

## Research - Authorisation of proposals to conduct research on humans within NSW public health system

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**Functional Sub group** Clinical/ Patient Services - Research

**Summary** All research projects involving humans must be authorised by the Chief Executive or their delegate before they may commence at a Public Health Organisation. This Policy Directive sets out the mechanism to be used by Public Health Organisations to authorise the commencement of human research projects within sites under their control.

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

**Audience** Human Research Ethics Committees, Researchers

**Distributed to** Public Health System, NSW Ambulance Service, NSW Department of Health, Public Health Units, Public Hospitals

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### Director-General

This Policy Directive may be varied, withdrawn or replaced at any time.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.

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**AUTHORISATION OF PROPOSALS TO CONDUCT RESEARCH  
ON HUMANS WITHIN THE NSW PUBLIC HEALTH SYSTEM**

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## 1. INTRODUCTION

### 1.1 Purpose

All research projects involving humans must be authorised by the Chief Executive or their delegate before they may commence at a Public Health Organisation. This Policy Directive sets out the mechanism to be used by Public Health Organisations to authorise the commencement of human research projects within sites under their control.

**Compliance with this policy is mandatory.**

### 1.2 Summary

This Policy Directive requires that, before commencement at a Public Health Organisation, a human research project must have:

- been ethically and scientifically reviewed and approved in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research, 2007* (the National Statement); and
- completed a site-specific assessment.

When the Chief Executive or their delegate has sighted the ethical approval and considered the site-specific assessment, he/she may authorise the commencement of the research project.

### 1.3 Background

All research involving humans must be ethically and scientifically reviewed and approved in accordance with the National Statement. Public Health Organisations are responsible for ensuring that research to be conducted within sites under their control, are reviewed for their ethical and scientific acceptability, in accordance with the National Statement and Departmental policy.

Ethical approval may be granted by the Public Health Organisation's own local HREC (for single-site research) or by a lead HREC (including its own local HREC if it is a lead HREC) for multi-centre research.

Ethical approval alone, however, is not sufficient for a Public Health Organisation to allow a human research project to commence at a site under its control. Public Health Organisations must also ensure that the research project meets its research governance requirements. Such research governance requirements might include:

- Whether the use of its resources (such as facilities, staff and equipment) are appropriate;
- Whether the project adheres to its site-specific policies (such as sign-offs from appropriate Heads of Department);
- Whether the researchers involved in the project have the relevant training, expertise and experience; and

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- Whether the project adheres to any other administrative requirements (such as evidence of adequate insurance and indemnity).

These research governance matters are generally site-specific and must therefore be considered for each research project and for each site at which the project is to be conducted. This review or 'site-specific assessment' must be undertaken before the project can be granted authorisation to commence at a site. This is the responsibility of the Public Health Organisation, not its HREC, as the site-specific assessment has a different purpose to, and is separate from, the review undertaken by an HREC.

## 1.4 Scope

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

- the mechanism to be used by a Public Health Organisation for undertaking a site specific assessment of proposals to conduct research within sites under its control;
- the requirement that Public Health Organisations have a Research Governance Officer;
- the requirement that proposals to conduct research within sites under the control of a Public Health Organisation, are granted authorisation to do so by the Chief Executive or delegate.

For the purposes of this Policy Directive, 'human research' has the meaning given in the NHMRC's *National Statement on Ethical Conduct in Human Research* (2007).

## 1.5 Implementation

This policy takes effect from **1 July 2007**. Public Health Organisations must implement the site-specific assessment of proposals to conduct research on humans in accordance with this Policy Directive from 1 July 2007.

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

## 2 AUTHORISATION OF PROPOSALS TO CONDUCT RESEARCH ON HUMANS WITHIN THE NSW PUBLIC HEALTH SYSTEM

### 2.1 Site Specific Assessment

2.1.1 The site specific assessment is the mechanism used by Public Health Organisations to assess the suitability of a human research project to be conducted at a site/s under its control, whether that project is multi-centre or single-site. The site specific assessment is a separate process to the ethical and scientific review undertaken by an ethical review body (such as a Human Research Ethics Committee (HREC)). It does not involve

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consideration of the research project by the Public Health Organisation's HREC.

2.1.2 All proposals to conduct research on humans within a site under the control of a Public Health Organisation, must undergo a site-specific assessment by that Public Health Organisation before the project can be granted authorisation to commence at the site.

