

Definitions

Certified Human Research Ethics Committee (HREC)

A HREC which has been assessed and certified by a NHMRC certification committee to conduct the scientific and ethical review of multi-centre human research projects.

Coordinating Principal Investigator (CPI)

The individual who takes overall responsibility for the research project and submits the project for scientific and ethical review. The CPI is responsible for ongoing communication with the HREC and passing on any outcomes from this to the Principal Investigators.

Human Research

According to the National Statement definition.

Multi-centre Human Research

Human research that is conducted at multiple sites within more than one State and Territory public health system.

Principal Investigator (PI)

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

State health department services.

Research Governance Officer (RGO)

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

Site

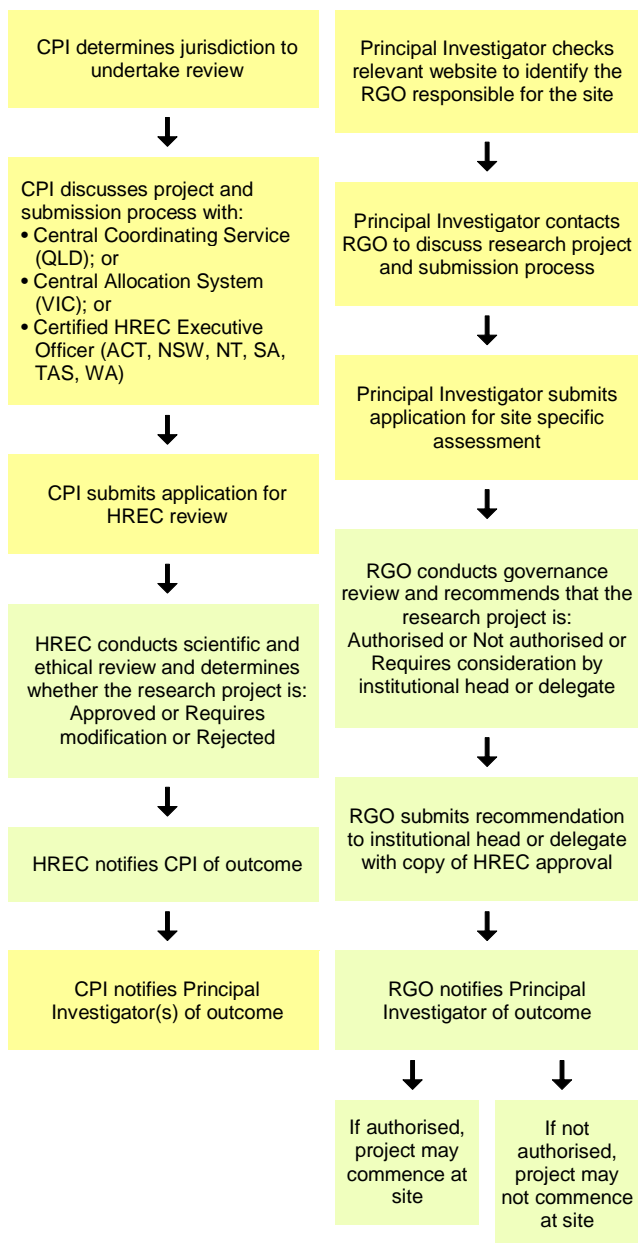
A facility, location or service where the research is being conducted.

Site Specific Assessment (SSA)

A review undertaken to examine the suitability of a multi-centre research study to take place at a particular site. The Site Specific Assessment will be undertaken in accordance with the relevant standard Site Specific Assessment form developed by each jurisdiction.

Overview

Scientific & Ethical Review (undertaken by HREC)



National Mutual Acceptance

of scientific and ethical review for multi-centre human research projects conducted in public health organisations

Australian Capital Territory
New South Wales
Northern Territory
Queensland
South Australia
Tasmania
Victoria
Western Australia

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Introduction

Australian state and territory Departments of Health have signed a Memorandum of Understanding for mutual acceptance of scientific and ethical review of multi-centre human research projects undertaken in Public Health Organisations. Currently New South Wales, Queensland, South Australia and Victoria are participating in National Mutual Acceptance (NMA).

