Research - Authorisation to Commence Human Research in NSW Public Health Organisations

Summary This policy directive sets out the requirements for site authorisation by the Chief Executive or delegate before human research can take place in NSW Public Health Organisations.

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Audience Research office staff;Researchers;Heads of Depts hosting research & supporting research

Secretary, NSW Health

AUTHORISATION TO COMMENCE 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 governance standards through an effective and efficient system of review, and is authorised by the Chief Executive or their delegate before commencement.

MANDATORY REQUIREMENTS

All human research that takes place in NSW Public Health Organisations must be reviewed in accordance with *Authorisation to commence human research: procedures* accompanying this policy statement, and authorised by the Chief Executive or their delegate before commencement.

Authorisation is conditional upon ethical and scientific approval of the research project, that has been granted in line with Policy Directive PD2010_055 *Ethical and scientific review of human research in NSW Public Health Organisations*.

Human research projects must not commence at a Public Health Organisation until the applicant has received written notification of authorisation by the Chief Executive or their delegate.

Public Health Organisations must establish structures and practices consistent with:

- *Authorisation to commence human research: procedures* accompanying this policy statement; and
- Guideline GL2010_015 *Operations Manual: Research Governance 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;
- Sufficient resources are provided for the effective and efficient processing of applications for site authorisation and target timelines set out in the Performance Management Framework – Monitoring Measures are met; and
- Delegation for authorisation is appropriately documented (section 5.1.1).

Principal Investigators are required to submit an application for site specific assessment for research that is to be conducted at a site under the control of a Public Health Organisation (section 3.4).

Co-ordinating Investigators are required to submit an application for access request review for research that requires support from a Public Health Organisation in the form of access to participants, tissue or data but does not involve the conduct of research at that Public Health Organisation (section 4.4).

Heads of departments (or divisional directors or other authority) responsible for the site where human research is to be conducted, are required to:

- Discuss each research project with the Principal Investigator;
- Assess whether the project meets appropriate governance requirements; and
- Provide a declaration of support for the project (section 3.4.2).

Heads of supporting departments responsible for providing additional support or services to the human research project conducted at the Public Health Organisation must provide a declaration of support for the project (section 3.4.2)

Research Governance Officers are required to:

- Provide advice to investigators seeking to undertake human research within NSW Public Health Organisations, in accordance with this policy directive; and
- Review applications for site authorisation and provide a recommendation to the Chief Executive or their delegate (sections 3.5 and 4.5).

REVISION HISTORY

Version	Approved by	Amendment notes
September 2010 (PD2010_056)	Deputy Director General Population Health	Issue of policy which replaces PD2007_043 *Research – Authorisation of proposals to conduct research on humans within NSW public health system*.

ATTACHMENTS

1. Authorisation to commence human research in NSW Public Health Organisations: procedures

Authorisation to commence human research in NSW Public Health Organisations

NSW HEALTH
PROCEDURES

Issue date: September 2010

PD2010_056

CONTENTS

1 BACKGROUND

1.1 About this document

This policy directive outlines the requirements and procedures related to authorisation to commence human research 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 should consult the Public Health Organisation involved, in order to determine the process adopted by that Public Health Organisation for the authorisation of these activities.

1.3 Key definitions

Access request review is a mechanism used by Public Health Organisations to ensure that the proposed research project complies with minimum governance requirements, and to consider whether to support the provision of access to participants, their tissue or data through the Public Health Organisation as requested by the project.

Chief Health Officer means the Chief Health Officer of the NSW Department of Health.

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.

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).

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

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

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

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

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

Research taking place in Public Health Organisations means research (i) conducted at sites under the control of Public Health Organisations; and (ii) involving participants, their tissue or data accessed through Public Health Organisations.