2.1.3 Applications for site specific assessment must be made on the standard Site Specific Assessment Form (the Form), appended at Appendix A. The Form sets out the minimum amount of information necessary for a Public Health Organisation to determine whether to allow the project to commence at sites under its control. The Form enables Public Health Organisations to consider:

- Whether the facilities and resources required for the research to proceed at the site have been identified, are appropriate and available.
- Whether the researchers involved in the project at the site have the necessary skills, experience, training and expertise to carry out their role in the research project.
- Whether, in all the circumstances, the Public Health Organisation wishes the research to be conducted at its site.

Public Health Organisations may request additional information about the research project, as is deemed necessary.

2.1.4 Public Health Organisations must only accept applications for site specific assessment which are submitted on the Form. The Form may be amended by the Department from time to time. A Public Health Organisation may make additions to the Form to encompass specific local issues, however questions may not be deleted from the Form. The Site Specific Assessment Form can be accessed from:

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

2.1.5 Applications for site specific assessment should be made by the principal investigator responsible for the research project at the site. For multi-centre research projects where there is not a principal investigator located at each site, the Form may be completed and submitted by a co-ordinating investigator.

2.1.6 The principal investigator is responsible for ensuring all sections of the Form are completed correctly, including the checklist, and that all requested supporting documentation is provided, including relevant signatures. Once completed, the Form should be submitted to the Research Governance Officer at the site.

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- 2.1.7 It is a matter for each Public Health Organisation to determine the sites under their control which require separate site specific assessment of research projects. For example, a site may be a single public hospital, a collection of public hospitals within a defined area, or an entire Area Health Service. When making this determination, Public Health Organisations will need to consider whether separate institutional approval is required for the use of facilities, staff and resources. The sites within the Public Health Organisation which require separate site-specific assessment should be made publicly available on its website.
- 2.1.8 A separate Form must be completed and submitted for each separate research project and for each site requiring separate site-specific assessment.
- 2.1.9 Where the principal investigator decides not to proceed with conducting the research project at the site, the Form should be withdrawn (this may be via email). Requests to withdraw the research project from site-specific assessment, must be made in writing to the relevant Research Governance Officer.
- 2.1.10 Site-specific assessments should, where possible, be conducted in an efficient and timely manner.
- 2.1.11 All documentation relating to the site-specific assessment for each research project must be kept on file in a secure and confidential manner by the relevant Public Health Organisation.

## **2.2 Research Governance Officer**

- 2.2.1 The Research Governance Officer is the person/s responsible within a Public Health Organisation for reviewing the Site Specific Assessment Form and making a recommendation to the Chief Executive/delegate as to whether or not the research project should proceed at that site. All Public Health Organisations must have an identified Research Governance Officer/s. The duties of the Research Governance Officer may be attributed to an already existing position within the Public Health Organisation.
- 2.2.2 The Research Governance Officer should generally have reporting lines to the Public Health Organisation's Director of Research or equivalent. Public Health Organisations may appoint more than one officer to fulfil this role.
- 2.2.3 The Research Governance Officer will check all applications for site specific assessment to determine whether the application is valid. A valid application is one which has been submitted on the standard Site Specific Assessment Form and is deemed to be complete by the Research

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Governance Officer (including the provision of all relevant signatures and supporting documentation). Invalid applications should not be accepted and the investigator should be requested to supply the missing documentation.

2.2.4 The Research Governance Officer will make one of the following recommendations for all valid applications for site-specific assessment:

- The research project should be authorised by the Chief Executive/delegate;
- The research project should not be authorised by the Chief Executive/delegate (with reasons); or
- The research project requires Chief Executive/delegate consideration (with reasons).

In providing this recommendation, advice may be sought from other Public Health Organisation personnel as is deemed necessary (for example, the Research Governance Officer may request advice from risk management officers in relation to insurance and indemnity issues).

2.2.5 The recommendation made by the Research Governance Officer (section (e) of the Standard Site Specific Assessment Form) should be submitted to the Chief Executive/delegate, along with the Form and a copy of the HREC approval letter.

2.2.3 Research Governance Officers will have access to the Research Ethics Database (RED): a web-based research application tracking and management tool. Research Governance Officers must use RED for the management of multi-centre research projects submitted for site-specific assessment, including the recording of decisions taken by the Chief Executive/delegate to grant/not grant authorisation.

