This guideline has been adopted and endorsed by St Vincent’s Health Network, Sydney. This cover sheet identifies variations specific to SVHNS. It is important that you read the cover sheet and the enclosed guideline in their entirety.

1. Scope
This document provides standard operating procedures for Research Governance Officers employed within NSW Public Health Organisations. The standard operating procedures apply to human research taking place within St Vincent’s health Network Sydney and to human research:
- conducted at sites under the control of the St Vincent’s Hospital Research Office; and/or
- involving participants, tissue or data accessed through these organisations.

2. Objective
NSW Public Health Organisations must establish structures and practices consistent with this Guideline in accordance with Policy Directive PD2010_056 Authorisation to commence human research in NSW Public Health Organisations.

3. Definitions related to SVHNS

<table>
<thead>
<tr>
<th>WORD</th>
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<td>Chief Executive</td>
<td>Chief Executive Officer</td>
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4. Variation in areas of practice

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<tr>
<th>Ministry of Health</th>
<th>SVH / SVHNS</th>
<th>Further comments</th>
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| Clause 4.1         | Insert after “delegate” : Site Specific Assessments are required to be submitted to the St Vincent’s Hospital Research Governance Officer for the following sites:  
- St Vincent’s Public Hospital Sydney  
- St Joseph’s Hospital  
- St Vincent’s Private Hospital |
5. **Mission Fit & Strategic Fit**

SVHNS is a mission based organisation. SVHNS ensures that committee establishments and processes are provided in accordance with the Mission and Values of St Vincent’s Health Australia (SVHA) as well as the frameworks of the Mary Aikenhead Ministries, Catholic teachings, the Code of Ethical Standards for Catholic Health and Aged Care Services in Australia and the NSW Ministry of Health.

6. **Compliance in SVHNS**

Compliance will be monitored by the St Vincent’s Hospital Director of Research and St Vincent’s Hospital Research Office Manager. The Chief Executive Officer is provided with monthly site approval activity reports and with the Research Office Annual Report. Compliance will also be monitored by the NSW Ministry of Health Office of Health and Medical Research.

7. **References**

- Catholic Health Australia: Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (2001)
- Policy Directive PD2011_028: Clinical Trial Research Agreements for Public Health Organisations
- NSW Health Policy Directive PD2011_006: Clinical Trials – Insurance and Indemnity
- SVH Intellectual Property Policy
Operations Manual: Research Governance Officers

Summary  This Guideline contains standard operating procedures to promote standard processes for the administration of applications for site authorisation and management of authorised projects across NSW Public Health Organisations.

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File number  10/3562
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Status  Review
Functional group  Clinical/Patient Services - Research, Governance and Service Delivery
Applies to  Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Affiliated Health Organisations - Declared, Public Health Units, Public Hospitals
Distributed to  Public Health System, NSW Ambulance Service, Ministry of Health
Audience  Research office staff

Secretary, NSW Health
This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is mandatory for NSW Health and is a condition of subsidy for public health organisations.
OPERATIONS MANUAL: RESEARCH GOVERNANCE OFFICERS

PURPOSE
This document provides standard operating procedures for Research Governance Officers employed within NSW Public Health Organisations.

KEY PRINCIPLES
The standard operating procedures contained in this Guideline have been developed to promote standard processes for the administration of applications for site authorisation and management of authorised research projects across NSW Public Health Organisations.

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

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

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

USE OF THE GUIDELINE
NSW Public Health Organisations must establish structures and practices consistent with this Guideline in accordance with Policy Directive PD2010_056 Authorisation to commence human research in NSW Public Health Organisations.

REVISION HISTORY

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<tr>
<th>Version</th>
<th>Approved by</th>
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<tr>
<td>September 2010</td>
<td>Deputy Director-General Population</td>
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<tr>
<td>(GL2010_015)</td>
<td>Health</td>
<td>New Guideline</td>
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BACKGROUND

1.1 About this document

This document provides standard operating procedures for Research Governance Officers employed within NSW Public Health Organisations. The standard operating procedures contained in this Guideline have been developed to promote standard processes for the administration of applications for site authorisation and management of authorised research projects across NSW Public Health Organisations.