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

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

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

1.4 Relationship to other NSW Health policies 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_055 *Ethical and scientific review of human research in NSW Public Health Organisations*

Policy Directive PD2009_033 *Clinical Trial Research Agreement for Public Health Organisations (Commercial Entities)*

Policy Directive PD2009_032 *Clinical Trial Research Agreement Public Health Orgs (Collaborative or Cooperative Research Groups)*

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

Guideline GL2010_015 *Research Governance Officers: Operations Manual*

2 INTRODUCTION

Providing authorisation to commence human research is an important component of research governance. It enables NSW Public Health Organisations to:

- ensure that the proposed research project complies with appropriate ethical, scientific, regulatory and professional standards;

- consider whether the project should be conducted at and supported by the Organisation; and
- be aware of all research taking place at sites under their control.

All human research that takes place in Public Health Organisations must be reviewed through site specific assessment (section 3) or access request review (section 4), and authorised by the Chief Executive or their delegate (section 5) before commencement.

Authorisation is conditional upon ethical and scientific approval of the project, that has been granted in line with Policy Directive PD2010_055 *Ethical and scientific review of human research in NSW Public Health Organisations*.

A summary of routes to obtaining authorisation from a Public Health Organisation through site specific assessment or access request review, and how they relate to obtaining ethical and scientific approval is provided at Annex A.

Guideline GL2010_015 *Operations Manual: Research Governance Officers* provides standard operating procedures to promote standard processes for the administration of applications for site authorisation across NSW Public Health Organisations.

3 SITE SPECIFIC ASSESSMENT

3.1 Purpose

The purpose of site specific assessment is to enable NSW Public Health Organisations to:

- ensure that the proposed research project complies with minimum governance requirements set out in section 3.3; and
- consider whether the project should be conducted at the proposed site and supported by the Public Health Organisation.

Site specific assessment is a separate process to ethical and scientific review of a research project.

The Human Research Ethics Committee (HREC) conducting ethical and scientific review will not review the application for site specific assessment. The decision of the HREC is not dependent on the decision by the Chief Executive or their delegate regarding authorisation.

The Research Governance Officer conducting site specific assessment will not undertake ethical and scientific review of the proposed project and associated documents to be used for research.

3.2 Research projects requiring site specific assessment

Research projects to be conducted at sites under the control of NSW Public Health Organisations, whether they have undergone full or expedited HREC review, must undergo site specific assessment before authorisation can be granted by the Chief Executive or their delegate.

For example, site specific assessment is required if the project involves one or more of the following activities at a site under the control of a Public Health Organisation.

- Enrolling participants into research (e.g. obtaining informed consent, screening);
- Carrying out protocol-specific research procedures with or on participants; and
- Managing and analysing data, tissue, and responses from surveys and questionnaires collected for or from research.

3.3 Governance requirements

NSW Public Health Organisations must be satisfied that, based on the information provided in the application, the research project meets the following conditions:

(i) The investigators have the necessary skills, training and experience to undertake their role, and where necessary, appropriate training and supervision have been arranged;

(ii) There are suitable and adequate facilities and resources for the project to be conducted at the site as proposed, and they are available for the duration of the project;

(iii) The project has been costed appropriately and there are sufficient funds to cover the costs of conducting research at the site;

(iv) Any legislative requirements, including notification, registration and licence application requirements have been addressed;

(v) Adequate indemnity and insurance arrangements are in place for clinical trials.

(vi) If the project is a clinical trial with an external sponsor, there is a written agreement clarifying the obligations, responsibilities and rights of the parties involved in the trial. A number of standard agreements are available for this purpose.

(vii) Research documents to be used at the site comply with requirements of the Public Health Organisation (e.g. use of site logo, format, provision of site contact details, specific wording to be used in participant information sheet - such as information relating to pregnancy for documents to be used at Catholic hospitals, signatures required on consent forms).

(viii) There is ethical and scientific approval for the project and research documents, in line with Policy Directive PD2010_055 *Ethical and scientific review of human research in NSW Public Health Organisations*.

3.4 Application requirements

3.4.1 Application form

Applications for site specific assessment to a NSW Public Health Organisation must be made by the Principal Investigator on one of the following forms, available through the Online Forms Website at https://ethicsform.org/au:

- The NSW Health Site Specific Assessment Form, for research projects that have been submitted for full HREC review.
- The NSW Health Site Specific Assessment Form for Low and Negligible Risk Research, for research projects that have been submitted for expedited review by a NSW Health HREC.