2.2.4 Research Governance Officers must use RED for the management of single-site commercially sponsored research projects submitted for site-specific assessment. Research Governance Officers may choose to also use RED for the management of all other single-site research applications submitted for site-specific assessment (this will only be possible however, in circumstances where the HREC has also chosen to use RED for the management of the corresponding single-site HREC application).

## **2.3 Authorisation of a research project**

2.3.1 Authorisation of a research project is the approval granted by the Chief Executive or their delegate for a research project to commence at a site. Only the Chief Executive or their delegate has the authority to grant/not grant authorisation for a research project to commence within, or in association with, their health facilities.

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- 2.3.2 It is a matter for the Public Health Organisation's Chief Executive to determine the appropriate delegation/s for authorising the commencement of research activities. Delegations may be granted to one or more officers within the Public Health Organisation, depending on the type of research activity and associated level of risk to research participants. For example, responsibility to grant/not grant authorisation of low risk research may be delegated to a General Manager/Executive Officer or appropriately senior officer within the facility.
- 2.3.3 Responsibility to grant/not grant authorisation for the commencement of research activities, cannot be delegated to the Public Health Organisation's HREC.
- 2.3.4 Public Health Organisations must document the appropriate delegation/s for authorisation of the commencement of research activities.
- 2.3.5 Authorisation to commence a research project may only be granted by the Chief Executive or delegate when a site-specific assessment is satisfactorily completed and the research project has been granted ethical approval. A research project cannot commence at a site until it has received ethical approval and authorisation from the Chief Executive or delegate.
- 2.3.6 The Chief Executive or their delegate may choose to not grant authorisation for a research project, notwithstanding that ethical approval has been granted. However, a Chief Executive or their delegate cannot grant authorisation for a research project that has not received ethical approval.
- 2.3.7 The Chief Executive or delegate, upon making its decision, should sign section (f) of the Form ("Authorisation by Chief Executive") and return the Form and any other accompanying documentation to the Research Governance Officer. The Research Governance Officer will notify the principal investigator of the outcome of the Chief Executive/delegate's decision.
- Only when the principal investigator has been notified in writing of the decision by the Chief Executive/delegate to authorise the research project, can the project commence at that site.
- 2.3.8 Public Health Organisations should establish a procedure for the handling of complaints concerning a decision to not grant authorisation for a research project to commence.

## **2.4 Interaction between the site specific assessment and the ethical review**

2.4.1 The ethical/scientific review and site-specific assessment may occur in parallel. However, a Chief Executive or their delegate may only grant authorisation for a research project to commence at a site under its control when the project has been granted ethical approval and the site specific assessment has been completed. The ethical review body reviewing the research project may be the Public Health Organisation's local HREC, or it may be a lead HREC (an HREC accredited by the Department to conduct a single ethical and scientific review of multi-centre research projects).

2.4.2 The reviewing HREC will not be required to review the Site Specific Assessment Form or the recommendation made by a Research Governance Officer, prior to reaching its final ethical opinion. Neither the Research Governance Officer nor the principal investigator will be required to notify the HREC of the outcome of the site specific assessment.

2.4.3 Where the investigator has submitted new or modified documentation to the reviewing HREC for consideration (due to, for example, a request by the HREC), the investigator must also submit this documentation to the Research Governance Officer at the site at which the research is to be conducted.

2.4.4 The Research Governance Officer may discuss aspects of the research project with the HREC. The HREC may discuss aspects of the research project with the Research Governance Officer.

## **2.5 Amendments to an authorised research project**

2.5.1 Requests for amendments to the authorised research project which may affect its ongoing ethical and scientific acceptability, must be submitted to the approving HREC for review. A copy of the request and the outcome of the HREC's review, must also be submitted by the principal investigator to the relevant Research Governance Officer (where the Research Governance Officer and the approving HREC's Executive Officer is one and the same officer within the Public Health Organisation, this requirement is not necessary).

2.5.2 The Research Governance Officer will determine whether or not separate authorisation is required from the site for the amendment request to be implemented. Where the Research Governance Officer has determined that site authorisation is not required (due to the minimal impact of the proposed amendment on the suitability of the research to be conducted at the site), the Research Governance Officer will inform the principal

investigator of this in writing (this may be via email). The principal investigator may then implement the amendment at the site.

