Standard operating procedures

NSW Population and Health Services Research Ethics Committee

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NSW GOVERNMENT

cancer institute NSW

Contents

About this document

This document provides standard operating procedures for the NSW Population & Health Services Research Ethics Committee, hereafter referred to as the Human Research Ethics Committee (HREC).

This document is based on NSW Ministry of Health document number GL2013_009: Human Research Ethics Committees: Standard Operating Procedures for NSW Public Health Organisations.

Scope

The HREC is jointly convened by the Cancer Institute NSW and the NSW Ministry of Health. The Cancer Institute NSW maintains the administrative responsibility for the HREC, and liaises with the appropriate individuals at the NSW Ministry of Health as required.

The HREC is accredited in NSW as a lead HREC for multi-centre research ethical review in the category of general research. The Cancer Institute NSW is certified by the NHMRC for its multi-centre ethical review processes in relation to the HREC under the national approach to Single Ethical Review. The scope of the HREC includes epidemiological research and the use of statewide data collections and/or record linkage studies.

Definitions & abbreviations:

Adverse event:	A physical reaction to a drug or other interventional procedure, but also emotional and/or psychological distress due, for example, to the nature of questions in a questionnaire; or a breach of privacy.
Board:	Cancer Institute NSW Board.
Cancer Institute NSW:	Cancer Institute NSW, as constituted under the *Cancer Institute NSW Act 2003.*
CCO:	Chief Cancer Officer & Chief Executive Officer, Cancer Institute NSW or their delegate.
Chairperson:	Chairperson, NSW Population & Health Services Research Ethics Committee.
CHeReL	The Centre for Health Record Linkage (CHeReL) links multiple sources of data and maintains a record linkage system that protects privacy. The CHeReL provides advice on the design, cost, feasibility and process of linkage studies

Contact Person	The person nominated by the Co-ordinating Principal Investigator / Principal Investigator that the HREC should correspond with in relation to this ethics application.
Co-ordinating Principal Investigator:	The individual who takes overall responsibility for the research project and submits the project for ethical and scientific review. They are responsible for ongoing communication with the HREC and passing on any outcomes from this to the Principal Investigators.
Epidemiological Research	Research that is 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.
Executive Director, OHMR:	Executive Director, Office for Health and Medical Research (OHMR), New South Wales Ministry of Health or their delegate.
Executive Officer:	Executive Officer, NSW Population & Health Services Research Ethics Committee.
Health Services Research	Human research involving the integration of epidemiologic, sociologic, economic and other analytic sciences to study health services.
HREA	Human Research Ethics Application
HREC:	Human Research Ethics Committee, a committee constituted in accordance with the National Statement to review and where appropriate approve and monitor the ethical and scientific aspects of human research.
Lead Committee / Lead HREC:	A Human Research Ethics Committee accredited by NSW Health to conduct the single ethical and scientific review of multi-centre research projects.
LNR:	Low and negligible risk research.
Low risk research:	Research where the only foreseeable risk to the participant is one of discomfort.
Multi-centre research:	Research that is conducted at more than one site within the NSW public health system, where the sites are within the jurisdiction of more than one NSW Ministry of Health HREC.

National Statement:	*National Statement on Ethical Conduct in Human Research 2007, updated May 2015,* or replacement.
NEAF	National Ethics Application Form.
Negligible risk research:	Research where there is no foreseeable risk of harm or discomfort and any foreseeable risk is not more that inconvenience to the participants.
NHMRC:	National Health and Medical Research Council.
OHMR:	Office of Health and Medical Research.
Online Forms website:	An online system that enables users to electronically complete their applications for ethical and scientific review and site authorisation.
PHSREC	NSW Population and Health Services Research Ethics Committee (NHMRC reference EC00410)
Population Health Research:	Human research directed towards preventing disease, prolonging life and promoting health through the organised efforts of society. Population health research does not include clinical trials
Principal Investigator:	The individual who takes responsibility for the overall conduct, management, monitoring and reporting of research conducted at a site and submits the research project for site authorisation. For single centre research, Co-ordinating Principal Investigator and Principal Investigator are synonymous.
Public health organisation:	As defined by section 7 of the *Health Services Act 1997 (NSW): a local health district, a statutory health corporation or an affiliated health organisation in respect of its recognised establishments and recognised services.*
Record linkage studies	The CHeReL offers four types of record linkage services: 1) linkage between and within records held in the Master Linkage Key (MLK); 2) linkage of other datasets to the MLK; 3) linkage of two or mote datasets that are not included in the MLK; and 4) deduplication of datasets. Record linkage studies may include other data linkage studies.
Research Governance:	A framework through which research is effectively oversighted, such that it meets appropriate standards

	of quality, safety, privacy, risk management and financial management.
Research Governance Officer:	The individual appointed within a Public Health Organisation who is responsible for the management of applications for site authorisation and oversight of authorised research projects.
Research protocol:	A document that details the objectives, design, methodology statistical considerations and organisation of a research project.
Research:	Original investigation undertaken to gain knowledge, understanding and insight as described in the *Australian Code for the Responsible Conduct of Research 2007.*
Site:	A facility, location or service where the research is being conducted.
Site authorisation:	The authorisation granted by the Chief Executive or delegate of the Public Health Organisation for the commencement of a research project.
SSA:	Site Specific Assessment – a mechanism used by Public Health Organisations to ensure that the proposed research project complies with minimum governance requirements, and to consider whether the research should be conducted and supported at a site.

SOP01: Objectives, functions, accountability and scope of responsibility of the HREC

Reference: SOP01 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the objectives, functions, accountability and scope of responsibility of the HREC.

Objectives

1.1 The objectives of the HREC are to:

(a) Protect the rights, mental & physical wellbeing, dignity & safety of participants in research;

(b) Promote ethical principles in human research;

(c) Review research in accordance with the *National Statement*;

(d) Facilitate ethical research through efficient and effective review processes;

(e) Protect the privacy and confidentiality of participants and/or their personal health information, either directly or indirectly, in the proposals referred to it;

(f) Promote and endorse ethical standards of research and information privacy in proposals referred to it, by provision of guidance to researchers and others as appropriate.

Functions

1.2 The functions of the HREC are to:

(a) Provide independent, competent and timely review of research proposals submitted to it for approval, in respect of their ethical acceptability;

(b) Act in accordance with NHMRC guidelines pertaining to HRECs, including the *National Statement*. The HREC will function as a properly constituted HREC in accordance with the *National Statement*;

(c) Provide advice to the CCO and the Executive Director, OHMR on the ethical acceptability of research proposals submitted to it for approval;

(d) Provide advice to the CCO and the Executive Director, OHMR on issues relating to the ethical conduct of research that might arise from time to time;

(e) As a Lead HREC accredited in NSW for general research, provide a single ethical opinion on multi-centre research projects which may be accepted by NSW public health organisations;

(f) Provide assistance or advice to other HRECs regarding issues that fall within the specific expertise of the HREC.

Accountability

1.3 The HREC is accountable to the CCO and the Executive Director, OHMR in the conduct of its business. The CCO and the Executive Director, OHMR shall be informed of the decisions of the HREC on proposals submitted to it on a regular basis, either through the submission of the minutes of HREC meetings, or through the submission of an annual report.

1.4 The HREC shall provide an annual report to the CCO and the Executive Director, OHMR at the end of each financial year, which will include information on membership, meeting attendance, the number of proposals reviewed by the HREC, a description of any complaints received and their outcome, general issues and other matters of an ethical nature as may have arisen.

1.5 The HREC will bring to the attention of the CCO and the Executive Director, OHMR any issues of significant concern regarding matters within its scope of responsibility.

1.6 The HREC will provide the following reports:

(a) Annual Report to the NHMRC;

(b) Annual Report to the NHMRC as a registered HREC, and additional reporting to meet the NHMRC Certification requirements;

(c) NSW Privacy Commissioner Report in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW).

(d) Final minutes of the monthly meetings to the Board, Cancer Institute NSW.

1.7 The HREC Terms of Reference, Standard Operating Procedures and membership will be available upon request by the general public, and accessible on the Cancer Institute NSW and NSW Ministry of Health websites.