1.2 Scope

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

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

1.3 Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>AU RED</td>
<td>Australian Research Ethics Database</td>
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<tr>
<td>CTN</td>
<td>Clinical Trial Notification</td>
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<tr>
<td>CTX</td>
<td>Clinical Trial Exemption</td>
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<td>HREC</td>
<td>Human Research Ethics Committee</td>
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<td>ICH-GCP</td>
<td>International Conference on Harmonisation – Good Clinical Practice</td>
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<td>RGO</td>
<td>Research Governance Officer</td>
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<tr>
<td>SAE</td>
<td>Serious adverse event</td>
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<td>SOP</td>
<td>Standard Operating Procedure</td>
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<td>SSA</td>
<td>Site Specific Assessment</td>
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<tr>
<td>SUSAR</td>
<td>Suspected unexpected serious adverse reaction</td>
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<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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1.4 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.

**Adverse event**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Lead HREC** is a local HREC accredited by the Director-General of the NSW Department of Health to conduct ethical and scientific review of human research on behalf of the NSW public health system in the categories of: (a) clinical trials/interventional clinical research; and/or (b) general research.
Local HREC is a NSW Health HREC established by a Public Health Organisation to provide ethical and scientific review of human research to be conducted at sites under its control.

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

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

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

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

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

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

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

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

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

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

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

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

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

Reviewing HREC is the HREC which undertook the ethical and scientific review and provided approval for the research project.
Serious adverse event (SAE):
For medicines, also referred to as serious adverse drug reaction, is any untoward medical occurrence that at any dose:

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

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

For devices is any adverse medical occurrence that:

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

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

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

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

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

Site authorisation is the authorisation granted by the Chief Executive or delegate of the Public Health Organisation for the commencement of a research project.
Site-specific assessment is a mechanism used by Public Health Organisations to ensure that the proposed research project complies with minimum governance requirements, and to consider whether the research should be conducted and supported at the proposed site.

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

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

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

RGO 001: Research Governance Officer functions

1.1. Each NSW Public Health Organisation will assign at least one Research Governance Officer and inform the NSW Department of Health of their name and contact details.

1.2. The name and contact details of each Research Governance Officer and the facilities, locations and services covered by them will be made publicly available on the Public Health Organisation and Department of Health websites.

1.3. The Research Governance Officer will have reporting lines to the Public Health Organisation’s Director of Research (or equivalent) or other suitable senior officer(s).

1.4. Responsibilities of Research Governance Officers will include, but not be limited to, the following:

**Pre-authorisation**

a) Advising and liaising with investigators, sponsors and other stakeholders regarding the preparation of applications for site authorisation.

b) Managing the process of site authorisation.

c) Assessing applications for site authorisation.

d) Ensuring collection of appropriate fees for site authorisation.

**Post-authorisation**

a) Managing and reviewing amendments to authorised research projects.

b) Having an oversight of authorised research projects through review of annual and final site progress reports submitted by the Principal Investigator.

c) Managing complaints related to the conduct of authorised research projects.

d) Conducting or co-ordinating audits of research projects, where required.

**Other**

a) Preparing reports to regulatory bodies, as required.

b) Communicating with a wide range of stakeholders in the research community by providing information, education and high level advice on research governance.

c) Managing support personnel and participating in all aspects of their recruitment, selection, induction, continued mentoring, performance management and the assessment of educational opportunities.

d) Maintaining records, including databases and filing systems.

e) Developing and maintaining web-based information for investigators.

f) Monitoring relevant regulatory and policy developments to ensure changes are incorporated into local policies and procedures.

g) Participating in the development and implementation of best practice policy, procedures, and standardised systems within the Public Health Organisation and the NSW public health system.
1.5. The Research Governance Officer will delegate tasks as appropriate.

1.6. An orientation package, developed by the Public Health Organisation, will be provided to new Research Governance Officers. A template will be available from the Department of Health.

1.7. Research Governance Officers will be encouraged to attend workshops, seminars and conferences related to their role. Examples include roundtable forums hosted by the Department of Health and training in the use of AU RED.
RGO 002: Australian Research Ethics Database (AU RED)

2.1. The Australian Research Ethics Database (AU RED) is an online research application tracking and management system. AU RED is accessed from the website: https://www.ethicsdatabase.org/au

2.2. Research Governance Officers will use 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.

2.3. From 01 January 2011, Research Governance Officers will 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.

2.4. AU RED will be used by the Department of Health to monitor aspects of performance, including timelines for site authorisation.

Users

2.5. Public Health Organisations will nominate prospective AU RED users to the Department of Health for authorisation and the issuing of user accounts.