Where the Research Governance Officer has determined that authorisation is required (for example, if the amendment is substantial and significantly impacts upon the use of institutional facilities, resources or staff), the Research Governance Officer should forward the request to the Chief Executive or their delegate for consideration as to whether, in all the circumstances, it is reasonable for the amendment to be implemented at the site. The Research Governance Officer will notify the principal investigator as to whether or not authorisation has been granted.

2.5.3 The determination as to whether or not an amendment request necessitates authorisation from the Chief Executive or their delegate, may need to be made by the Public Health Organisation on a per project basis.

2.5.4 If, in the course of reviewing an amendment request, the Research Governance Officer is of the opinion that the amendment may impact upon the ethical and/or scientific acceptability of the project, and a request has not been submitted to the approving HREC, the Research Governance Officer should notify the principal investigator that HREC review of the request may be required before the project can be authorised and implemented at the site.

## 3 ACRONYMS AND DEFINITIONS

### ACRONYMS

**CTN:** Clinical Trial Notification scheme

**CTX:** Clinical Trial Exemption scheme

**HREC:** Human Research Ethics Committee

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

**NHMRC:** National Health and Medical Research Council

**RED:** Research Ethics Database

**TGA:** Therapeutic Goods Administration

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## DEFINITIONS

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

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

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

**Ethical approval:** The decision of an ethical review body to grant ethical approval for the research project, after it has been ethically and scientifically reviewed.

**Ethical review body:** A body established by an institution to review a research project for its ethical acceptability, in accordance with the National Statement. For research involving no more than low risk, this may be a non-HREC level of review. For research involving more than low risk, this must be an HREC constituted in accordance with the National Statement.

**Final ethical opinion:** The decision of an ethical review body established under the National Statement (such as an HREC), to grant/not grant ethical approval for the research project.

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

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

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

**NEAF:** National Ethics Application Form

**On-line Forms Website:** The website which enables researchers to complete the National Ethics Application Form and Site Specific Assessment Form on-line.

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**Research Governance Officer:** The officer/s within a Public Health Organisation who is responsible for reviewing the Site Specific Assessment Form and making a recommendation to the Chief Executive/delegate as to whether a research project should be granted authorisation at that site.

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

**Site:** The location(s) at which study-related activities are conducted.

**Site-specific assessment:** A review undertaken to examine the suitability of a research project to take place at a site within a Public Health Organisation. The Site specific assessment will be undertaken in accordance with the standard Site Specific Assessment Form developed by the Department.

Robert D McGregor AM  
**Acting Director-General**

**Site-Specific Assessment (SSA) Form**

- *This form must be completed by the Principal Investigator responsible for the research project at this site.*
- *The completed form must be forwarded to the site's Research Governance Officer for authorisation and the signature of the Chief Executive/or delegate.*

SSA is a component of research governance and involves assessment of the suitability of the site and the Investigator(s) for the proposed research.

**1. Project details**

HREC Application Reference Number:

Name/ID of HREC reviewing the research project:

Project Title (in full):

**2. Project summary**

Provide a brief description (half page) of the project details to enable the research governance officer to understand the nature and impact of the research project at the research site.

## Site-Specific Assessment (SSA) Form

### 3. Research Personnel (at your site only)

Provide details of researchers' qualifications, expertise/skills and experience in areas related to the research project.

#### Principal Investigator

Title:

First name:

Surname:

Mailing address:

Suburb/Town:

State:

Post code:

Organisation Name:

Position:

Business phone number:

Fax number:

Email address:

Qualifications:

Expertise:

Experience:

Role in research project:

Department:

Is evidence of current Professional Medical Registration attached? Yes  No  N/A

(Not applicable in NSW and Queensland)

Is a *Curriculum Vitae* attached (2 page maximum). Yes  No  N/A

#### Associate Investigator

Title:

First name:

Surname:

Mailing address:

Suburb/Town:

State:

Post code:

Organisation Name:

Position:

Business phone number:

Fax number:

Email address:

Qualifications:

Expertise:

Experience:

Department:

Role in research project:

Is evidence of current Professional Medical Registration attached? Yes  No  N/A

(Not applicable in NSW and Queensland)

Is a *Curriculum Vitae* attached (2 page maximum). Yes  No  N/A

[Copy and paste more boxes as required]

#### Contact person for this research project

Title:

First name:

Surname:

Mailing address:

Suburb/Town:

State:

Post code:

Organisation Name:

Position:  
 Department:  
 Business phone number:  
 Mobile number:  
 Fax number:  
 Email address:

**4. Training**

Will any of the researchers require extra training to enable their participation in this project?

