREC:
- The project was reviewed by the local HREC after 1 July 2007 (for projects reviewed prior to 1 July 2007, refer to SOP 033);
 - The additional site at which the project is to be conducted is not within the jurisdiction of the local NSW Health HREC which originally reviewed the project; and
 - The local NSW Health HREC which originally reviewed the project is not a lead HREC.
- 35.3 Where the conditions under 35.2 apply, the local HREC must transfer responsibility for the project to the lead HREC. If the project has been registered in AU RED by the local HREC, the local HREC must transfer responsibility to the lead HREC in AU RED.
- 35.4 The lead HREC to whom the project has been transferred will undertake a review of the project and, if the project is approved, will become responsible for the ongoing review functions for that project, including the single review of amendments and reports of serious and unexpected adverse events in accordance with SOPs 022 and 023. The lead HREC will assume responsibility for the oversight of the project from the date of the lead HREC meeting at which the project was approved.
- 35.5 Where the local HREC has not completed its review at the time of transferring the project to a lead HREC in accordance with 35.3, then the local HREC shall discontinue its review, and await the decision of the lead HREC.
- 35.6 Where the local HREC has already approved the project at the time of its transfer to a lead HREC in accordance with 35.3, then the following shall occur:
- (i) If the project has already commenced at the local HREC's site, the project may continue in operation at that site, pending the decision of the lead HREC.
 - (ii) If authorisation has been given for the project to commence at the local HREC's site, but the project has not yet commenced, the

project may commence at the site, pending the decision of the lead HREC.

- (iii) If authorisation has not yet been given for the project to commence at the local HREC's site (because the site specific assessment has not been completed), then the project may proceed through the site specific assessment at the local site, and commence at the local site if it receives authorisation, pending review by the lead HREC

35.7 Where the local HREC has approved the project for commencement at its site, and the lead HREC subsequently also approves the project, but with modifications or conditions, then the modifications and conditions apply to the project at the local HREC's site.

35.8 Where the local HREC has approved the project for commencement at its site, and the lead HREC subsequently rejects the project, then the following shall occur:

- (i) The Research Governance Officer at the local site shall be notified of the decision of the lead HREC not to approve the project.
- (ii) The Research Governance Officer at the local site shall inform the Chief Executive or their delegate who authorised the project at the local site of the rejection of the lead HREC.
- (iii) The lead HREC, the local HREC and the Chief Executive or their delegate at the local site shall confer as soon as possible and determine whether the project should be suspended at the local site, pending any appeal against the lead HREC's decision pursuant to SOP 030. This suspension may occur because the local HREC decide to suspend its previous ethical approval, or the CE or delegate at the local site decide to revoke authorisation of the project, or both.

35.9 Where the local HREC has rejected a project that is subsequently approved by the lead HREC, and the principal investigator wishes to re-submit a site specific assessment application for that site, the Research Governance Officer shall process the site specific in assessment in the usual way, but must bring it to the attention of the Chief Executive or their delegate that the project was previously rejected by the local HREC. The Chief Executive or their delegate may take this factor into account when determining whether or not to authorise the commencement of the project at that site. This may involve the Chief Executive or their delegate making appropriate inquiries, through the Research Governance Officer, into relevant matters, such as the reasons for the local HREC's previous rejection, whether the project was significantly modified before its approval by the lead HREC, and whether the concerns of the local HREC were adequately dealt with by the lead HREC.

35.10 Where the local HREC that originally approved the single-site project after 1 July 2007 is also a lead HREC, there will be no need for the project to be submitted to another lead HREC, as that HREC has been accredited to provide single reviews of multi-centre research from 1 July 2007.

APPENDIX C: Standard Letters

The standard letters documented below should be used for all multi-centre research projects. The letters have been colour-coded as follows:

- Blue text: this text must be completed by the user
- Red text: this text will be automatically populated by RED

The standard letters may be saved and edited at the discretion of the Executive Officer/Research Governance Officer.

Letter 1 Acknowledgement of a valid application – Lead HREC

[Date of letter]

[Name of Co-ordinating Principal Investigator]

[Address]

Dear [Name of Co-ordinating Principal Investigator]

HREC multi-centre project number: [.....]

Project title: [Full project title]

Protocol number: [where applicable]

Thank you for submitting the above multi-centre research project to the [Name of lead HREC] for single ethical and scientific review. This HREC will review your proposal at its meeting to be held on [date].

Your project has been assigned the HREC multi-centre project number: [.....]. This number must be quoted in all correspondence to this HREC.