Scope of responsibility

Lead HREC in NSW for general research

1.8 The HREC may review multi-centre human research applications in the category of general research, where the research will take place in any institutions governed by

NSW Public Health Organisations, and where a component of the research meets the description in 1.9 below. Population health research includes, but is not limited to, epidemiological research, record linkage studies, and health services research. Population health and/or public health research does not include clinical trials.

Population health research in NSW

1.9 The HREC will review

1.9.1. Population health research utilising and/or linking routinely collected health (and other) data, including:

(a) data collections owned or managed by NSW Ministry of Health (e.g. NSW Admitted Patient Data Collection; Perinatal Data Collection; NSW Emergency Department Data Collection; and New South Wales Population Health Surveys);

(b) data collections owned or managed by the Cancer Institute NSW, (e.g. NSW Central Cancer Registry, NSW Pap Test Registry, Breast Screen Registry).

1.9.2. Applications from the NSW Ministry of Health and Cancer Institute NSW in relation to the conduct, management or modification of their data collections (referred to in 1 above)

Research proposals utilising population health data collections owned and/or managed by NSW Ministry of Health or the Cancer Institute NSW will be reviewed in accordance with NSW Ministry of Health Policy Directive PD2010_055 *Research – Ethical and Scientific Review of Human Research in NSW Public Health Organisations* or replacement.

The review of research proposals as described above will not incur any fee to the Cancer Institute NSW nor the NSW Ministry of Health.

1.10 The HREC may review research applications which meet the description in 1.8 and 1.9 above and which are being conducted at external institutions/organisations and investigators as approved by the CCO, in accordance with NSW Ministry of Health policy directive PD 2008_046 or replacement. The review of such research will not incur a fee as the mandatory review of the research application described in SOP 1.9 is an appropriate reason for providing the services of the HREC to the External Entity free of charge in accordance with NSW Ministry of Health Policy Directive PD 2008_046 or replacement.

1.11 The HREC may provide assistance or advice to other ethics committees regarding issues that fall within the specific expertise of the HREC.

1.12 The HREC will, in its assessment of proposals, examine the extent of the proposals' compliance with the NSW Ministry of Health's policy on information privacy and

confidentiality, including the NSW Health Privacy Manual and the relevant privacy legislation that exists at both State and Federal level.

Role of the Chairperson

1.13 The Chairperson is responsible for the conduct of HREC business and for ensuring that the HREC reaches decisions on all matters. Where the Chairperson is not available, the meeting will be chaired by a Deputy Chairperson, or their delegate.

HREC Executive Committee

1.14 The HREC has an Executive Committee comprising at least the HREC Chairperson (or their delegate) and the Executive Officer (or their delegate). The Deputy Chairperson or other Committee member may join the Executive Committee as required to manage the workload.

1.15 The HREC Executive Committee is delegated to undertake expedited review and approval of business that does not require full HREC review, including some or all of the following:

(a) Low and negligible risk research applications;

(b) Amendments to current HREC approved research projects, which do not require review by the full HREC;

(c) Responses to HREC queries, as approved by the full HREC for HREC Executive Committee review and approval;

(d) Annual progress reports and final reports;

(e) Adverse events;

(f) Protocol Deviations.

Executive Officer

1.16 The Executive Officer is delegated to undertake expedited review and approval of administrative business that does not require full HREC review, including some or all of the following:

(a) Request for approval for change in personnel (but not change in Co-ordinating Principal Investigator);

(b) Minor administrative amendments to current projects and informed consent documents;

(c) Responses to HREC queries, as approved by the full HREC or Executive Committee for Executive Officer review and approval;

1.17 The decisions of the HREC Executive Committee and the Executive Officer are noted at the next HREC meeting.

SOP02: Composition of the HREC

Reference: SOP02 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the composition of the HREC

2.1 The membership of the HREC is in accordance with the *National Statement*. Minimum membership comprises eight members. As far as possible, men and women are represented in equal numbers and at least one third of the members are external to the institution for which the HREC is reviewing research. The core membership comprises representatives from each of the following categories:

(a) A Chairperson with suitable experience whose other responsibilities will not impair the HREC capacity to carry out its obligations under *the National Statement*;

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

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

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

(e) At least one member who is a lawyer, where possible one who is not engaged or employed to advise the NSW Ministry of Health or the Cancer Institute NSW; and

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

2.2 No member may be appointed in more than one of the above categories. However in each category, multiple members may be appointed in order to ensure that the HREC has the expertise required to assess the proposals regularly submitted for its consideration.

2.3 In addition to the membership outlined in 2.1, wherever possible, membership will also include:

(a) A NSW Ministry of Health Public Health Officer Trainee and/or a NSW Ministry of Health Biostatistical Officer trainee; and

(b) A nominee of the NSW Ministry of Health Deputy Secretary, Population and Public Health and Chief Health Officer.

2.4 Where required, the HREC may seek advice and assistance from experts to assist with consideration of a project.

2.5 The HREC must, however, be satisfied that such experts have no conflicts of interest in relation to the project under consideration, arising from any personal involvement or participation in the project, any financial interest in the outcome of the project or any involvement in a competing project.

2.6 Any person(s) consulted by the HREC will be required to provide an undertaking of confidentiality and will not be able to vote on any matter.

SOP03: Appointment of members to the HREC

Reference: SOP03 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the process for appointment of members to the HREC

3.1 The CCO and the Executive Director, OHMR will appoint the members of the HREC (including Chairperson and Deputy Chairperson), in consultation with the HREC as deemed appropriate.

3.2 Prospective members will be recruited through appropriate means, such as spontaneous expressions of interest, objective nominations and externally advertised calls for expressions of interest.

3.3 Prospective members may be invited to attend meetings as an observer, provided that an undertaking of confidentiality is given. Such people are not entitled to vote on any matter.

3.4 Prospective members are asked to provide a copy of their curriculum vitae to a selection committee. The selection committee will have a minimum composition of the Chairperson, the Executive Officer and another member of the HREC. The selection committee shall review nominations and/or interview prospective applicants and make a recommendation regarding membership to the CCO and the Executive Director, OHMR.

3.5 Appointments will allow for continuity, the development of expertise within the HREC, and the regular input of new ideas and approaches.

3.6 Members are appointed as individuals for their knowledge, qualities and experience. They are not appointed as representatives of any organisation, community or opinion.

3.7 Membership of the HREC will be made publicly available.

3.8 The CCO will provide newly-appointed members with a formal letter of appointment which includes:

- Date of appointment;

- Length of appointment;
- Category of membership (as per 2.1) and any formally appointed roles;
- Assurance that legal protection will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as an HREC member;
- Meeting attendance responsibilities; and
- General responsibilities as an HREC member.

3.9 Upon appointment, members are asked to sign the 'Code of Conduct for Committees of the Cancer Institute NSW' and a statement undertaking:

(a) That all matters of which they become aware during the course of their work on the HREC will be kept confidential;

(b) That any conflicts of interest, which exist or may arise during their tenure on the HREC, will be declared; and

(c) That they have not been subject to any criminal conviction or disciplinary action, which may prejudice their standing as an HREC member.

3.10 Members are appointed for an initial period of one year. Thereafter members may be appointed for a two year term, and may then be re-appointed for a consecutive 3 year term. Members may serve a maximum of six years consecutively, unless otherwise approved by the CCO and the Executive Director, OHMR.

3.11 Members are advised when their term has expired. The Chairperson makes a recommendation to the CCO and the Executive Director, OHMR regarding re-appointment.

3.12 Membership lapses if a member fails, without reasonable excuse to attend (or provide comprehensive written comments to) three consecutive meetings of the HREC, unless exceptional circumstances exist. The Chairperson will notify the member, in writing, of such a lapse of membership. Steps will be taken to fill the vacancy.

3.13 Members seeking to resign or take a leave of absence for an extended period are asked to give notice to the Chairperson. Steps are taken to fill the vacancy.

3.14 The CCO and the Executive Director, OHMR may agree to terminate the appointment of any member of the HREC if they are of the opinion that:

(a) It is necessary for the proper and effective functioning of the HREC;

(b) The person is not a fit and proper person to serve on an HREC; or

(c) The person has failed to carry out their duties as an HREC member.

