

Research - Ethical & Scientific Review of Human Research in NSW Public Health Organisations

Summary This policy directive sets out the requirements for ethical and scientific review of human research that takes place in NSW Public Health Organisations.

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ETHICAL AND SCIENTIFIC REVIEW OF HUMAN RESEARCH IN NSW PUBLIC HEALTH ORGANISATIONS

PURPOSE

The purpose of this policy directive is to ensure that all human research that takes place in NSW Public Health Organisations meets appropriate ethical and scientific standards through an effective and efficient system of review.

MANDATORY REQUIREMENTS

All human research that takes place in NSW Public Health Organisations must be reviewed, approved and conducted in accordance with the *National Statement on Ethical Conduct in Human Research (2007)* by the National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors' Committee.

This requirement must be met in order for Public Health Organisations to grant authorisation for the commencement of human research projects, in accordance with Policy Directive PD2010_056 *Authorisation to commence human research in NSW Public Health Organisations*.

Public Health Organisations must establish structures and practices consistent with:

- *Ethical and scientific review of human research in NSW Public Health Organisations: procedures* accompanying this policy statement;
- Guideline GL2010_013 *Operations Manual: Human Research Ethics Committees*; and
- Guideline GL2010_014 *Operations Manual: Human Research Ethics Committee Executive Officers*.

IMPLEMENTATION

Chief Executives of NSW Public Health Organisations are required to ensure that:

- The requirements and procedures outlined in this policy directive are communicated to all staff involved in human research;
- Structures and practices consistent with this policy directive are established; and
- Sufficient resources are provided for the effective and efficient processing of applications for ethical and scientific review submitted to its Human Research Ethics Committee (HREC).

Co-ordinating Investigators (and for single-centre research **Principal Investigators**) are required to:

- Submit applications for ethical and scientific review by NSW Health HRECs on one of the following forms, available through the Online Forms Website at <https://ethicsform.org/au/>:
 - The National Ethics Application Form (NEAF), for all applications for full HREC review (section 3.2).

- The Application Form for Ethical and Scientific Review of Low and Negligible Risk Research, for all applications for expedited HREC review of low and negligible risk research (section 4.2).
- Ensure that, if required, the research project satisfies any specific review requirements in relation to: research involving persons in custody and/or staff of Justice Health; research that may affect the health and wellbeing of Aboriginal people and communities; research requiring access to statewide data collections; and clinical trials with persons unable to provide consent (section 5).

NSW Health HREC Executive Officers are required to:

- Follow the procedures outlined in this policy directive; and
- Provide advice to investigators seeking to undertake human research within NSW Public Health Organisations, in accordance with this policy directive.

REVISION HISTORY

Version	Approved by	Amendment notes
September 2010 (PD2010_055)	Deputy Director General Population Health	Issue of policy directive which replaces Policy Directive 2007_072 <i>Research – Model for Single Ethical and Scientific Review of Multi-centre Research</i> and rescinds Policy Directive 2007_026 <i>Human Research Ethics Committees: National Ethics Application Form – Application within NSW Health</i> .

ATTACHMENTS

1. Ethical and scientific review of human research in NSW Public Health Organisations: procedures

*Ethical and scientific review of human research in NSW
Public Health Organisations*

NSW  **HEALTH**
PROCEDURES

Issue date: September 2010

PD2010_055

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1 BACKGROUND

1.1 About this document

This policy directive outlines the requirements and procedures related to ethical and scientific review and approval of human research that takes place in NSW Public Health Organisations.

1.2 Scope

Human research taking place in NSW Public Health Organisations means research:

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

Activities other than research are outside the scope of this policy directive. These may include quality assurance or quality improvement activities, clinical audits, management of health services and teaching activities.

Individuals engaged in these activities within Public Health Organisations should refer to Guideline GL2007_020 *Human Research Ethics Committees – Quality Improvement & Ethical Review: A Practice Guide for NSW*, and consult the Public Health Organisation involved in order to determine the process adopted by that Public Health Organisation for the ethical review of these activities.