2.6. Registered users of AU RED will sign a confidentiality undertaking (issued by the Department of Health) indicating that they will use the information contained in the system in a confidential manner.

Assistance

2.7. Instructions on how to use AU RED will be available from a user manual, available from the website: https://www.ethicsdatabase.org/au

2.8. A helpdesk will be available to provide technical support for AU RED users between the hours of 10:00 and 16:00 AEST, Monday to Friday:

   Phone: (02) 9037 8404 | Email: helpdesk@infonetica.net
RGO 003: Submission of new applications

3.1. In accordance with Policy Directive 2010_056 *Authorisation to commence human research in NSW Public Health Organisations*, human research projects will not commence at a Public Health Organisation until the investigator has received written notification of authorisation by the Chief Executive or their delegate.

3.2. All applications for site authorisation will be submitted to the Research Governance Officer using one of the following forms:

   a) The NSW Health Site Specific Assessment Form, for research projects that have been submitted for full HREC review; or

   b) 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; or

   c) Access Request Form.

3.3. The forms will be completed via the Online Forms Website: [https://ethicsform.org/au/](https://ethicsform.org/au/)

3.4. Investigators will create an account to access the Online Forms Website to generate an application.

3.5. The Online Forms Website provides guidance on how to complete the forms and on supporting documents required for making an application.


3.7. Each Public Health Organisation will determine and make publicly available the format (electronic or hardcopy) and the number of copies required for applications for site authorisation.

3.8. Each Public Health Organisation will determine whether electronic signatures on the application form are acceptable.

3.9. A helpdesk will be available to provide technical support for Online Forms users between the hours of 10:00 and 16:00 AEST Monday to Friday.

   Phone: (02) 9037 8404 | Email: helpdesk@inforentica.net

3.10. Investigators will be able to access additional information by contacting the Research, Ethics and Public Health Training Branch:

   Phone: (02) 9391 9427 | Email: healthethics@doh.health.nsw.gov.au
RGO 004: Site specific assessment

4.1. Research projects to be conducted at sites under the control of NSW Public Health Organisations will undergo site specific assessment before authorisation can be granted by the Chief Executive or their delegate.

4.2. Site specific assessment will be required if the project involves one or more of the following activities at a site under the control of a Public Health Organisation.

   a) enrolling participants into research (e.g. obtaining informed consent, screening);
   b) carrying out protocol-specific research procedures with or on participants; and
   c) managing and analysing data, tissue, and responses from surveys and questionnaires collected for or from research.

4.3. Site specific assessment is a separate process to ethical and scientific review of a research project. Research Governance Officers conducting site specific assessment will not undertake ethical and scientific review of the proposed project and associated documents to be used for research.

Application

4.4. The Principal Investigator will make an application for site specific assessment using one of the following forms, available through the Online Forms Website at https://ethicsform.org/au:

   a) The NSW Health Site Specific Assessment Form, for research projects that have been submitted for full HREC review.
   b) 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.

4.5. For a multi-centre study, the Co-ordinating Investigator will generate forms for completion by the Principal Investigators. For a single centre study, the Co-ordinating Investigator and Principal Investigator will be the same person.

4.6. The completed Site Specific Assessment Form and supporting documents will be submitted to the Research Governance Officer responsible for the site.

4.7. A separate application will 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 will be made for each site.

4.8. Investigators will not need to wait for the outcome of ethical and scientific review of the research project before preparing an application for site authorisation. If the project is a clinical trial, investigators will be encouraged to submit documentation on insurance and indemnity arrangements and a copy of the clinical trial agreement at the earliest possible opportunity.

4.9. Upon receipt, the application will be date stamped (date received) and acknowledged by letter or e-mail by the Research Governance Officer.
Assessment

4.10. The Research Governance Officer will assess the submitted Site Specific Assessment Form or Site Specific Assessment Form for Low and Negligible Risk Research to confirm that:

a) all relevant questions on the application form have been completed;
b) all required supporting documents have been submitted;
c) the research project meets the following conditions:
   i. any legislative requirements, including notification, registration and licence application requirements have been addressed;
   ii. adequate indemnity and insurance arrangements are in place for clinical trials;
   iii. 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;
   iv. 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); and
   v. there is ethical and scientific approval for the project and research documents, in line with Policy Directive 2010_055 Ethical and scientific review of human research in NSW Public Health Organisations.

d) 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.