The Online Forms Website provides guidance on how to complete 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

3.4.2 Obtaining declaration of support

The head of department (or divisional director or other authority) responsible for the site must discuss the proposed research project and its resource implications with the Principal Investigator, and declare in the form that the project satisfies conditions (i) to (iii) outlined in section 3.3 of this policy directive and is supported. Where the head of department is acting as the Principal Investigator, declaration must be obtained from the head of department's manager.

Where the project requires additional support and provision of services from other departments within the Public Health Organisation, the Principal Investigator must obtain a declaration of support from the heads of these departments in the form. Examples of supporting departments include pharmacy, pathology, medical imaging, medical records and treatment units providing care.

Where the project requires access to data from specific collections held at the Public Health Organisation, the Principal Investigator must obtain a declaration of support from an appropriate authority for data provision in the form. The authority, as determined by the Public Health Organisation, is generally the data custodian who is responsible for the management of that data collection.

3.4.3 Submitting the form

The completed form and supporting documents must be submitted to the Research Governance Officer responsible for the site.

Contact details for Research Governance Officers and information on the facilities, locations and services covered by them are maintained on the NSW Department of Health website at: http://www.health.nsw.gov.au/ethics/research/contacts.asp

A separate application must be made for each site at which the research project is to be conducted. For example, even if the project is to be conducted at two sites under the control of a single Public Health Organisation, a separate application must be made for each site.

Principal Investigators should contact the relevant Research Governance Officer and individuals that need to provide a declaration, and start to prepare an application for site specific assessment at the earliest possible opportunity. It is not necessary to wait for the outcome of ethical and scientific review of the project before preparing and submitting an application.

If the project is a clinical trial, Principal Investigators should submit documentation on insurance and indemnity arrangements and a copy of the clinical trial agreement

to the Research Governance Officer at the earliest possible opportunity, ahead of making a full application.

3.5 Assessment requirements

Research Governance Officers must assess the application and confirm that:

- all relevant questions on the form have been completed;
- all required supporting documents have been submitted;
- the research project satisfies conditions (iv) to (viii) outlined in section 3.3 of this policy directive; and
- the form contains signatures of: all investigators who will conduct research at the site; the head of department (or divisional director or other authority) of the site; and, where applicable, heads of supporting departments and the nominated authority for data provision.

Research Governance Officers should conduct the assessment in an efficient and timely manner. For clinical trials this includes initiating review of documentation on insurance and indemnity and clinical trial agreements at the earliest possible opportunity, following submission by the Principal Investigator.

Following assessment, Research Governance Officers must make a recommendation to the Chief Executive or delegate regarding authorisation of the project.

Research Governance Officers must use an online research application tracking and management system known as the Australian Research Ethics Database (AU RED) for the management of applications for site specific assessment that are associated with full HREC review for research projects to be conducted at sites under the control of Public Health Organisations.

From 01 January 2011, Research Governance Officers must use AU RED for the management of all applications for site specific assessment (i.e. those associated with full and expedited HREC review) for research projects to be conducted at sites under the control of Public Health Organisations.

The requirement to use AU RED does not prevent the parallel use of other research management systems employed by Public Health Organisations.

4 ACCESS REQUEST REVIEW

4.1 Purpose

The purpose of access request review is to enable NSW Public Health Organisations to:

- ensure that the proposed research project complies with minimum governance requirements set out in section 4.3; and
- consider whether to support the project.

4.2 Research projects requiring access request review

A research project that requires support from a NSW Public Health Organisation in the form of access to participants, tissue or data but does not involve the conduct of research at that Public Health Organisation is not required to undergo site specific assessment.

However, an access request must be lodged with the Public Health Organisation and the application reviewed before authorisation can be granted by the Chief Executive or their delegate.

Access request review is required when the project involves one or more of the following at the Public Health Organisation:

- Participant recruitment through posters, leaflets, handouts, and letter of invitation but not recruitment through direct contact with potential participants or enrolment;
- Distribution of surveys and questionnaires through staff of the Public Health Organisation but not collation and analysis of responses at that Public Health Organisation; and
- Access to data or tissue held at the Public Health Organisation but not processing or analysis at that Public Health Organisation.