3.15 The Chairperson and Deputy Chairperson will be appointed by the CCO and the Executive Director, OHMR conjointly. The HREC may nominate candidates for the position of Chairperson and Deputy Chairperson.

3.16 In the absence of the Chairperson, the Deputy Chairperson, or delegate, will perform the role and duties of the Chairperson.

3.17 The HREC may appoint sub-committees to carry out scientific or technical review of a research proposal, or ethical review of minimal risk research, submitted to the HREC.

3.18 The Chairperson of any such sub-committee will be appointed by the CCO and the Executive Director, OHMR. Members of any such sub-committee need not be members of the HREC

SOP04: Conditions of membership of the HREC

Reference: SOP04 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the conditions of membership of the HREC

Requirements

4.1 Members will:

(a) Agree to their name and category of membership being made publicly available.

(b) Be required to sign the 'Code of Conduct for Committees of the Cancer Institute NSW' and a statement undertaking :

- To keep all matters of which the member becomes aware during the course of their work on the HREC confidential;
- To declare any conflicts of interest, which exist or may arise during their tenure on the HREC; and
- That the member has not been subject to any criminal conviction or disciplinary action, which may prejudice their standing as an HREC member.

Reimbursement

4.2 Members will not be offered remuneration. The exception to this is the Chairperson or Deputy Chairperson who may be offered remuneration at the discretion of the CCO and the Executive Director, OHMR. Remuneration of the Deputy Chairperson will be limited to no more than two members who have been formally appointed to the position of Deputy Chairperson.

4.3 Members will be reimbursed for legitimate expenses incurred in attending HREC meetings or in otherwise carrying out the business of the HREC.

Education

4.4 Newly appointed members will be provided with adequate orientation/training which may involve the following:

(a) Introduction to other members prior to the HREC meeting

(b) Provision of an orientation package

(c) "Partnering" with another HREC member in the same category

(d) Priority given to participate in training sessions

4.5 All members will be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the HREC. Expenses for these activities will be covered by the Cancer Institute NSW and NSW Ministry of Health at the discretion of the Director Strategic Research Investment, Cancer Institute NSW.

4.6 Members will be asked to participate in relevant specialised working groups as required.

4.7 Members will be expected to become familiar with the *National Statement* and consult other guidelines relevant to the review of specific research applications.

Liability coverage

4.8 The Cancer Institute NSW and NSW Ministry of Health, through the NSW Treasury Managed Fund (TMF), will provide indemnity for members of the HREC for any liabilities that arise as a result of the member exercising their duties as a member in good faith.

SOP05: Meeting schedules

Reference: SOP05 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the HREC meeting schedule

5.1 The HREC schedules meetings every month with the exception of January. The HREC will hold no fewer than 8 scheduled meetings per year for the purposes of reviewing new applications.

5.2 The schedule of meeting dates and application closing dates are made publicly available.

5.3 The Chairperson, in initial consultation with the Executive Officer, may recommend the cancellation or postponement of a scheduled meeting for reasons such as a quorum not being achievable, with final approval from the COO and Executive Director, OHMR.

SOP06: Submission of applications for ethical review

Reference: SOP06 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

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

6.1 All applications for ethical review by the HREC must be submitted by close of business on the relevant closing date.

6.2 Procedures for submission are explained in the 'Guidelines for Submission to the NSW Population & Health Services Research Ethics Committee', available on request and from the Cancer Institute NSW website.

6.3 The closing dates for receipt of submissions for ethical consideration will be at least 14 working days prior to each HREC meeting.

6.4 Dates will be available to prospective applicants on the Cancer Institute NSW and NSW Ministry of Health websites.

6.5 All proposals for ethical assessment must be submitted using the National Ethics Application Form (NEAF) or the Low and Negligible Risk (LNR) application form accessible at www.ethicsform.org/au until such time that the PHSREC is informed by the NSW Ministry of Health that the NEAF has been decommissioned for Public Health Organisation HRECs. From this time all proposals for ethical assessment must be submitted using the Human Research Ethics Application (HREA) accessible at hrea.gov.au.

6.6 The applicant will be required to complete all sections of the application form and include all relevant documentation.

6.7 Prior to submitting a protocol to the HREC for review, Co-ordinating Principal Investigators are to seek the necessary approvals from the data custodian/s for the data items they wish to access.

6.8 The applicant will be required to submit as many copies of the application and supporting documentation as the HREC considers necessary to enable it to carry out a proper review.

6.9 The Executive Officer will undertake an administrative review of the application prior to acceptance onto the agenda, to ensure that the application has been completed and that there are no obvious omissions.

6.10 Inclusion of an application on the meeting agenda will be at the discretion of the Executive Officer, in consultation with the Chairperson.

SOP07: Role of the Executive Officer

Reference: SOP07 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the responsibilities of the Executive Officer

7.1 In order to ensure the smooth operations and timely consideration of the day to day business of the PHSREC, the Chairperson has given the Executive Officer the delegated authority to:

(a) Determine whether a project needs Human Research Ethics Committee approval

(b) Determine whether an application meets the requirements to be considered by the Committee and reject any application that does not

(c) Review amendments and variations to approved protocols and make recommendations to the Executive Committee of the PHSREC

(d) To educate and advise researchers about ethical issues relating to research involving humans and the requirements of the National Statement on Ethical Conduct in Human Research (2007)

(e) Provide ethical advice and assistance to applicants and potential applicants to the PHSREC

(f) Investigate complaints to research approved by the PHSREC as per SOP21

(g) Liaise and assist HREC Executive Officers from other Public Health Organisations in accordance with the Memorandum of Understanding for National Mutual Acceptance of Single Ethical and Scientific Review of Multicentre Human Research

7.2 The correspondence issued on behalf of the HREC will be signed over either the Chairperson's or Executive Officer's name as detailed below:

(a) Approval letters will be signed over the Chairperson's name.

(b) Requests for further information will be signed over the Executive Officer's name

(c) Advice that a project will not be approved or approval will be withdrawn will be signed over the Chairperson's name.

(d) Outcomes of annual report submissions will be signed over the Executive Officer's name.

(e) Outcomes of submissions (such as Adverse Events) reviewed by the Executive Committee will be signed over the Executive Officer's name.

7.3 The Chairperson may grant the Executive Officer delegation to sign correspondence on their behalf. The Executive Officer may grant ethics support staff delegation to sign correspondence on their behalf. Evidence of these delegations is to be kept on file by the Executive Officer.

7.4 The correspondence issued on behalf of the HREC may be issued in either the form of a signed letter or formal email sent from the signatory.

7.5 On receipt of a completed submission for ethical review, the Executive Officer or the Executive Officer's delegate will:

(a) Ensure each application has been assigned a unique identification number, known as the Project Number.

(b) Open and maintain a confidential file for each application, including the original application and all subsequent information and correspondence relevant to the application. This file will be kept securely and confidentially in accordance with the requirements of the State Records Act 1998 and the Cancer Institute NSW Functional Retention and Disposal Authority.

(c) Provide applicants with correspondence confirming the receipt of their application, and provide details of the project number, and the date of the HREC meeting at which the proposal will be reviewed.

(d) Record the application on the designated research register at the Cancer Institute NSW.

7.6 Prior to the HREC meeting, the Executive Officer or the Executive Officer's delegate will:

(a) Distribute to HREC members all relevant documentation relating to the research proposals received for review.

(b) Compile and distribute the meeting agenda to HREC members, as per SOP 09.

(c) Delegate consideration of certain scientific, technical or legal matters to a member or sub-committee of its members, or seek expert external advice, as required.

SOP08: Research Governance

Reference: SOP08 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the separation of ethics and governance review

8.1 The HREC will be responsible for ethical review and oversight only. Matters of research governance, including responsibility for determining whether the resources, facilities and staff at the site at which the research is to be conducted are appropriate, are the responsibility of the individual institutions at which the research will be conducted.

8.2 For proposals involving access to data held or managed by either the Cancer Institute NSW or the NSW Ministry of Health, the Co-ordinating Principal Investigator must contact the relevant Data Custodian before applying to the HREC. Data custodians for these collections are required to sign off on access to data for each registry or dataset which is part of the current application. The Data Custodian Sign Off form must be submitted to the HREC.