You will be notified in writing of the outcome of the HREC's review of your proposal within 10 working days of the meeting at which the proposal is considered, unless otherwise notified.

Please note, an application for site-specific assessment must also be submitted to the Research Governance Officer responsible for the sites at which you wish to conduct this project. You cannot commence this project at a site until the Chief Executive or delegate of the relevant site has granted authorisation.

Detailed information about the NSW Health model for single ethical and scientific review of multi-centre research and the site-specific assessment process can be obtained from the Department's website:

<http://www.health.nsw.gov.au/healthethics>

Should you require any additional information regarding the HREC's consideration of the proposal, please contact the Executive Officer, [name] on [phone number and email address].

Yours sincerely

[Name]

Executive Officer

[Name of lead HREC]

Letter 2 Invalid application - lead HREC

[Date of letter]

[Name of Co-ordinating Principal Investigator]
[Address]

Dear [Name of Co-ordinating Principal Investigator]

HREC multi-centre project number: [.....]

Project title: [full project title]

Protocol number: [where applicable]

Thank you for submitting the above multi-centre research project to the [insert name of lead HREC] for single ethical and scientific review, which was received on [date].

Your project has been assigned the HREC multi-centre project number: [.....]. This number must be quoted in all correspondence to this HREC.

Unfortunately, the application is not valid, for the following reasons:
[Give Details]

You are welcome to re-submit the application, taking into account the above points. The 60 day time frame for will not commence until a valid application has been received.

Detailed information about the NSW Health model for single ethical and scientific review of multi-centre research and the site-specific assessment process can be obtained from the Department's website:
<http://www.health.nsw.gov.au/healthethics>

Should you require any additional information, please contact the Executive Officer, [name] on [phone number and email address].

Yours sincerely

[Name]
Executive Officer
[Name of lead HREC]

Letter 3 Approval by lead HREC

[Date of letter]

[Name of Co-ordinating Principal Investigator]
[Address]

Dear [Name of Co-ordinating Principal Investigator]

HREC multi-centre project number: [.....]
Project title: [Full project title]
Protocol number: [where applicable]

Thank you for submitting the above project for single ethical and scientific review. This project was first considered by the [Name of HREC] lead HREC at its meeting held on [Date]. This HREC has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

This lead 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 this research project. The documents reviewed and approved include:

- [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. [Insert any special conditions of approval imposed by the HREC].
2. The co-ordinating investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
 - unforeseen events that might affect continued ethical acceptability of the project.
3. Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review in the specified format.
4. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
5. The co-ordinating investigator will provide an annual report to the HREC and at completion of the study in the specified format.

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

Should you have any queries about the HREC's consideration of your project please contact [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]

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The HREC wishes you every success in your research.

Yours faithfully

[Name]
[Executive Officer or Chair]
[Name of lead HREC]

Letter 4 Rejection by lead HREC

[Date of letter]

[Name of Co-ordinating Principal Investigator]
[Address]

Dear [Name of Co-ordinating principal investigator]

HREC multi-centre project number: [.....]

Project title: [Full project title]

Protocol number: [where applicable]

Thank you for submitting the above project which was first considered by the [Name of Lead HREC] at its meeting held on [date]. This lead HREC has been accredited by the NSW Department of Health to provide the single ethical and scientific review of proposals to conduct research within the NSW public health system.

This lead 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

[Name]
[Executive Officer or Chair]
[Name of lead HREC]

Letter 5 Request for additional information by lead HREC

[Date of letter]

[Name of Co-ordinating Principal Investigator]
[Address]

Dear [Name of Co-ordinating Principal Investigator]

HREC multi-centre project number: [.....]

Project title: [Full project title]

Protocol number: [where applicable]

Thank you for submitting the above [project/amendment](#), which was first considered by the [Name of Lead HREC] at its meeting held on [insert date].

In order to make a determination of the ethical and scientific acceptability of your project, please respond to the following request for additional [information/clarification or modification](#):

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 HREC's consideration of your project, please provide the requested information as soon as possible. Your response may be emailed to the Executive Officer [\[Email address\]](#) however this should be accompanied by a hard copy [\[or insert relevant procedure\]](#).

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 [\[Name and contact details of HREC Executive Officer or Chairperson\]](#).