The scope of NMA includes any form of human research as defined in the *National Statement on Ethical Conduct in Human Research* (2007) for which an application must be made to a HREC for the purpose of being conducted at a public health organisation.

Each proposal for a multi-centre human research project conducted across the participating states and territories will be scientifically and ethically reviewed once only by a Public Health Organisation HREC that has been certified by the NHMRC.

Under NMA, each state/territory will ensure that its Certified HRECs are indemnified for their decisions in reviewing multi-centre human research projects. For commercially sponsored projects, the sponsor will continue to provide indemnity to the Certified HREC. The exception is for those projects that require specialist review (see *Exclusion* section).

All human research that takes place in a participating state or territory Public Health Organisation must be authorised by the Chief Executive or their delegate before the research can commence. Authorisation will only be provided once:

- the research project has been reviewed and approved by an HREC that is constituted and operates in accordance with the *National Statement on Ethical Conduct in Human Research* (2007); and
- the research project has been reviewed by each Public Health Organisation through a process of site specific assessment.

NSW, QLD and VIC have had an Interstate Mutual Acceptance arrangement in place since October 2011. The NMA initiative superseded that interstate system.

Making an Application

Application Form

Applications for scientific and ethical review must be prepared using the National Ethics Application Form (NEAF) completed on the Online Forms website <https://au.ethicsform.org> or for WA at: <http://ww2.health.wa.gov.au/Health-for/Researchers-and-educators/Research-governance> For research projects in VIC, a Victorian Specific Module (VSM) must be completed

(<https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research> and <https://www2.health.vic.gov.au/about/clinical-trials-and-research/health-and-medical-research>)

For research projects in WA, a Western Australian-Specific Module must be completed (<http://ww2.health.wa.gov.au/Health-for/Researchers-and-educators/Research-governance>).

For research projects in the ACT, ACT specific forms, as per website, must be completed (<http://www.health.act.gov.au/datapublications/research/human-research-ethics-committee>).

Submission

The application submission process depends on the jurisdiction to which the applicant wishes to submit the application for review.

In QLD, applications must be allocated using the Central Coordinating Service (CCS) website and in VIC applications are allocated by the Central Allocation System (CAS).

In ACT, NSW, NT and TAS, the selection of the certified HREC is at the discretion of the applicant.

In SA and WA the applicant should apply to their own organisation's certified HREC; if not applicable, the investigator should identify a suitable HREC.

Exclusions

Certain multi-centre research projects are excluded from National Mutual Acceptance because of state/territory specific requirements. These are:

- Projects involving persons in custody or staff of the jurisdictional Justice Health departments
- Projects specifically affecting the health and wellbeing of Aboriginal and Torres Strait Islander people and communities

- Projects requiring access to state-wide data collections (NSW only)
- Projects involving access to coronial material
- First Time in Human or Patient (FTIH/FTIP) and Phase 1 clinical trials (in ACT, NT and SA only).

The excluded projects will continue to be reviewed under the current local jurisdictional arrangements. Contact the relevant jurisdiction(s) for further details.

Research Governance – Site Authorisation

Research governance is the framework by which institutions, investigators and their managers share responsibility and accountability for research conducted according to ethical principles, scientific, regulatory and professional standards and the principles of risk management.

Site authorisation is one aspect of research governance. Public Health Organisations undertake site specific assessments (SSAs) for all multi-centre human research projects that are to be conducted at a site under their control, in compliance with the relevant jurisdictional standard operating procedures. An SSA must be completed for all research projects to be conducted at sites under the control of the participating state or territory Public Health Organisations.

SSA Forms

Applications for site specific assessment must be submitted using the SSA form for the state or territory in which the site is located.

A separate SSA application must be made for each site at which the research project is to be conducted.

The NEAF and SSA forms must be completed online via the Online Forms website <https://au.ethicsform.org> or for WA at <http://ww2.health.wa.gov.au/Health-for/Researchers-and-educators/Research-governance>.

Further Information

For jurisdictional details, please refer to the factsheet.

For details on the ethics application process in each state or territory, please visit the relevant Health Department websites.