8.3 While the HREC will determine the ethical acceptability of research proposals seeking access to the data collections described in 8.2, the authority to release data lies with the data custodian of the particular data collection and the NSW Secretary Health or their delegate for individually identified data.

8.4 For studies requiring linkage of NSW Health datasets, it is recommended that the linkage is performed by the Centre for Health Record Linkage (CHeReL). If the research involves linkage to the NSW Central Cancer Registry, there is a requirement that the linkage must be performed by the CHeReL.

8.5 For projects involving linkage by the Centre for Health Record Linkage (CHeReL), the Co-ordinating Principal Investigator must submit the full application and supporting documents to the CHeReL for technical feasibility sign off, prior to submitting to the HREC.

SOP09: Agenda preparation

Reference: SOP09 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the process for preparing an agenda for a meeting of the PHSREC

9.1 The Executive Officer, or their delegate, will prepare an agenda for each HREC meeting.

9.2 All completed applications and relevant documentation received by the Executive Officer by the closing date will be included on the agenda for the HREC's consideration at its next available meeting.

9.3 Correspondence and other documents received after the closing date may be included on the agenda at the discretion of the Chairperson or Executive Officer.

9.4 The agenda format will include where appropriate the following items:

(a) Attendance / apologies;

(b) Declarations of Conflicts of Interest;

(c) Confirmation of the minutes of the previous meeting;

(d) Business arising from previous minutes (including the unique local project number and/or the AU-RED / REGIS number);

(e) New proposals for ethical review (including the names of the nominated spokespersons, and unique local project number and the AU-RED / REGIS number;);

(f) Amendments (including the unique local project number);

(g) Progress/Annual and Final reports (including the unique local project number);

(h) Correspondence;

(i) Other business;

(j) Items reviewed and approved by Executive sub-committee or Executive Officer, out-of-committee; and

(k) Notification of next meeting.

9.5 The agenda, including a copy of each new application and relevant documents, will be distributed to all members of the HREC at least seven calendar days prior to the meeting.

9.6 Inclusion of a new application on the meeting agenda requires the addition of a new application to 'start the clock' and assign the application to the specified meeting as per the Agenda.

SOP10: Conducting a meeting of the HREC

Reference: SOP10 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the format for the conduct of the meeting of the PHSREC

10.1 The HREC will meet on a regular basis. Meetings will be scheduled for each month of the year with the exception of January.

10.2 Meetings will usually be held in the Boardroom of the Cancer Institute NSW, Level 9, 8 Central Avenue, Australian Technology Park, Eveleigh, NSW 2015.

10.3 Meeting dates and agenda closing dates will be readily available to the public and can be accessed from the Cancer Institute NSW and NSW Ministry of Health websites.

10.4 HREC members may attend the meeting in person or via a telecommunication link, or a video link.

10.5 Members should negotiate with the Executive Officer if attendance in a manner other than in person is to be a regular occurrence.

10.6 HREC members who are unable to attend a meeting may contribute to the meeting through a written submission to the Executive Officer or Chairperson.

10.7 The Chairperson, in initial consultation with the Executive Officer, may cancel or postpone a scheduled meeting if a quorum cannot be achieved, with final approval from the COO and Executive Director, OHMR

10.8 The HREC meetings will be conducted in private, to ensure confidentiality and open discussion. The HREC may however, agree to the presence of visitors or observers at the meeting.

Quorum requirements

10.9 A quorum is required at each meeting for the HREC to reach a final decision on any agenda item. The quorum for meetings is the minimum membership as described in the National Statement Sections 5.1.28 – 5.1.31 attending in person or via telephone or videoconference.

10.10 Where there is less than a full attendance of the minimum membership at a meeting, the Chairperson must be satisfied "that the views of those absent who belong to the minimum membership have been received and considered", for instance through prior submission of written comments (National Statement 5.2.30).

Attendance of investigators

10.11 At the request of the HREC Chairperson, the Co-ordinating Principal Investigator or their delegate may be invited to make a formal presentation or to respond directly to requests from the HREC for further information, clarification or reassurance (National Statement Section 5.2.18). The Co-ordinating Principal Investigator or their delegate may attend in person or via telephone or video conference.

10.12 Where the Co-ordinating Principal Investigator is unable to attend, another investigator or collaborator is invited to attend, if appropriate. Representatives of the sponsor are not to attend the meeting in place of the Co-ordinating Principal Investigator.

10.13 Other members of the research team may attend with the Co-ordinating Investigator.

Attendance of observers

10.14 At the discretion of the Chairperson and Executive Officer, attendance as observers of people other than members or researchers (National Statement Section 5.1.37) at meetings is permitted provided that an undertaking of confidentiality is given. Such people are not entitled to vote on any matter.

Declaration of interest

10.15 Any member of the HREC who has any interest in a proposal or other related matter considered by the HREC, should as soon as practicable declare such interest. Conflict of interest includes financial interests, personal, professional or institutional benefits or advantages that depend significantly on the research outcomes.

10.16 Declarations are made orally at the meeting prior to the matter being considered or in writing to the Chairperson prior to the meeting. The HREC determines whether the level of interest results in:

a) A substantial conflict of interest: in this case, a member is excluded from the meeting until the HREC has concluded consideration of the matter. Being an investigator on a research project is considered to represent a substantial conflict of interest.

b) A non-substantial conflict of interest: in this case the member has the discretion to leave during the discussion of the matter.

10.17 The minutes must record the declaration of interest and the decision of the HREC on the procedures to be followed.

Spokespersons

10.18 The HREC has the discretion to appoint one or more HREC members as spokespersons for an agenda item.

10.19 Allocation of spokespersons is made by the Executive Officer in consultation with the Chairperson, as necessary.

SOP11: Consideration of research proposals requiring ethical review

Reference: SOP11 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

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

11.1 The HREC will consider a new application at its next available meeting provided that the application is received by the Executive Officer by the relevant closing date and the application is complete.

11.2 The application will be reviewed by all members of the HREC who are present at the meeting or have provided written comments in lieu of attendance.

11.3 The HREC will ethically assess each application in accordance with the National Statement. The HREC must ensure that it is sufficiently informed on all aspects of the research protocol, including its scientific validity, in order to make an ethical assessment.

11.4 At least one member of the HREC will be designated as the 'spokesperson' for the project, for the purpose of initiating discussion of the project at the meeting.

11.5 The HREC's assessment will include consideration of the following matters:

(a) How significant is the research/project?

(b) Is the design of the project valid?

(c) Will the project achieve its aims?

(d) Is it essential that identifiable or potentially identifiable data be used for the project?

(e) Does the investigator have the skills to successfully complete the project?

(f) Is the requested level of access to data the minimum required in order to achieve the project's objectives?

(g) Will informed consent be obtained from the participants?

(h) If informed consent will not be obtained, what justification is there for this?

(i) Does the public interest in the proposed project outweigh the public interest in the protection of privacy?

(j) How will the data be stored and protected?

11.6 The HREC will consider whether an advocate for any participant or group of participants should be invited to the HREC meeting to ensure informed decision-making.

11.7 The HREC may take into account the views or opinions on the research proposal held by another properly constituted HREC. The HREC may take into account the views or opinions of any scientific review of the research proposal undertaken by a recognised peer group.

SOP12: Decision-making

Reference: SOP12 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the process for decision-making by the HREC

12.1 HREC members are allowed reasonable opportunity to express relevant views on matters on the agenda.

12.2 The HREC will endeavour to reach a decision concerning ethical acceptability of a proposal by unanimous agreement.

12.3 Where a unanimous decision is not reached, the Chairperson will need to facilitate the expression of opinion from all members, identify points of agreement and judge when a sufficient degree of general agreement has been reached.

12.4 Any significant minority view (i.e. 2 or more members) will be noted in the minutes.

12.5 Discussions of significant issues and decisions are recorded in the minutes. Where members wish, a record of their formal dissent from the decision of the HREC is recorded in the minutes.

12.6 To encourage free and open discussion and to emphasise the collegiate character of the HREC, particular views are not attributed to particular individuals in the minutes, except in circumstances where a member seeks to have their opinions or objections recorded.

12.7 An HREC member unable to attend a meeting may submit comments in writing on agenda items to the Executive Officer or Chairperson. Submission of written comments is recorded in the minutes.