Yes  No

If Yes, list the researchers, describe the training that is required and who will provide this training.

Researcher	Training required	Who will provide training?

*[Insert more rows as required]*

**5. Recruitment of Participants**

What is the proposed number of participants to be recruited at this site?

**6. Participant details**

What categories of people will be recruited? *(e.g. children and young people, people with an intellectual or mental impairment, people highly dependent on medical care, people in dependent or unequal relationships, Aboriginal & Torres Strait Islander people, persons in custody, etc)*

**7. What additional time and resources above their routine duties will be required of the research team throughout the research project?**

Name: Department/location: Additional time spent (hours/week):	
Name: Department/location: Additional time spent (hours/week):	
Name: Department/location: Additional time spent (hours/week):	
Name: Department/location: Additional time spent (hours/week):	

*[Insert more rows as required]*

## 8. Anticipated start and finish dates for the research project?

Start date (dd/mm/yy):  
Finish date (dd/mm/yy):  
Duration (months):

## 9. Departments and services involved in research.

List and specify the departments/locations involved in the research, which are part of this site.

Department/location	Name of responsible person

*Note: A signed declaration from the Head of Department / organisation must be attached (see #14. Declarations).  
[Insert more rows as required]*

## 10. Study budget.

An explanation of how the research project will be funded at the site must be provided to ensure adequate financial arrangements are planned. To assess the financial impact of the research any costs incurred by the organisation should be provided.

Type of funding	Source of funding	Amount (\$/year or \$/participant)
Commercially Sponsored		
Sponsored, other (e.g. collaborative groups)		
External funding (e.g. NHMRC, Foundations, etc)		
Internal/Departmental funding		

*[Give details of the type and name of the funding organisation]*

## Other financial, material and capital support.

Infrastructure charge	
Supply of drug(s)	
Loan of equipment	
Other	

*[Give details of support given]*

**Which organisation will receive and manage this funding and/or will be the Administering Organisation?**

*[Give full address for correspondence]*

Organisation Name: Details of contact person Title: First name: Surname: Position: Department: Mailing address: Suburb/Town: State: Post code: Business phone number: Mobile number: Fax number: Email address: Insert the <u>account number(s)/cost centre details</u> into which funds are to be deposited.  # ..... # .....
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**11. Site-specific policies.**

For organisations that have site specific policies.

*(e.g. Wording related to the use of contraception in participant information and consent documents.)*

***This must not be used by the site to require re-review of the consent documents by the local HREC***

Does the research comply with site-specific policies/requirements?    Yes     No

If no, please give an explanation.

**12. Clinical trials information.**

***If the study is a clinical trial the following sections must be completed.***

Is the research project being conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes?

Yes     No

If yes, attach the relevant TGA Form to this form.

*See Standard Operating Procedures.*

Is the Medicines Australia Standard Indemnity Form(s), signed by the sponsor attached?

Yes     No     N/A

(If no or N/A please give an explanation)

Is evidence of adequate insurance cover attached?

Yes  No  N/A

(If no or N/A please give an explanation)

Is the Medicines Australia Standard Clinical Trial Agreement(s), signed by the sponsor attached?

Yes  No  N/A

(If no or N/A please give an explanation)

### 13. Biosafety, chemical and radiation safety

It may be necessary for research organisations to complete notification, registration or licence requirements for research involving biosafety, regulatory issues and/or radiation. If so, evidence of this is required.

If "yes" is ticked below, appropriate documentation of approval must be attached or forwarded to the site's Research Governance Officer when available.