4.11. The Research Governance Officer will 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.

4.12. The Research Governance Officer will, at their discretion, discuss aspects of the application with relevant personnel from the Public Health Organisation and the reviewing HREC.

4.13. Following assessment, the Research Governance Officer will make a recommendation to the Chief Executive or delegate regarding authorisation of the project and indicate whether authorisation:

a) is recommended;
b) is not recommended; or

c) requires consideration by the Chief Executive or delegate.
4.14. The Research Governance Officer will provide reasons for their decision if authorisation is not recommended or requires consideration by the Chief Executive or delegate. Any project monitoring by the site, requested by the reviewing HREC, will be highlighted.

4.15. The completed form will be submitted to the Chief Executive or delegate with a copy of the HREC approval letter and any document requiring the signature of the Chief Executive or delegate.
RGO 005: Access request review

5.1. 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 will not be required to undergo site specific assessment.

5.2. However, the Co-ordinating Investigator will be required to submit an access request to the Public Health Organisation for review before authorisation can be granted by the Chief Executive or their delegate.

5.3. Access request review will be required when the project involves one or more of the following at the Public Health Organisation:
   a) Participant recruitment through posters, leaflets, handouts, and letter of invitation but not recruitment through direct contact with potential participants or enrolment;
   b) 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
   c) Access to data or tissue held at the Public Health Organisation but not processing or analysis at that Public Health Organisation.

Application

5.4. The Co-ordinating Investigator will make an application for access request review using the Access Request Form available from the Online Forms Website at https://ethicsform.org/au/.

5.5. The completed Access Request Form and supporting documents will be submitted to the Research Governance Officer responsible for the relevant facility, location or service.

5.6. Only one access request per Research Governance Officer will be 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.

5.7. Upon receipt, the application will be date stamped (date received) and acknowledged by letter or e-mail by the Research Governance Officer.

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

Review

5.9. The Research Governance Officer will review the submitted Access Request Form to confirm that:
   a) all relevant information is provided;
   b) all required supporting documents have been submitted; and
   c) 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 2010_055 Ethical and scientific review of human research in NSW Public Health Organisations; and

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

5.10. The Research Governance Officer will conduct the review in an efficient and timely manner.

5.11. The Research Governance Officer will, at their discretion, discuss aspects of the application with relevant personnel from the Public Health Organisation and the reviewing HREC.

5.12. Following review, the Research Governance Officer will make a recommendation to the Chief Executive or delegate regarding authorisation of the project, unless they are delegated to provide site authorisation for research projects requesting access only, and indicate whether authorisation:

   a) is recommended;
   b) is not recommended; or
   c) requires consideration by the Chief Executive or delegate.

5.13. The Research Governance Officer will provide reasons for their decision if authorisation is not recommended or requires consideration by the Chief Executive or delegate.
RGO 006: Withdrawal of applications

6.1. The investigator will be able to withdraw an application for site authorisation at any time prior to receipt of Chief Executive or delegate authorisation.

6.2. Requests will be made in writing to the Research Governance Officer, who will acknowledge the request in writing.
RGO 007: Notification of site authorisation

7.1. The Research Governance Officer will provide written notification of the outcome of the application for site authorisation.

7.2. The letter will include the version number and date of research project documents, authorised for use at the site and will be accompanied by any documents, such as a clinical trial agreement, which require the signature of the Chief Executive or delegate.

7.3. When authorisation is not granted, reasons will be provided to the investigator.
RGO 008: Amendments to authorised research projects

8.1. The investigator who has been granted site authorisation will notify any amendments to the authorised research project to the Research Governance Officer.

8.2. For research conducted at a site under the control of a NSW Public Health Organisation, this will be the Principal Investigator. 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, this will be the Co-ordinating Investigator.

Amendments that require approval from the reviewing HREC

8.3. Amendments to an authorised research project, which affect the research project’s ethical and scientific acceptability and are submitted to the reviewing HREC for consideration, will be notified to the Research Governance Officer.

8.4. A copy of the letter from the reviewing HREC approving the amendments to the project and any associated documents will be submitted to the Research Governance Officer, who will acknowledge its submission.

8.5. Where amendments are made to documents to be distributed at the Public Health Organisation, the updated HREC approved documents will be submitted to the Research Governance Officer.

8.6. Where amendments affect the Participant Information Sheet and Consent Form of a multi-centre study, the investigator will submit the amended master version as well as the amended site version to the Research Governance Officer.