Decisions available to the HREC

12.8 Following consideration of a proposal, the HREC will make one of the following decisions, which is recorded in the minutes:

(a) Approve the application as being ethically and scientifically acceptable;

(b) Request modification or further information/clarification pending a reconsideration of the proposal;

(c) Seek further advice from external expert reviewers(s); or

(d) Reject the application.

12.9 The Chairperson will ensure that one of the above decisions is made on every application considered at the meeting.

12.10 For proposals where the HREC has requested clarification, the provision of further information, or requested changes, the Chairperson will ensure that:

a) Further information or clarification required is specifically identified at the meeting; and

b) Delegation of responsibility for considering the further information or clarification and confirming the final HREC opinion is clearly agreed. i.e. the information will need to be re-submitted to the full HREC, a number of HREC members, the Executive Committee or the Executive Officer.

12.11 The HREC will endeavour to reach a final decision within 60 calendar days of the meeting submission date. The 60 day "clock" will be "turned off" in the AU-RED database while the application is in the hands of the investigator(s).

SOP13: Duration of HREC approval

Reference: SOP13 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the duration of approval for a research project

13.1 Ethical approval for a new research proposal is generally valid for up to 5 years, except where action is taken to suspend or terminate the decision.

13.2 Ongoing ethical approval is subject to the provision of annual progress reports.

13.3 Any request to extend the duration of the research project is submitted by the Co-ordinating Investigator as an amendment for review in the first instance.

13.4 The HREC will use its discretion to grant an extension of approval. In making this decision, the HREC will take into consideration: the length of time since the original approval; whether participants are still being actively recruited and whether active data collection is still underway.

SOP14: Minutes preparation

Reference: SOP14 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the preparation of HREC minutes

14.1 The Executive Officer, or their delegate, will prepare and maintain minutes of all meetings of the HREC, in consultation with the Chairperson and other members as necessary.

14.2 The minutes reflect each item listed for discussion on the agenda:

(a) Attendance/apologies;

(b) Declarations of Conflicts of Interest - the minutes must record the declaration of interest and the decision of the HREC on the procedures to be followed;

(c) Confirmation of the minutes of the previous meeting;

(d) Business arising from previous minutes;

(e) HREC deliberations and decisions on new proposals for ethical review including;

- Summary of written comments submitted by members
- Summary of advice given by expert or lead reviewers
- Summary of the main issues considered with reference to the *National Statement;*
- Decisions of the HREC; and
- If applicable, formal dissent from the decision as per SOP 12.

(f) Amendments;

(g) Progress/Annual and Final reports;

(h) Correspondence;

(i) Other business;

(j) Items reviewed and approved by Executive sub-committee or Executive Officer, out-of-committee; and

(k) Notification of next meeting.

14.3 To encourage free and open discussion and to emphasise the collegiate character of the HREC, particular views should not be attributed to particular individuals in the minutes, except in circumstances where a member seeks to have their opinions or objections recorded.

14.4 The Executive Officer prepares the minutes and circulates them to the Chairperson, Deputy Chairperson or an appropriate member of the HREC for review. This should occur within 7 calendar days of the meeting.

14.5 The minutes are submitted as an agenda item at the next meeting of the HREC for ratification as a true record. All members will be given the opportunity to seek amendments to the minutes prior to their finalisation.

14.6 The minutes are confidential to the HREC and are not disclosed to investigators or sponsors.

14.7 The minutes of the HREC meeting are made available to the Cancer Institute NSW Board, the Executive Director, OHMR and, upon request, to the Research Governance Officer of the site where the research is to be conducted.

SOP15: Notification to investigators of the decision of the HREC

Reference: SOP15 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the process of notifying investigators of the outcome of the HREC's deliberations

15.1 The HREC upon making its decision, will inform the Co-ordinating Investigator and Contact Person in writing of the outcome of ethical review, within 10 working days of the meeting unless otherwise notified.

15.2 If the HREC determines that further information, clarification or modification is required for the consideration of the project, correspondence will be sent to the Co-ordinating Investigator which should articulate the reasons for the determination, and clearly set out the information that is required.

15.3 Where possible, requests for additional information / clarification / modification should refer to the National Statement or other relevant guidelines and/or legislation.

15.4 If the requested information is not received by the HREC within three (3) months or three (3) meetings (whichever occurs sooner), the project will be dismissed and the applicant will need to re-submit the application for review at a later date.

15.5 The HREC will endeavour to foster open communication with applicants to resolve outstanding requests for information, clarification or modification of projects relating to ethical issues. The HREC may nominate one of its members to communicate directly with the applicant, or invite the applicant to attend the relevant HREC meeting.

15.6 Any notification of ethical approval must include reference to the following:

(a) The title of the project;

(b) The name of the Co-ordinating Principal Investigator;

(c) The unique local project number and the AU-RED (or REGIS) number;

(d) Specific reference to all documents reviewed by the HREC including the version number and date of such documents;

(e) The date of the meeting during which the application was considered;

(f) The date of ethical approval by the HREC;

(g) The duration of the approval;

(h) Whether the HREC granted a waiver of consent;

(i) The names of the sites for which ethical approval was granted (only in the case of public health organisations, or organisations named as a party on an External Entity Agreement with the Cancer Institute NSW under NSW Health Policy Directive PD PD2008_046 or replacement);

(j) That the letter constitutes ethical approval only and that there will be requirements for separate research governance authorisation at participating sites; and

(k) The conditions of approval (see below):
- The Co-ordinating Principal Investigator will report anything which might warrant a review of ethical approval of the research, including unforeseen events that might affect continued ethical acceptability.
- Proposed amendments to the research proposal or conduct of the research which may affect the ethical acceptability of the research are to be provided to the HREC for review.
- The HREC will be notified giving reasons, if the research is discontinued before the expected date of completion.
- The Co-ordinating Principal Investigator will provide an annual progress report to the HREC and at the completion of the study.

15.7 If the HREC deems the project to be ethically or scientifically unacceptable, the notification of the HREC's decision should include the grounds for rejecting the project with reference to the National Statement and/or other relevant guidelines and/or legislation.

15.8 Where applicable, the Executive Officer, or their delegate, will be responsible for providing copies of approval correspondence to:

- The Research Project Manager or Project Officer, Centre for Health Record Linkage (CHeReL)

- The Data Access and Research Liaison Service (DARLS) Coordinator, Cancer Institute NSW

15.9 For new applications, following the electronic transmission of the outcome letter to the Co-Ordinating Principal Investigator, the AU-RED database (or REGIS) is updated with the outcome as either 'approved' or 'request for further information' to 'stop the clock'. The post-approval steps are as per the AU-RED established processes provided by the NSW Ministry of Health. Any other outcome will also 'stop the clock' in AU-RED.

SOP16: Expedited review

Reference: SOP16 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the procedure for the expedited review of research

16.1 The HREC has an Executive Committee comprising at least the HREC Chairperson (or their delegate) and the Executive officer (or their delegate). The Executive Committee is delegated to undertake expedited review and approval of business that does not require full HREC review, including some or all of the following:

- Low and negligible risk (LNR) research applications
- Amendments to current HREC approved research projects
- Responses to HREC queries, as approved by the full HREC for HREC Executive Committee review and approval
- Annual progress reports and final reports
- Serious Adverse Events
- Protocol deviations

16.2 Low risk research applications are those where the only foreseeable risk is one of discomfort to participants. Negligible risk is where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than an inconvenience to the participants.

16.3 The types of research that the HREC will consider to be LNR are those where:

- The level of intrusiveness and disruption to participants is minimal (taking into account who the participants are and whether they constitute a vulnerable population);
- The project does not (or does not have the potential to) involve sensitive information about participants;
- The threat to a participant's privacy and confidentiality is remote; and
- The project involves the use of data which has been stripped of identifiable information (such as name, address, dates of birth or death) and the potential to re-identify the information is remote.

The following examples would not qualify for LNR review, since there is a potential for re-identification of information:

- projects investigating rare events or outcomes
- projects requiring the release of full date variables

16.4 The Executive Committee may seek advice from other HREC members or suitably qualified experts, as appropriate, before making a decision.