Yours sincerely

[\[Name\]](#)
[\[Executive Officer or Chair\]](#)
[\[Name of lead HREC\]](#)

Letter 6 Approval of an amendment by lead HREC

[Date of letter]

[Name of Co-ordinating Principal Investigator]
[Address]

Dear [Name of Co-ordinating Principal Investigator]

HREC multi-centre project number: [.....]
Project title: [Full Title]
Protocol number: [where applicable]
Amendment Number: [.....]
Amendment Date: [.....]

The above amendment was reviewed at the meeting of the [HREC], [Chair], [Deputy Chair], [Sub-committee], [Other] held on [date]

I am pleased to advise that the documents reviewed and approved at the meeting were:

- [List all documents with version numbers and dates]

This lead 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*.

A copy of this letter must be forwarded to all Principal Investigators at every site for submission to the relevant Research Governance Officer.

Yours faithfully

[Name]
Executive Officer HREC Chair
[Name of lead HREC]

Letter 7 Non-approval of an amendment by lead HREC

[Date of letter]

[Name of Co-ordinating Principal Investigator]
[Address]

Dear [Name of Co-ordinating Principal Investigator]

HREC multi-centre project number: [.....]

Project title: [Full Title]

Protocol number: [where applicable]

Amendment Number: [.....]

Amendment Date: [.....]

The above amendment was reviewed at the meeting of the [HREC], [Chair], [Deputy Chair], [Sub-committee], [Other] held on [date]

I regret to inform you that the amendment was not approved for the following reasons:

- [List reasons for rejection]

The study should continue in accordance with the documentation previously approved by the Committee. You may modify or adapt the amendment, taking into account the concerns outlined above and re-submit the revised document(s).

A copy of this letter must be forwarded to all Principal Investigators at every site for submission to the relevant Research Governance Officer.

Yours faithfully

[Name]
[Executive Officer or Chair]
[Name of lead HREC]

Letter 8 Acknowledgment of Annual Progress Report

[Date]

[Name of Co-ordinating Principal Investigator]
[Address]

Dear [Name of Co-ordinating Principal Investigator]

HREC multi-centre project number: [.....]

Project title: [Full Title]

Protocol number: [where applicable]

Thank you for sending the progress report for the above study dated [date].

The report was reviewed at the meeting of the [HREC], [Chair], [Deputy Chair], [Sub-committee], [Other] held on [date].

Yours sincerely

[Name]
Executive Officer
[Name of lead HREC]

Letter 9 Reminder for Annual Progress Report

[Date]

[Name of Co-ordinating Principal Investigator]
[Address]

Dear [Name of Co-ordinating Principal Investigator]

HREC multi-centre project number: [.....]

Project title: [Full Title]

Protocol number: [where applicable]

This study was given ethical approval by the Committee on [date].

It is a condition of approval by the Human Research Ethics Committee that the Co-ordinating Principal Investigator should submit a progress report for the study 12 months after the date on which the approval was given, and then annually thereafter. To date, the Committee has not yet received the annual progress report for the study, which was due on [date]. It would be appreciated if you could complete and submit the report by no later than [date one month ahead].

Failure to submit progress reports may lead to a suspension of the ethical approval of the study.

Yours faithfully

[Name]

Executive Officer

[Name of lead HREC]

Letter 10 Valid SSA form

[Date of letter]

[Name of Site Principal Investigator]
[Address]

Dear [insert name of Site Principal Investigator]

HREC multi-centre project number: [.....]
Project title: [full title]
Protocol number: [where applicable]

Thank you for submitting the Site Specific Assessment (SSA) Form to conduct research as the Principal Investigator at [name of site]. I can confirm that the submission was received on [date].

The Research Governance Officer will make an assessment of the suitability of this project.

Please note, you cannot commence this project at this site until you receive authorisation from the Chief Executive or their delegate.

Yours sincerely

[Name]
Research Governance Officer
[Name of Site]

Letter 11 Invalid SSA Form

[Name of Site Principal Investigator]
[Address]

[Date]

Dear [Name of Site Principal Investigator]

HREC multi-centre project number: [.....]
Project title: [full title]
Protocol number: [where applicable]

Thank you for submitting the Site Specific Assessment (SSA) Form to conduct research as the Principal Investigator at [name of site]. I can confirm that the submission was received on [date].

Unfortunately the application is not valid for the following reason(s):
[Give Details]

You are welcome to re-submit the SSA Form, taking into account the above points.

Yours sincerely

[Name]
Research Governance Officer
[Name of Site]

Letter 12 Authorisation granted

[Date of letter]

[Name of Site Principal Investigator]
[Address]

Dear [Name of Site Principal Investigator]

HREC multi-centre project number: [.....]