8.7. The Research Governance Officer will provide authorisation to implement the changes in writing.

Amendments that alter authorised research taking place at the Public Health Organisation

8.8. Amendments that alter authorised research taking place at the Public Health Organisation will be submitted to the Research Governance Officer for review. These include but are not limited to amendments to:

   a) research protocol, with amendments that affect the ethical and scientific acceptability of research having been approved by the reviewing HREC;

   b) research project budget, having been approved by the relevant heads of departments (or divisional directors or other authority) responsible for the site where the research project is being conducted;

   c) indemnity and insurance offered to the site;

   d) research project personnel;

   e) clinical trial agreement executed between the sponsor and the site; and

   f) CTN/CTX form.

8.9. The Research Governance Officer will determine whether the amendment significantly affects the use of site facilities, resources or staff, and whether the
Chief Executive or delegate authorisation is required for the change to be implemented.

8.10. The Research Governance Officer will provide authorisation to implement the changes in writing.
RGO 009: Urgent safety-related measures

9.1. Where it is necessary to eliminate an immediate hazard to research participants, modifications or changes to the research project will be implemented without prior HREC review and site authorisation.

9.2. The Co-ordinating Investigator will notify the HREC and Research Governance Officer of amendments arising from urgent safety-related events immediately and in writing (email is acceptable). The Co-ordinating Investigator will submit the implemented modification or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) to the HREC for review within 5 working days and the Principal Investigator will advise the Research Governance Officer of developments.

9.3. Reports of urgent safety-related measures are in addition to adverse event reporting requirements.
RGO 010: Adverse event reporting

Clinical trials involving therapeutic products

10.1. For clinical trials involving therapeutic products, adverse event reporting will meet the requirements of the National Health and Medical Research Council, Australian Health Ethics Committee (AHEC) Position Statement “Monitoring and reporting of safety for clinical trials involving therapeutic products” (May 2009), which can be found at: http://www.nhmrc.gov.au/health_ethics/hreces/reference/_files/090609_nhmrc_position_statement.pdf

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

10.3. For single centre research projects, the Co-ordinating Investigator will provide these safety reports to the reviewing HREC.

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

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

Other human research

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

10.7. Depending on the complexity, design and risk perceived, the Public Health Organisation has the discretion to require that additional information be reported.
### Table 1: Safety reporting to the reviewing NSW Health HREC: for clinical trials involving therapeutic products.

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Items to be reported to HREC</th>
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| In a prompt manner    | • Serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs), with comment from the Co-ordinating Investigator.  
                        |   o Only from sites for which the HREC has given ethical and scientific approval.  
                        |   o Reporting within 72 hours of the event occurring, unless the Co-ordinating Investigator considers immediate notification is required.  
                        |   o Where there is only a local Data and Safety Monitoring Board for the project (e.g. investigator-initiated trial), notification within 24 hours of the event occurring.  
                        |   (For multi-centre research projects the Principal Investigator, rather than the Co-ordinating Investigator, provides the above report.)  
                        |   • Information which materially impacts the continued ethical acceptability of the trial.  
                        |   • Information that requires, or indicates the need for, a change to the trial protocol, including changed safety monitoring in the view of the Co-ordinating Investigator or sponsor. |
| At least 6-monthly    | • Listing of all suspected unexpected serious adverse reactions, Australian and international, occurring with a compound or device including sponsor and Co-ordinating Investigator comment as to whether action is planned for the trial on the basis of the reports.  
                        |   (European Union format is acceptable.)                                                                                                   |
| At least annually     | • An updated Investigator Brochure (IB), or  
                        |   • A European Union Annual Safety Report (EU ASR) or similar format report, or  
                        |   • Current, approved product information (PI), if appropriate (e.g. in a study for a product approved in Australia or where an Investigator Brochure is no longer maintained).  
                        |   • Include sponsor and Co-ordinating Investigator comment as to whether action is planned for the trial on the basis of the report.  
                        |   • For trials that are investigator or collaborative group sponsored in which an IB, EU ASR or PI is not available, then a trial update may be submitted that provides appropriate review of safety information in the previous 12 months  
                        |   • Include Co-ordinating Investigator’s own opinion in regard to potential impact on ethical acceptability and need for action.  
                        |   • Other reports consistent with section 5.5.5 of the National Statement and Good Clinical Practice adopted by the Therapeutic Goods Administration. |
Notification of HREC review outcome

10.8. The HREC will inform the Co-ordinating Investigator of the outcome of the review within 10 working days of the meeting, unless immediate notification is required for urgent safety reasons.