16.5 The Executive Officer is delegated to undertake expedited review and approval of administrative business that does not require full HREC review, including some or all of the following;

- Request for approval for change in personnel (but not change in Co-ordinating Principal Investigator)
- Minor administrative amendments to current projects and informed consent documents
- Responses to HREC queries, as approved by the full HREC for Executive Officer review and approval.

16.6 The decisions of the HREC Executive Committee and the Executive Officer are included in the agenda of the next HREC meeting.

16.7 Where the Chairperson considers that the matter under consideration may involve a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the matter must be considered by the full HREC and cannot be dealt with by expedited review.

SOP17: Submission of amendments and extensions to ethically approved projects

Reference: SOP17 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

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

17.1 Proposed changes to approved research projects, including changes to the conduct of the research, requests for extensions to the length of ethical approval and changes in personnel, must be submitted by the Co-ordinating Principal Investigator to the HREC for approval.

17.2 The Co-ordinating Principal Investigator will submit a signed request for amendment which outlines the nature of the proposed changes, the reasons for the request and an assessment of any ethical implications arising from the request on the conduct of the research.

17.3 Any amended document (such as a revised protocol or Participant Information Sheet /Consent Form) must have the changes tracked or highlighted and contain revised version numbers and dates.

17.4 Request for amendments will be reviewed by the Executive Committee at the next available meeting, as per SOP 16, or may be referred to the full HREC for review at the next available meeting.

17.5 If it is determined that further information or modification is required, the correspondence to the Co-ordinating Principal Investigator will clearly articulate the reasons for this determination and stipulate the information required. Such requests will refer to the National Statement or relevant legislation where necessary.

17.6 Where a proposed amendment will fundamentally alter the nature of the research and the extent of the involvement of, or risk to participants, the HREC has the discretion to request submission of a new application for full ethical review. Examples include:

(a) A change in the primary purpose or objective of the research, such as the introduction of additional genetic or genomic studies;

(b) A substantial change in research methodology; or

(c) Recruitment of a new type of participant (especially if these would be regarded as being from vulnerable groups).

Changes to research personnel

17.7 Where a new Co-ordinating Principal Investigator is to be appointed, the request for approval for a change in personnel must carry the signature of the exiting Co-ordinating Principal Investigator and the signature of the new Co-ordinating Principal Investigator.

17.8 Where another investigator is to be appointed to the research team, the HREC will be notified in writing by the Co-ordinating Principal Investigator.

Adding a site to a research project

17.9 The Co-ordinating Principal Investigator will request approval in writing to the HREC to add sites to approved research projects.

Amendment approval letter

17.10 The amendment approval letter will state that the letter constitutes ethical approval only and that there may be requirements for separate research governance authorisation at participating sites.

SOP18: Reporting and Handling Adverse Events

Reference: SOP18 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

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

18.1 It is a condition of ethical approval that the Co-ordinating Principal Investigator advises the HREC in a timely manner of any adverse events that take place.

18.2 Reporting should be made in writing to the Chairperson of the HREC. The report should include comment from the investigator on whether, in their opinion, the adverse event was related to the project.

18.3 In general, adverse events will be considered by the Executive Committee at its next scheduled meeting. The Executive Committee will determine the appropriate course of action, which may include:

(a) Notation on file of the occurrence;

(b) Increased monitoring of the project;

(c) Suspension of ethical approval;

(d) Termination of ethical approval; or

(e) Request for an amendment to the project.

18.4 For adverse events deemed by the Chairperson as serious and requiring immediate attention, the Chairperson will take such action as considered necessary. In these circumstances, discussion will be brought to the HREC for ratification.

SOP19: Monitoring of ethically approved projects

Reference: SOP19 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the process of monitoring studies/project approved by the HREC

19.1 The HREC requires, as a condition of ongoing approval of a project, that the Co-ordinating Principal Investigator reports to the HREC anything which may warrant review of ethical approval of the protocol including:

a) Proposed changes in the protocol;

b) Any unforeseen events that might affect continued ethical acceptability of the project;

c) New information from published or unpublished studies which may have an impact on the continued ethical acceptability of the research, or which may indicate the need for amendments to the research protocol.

The HREC also requires that investigators inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion.

19.2 The HREC will monitor approved research projects to ensure compliance with the conditions of approval and to protect the rights, safety and welfare of participants. Monitoring includes review of annual progress reports and final reports, safety reports and reports of protocol deviations.

19.3 The HREC has the discretion to adopt other appropriate mechanisms for monitoring including:

a) discussion of relevant aspects of the project with the investigators at any time;

b) random inspections of research sites;

c) random inspections of data and signed consent forms; or

d) interviews, with prior consent, of research participants.

19.4 The HREC also has the discretion to recommend in the letter of approval that the site co-ordinates onsite monitoring at recommended intervals or randomly throughout the project.

19.5 Where the HREC is satisfied that the circumstances have arisen such that a research project is not being, or cannot be conducted in accordance with the approved project, the HREC may withdraw approval in accordance with SOP 20.

The HREC will inform the Co-ordinating Principal Investigator of its intention to take any action.

Annual progress reports

19.6 The HREC will require applicants to provide an annual report, and a final report at the project's completion. Continuing approval of the research will be subject to the Co-ordinating Principal Investigator's completion of annual reports. The first report should be submitted 12 months from the date of ethical approval.

19.7 The Executive Officer, or their delegate, will send a reminder letter for an impending due annual report, and two follow-up reminder letters if the report is not received. The second follow-up reminder letter will inform the Co-ordinating Principal Investigator that the study will be referred to the Chairperson, in the event that a report is not received within 21 calendar days. After 21 calendar days, if a report has not been received, the Chairperson will consider further action. Where suspension of HREC approval is proposed, the matter will be considered at a full HREC meeting.

19.8 The HREC requires that annual reports are provided in the standard reporting template which is available on the Cancer Institute NSW website.

19.9 The HREC will have the discretion to request more frequent progress reports, depending on the complexity, design and perceived risk of a project.

Final reports

19.10 Final reports will be submitted to the HREC by the Co-ordinating Principal Investigator in the standard reporting template upon completion of the research project. Final reports will include a copy of the final results and/or publications if available.

19.11 The HREC file will be archived once the final report is acknowledged.

Protocol deviation/violation reports

19.12 Protocol deviations are minor or administrative departures from HREC approved protocol procedures whereby data is unusable or not available, but which do not affect the scientific soundness of the research plan, or the rights, safety or welfare of research participants. There is no requirement to report protocol deviations to the HREC.

19.13 Protocol violations are instances where the protocol requirements and/or regulatory guidelines were not followed, and are generally more serious in nature than protocol deviations. Protocol violations are considered to potentially affect the scientific soundness of the research plan and/or the rights, safety or welfare of research participants. Examples include: failure to obtain participant consent; potential breaches of participant privacy and participant inclusion/exclusion violations.

19.14 Co-ordinating Principal Investigators or Principal investigators will provide to the HREC written reports of protocol violations in a timely manner.

SOP20: Withdrawal or Suspension of ethical approval

Reference: SOP20 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

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

20.1 The HREC will suspend or withdraw ethical approval if satisfied that a research project is not being, or cannot be, conducted in accordance with the original approval or that the rights, safety or welfare of participants may be compromised.

20.2 Ethical approval of a project may be suspended or withdrawn in the following circumstances:

a) If serious misconduct by an investigator is reasonably suspected or proven;

b) If the wellbeing of participants is jeopardised; or

c) If an investigator has failed to comply with any conditions imposed by the HREC, including monitoring requirements.

20.3 Suspension can relate to some or all project activities. At a minimum, suspension will involve cessation of participant recruitment. The HREC will specify which aspects of the project will cease and when activities can recommence.

20.4 Where the HREC suspends ethical approval, the Co-ordinating Principal Investigator and Research Governance Officer at each relevant site (where appropriate) will be notified in writing within 3 working days of the decision to suspend, unless immediate notification is required for urgent safety reasons.

20.5 The HREC will advise the CCO and the Executive Director, OHMR of the withdrawal of ethical approval of any project.

SOP21: Handling of Complaints about the ethical review process

Reference: SOP21 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

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

21.1 A complaint about the HREC's review process will be directed to the attention of the Chairperson of the HREC, detailing the grounds of the concern or complaint.