Project title: [Full project title]

Protocol number: [where applicable]

Thank you for submitting an application for authorisation of this project. I am pleased to inform you that authorisation has been granted for this study to take place at the following sites:

List each site at which the research project has been granted approval separately.

The following conditions apply to this research project. These are additional to those conditions imposed by the Human Research Ethics Committee that granted ethical approval:

1. [Insert any special conditions of approval imposed by the site];
2. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and which are submitted to the lead HREC for review, are copied to the research governance officer;
3. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing site acceptability of the project, are to be submitted to the research governance officer.

Yours faithfully

[Name]
Research Governance Officer
[Name of site]

Letter 13 Authorisation not granted

[Date of letter]

[Name of Site Principal Investigator]
[Address]

Dear [Name of Site Principal Investigator]

HREC multi-centre project number: [.....]
Project title: [Full project title]
Protocol number: [where applicable]

Thank you for submitting an application for authorisation of this project. I regret to inform you that authorisation has not been granted for the reasons outlined below:

[Clearly state the reasons for rejection of authorisation]

Should you wish to discuss this review of your project, please contact [Name and contact details of the Research Governance Officer]

Yours faithfully

[Name]
Research Governance Officer
[Name of site]

APPENDIX D

Quality Assurance Review Form and Quality Assurance Summary Report

Quality Assurance Review Form

Name of lead HREC:

Name of re-reviewing local HREC:

Name of project:

Protocol Number (if applicable):

HREC Reference Number:

Nature of research project re-reviewed (mark appropriate options):

- Clinical drug trial
- Clinical device trial
- Other clinical research
- Population health research
- Health services research
- Epidemiological research
- Qualitative research
- Other.....

Outcome of lead HREC review: (mark appropriate option)

- Approved
- Approved with conditions
- Not approved

Date of Outcome of lead HREC review:

Date of re-review by local HREC:

Re-review

Q1: Does the local HREC agree with the decision to approve/not approve the project?

Q2: Would the local HREC have taken any steps other than those taken by the lead HREC in reviewing the project (eg, interviewing the investigator, asking for further information)?

Q3: Would the local HREC have imposed any conditions on the project that have not been imposed by the lead HREC?

Q4: Does the local HREC consider that any of the conditions imposed by the lead HREC were unnecessary/unreasonable?

Q5: Does the local HREC have any concerns regarding the decision of the lead HREC?

Q6: Were any of the concerns of the local HREC of such a magnitude that it either (a) contacted the Health Research and Ethics Branch or (b) contacted the Chair and/or Executive Officer of the lead HREC to request that the project be suspended?

Q7: Any other comments from the local HREC about the lead HREC review?

Quality Assurance Summary Report of
[insert name of local HREC conducting re-reviews]

This HREC re-reviewed [insert number] of projects in the quality assurance period. These were made up of the following numbers of projects:

- [insert no.] Clinical drug trials
- [insert no.] Clinical device trials
- [insert no.] Other clinical research
- [insert no.] Population health research
- [insert no.] Health services research/
- [insert no.] Epidemiological research
- [insert no.] Qualitative research
- [insert no.] Other

In respect of the projects re-reviewed, we found the following:

In **[insert no.]** projects, we would have reached substantially the same ethical opinion as the lead HREC (that is, we agreed with the approval/non approval of the lead HREC and would not have imposed any substantially different conditions).

In **[insert no.]** projects, we would have come to the same ethical opinion as the lead HREC but would have imposed substantially different conditions.

In **[insert no.]** projects, we are unable to ascertain whether or not we would have come to substantially the same ethical opinion as the lead HREC or imposed the same conditions (for example, because the lead HREC did not seek information that this HREC would have sought, or because such information is not available to us).

In **[insert no.]** projects we contacted the Health Research and Ethics Branch because of serious concerns regarding the lead HREC's opinion.

In **[insert no.]** projects, we contacted the Chair/Executive Officer of the lead HREC and requested that the project be suspended.

Please mark which statement is most applicable:

- In general, we have confidence in the decisions of the lead HRECs that we re-reviewed.
- In general, we have confidence in the decisions of some of the lead HRECs that we-reviewed, but not in others.
- In general, we do not have confidence in the decisions of any of the lead HRECs that we reviewed.

General comments regarding the quality of lead HREC decisions that were re-reviewed:

General comments as to whether it is necessary to improve the standard of lead HREC review, and suggestions as to how such improvements should be effected.

Any other comments

.....
Signature of HREC Chair

.....
Date