10.9. For multi-centre research projects, the Co-ordinating Investigator will provide a copy of the HREC review outcome to the Principal Investigators involved in the study. Each Principal Investigator will provide a copy of this HREC review outcome to the site Research Governance Officer.

10.10. The HREC will have the discretion to notify the review outcome directly to the Principal Investigators and Research Governance Officers for safety reasons, in which case the Co-ordinating Investigator will be informed of this action.

Notification within the Public Health Organisation

10.11. Serious adverse events are clinical incidents which will also be managed in accordance with PD2007_061 Incident Management.

10.12. If a serious adverse event is a “Reportable Incident” it requires a root cause analysis in accordance with Division 6C of the Health Administration Act 1982 (NSW).
RGO 011: Monitoring and oversight of authorised research projects

Monitoring

11.1. The HREC will monitor approved research projects to ensure compliance with the conditions of approval and to protect the rights, safety and welfare of participants. This will include review of annual and final progress reports, safety reports and reports of protocol violations.

11.2. Depending on the complexity, design and risk perceived, the HREC has the discretion to recommend in the letter of approval that the site co-ordinates on-site monitoring at recommended intervals or randomly throughout the research project.

11.3. Public Health Organisations will permit and assist with monitoring, audit and inspection by the reviewing HREC, regulatory bodies and where applicable, the clinical trial sponsor.

11.4. Public Health Organisations will have the discretion to conduct on-site monitoring independently of HREC requests, including but not limited to:
   a) audit or inspection of research conduct to see if it is in compliance with:
      - the current version of the approved protocol;
      - conditions of HREC approval, including consent documentation, number of research participants, commencement/completion/withdrawal dates;
      - ICH-GCP; and
      - conditions of site authorisation
   b) audit or inspection of data storage and security; and
   c) interviews (or other forms of feedback) with research participants.

Oversight

11.5. Research Governance Officers will maintain an oversight of authorised research projects through review of annual and final progress reports submitted by the Principal Investigator.

11.6. For single centre projects, Research Governance Officers will work with the HREC to review the annual and final progress reports submitted by the Principal Investigator.

11.7. For multi-centre projects, Research Governance Officers will review annual and final site progress reports submitted by the Principal Investigator. The Principal Investigator will also forward to the Research Governance Officer any recommendations made by the HREC following review of these reports, unless the HREC elects to inform the Research Governance Officer directly.
RGO 012: Appeals on authorisation decisions

12.1. The investigator will be able to seek a review of a decision by the Public Health Organisation not to authorise a research project. The appeal will be made in writing to the Chief Executive. It is a matter for the Chief Executive to determine the management of these appeals.
RGO 013: Complaints about the conduct of an authorised research project

13.1. Each NSW Public Health Organisation will have a written procedure for handling complaints about the conduct of an authorised research project; the procedure will be made publicly available.

13.2. Complaints about the conduct of an authorised research project will be reported to the nominated contact of the reviewing HREC (e.g. Executive Officer) and/or the Public Health Organisation (e.g. Research Governance Officer). The complainant will receive an acknowledgement in writing, where possible.

13.3. Where the complaint is submitted to the Public Health Organisation nominee, they will inform the Executive Officer of the reviewing HREC of the nature of the complaint if it is likely to have implications to the ongoing approval of the project by the reviewing HREC.

13.4. Where the complaint is submitted to the reviewing HREC nominee, they will inform the Research Governance Officer responsible for the site that is the subject of the complaint.

13.5. The Public Health Organisation will investigate the complaint and conduct an audit of the research project if necessary. Where the complaint relates to suspected research misconduct, the matter will be dealt with in accordance with the *Australian Code for the Responsible Conduct for Research* (2007) by the National Health and Medical Research Council, Australian Research Council, and Universities Australia.

13.6. The Public Health Organisation will inform the following parties of the final outcome of any investigation/audit:

   a) the complainant;

   b) the Principal Investigator and/or other investigators to whom the complaint relates; and

   c) the reviewing HREC (if it has been notified of the complaint).
RGO 014: Suspension or withdrawal of site authorisation

14.1. Where the Chief Executive or delegate determines that it is no longer appropriate for the research to take place at the Public Health Organisation, they will have the discretion to suspend or withdraw site authorisation.