21.2 All complaints received will be reported to the CCO and the Executive Director, OHMR in an appropriate timeframe, depending on the seriousness of the complaint and the timeframe in which it is resolved. All complaints will at least be notified in the annual reports made pursuant to SOP 27.

21.3 The Executive Officer will send a letter to the complainant acknowledging receipt of their complaint, and outlining the mechanism by which the complaint will be investigated.

21.4 The Chairperson and the Executive Officer will investigate the complaint, and make a recommendation to the HREC on the appropriate course of action. This investigation should take no longer than two (2) weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist.

21.5 If the complainant is not satisfied with the outcome of the preliminary investigation, then they can refer their complaint to the CCO and Executive Director, OHMR or ask the Chairperson to do so.

21.6 The Chairperson will provide to the CCO and the Executive Director, OHMR all relevant information about the allegation(s).

21.7 The CCO and the Executive Director, OHMR will jointly determine in their discretion, if the complaint warrants further investigation. If they believe that no further investigation is required, they will inform the Chairperson and the complainant.

21.8 If it is determined that the complaint does warrant further investigation, then the CCO and the Executive Director, OHMR will jointly convene a suitable panel to review the complaint, ensuring that both the complainant and the HREC are afforded due process.

21.9 The panel will include, at least, the following members:

a) The CCO and/or Executive Director OHMR, one of whom will act as Convenor of the panel; and

b) Two nominees each of the CCO and Executive Director OHMR who are not members of the HREC.

21.10 The panel may access any documents relating to the project.

21.11 The panel may interview other parties, and obtain internal and external expert advice as it sees necessary.

21.12 In conducting its review, the panel shall be concerned with ascertaining whether the HREC:

- acted in accordance with The National Statement;
- acted in accordance with its Terms of Reference;
- acted in accordance with its Standard Operating Procedures;
- otherwise acted in an unfair or biased manner.

21.13 The CCO and the Executive Director, OHMR will notify the complainant and the HREC of the outcome of the panel's investigation. The outcomes of this process may include:

- The complaint is dismissed;
- The complaint is referred back to the HREC for consideration.

21.14 The panel may also make recommendations about the operation of the HREC including such actions as:

- Review of the Terms of Reference;
- Review of the Standard Operating Procedures;
- Review of HREC membership;
- Other actions as appropriate.

SOP22: Handling of appeals concerning the HREC's rejection of an application

Reference: **SOP22 – NSW Population & Health Services Research Ethics Committee**

Date: March 2017

Subject: To describe the process of receiving and handling appeals from investigators about the HREC's rejection of an application

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

a) submit a new application to the HREC taking due account of the HREC's concerns; or

b) lodge an appeal with the HREC Chairperson specifying the grounds of the appeal.

22.2 All appeals received will be reported to the CCO and the Executive Director, OHMR in an appropriate timeframe, depending on the seriousness of the appeal and the timeframe in which it is resolved. All appeals will at least be notified in the annual reports made pursuant to section SOP 27.

22.3 The Executive Officer will send a letter to the appellant acknowledging receipt of their appeal, and outlining the mechanism by which the appeal will be investigated.

22.4 The Chairperson and the Executive Officer will investigate the appeal, and make a recommendation to the HREC on the appropriate course of action. This investigation should take no longer than two (2) weeks from the time of the appeal, unless exceptional circumstances exist.

22.5 If the appellant is not satisfied with the outcome of the preliminary investigation, then they can refer their appeal to the CCO and the Executive Director, OHMR or ask the Chairperson to do so.

22.6 The Chairperson will provide to the CCO and the Executive Director, OHMR all relevant information about the appeal.

22.7 The CCO and the Executive Director, OHMR will jointly determine in their discretion, if the appeal warrants further investigation. If they believe that no

further investigation is required, they will inform the Chairperson and the complainant.

22.8 If it is determined that the appeal does warrant further investigation, then the CCO and the Executive Director, OHMR will jointly convene a suitable panel to review the appeal, ensuring that both the appellant and the HREC are afforded due process.

22.9 The panel will include, at least, the following members:

(a) The CCO and/or Executive Director OHMR, one of whom will act as Convenor of the panel; and

(b) Two nominees each of the CCO and Executive Director OHMR who are not members of the HREC, at least one of whom is an expert in the discipline of research of the project under consideration.

22.10 The panel will afford the HREC and the appellant the opportunity to make submissions.

22.11 The panel may access any documents relating to the project.

22.12 The panel may interview other parties, and obtain internal and/or external expert advice as it sees necessary.

22.13 In conducting its review, the panel shall be concerned with ascertaining whether the HREC:

- acted in accordance with The National Statement;
- acted in accordance with its Terms of Reference;
- acted in accordance with its Standard Operating Procedures;
- otherwise acted in an unfair or biased manner.

22.14 The CCO and the Executive Director, OHMR will notify the appellant and the HREC of the outcome of the panel's investigation. The outcomes of this process may include:

- The appeal is dismissed;

- The appeal is referred back to the HREC for consideration.

22.15 Should the HREC be requested to review its decision, then the outcome of that review by the HREC will be final. Neither the Panel, the CCO nor the Executive Director, OHMR can reverse the final determination of the HREC.

SOP23: Handling of appeals concerning the HREC's approval of an application

Reference: SOP23 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the process of receiving and handling appeals about the HREC's approval of an application

23.1 Where the HREC has approved an application and:

(a) an ethical or scientific issue is subsequently identified by any party; or

(b) It has become apparent that the decision was based on inconsistent application of policy and guidelines

An appeal will be lodged with the Chairperson in the first instance specifying the grounds of the appeal.

23.2 All appeals received will be reported to the CCO and the Executive Director, OHMR in an appropriate timeframe, depending on the seriousness of the appeal and the timeframe in which it is resolved. All appeals will at least be notified in the annual reports made pursuant to section SOP 27.

23.3 The Executive Officer will send a letter to the appellant acknowledging receipt of their appeal, and outlining the mechanism by which the appeal will be investigated.

23.4 The Chairperson and the Executive Officer will investigate the appeal, and make a recommendation to the HREC on the appropriate course of action. This investigation should take no longer than two (2) weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist.

23.5 If the appellant is not satisfied with the outcome of the preliminary investigation, then the appellant can refer the appeal to the CCO and the Executive Director, OHMR or ask the Chairperson to do so.

23.6 The Chairperson will provide to the CCO and the Executive Director, OHMR all relevant information about the appeal.

23.7 The CCO and the Executive Director, OHMR will jointly determine in their discretion, if the appeal warrants further investigation. If they believe that no further investigation is required, they will inform the Chairperson and the appellant.

23.8 If it is determined that the appeal does warrant further investigation, then the CCO and the Executive Director, OHMR will jointly convene a suitable panel to review the appeal, ensuring that both the appellant and the HREC are afforded due process.

23.9 The panel will include, at least, the following members:

a) The CCO and/or Executive Director OHMR as Convenor of the panel; and

b) Two nominees each of the CCO and Executive Director OHMR who are not members of the HREC, at least one of whom is an expert in the discipline of research of the project under consideration.

23.10 The panel will afford the HREC and the appellant the opportunity to make submissions.

23.11 The panel may access any documents relating to the project.

23.12 The panel may interview other parties, and obtain internal and/or external expert advice as it sees necessary.

23.13 In conducting its review, the panel shall be concerned with ascertaining whether the HREC:

- acted in accordance with The National Statement;
- acted in accordance with its Terms of Reference;
- acted in accordance with its Standard Operating Procedures;
- otherwise acted in an unfair or biased manner.

23.14 The CCO and the Executive Director, OHMR will notify the appellant and the HREC of the outcome of the panel's investigation. The outcomes of this process may include:

- The appeal is dismissed;
- The appeal is referred back to the HREC for consideration.

23.15 Should the HREC be requested to review its decision, then the outcome of that review by the HREC will be final. Neither the Panel, the CCO nor the Executive Director, OHMR can reverse the final determination of the HREC.

SOP24: Handling of Complaints/Concerns about the Conduct of a research project

Reference: SOP24 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

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

24.1 Any person, being a project participant, researcher or other interested person, with a complaint about the conduct of a project, should bring the complaint to the attention of the Executive Officer of the HREC. Where the research is being conducted in a Public Health Organisation, the complaint may also be made to the Research Governance Officer of the Public Health Organisation.