1.3 Key definitions

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

Data Custodian is an individual with day-to-day responsibility for data collection, usually the director/manager of the location where the collection is maintained.

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

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

NSW Health means the NSW public health system and the Department of Health.

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

NSW public health system under the *Health Services Act 1997 (NSW)* consists of all Area Health Services, all statutory health corporations, all affiliated health

organisations with respect to their recognised services, and the Director-General with respect to health support and ambulance services.

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

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

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

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

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

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

1.4 Relationship to other NSW Health policy directives and guidelines

This policy directive should be read in conjunction with the following NSW Health policy directives and guidelines:

Policy Directive PD2010_057 *Human and animal research and the National Health and Medical Research Council Act 1992*

Policy Directive PD2010_056 *Authorisation to commence human research in NSW Public Health Organisations*

Policy Directive PD2008_030 *HREC and Research Governance – Fee Policy for Review of Commercially Sponsored Research*

Policy Directive PD2007_035 *Human Research Ethics Committees: Standards for Scientific Review of Clinical Trials*

Guideline GL2010_013 *Operations Manual: Human Research Ethics Committees*

Guideline GL2010_014 *Operations Manual: Human Research Ethics Committee Executive Officers*

2 INTRODUCTION

2.1 Types of ethical and scientific review

All human research that takes place in NSW Public Health Organisations must be reviewed and approved in accordance with the *National Statement on Ethical Conduct in Human Research (2007)* [*National Statement*].

This requirement must be met in order for Public Health Organisations to grant authorisation for the commencement of human research projects, in accordance

with Policy Directive PD2010_056 *Authorisation to commence human research in NSW Public Health Organisations*.

Public Health Organisations may establish their own Human Research Ethics Committee (HREC) or use the review outcome of an HREC established by another institution. In either circumstances, the HREC that undertakes the review must be constituted and operate in accordance with the *National Statement*.

Public Health Organisations with an established HREC must provide two pathways for ethical and scientific review:

- a full HREC review (section 3); and
- an expedited HREC review for low and negligible risk research (section 4).

A summary of routes to obtaining ethical and scientific approval from a NSW Health HREC, and how they relate to obtaining authorisation for the commencement of research projects at Public Health Organisations, is provided at Annex A.

Guideline GL2010_013 *Operations Manual: Human Research Ethics Committees* provides standard operating procedures and a 'terms of reference' template to assist Public Health Organisations to ensure that their HRECs are constituted and operate in accordance with the *National Statement*.

Guideline GL2010_014 *Operations Manual: Human Research Ethics Committee Executive Officers* promotes standard processes for the administration of applications for ethical and scientific review of human research across NSW Public Health Organisations.

2.2 Single ethical and scientific review of multi-centre research

NSW Public Health Organisations must support the NSW Health system of single ethical and scientific review, in line with the *National Statement* requirement to minimise duplication of ethical review. Notwithstanding the special requirements stipulated in section 5 of this policy directive, under this system a human research project will be ethically and scientifically reviewed once only, irrespective of the number of NSW Health sites involved in the project.

Each Public Health Organisation must accept ethical and scientific review undertaken by its local HREC or a lead HREC as sufficient review for the purposes of the project being conducted at site(s) under its control. This applies to both full and expedited HREC review.

- A local HREC is an HREC established by a Public Health Organisation to provide ethical and scientific review of human research to be conducted at sites under its control. Some Public Health Organisations support more than one local HREC.
- A lead HREC is a local HREC accredited by the Director-General of the Department of Health to conduct ethical and scientific review of human research on behalf of the NSW public health system in the categories of: (a) clinical trials/interventional clinical research; and/or (b) general research. The accreditation standards are available at:

http://www.health.nsw.gov.au/resources/ethics/research/Third_round_Accreditation_Standards_and_Guidance_Apr_10_pdf.asp

Where the human research project involves the conduct of research at sites under the jurisdiction of more than one local HREC, the project must be reviewed by a lead HREC.