14.2. The Research Governance Officer will immediately notify the reviewing HREC and the Principal Investigator to whom the site authorisation was granted. The Research Governance Officer will consult the reviewing HREC to ensure the safety and welfare of research participants are not compromised by the suspension or withdrawal of site authorisation. The agreed course of action will be documented and forwarded to the reviewing HREC and Principal Investigator within 3 working days.

14.3. The Principal Investigator will not continue with the research if the Chief Executive or delegate has suspended or withdrawn site authorisation, other than to ensure the safety and welfare of the research participants.

Lead HREC rejection of research previously approved by a local HREC

14.4. A single centre research project will be reviewed by a lead HREC in order to become a multi-centre project. If the HREC which approved the original research application is not a lead HREC, a new application will be submitted to a lead HREC.

14.5. Where a research project previously approved by a local HREC is rejected by a lead HREC, the following will occur:

   a) The Research Governance Officer at the existing site will be notified of the decision of the lead HREC by the Principal Investigator.

   b) The Research Governance Officer will inform the Chief Executive or delegate that the lead HREC has rejected the application.

   c) The Chief Executive will confer and determine whether the research project requires suspension or withdrawal of previous ethical approval or site authorisation, or both. The Principal Investigator may appeal the final decision.
RGO 015: Discontinuation of authorised research project by the investigator or sponsor

15.1. The Principal Investigator will inform the Research Governance Officer of a research project which is:
   a) abandoned – has never commenced;
   b) prematurely terminated – commenced at the site but terminated on ethical, safety, financial or other grounds; or
   c) suspended – commenced at the site but temporarily stopped for any reason. The suspension applies to certain aspects of the project such as recruitment or the entire project.

15.2. Where the research project is prematurely terminated or suspended the Principal Investigator will notify the research participants in writing.

15.3. Where the project is abandoned, prematurely terminated or suspended by the Principal Investigator, they will inform the Co-ordinating Investigator who will promptly inform the reviewing HREC.

15.4. The Principal Investigator will demonstrate that the issues relating to suspension have been adequately addressed, and have obtained approval from the reviewing HREC and authorisation from the site before recommencing the suspended procedure.
RGO 016: Storage and retention of site authorisation records

16.1. All documentation relating to site authorisation (including the letter from the approving HREC, final research protocol, copy of the signed CTN/CTX form, clinical trial agreement, and documentation relating to amendments to authorised research projects) will be kept on file in a secure and confidential manner by the Research Governance Officer.

16.2. Site authorisation records will be kept as confidential files in accordance with the State Records Act 1998. The following documents issued by the State Record Authority of NSW, which regulates record keeping in NSW Health, contain a section on research management:

- General Retention and Disposal Authority: Public Health Services: Patient/Client Records (GDA17)
- General Retention and Disposal Authority: Public Health Services: Administrative Records (GDA 21).

16.3. Documents provided for site authorisation which are no longer required will be disposed of in a secure manner.
RGO 017: Payment of fees

17.1. Applications for site authorisation using the Site Specific Assessment Form will be subject to a fee.

17.2. The fees structure is outlined in the PD2008_030 HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research.

17.3. The Principal Investigator will provide the Research Governance Officer with details of the organisation to which the invoice will be sent.

17.4. The Public Health Organisation will determine whether the invoices will be paid at the time of application.

17.5. The Public Health Organisation will determine whether to withhold a letter of authorisation until the fee is received.
Appendix A: Summary of routes of obtaining Human Research Ethics Committee (HREC) approval and site authorisation for research taking place in NSW Public Health Organisations

**Research Involving More Than Low Risk**

Research in which the risk to participants is more serious than discomfort (as described in the National Statement)

- Full HREC review using the National Ethics Application Form (NEAF)
- Site authorisation using the Site Specific Assessment (SSA) Form
- Site authorisation using the Access Request Form
- HREC approval
- Chief Executive/delegate authorisation
- Project commencement

**Low and Negligible Risk Research**

Research in which the risk to participants is no more than discomfort or inconvenience (as described in the National Statement)

- Expedited HREC review using the Application Form for review of Low and Negligible Risk Research
- Site authorisation using the Site Specific Assessment (SSA) Form for Low and Negligible Risk Research
- Site authorisation using the Access Request Form
- HREC approval
- Chief Executive/delegate authorisation
- Project commencement