24.2 Where the complaint is submitted to the Research Governance Officer, they will inform the Executive Officer of the approving HREC of the nature of the complaint if it is likely to have implications for the ongoing approval of the project by the HREC.

24.3 Where the complaint is submitted to the Executive Officer, they will inform the Research Governance Officer responsible at the site that is the subject of the complaint.

24.4 Where the complaint involves an allegation of research misconduct, the complaint will be managed in accordance with the local complaint handling procedures of the organisation at which the researcher is located.

24.5 All complaints received will be reported to the CCO and the Executive Director, OHMR in an appropriate timeframe, depending on the seriousness of the complaint and the timeframe in which it is resolved. All complaints will at least be notified in the annual reports made pursuant to SOP 27.

For complaints to be investigated by the HREC:

24.6 The Executive Officer will document in writing, the grounds of the concern or complaint.

24.7 The Executive Officer will notify the Chairperson as soon as possible after a complaint is received.

24.8 The Executive Officer will send a letter of acknowledgement to the complainant and a letter of notification to the Co-ordinating Principal Investigator, outlining the complaint and the mechanism for investigating the complaint, as listed below.

24.9 The Executive Officer and the Chairperson of the HREC will investigate the complaint and make a recommendation to the HREC on the appropriate course of action.

24.10 This investigation shall take no longer than two (2) weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist.

24.11 If the complaint is substantiated, action may include:

(a) The requirement for amendments to the project, including increased monitoring by the HREC;

(b) Suspension of ethical approval for the project;

(c) Termination of ethical approval for the project; or

(d) Other action to resolve the complaint.

24.12 The complainant shall be informed, in writing, of the outcome of the Chairperson's investigation.

24.13 If the complainant is not satisfied with the outcome of the investigation, then they he/she can refer their complaint to the CCO and the Executive Director, OHMR or request the Chairperson to do so.

24.14 The Chairperson will provide to the CCO and the Executive Director, OHMR all relevant information about the complaint.

24.15 The CCO and the Executive Director, OHMR will jointly determine in their discretion, if the complaint warrants further investigation. If they believe that no further investigation is required, they will inform the Chairperson and the complainant.

24.16 If it is determined that the complaint does warrant further investigation then the CCO and the Executive Director, OHMR will jointly convene a suitable panel to review the complaint, ensuring that both the complainant and the HREC are afforded due process.

24.17 The panel will include, at least, the following members:

(a) The CCO and/or Executive Director OHMR as Convenor of the panel; and

(b) Two nominees each of the CCO and Executive Director OHMR who are not members of the HREC, at least one of whom is an expert in the discipline of research of the project under consideration.

24.18 The panel will afford the HREC and the complainant the opportunity to make submissions.

24.19 The panel may access any documents relating to the project.

24.20 The panel may interview other parties, and obtain internal and/or external expert advice as it sees necessary.

24.21 The CCO and the Executive Director, OHMR will notify the complainant and the HREC of the outcome of the panel's investigation. The outcomes of this process may include:

- The complaint is dismissed;

- The CCO and the Executive Director, OHMR direct appropriate action to be taken to resolve the complaint which may include suspension or termination of ethical approval by the HREC as per SOP 20.

SOP25: Confidentiality and Security of Applications and Proceedings

Reference: SOP25 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the process of ensuring confidentiality and security of the applications and proceedings of HREC

25.1 Members of the HREC will treat as, and keep, confidential all information and documents which relate to proposals considered by the HREC.

25.2 Members are required to sign a confidentiality agreement upon joining the HREC.

25.3 All relevant records of the HREC, including applications, membership, agendas, minutes and correspondence, will be kept as confidential files in accordance with the requirements of the State Records Act 1998 and the Cancer Institute NSW Functional Retention and Disposal Authority.

25.4 All hard copy documents are to be disposed of in a secure manner, such as by shredding or by placing in confidential bins. HREC members who do not have access to secure disposal should leave their documents with the Executive Officer for disposal.

SOP26: Record keeping

Reference: SOP26 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the procedure for the preparation and maintenance of records of the HREC

26.1 The Executive Officer, or their delegate will:

(a) Prepare and maintain confidential records of the HREC's activities, including agendas and minutes of all meetings of the HREC.

(b) Prepare and maintain a confidential electronic record for each application received and reviewed, including the original application and all subsequent information and correspondence relevant to the application. This file will be kept securely and confidentially at the Cancer Institute NSW in accordance with the requirements of the State Records Act 1998 and the Cancer Institute NSW Functional Retention and Disposal Authority.

26.2 All relevant records of the HREC, including applications, membership, agendas minutes and correspondence, will be kept as confidential files in accordance with the requirements of the State Records Act 1998 and the Cancer Institute NSW Functional Retention and Disposal Authority.

26.3 A register of all the applications received and reviewed shall be maintained in accordance with the National Statement.

SOP27: Reporting requirements of the HREC

Reference: SOP27 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

Subject: To describe the reporting requirements for the HREC

Reports to the CCO and the Executive Director, OHMR

27.1 The CCO and the Executive Director, OHMR shall be informed of the decisions of the HREC on proposals submitted to it on a regular basis. This will occur either through the submission of the minutes of HREC meetings, or through the submission of an annual report.

27.2 The annual report will include the following;

- information on membership and membership changes;
- the number of meetings;
- meeting attendance;
- the number of research proposals reviewed, approved and rejected;
- information about monitoring procedures for research in progress, and issues identified by the HREC in undertaking its monitoring role;
- description of any appeals and complaints received and their outcome;
- description of any research where HREC approval has been suspended or withdrawn and the reasons for this action;
- resources required to assist the HREC in fulfilling its role.

Reports to the NHMRC

27.3 The HREC will complete and submit reports on behalf of the Cancer Institute NSW and NSW Ministry of Health as follows:

a) Significant changes to the ethical review processes and changes to the PHSREC Membership will be proactively reported to the NHMRC as per Section 4.1.2 of the NHMRC Certification Handbook, November 2012.
b) Annual Report to the NHMRC as a registered HREC, and additional reporting to meet the NHMRC Certification requirements;

Reports to the NSW privacy commissioner

27.4 Each year, the HREC will provide reports to the NSW Privacy Commissioner in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW).

SOP28: Amendment to the Terms of Reference and the Standard Operating Procedures

Reference: SOP28 – NSW Population & Health Services Research Ethics Committee

Date: March 2017

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

28.1 The Terms of Reference and the Standard Operating Procedures will be reviewed at least every three years.

28.2 The Terms of Reference and the Standard Operating Procedures may be amended by the procedure outlined below.

Amendment to the terms of reference or the standard operating procedures brought forward by HREC members:

28.3 The proposal must be in writing and circulated to all HREC members for their consideration.

28.4 The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register their views in writing;

28.5 The proposal brought forward shall be referred to the CCO and the Executive Director, OHMR for review and agreement, where two thirds of the HREC members agree to the amendment.

28.6 The CCO and the Executive Director, OHMR will consider the proposal and notify the HREC of the outcome of their consideration. If the CCO and the Executive Director, OHMR agree to the amendment, the Terms of Reference and/or Standard Operating Procedures will be so amended by the Executive Officer and the amendment will be ratified at the next HREC meeting, and will take effect from that date.

Amendment to the terms of reference or the standard operating procedures brought forward by either the CCO or the Executive Director, OHMR:

28.7 The CCO and the Executive Director, OHMR may put forward a proposal for amendment to the Terms of Reference or the Standard Operating Procedures. Such proposals must be in writing and must first be agreed by both the CCO and the Executive Director, OHMR. The proposal shall then be circulated to all HREC members for their consideration;

28.8 The proposal will be tabled at the next scheduled HREC meeting;

28.9 The HREC will provide its advice on the proposal to the CCO and the Executive Director, OHMR as soon as practicable after the meeting at which it was considered;

28.10 The CCO and the Executive Director, OHMR will consider the advice of the HREC, and if both agree to proceed with the amendment, the Terms of Reference and/or the Standard Operating Procedures will be so amended by the Executive Officer. The amendment will be tabled at the next HREC meeting, and will take effect from that date.