2.3 Exemption from ethical and scientific review

In accordance with the *National Statement*, NSW Public Health Organisations have the discretion to exempt from ethical review research that:

- is negligible risk research; and
- involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

Investigators with a research project that fulfils the above criteria should consult the HREC Executive Officer to ensure that the project is exempt from ethical and scientific review.

Investigators are reminded that academic journals often require evidence that a research project has been reviewed by an HREC or that it has been exempt from review by an HREC.

3 FULL HUMAN RESEARCH ETHICS COMMITTEE REVIEW

3.1 Types of research requiring full HREC review

In accordance with the *National Statement*, the following types of human research must be ethically and scientifically reviewed and approved by an HREC before they take place in NSW Public Health Organisations.

- Research that involves more than low risk to participants.
- Research that includes any of the following:
 - Interventions and therapies, including clinical and non-clinical trials and innovations or new treatment modalities;
 - Active concealment or planned deception of participants;
 - Exposure of illegal activities; and
 - Research specifically targeting Aboriginal or Torres Strait Islander peoples.
- Research that includes any of the following, except where the project uses collections of non-identifiable data and involves only negligible risk to participants:
 - Human genetics;
 - Human stem cells;
 - Women who are pregnant and the human foetus;

- People who are highly dependent on medical care who may be unable to give consent;
- People with a cognitive impairment;
- People with an intellectual disability or a mental illness; and
- People who may be involved in illegal activities.

3.2 Applications for full HREC review

All applications for full HREC review by a NSW Health HREC, whether in its capacity as local or lead HREC, must be made by the Co-ordinating Investigator using the National Ethics Application Form (NEAF), accessed through the Online Forms Website at <https://ethicsform.org/au/>. The Online Forms Website provides guidance on completing the NEAF and supporting documents required for making an application.

The completed NEAF and supporting documents must be submitted to the Executive Officer of the HREC that will review the application. Contact details for NSW Health HREC Executive Officers are maintained on the NSW Department of Health website at: <http://www.health.nsw.gov.au/ethics/research/contacts.asp>

Executive Officers must use an online research application tracking and management system known as the Australian Research Ethics Database (AU RED) for the management of all applications for full HREC review for research projects involving NSW Health sites. This does not prevent the parallel use of other research management systems employed by Public Health Organisations.

4 EXPEDITED HUMAN RESEARCH ETHICS COMMITTEE REVIEW

4.1 Types of research that may undergo expedited HREC review

Under the *National Statement*, institutions may establish non-HREC levels of ethical review for research that involves no more than low risk.

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

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

4.2 Applications for expedited HREC review

Applications for expedited review of research with low and negligible risk to participants by a NSW Health HREC must be made by the Co-ordinating

Investigator using the Application Form for Ethical and Scientific Review of Low and Negligible Risk Research.

The form can be accessed through the Online Forms Website at <https://ethicsform.org/au/>. The Online Forms Website provides guidance on completing the form and supporting documents required for making an application.

A copy of the form can be downloaded from the NSW Department of Health website at: <http://www.health.nsw.gov.au/ethics/research/resources.asp>

The completed form and supporting documents must be submitted to the Executive Officer of the HREC that will review the application. Contact details for NSW Health HREC Executive Officers are maintained on the NSW Department of Health website at: <http://www.health.nsw.gov.au/ethics/research/contacts.asp>

The Co-ordinating Investigator should consult the HREC Executive Officer to determine if the research project can be classified as low or negligible risk research, before completing the form.

The Executive Officer has the discretion to request that the research project is submitted for a full review using NEAF if they consider the risk to participants to be greater than low risk.

The HREC has the discretion to request a full review using NEAF following assessment of the application for expedited review if it considers the risk to participants to be greater than low risk.

From 01 January 2011, Executive Officers must use AU RED for the management of all applications for expedited HREC review for research projects involving NSW Health sites. This does not prevent the parallel use of other research management systems employed by Public Health Organisations.

