

FAQ: Site-specific Assessment

What is a site-specific assessment (SSA)?

The mechanism used by public health organisations to determine the suitability of a research project to be conducted at site(s) under their control. A site-specific assessment must be conducted regardless of whether the project is multi-centre or single site.

How do I submit an SSA application?

Applications for site-specific assessment must be made on the web-based SSA form. The form is linked to the NEAF and can be accessed from the following website:

<http://www.health.nsw.gov.au/ethics/research/governance.asp>

Once the application is completed, it must be printed and submitted to the appropriate Research Governance Officer in paper copy. Details of Research Governance Officers are maintained on the NSW Department of Health website:

What is the role of the local principal investigator?

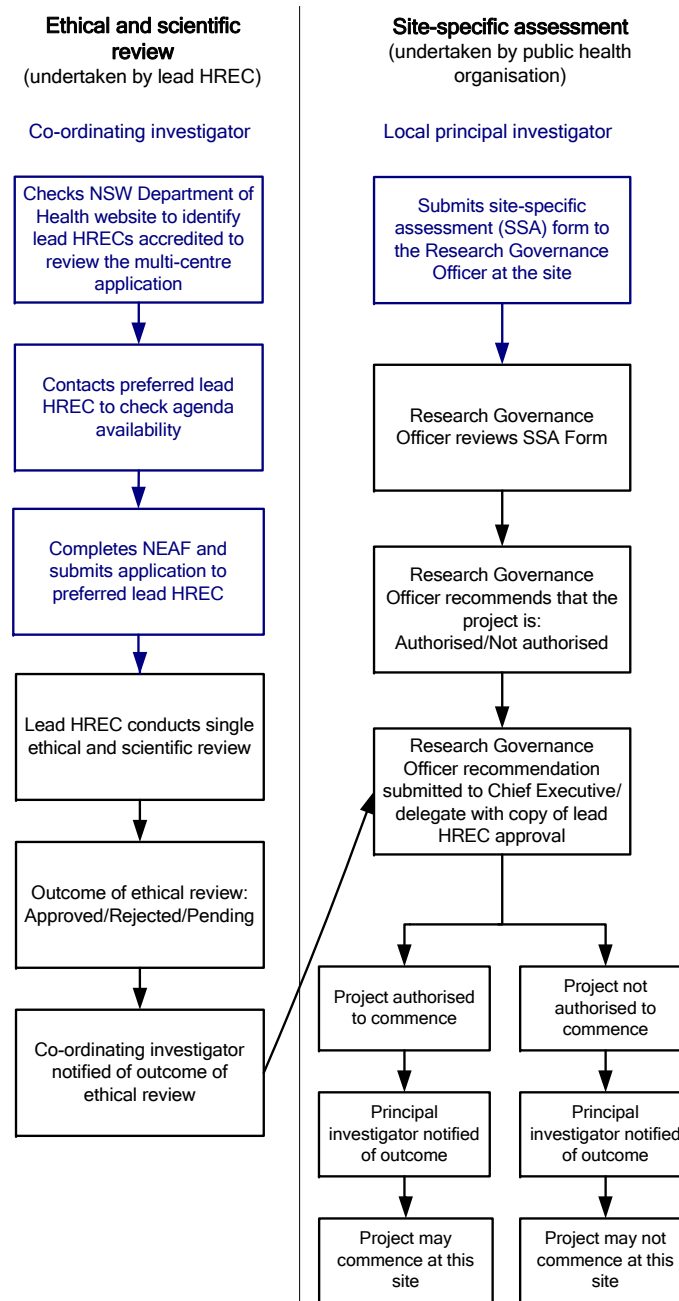
The local principal investigator is the person responsible for the conduct of the research project at an individual study site. This includes:

- submitting the SSA form to the Research Governance Officer;
- communicating with the Research Governance Officer in relation to the SSA; and
- liaising with the co-ordinating investigator of the study (where applicable).

What is the role of the Research Governance Officer?

The Research Governance Officer is responsible for reviewing the SSA form and making a recommendation to the Chief Executive or their delegate, as to whether or not the research project should proceed at that site.

Figure 1: Overview of the single ethical review system



Single ethical review of **multi-centre research**

Information for researchers
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Overview

In 2007 a system of single ethical and scientific review was implemented within the NSW public health system, such that every research project is ethically and scientifically reviewed once only. The system was introduced in order to reduce inefficiencies associated with the review of multi-centre research, and to provide for an effective, timely and quality ethical and scientific review process.

The aim of this brochure is to provide researchers with information about how the system works and to provide answers to some frequently asked questions (FAQ).

Under the system, lead Human Research Ethics Committees (HRECs) are accredited to conduct a single ethical and scientific review on behalf of all sites within the NSW public health system at which a research project is to be conducted, thereby eliminating the need for each local HREC to conduct its own review.

Public health organisations (area health services and other statutory bodies as defined under the *Health Services Act 1997*) retain responsibility for authorising the conduct of research within their institutions. As such, public health organisations are required to undertake a site-specific assessment of each research project, thereby allowing the organisation to consider whether it has the capacity to conduct the research at that site. This site-specific assessment considers such matters as resources, patient availability and staff.

The site-specific assessment and ethical review may occur in parallel, however the decision to authorise or not authorise the conduct of a research project may only be made by the public health organisation once the lead HREC has granted approval and the site-specific assessment has been satisfactorily completed.

FAQ: Ethical and scientific review

What is multi-centre research?

Research which is to be conducted at more than one site within the NSW public health system and within the jurisdiction of more than one local HREC.

What is a local HREC?

The HREC associated with the site at which a research project is to be conducted and which is responsible for the ethical review of single-site research at the site.

What is a lead HREC?

An HREC accredited to conduct the single ethical and scientific review of multi-centre research projects. Details of lead HRECs are maintained on the NSW Department of Health website:
www.health.nsw.gov.au/ethics/research/index.asp

What is the role of the co-ordinating investigator?

The co-ordinating investigator is the person responsible for the overall co-ordination of a multi-centre research project. This includes:

- determining a preferred lead HREC and contacting the HREC to check agenda availability;
- submitting an application for ethical review to the lead HREC;
- communicating with the lead HREC in relation to the application; and
- distributing HREC documentation to local principal investigators (where applicable).

Which lead HREC should I submit my application to?

Applications can be submitted to any NSW Health lead HREC, provided that the HREC is accredited in the research area of the project (e.g. clinical trials must be submitted to a lead HREC accredited in clinical trials/interventional clinical research).

Where possible, the application should be submitted to a lead HREC associated with one or more of the sites at which the research is to be conducted.

How do I submit an application for ethical review?

Applications for ethical review of multi-centre research within the NSW public health system must be made using the web-based National Ethics Application Form (NEAF). NEAF can be accessed from the following website:

www.health.nsw.gov.au/ethics/research/index.asp

The first time you access the website you will need to create an account (this takes a few minutes). Once the application is completed, it must be printed and submitted to the lead HREC in paper copy.

When can my research project commence?

Once the lead HREC has granted approval and the site-specific assessment has been satisfactorily completed.

Are there any exceptions to the single ethical review principle?

Yes, research projects involving:

- persons in custody in NSW; or
- access to data collections owned or maintained by NSW Health; or
- projects specified within section 6.4 of the NSW Aboriginal Health Information Guidelines.

Does the system apply outside of NSW Health?

No. The system is provided for the benefit of the NSW public health system only.

Where can I get more information?

www.health.nsw.gov.au/ethics/research/index.asp
and by posting a query on
HEALTHETHICS@doh.health.nsw.gov.au

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