4.3 Governance requirements

NSW Public Health Organisations must be satisfied that, based on the information provided in the application, the research project meets the following conditions:

(i) There is ethical and scientific approval for the project and research documents, in line with Policy Directive PD2010_055 *Ethical and scientific review of human research in NSW Public Health Organisations*.

(ii) The facilities, locations and services have appropriate resources and agreed to provide the access required by the project.

4.4 Application requirements

4.4.1 Application form

Access request must be made by the Co-ordinating Investigator using the Access Request Form, available from the Online Forms Website at

https://ethicsform.org/au/. The Online Forms Website provides guidance on how to complete the Access Request Form and supporting documents required for making an application.

4.4.2 Obtaining written evidence of support

Co-ordinating Investigators must obtain a written agreement from relevant staff of the facilities, locations and services that will provide the access required. Relevant staff may be, for example:

- individuals who agree to put up posters about the research project;
- individuals who agree to distribute leaflets or handouts about the project;
- doctors who agree to hand out letters of invitation to potential participants, or notify them of the project;
- Head of department who agrees to distribute questionnaires or surveys to staff by e-mail;
- Head of department or data custodian who agrees to provide access to medical records, data or tissue held in collections or databases under their management, in line with ethical conditions imposed by the approving HREC.

4.4.3 Submitting the form

The completed Access Request Form and supporting documents must be submitted to the Research Governance Officer responsible for the relevant facility, location or service. Contact details for Research Governance Officers and information on the facilities, locations and services covered by them are maintained on the NSW Department of Health website at: http://www.health.nsw.gov.au/ethics/research/contacts.asp

Only one access request per Research Governance Officer is required for each research project, even if the project requires access from a number of facilities, locations or services covered by that Research Governance Officer.

The Research Governance Officer has the discretion to request that the application is submitted for site specific assessment if they consider that the project involves the conduct of research at the site.

4.5 Review requirements

Research Governance Officers must review the application and confirm that:

- all relevant information is provided;
- all required supporting documents have been submitted; and
- the research project satisfies conditions (i) and (ii) outlined in section 4.3 of this policy directive.

Research Governance Officers should conduct the review in an efficient and timely manner.

Following review, Research Governance Officers must make a recommendation to the Chief Executive or delegate regarding authorisation of the project.

5 GRANTING AUTHORISATION

5.1 Granting authorisation

Authorisation to commence research at a NSW Public Health Organisation may only be granted by the Chief Executive or their delegate and when the research project complies with minimum governance requirements set out in this policy directive (sections 3.3 and 4.3).

Public Health Organisations may request further information about the proposed project, in addition to that provided in the Site Specific Assessment Form or Access Request Form and supporting documents, to make a decision about authorisation.

The Chief Executive or their delegate may choose not to grant authorisation, even if the project has ethical and scientific approval in line with Policy Directive PD2010_055 *Ethical and scientific review of human research in NSW Public Health Organisations*.

Research projects must not commence at a Public Health Organisation until the applicant has received written notification of authorisation by the Chief Executive or their delegate.

5.1.1 Delegations

Chief Executives of NSW Public Health Organisations must determine the appropriate delegation for authorisation and ensure that this is documented.

Delegations may be granted to one or more individuals within the Public Health Organisation, depending on the type of research activity and associated level of risk to research participants. Responsibility for authorisation, however, must not be delegated to the Public Health Organisation's Human Research Ethics Committee.

For research to be conducted at a Public Health Organisation that involves no more than low risk to participants, and for application for access request, the Chief Executive may delegate the responsibility for authorisation to the Research Governance Officer.

5.1.2 Authorisation by the Chief Health Officer

Where there is a serious threat to public health, the Chief Health Officer may request the Chief Executives of Public Health Organisations to authorise the immediate commencement of relevant research projects at sites under their control. Chief Executives will need to use their best endeavours to accommodate such a request.

Under these circumstances, the Chief Health Officer will determine the process by which the project undergoes appropriate ethical and scientific review.

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