5 HUMAN RESEARCH WITH SPECIFIC REVIEW REQUIREMENTS

Certain human research projects must satisfy specific review requirements in addition to review by a local or lead HREC, before they take place in NSW Public Health Organisations. These requirements, outlined in this section, are not mutually exclusive.

5.1 Research involving persons in custody and/or staff of Justice Health

All research projects involving persons in custody in NSW and/or staff of NSW Justice Health require review by the NSW Justice Health HREC.

Research projects only involving persons in custody and/or staff of NSW Justice Health will be reviewed by the NSW Justice Health HREC alone. Projects that also involve other participants should be reviewed by the NSW Justice Health HREC and other appropriate HRECs.

Further information is available from:

<http://www.justicehealth.nsw.gov.au/research/hrec.html>

5.2 Research that may affect the health and wellbeing of Aboriginal people and communities

Approval from the Aboriginal Health and Medical Research Council (AH&MRC) Ethics Committee is required where the research project involves research in, or concerning, NSW and any one of the following applies:

- The experience of Aboriginal people is an explicit focus of all or part of the research;
- Data collection is explicitly directed at Aboriginal people;
- Aboriginal peoples, as a group, are to be examined in the results;
- The information has an impact on one or more Aboriginal communities; or
- Aboriginal health funds are a source of funding.

One of AH&MRC Ethics Committee's major criteria in assessing an application is to ensure that there is Aboriginal community involvement in, and control over, the research. Investigators will need to show evidence that they have the support of each local Aboriginal Community Controlled Health Service (ACCHS) or an alternative appropriate Aboriginal organisation, subject to the agreement of the Ethics Committee, where the research is being conducted.

The AH&MRC Ethics Committee reviews applications from the perspective of the impact on Aboriginal people. The review is required in addition to review by a lead or local HREC.

The AH&MRC Ethics Committee accepts applications at any stage in their progress through another HREC. Each investigator can decide whether they will seek AH&MRC Ethics Committee approval before submitting to other HRECs, or after approval by other HRECs, or simultaneously.

Further information is available from:

<http://www.ahmrc.org.au/Ethics%20and%20Research.htm>

5.3 Research requiring access to statewide data collections

All research projects requiring access (including linkage) to statewide data collections owned or managed by NSW Health or the Cancer Institute NSW must be reviewed by the NSW Population and Health Services Research HREC.

Prior to making a submission to the NSW Population and Health Services Research HREC, researchers are required to complete a 'Data Custodian Sign Off Form', available from the Cancer Institute NSW website, and submit this with their research proposal to the relevant Data Custodian for review and sign-off.

Researchers wishing to access data from the NSW Central Cancer Registry are required to complete the 'Data Request Form' available from the Cancer Institute NSW website, and submit it to the NSW Central Cancer Registry Data Custodian together with the above documentation.

If the project involves data linkage by the Centre for Health Record Linkage, researchers are required to obtain a letter of support (for technical feasibility) from the Centre for Health Record Linkage prior to ethics review.

Further information is available from:

http://www.cancerinstitute.org.au/cancer_inst/research/ethicspopdatagov.html

5.4 Clinical trials with persons unable to provide consent

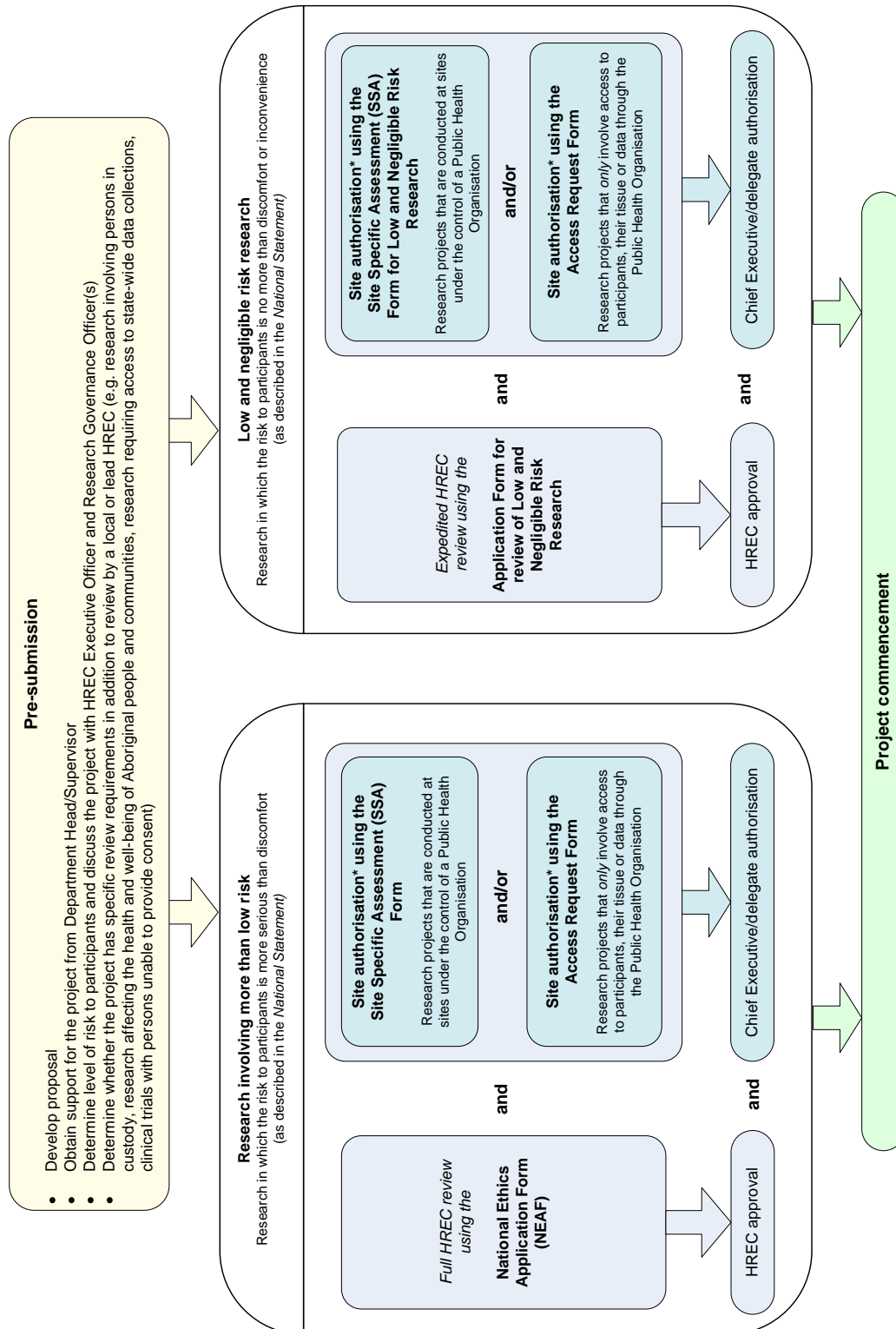
Under the *Guardianship Act 1987 (NSW)*, a person unable to consent may not participate in a clinical trial unless the trial has been approved by the Guardianship Tribunal. In reviewing such a trial, the Guardianship Tribunal will decide whether consent can be granted by the person responsible or should be granted by the Tribunal.

The Guardianship Tribunal will not deal with an application for approval of a clinical trial until:

- it receives proof that the relevant ethics committees have approved the clinical trial; and
- all the centres conducting the clinical trial have provided the Tribunal with the patient information sheets and consent forms for the clinical trial.

Further information is available from: <http://www.gt.nsw.gov.au/applications/clinical-trial.cfm>

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



*The requirement for site authorisation is detailed in PD2010_056 Authorisation to commence research in NSW Public Health Organisations