1. Is Institutional Biosafety Committee (IBC) notification and/or licence application to the Office of the Gene Technology Regulator (OGTR) for approval of genetically modified organisms required? Yes  Attached  No
2. Is committee approval of chemical safety required (drugs/pharmacy committee)? Yes  Attached  No
3. Will the project require NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) assessment? Yes  No
4. Will the project require application for a licence to the NHMRC Licensing Committee to conduct embryo research? Yes  No
5. For projects where Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code compliance is required, is additional State-specific radiation safety approval and registration required? Yes  No

*See Standard Operating Procedures for additional details.*

**14. Declarations**

**(a) Declaration by the Principal Investigator and Associate Investigator(s)**

<p><b>HREC Application Reference number:</b></p> <p><b>Project Title (in full):</b></p> <p><b>Principal Investigator:</b></p>
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1. I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility at this site.
2. I will only start this research project after obtaining authorisation from the site and approval from the responsible Human Research Ethics Committee (HREC);
3. I accept responsibility for the conduct of this research project according to the principles of the NHMRC *National Statement on Ethical Conduct in Human Research*.
4. I undertake to conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved.
5. I undertake to conduct this research in accordance with relevant legislation and regulations.
6. I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC and NHMRC
7. I will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements.
8. I will inform the HREC and the research governance officer if the research project ceases before the expected date. I will discontinue the research if the HREC withdraws ethical approval.
9. I will adhere to the conditions of authorisation stipulated by the authorising authority at the site where I am Principal Investigator. I will discontinue the research if the authorising authority withdraws authorisation at the site where I am Principal Investigator.
10. I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, research governance officer, the sponsor or an independent body for audit and monitoring purposes.
11. I understand that information relating to this research, and about me as a researcher, will be held by the HREC, research governance officer, and on the Research Ethics Database (RED). This information will be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cth) and relevant laws in the States and Territories of Australia.

Signature of Principal Investigator .....

Print name ..... Date .....

Signature of Associate Investigator .....

Print name ..... Date .....

*[Copy and paste more Signatures of Associate Investigator as required]*

**(b) Declaration by Head of Department \*(or Divisional Director or other authority) where the Principal Investigator will do the research.**

<p><b>HREC Application Reference number:</b></p> <p><b>Project Title (in full):</b></p> <p><b>Principal Investigator:</b></p>
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I certify that I have read the research project application named above.

I certify that I have discussed this research project and the resource implications for this Department, with the Principal Investigator.

I certify that all researchers/students from my Department involved in the research project have the skills, training and experience necessary to undertake their role.

I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site.

My signature indicates that I support this research project being carried out using such resources.

Name of Head of Department (or appropriate person): .....

Name of Department (or relevant section): .....

Signature ..... Date .....

Print name .....

\*Where an investigator is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible. Investigators must not approve their own research on behalf of their Department.

**(c) Declaration by Head of Supporting Department**

This form is to be completed by the Head of any Department that is providing support or services to the research project, but which does not have any member(s) on the research team.

<p><b>HREC Application Reference number:</b></p> <p><b>Project Title (in full):</b></p> <p><b>Principal Investigator:</b></p>
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I have discussed this project with the Principal Investigator and have read the research project. I am (*tick whichever applies*)

- able to perform the investigations/services indicated, within the present resources of the Department;
- able to perform the investigations/services indicated, if the following financial assistance is provided:

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- unable to undertake the investigations/services indicated, on the following grounds:

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Name ..... Date .....

Signature .....

Department .....

**(d) Declaration by the Authority for Data Provision**

This form is to be completed by the person authorised to provide data services for research projects.

<b>HREC Application Reference number:</b> <b>Project Title (in full):</b> <b>Principal Investigator:</b>
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I have considered this proposal and consulted the appropriate personnel and I confirm that I have seen all relevant documents that are required. The Department(s) is (*tick whichever applies*):

- able to confirm that the data services indicated will be provided, within the present resources;
- able to confirm that the data services indicated will be provided, if the following financial assistance is provided:

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- unable to provide data services indicated, on the following grounds:

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I certify that I will give due regard to any ethical conditions imposed by the approving HREC when deciding whether, and in what form, I will release data to the investigator.

Name ..... Date .....

Position .....

Signature .....

Department .....

**(e) Recommendation by the Research Governance Office**

<b>HREC Application Reference number:</b>
<b>Project Title (in full):</b>
<b>Principal Investigator:</b>

The Site-Specific Assessment (SSA) form for the above research project has been completed (with all attachments).

- SSA authorisation is:
- Recommended
  - Not recommended
  - Requires Chief Executive/delegate consideration

If not recommended or requires Chief Executive/delegate consideration, give reasons.

--

Research Governance Officer (or equivalent)

Name .....

Signature ..... Date .....

**(f) Authorisation by Chief Executive (or delegate)**

<b>HREC Application Reference number:</b>
<b>Project Title (in full):</b>
<b>Principal Investigator:</b>

This research is:      authorised          not authorised     

Specify, conditions applying to authorisation or reasons for not authorising.

--

My signature indicates that I authorise/ do not authorise this research project to commence at this site.

Signature ..... Date .....

Name of Chief Executive (or delegate): .....

Name of Organisation .....

## Checklist

Please complete the checklist with Yes: No: NA (Not Applicable). Include this checklist with the SSA Form.

<p><b>HREC Application Reference number:</b></p> <p><b>Project Title (in full):</b></p> <p><b>Principal Investigator:</b></p>
---

	Person Completing Form <b>Yes:No:NA</b>	Office Use Only <b>Yes:No:NA</b>
Has a CV been attached for each researcher?		
Have you attached proof of Professional Medical Registration? (NA in NSW and Queensland)		
Has a contact person for this research project been nominated?		
Have you completed all financial details in #10?		

Has a copy of the HREC approval letter been provided?		
Has a copy of the ethics application form been provided?		
Has a copy of the protocol been provided?		
Has a copy of the Investigator's Brochure/drug information/device information been provided?		
Are all Participant Information and Consent Form(s) attached and show the name of the Institution and contact details of the Principal Site Investigator? <u>The version number, standard organisation name and date should be in the footer.</u>		
Has a copy of advertising been provided?		
Has a copy of any questionnaires been provided?		
Has a copy of any other document, which will be given to research participants been provided? Eg: identification card, patient diary		

If a clinical trial, are CTN/CTX forms, <b>signed</b> by the approving HREC and Principal Site Investigator, attached?		
Is the Medicines Australia Standard Indemnity Form, <b>signed</b> by the sponsor, attached?		
Is evidence of adequate insurance cover attached?		
Is the Medicines Australia Standard Clinical Trial Agreement(s), <b>signed</b> by the sponsor, attached?		

Has evidence of Biosafety approval been provided?		
Has committee approval of chemical safety been provided (pharmacy/drug)?		
Has evidence of an application for NHMRC Gene Related Therapies assessment been provided?		

Has evidence of an application for a licence to the NHMRC Licensing Committee, to conduct embryo research, been provided?		
Has evidence of Radiation Safety approval been provided?		
Have you included any other site-specific policy documents required by the Institution(s) at which you intend to conduct your research?		

Is a "Declaration by Principal Investigator" signed and attached?		
Is a "Declaration by Head of Department" signed and attached?		
Is a "Declaration by Head of Supporting Department" signed and attached for each supporting Department (if applicable)?		
Is a "Declaration by the Authority for Data Provision" signed and attached (if applicable)?		
Are all pages (including attachments) numbered and dated in the footer?		

## APPENDIX B

### **Guidance in using the standard Site Specific Assessment Form (SSA Form)**

The following information is intended to provide guidance to researchers in completing the standard Site Specific Assessment Form and to Public Health Organisations in using that Form to assess the suitability of a project to be conducted within institutions under its control.

#### Section 1: Project details

##### *Purpose*

To enable the Research Governance Officer to discuss any aspects of the project with the reviewing HREC should they wish to do so, and to enable the Research Governance Office to register the site-specific assessment in RED.

##### *Specific guidance*

The investigator should list the site to which this site-specific assessment relates. Applications for site-specific assessment must be made for each research project and for each site at which the research is to be conducted.

For investigators using the NSW Health on-line forms website, the HREC Reference Number, HREC ID and Project Title will be automatically populated from NEAF.

#### Section 2: Project summary

##### *Purpose*

To enable the Research Governance Officer to readily ascertain the nature of the research project and its implications for the Public Health Organisation.

##### *Specific guidance*

The answer to question 1.2 from NEAF can be included here (for investigators using the NSW Health on-line forms website, this information will be automatically populated from NEAF).

#### Section 3: Research personnel

##### *Purpose*

To enable the Public Health Organisation to consider whether the researchers involved in the project have the requisite skills, experience, training and expertise to conduct the research project at the site.

##### *Specific guidance*

This section relates to the researchers involved in the project at the site. A current CV (2-page maximum) must be provided for each researcher. If the site already has a copy of the CV on file, you may not need to submit another copy (and the N/A box can be checked), however this should be confirmed with the site. For investigators using the NSW Health on-line forms website, the information pertaining to the Principal Investigator will be automatically populated from NEAF.

#### Section 4: Training

##### *Purpose*

To enable the Public Health Organisation to consider whether extra researcher training is necessary to fulfil their role in the research project.

#### Section 5: Recruitment of participants

##### *Purpose*

To enable the Public Health Organisation to consider whether it has the appropriate resources to cope with the targeted recruitment.

#### Section 6: Participant details

##### *Purpose*

To enable the Public Health Organisation to consider whether research involving the identified participant groups is appropriate at this site. For example, the Public Health Organisation should consider the extent to which the proposed targeted participant group has been involved in other research projects, to ensure there is not an unfair burden of participation in research on that particular group.

#### Section 7: Additional time and resources which will be required of the research team throughout the research project.

##### *Purpose*

To enable the Public Health Organisation to consider whether the additional time spent by its researchers in undertaking the research project at the site, has been identified and is appropriate.

#### Section 8: Anticipated start and finish dates for the research project.

##### *Purpose*

To enable the Public Health Organisation to consider whether the requested use of facilities, staff and resources will be available and whether it is appropriate to allow the research project to commence at this site, given the expected commencement and duration of the research project.

#### Section 9: Departments and services involved in research.

##### *Purpose*

To enable the Public Health Organisation to be aware of the departments and/or locations involved in the research project, which are part of this site.

## Section 10. Study budget.

### *Purpose*

To enable the Public Health Organisation to consider whether a budget for the research to proceed at the site has been identified, is appropriate and available, and whether it will incur any costs associated with the site's participation in the research project. The provision of information regarding the cost centre into which research funds are to be deposited, enables the Public Health Organisation to be assured of the proper financial management of such funds.

## Section 11. Site-specific policies.

### *Purpose*

To enable those sites which have documented site-specific policies which researchers must comply with, to ensure that such site-specific requirements are met.

### *Specific guidance*

This section enables the Public Health Organisation to ensure that any policies or requirements specific to this site, are met. For example, a 3<sup>rd</sup> schedule hospital may require specific wording to be used in informed consent documents regarding the use of contraception. This section must not be used by the Public Health Organisation to require re-review of the research project or informed consent documents by an HREC.

## Section 12. Clinical trials information.

### *Purpose*

To ensure that insurance and indemnity provisions are adequate.

### *Specific guidance*

The Medicines Australia Standard Clinical Trial Agreement referred to in this Section, is available at:

<http://www.medicinesaustralia.com.au/pages/page39.asp>.

Where a company uses the standard agreement without alteration the Public Health Organisation should accept this agreement without further review.

## Section 13. Biosafety, chemical and radiation safety.

### *Purpose*

To enable the Public Health Organisation to ensure that biosafety, drug committee and radiation safety approvals have been obtained where necessary.

### *Specific guidance*

Some types of research projects (such as research involving gene therapy), necessitate review and/or approval by an Institutional Biosafety Committee (IBC), the Office of the Gene Technology Regulator (OGTR) and the Gene and Related Therapies Research Advisory Panel (GTRAP). If the research project requires review and/or approval by one or more of these bodies, this should be documented.

For research projects where Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code compliance is required, the researcher should have identified this in the submission to the reviewing HREC. It is not necessary to include any other information here, unless this is specifically requested by the site.

#### Section 14. Declarations

##### *Purpose*

To ensure that the principal investigator and associate investigators understand and accept their responsibilities in relation to the conduct of the research project at the site. This section also requires appropriate approvals to have been obtained from the Head of Department/Supporting Department involved in the research project, thereby ensuring that each Department is aware of the research project, that the researcher/s involved in the project have the necessary skills and expertise to undertake their role, and that the Department supports the conduct of the project and the associated use of Departmental resources.

##### *Specific guidance*

The 'Declaration by Authority for Data Provision' should be completed where a research project involves access to data relating to the health of an individual/s, which are held in data collections owned or managed by the NSW Department of Health or a Public Health Organisation. The 'authority for data provision' will generally be the data custodian who has responsibility for the management of the data collection. The Authority for Data Provision may request that the researchers supply additional information regarding the proposed data to be accessed.

For research projects involving access to unit record data relating to the health of an individual/s, which are held in data collections owned by the NSW Department of Health, the Policy Directive PD2006\_077 *Data Collections – Disclosure of unit record data held for research or management of health services* must be complied with.

**Figure 1.**

**Authorisation for the commencement of a research project within a Public Health Organisation.**

