# National Mutual Acceptance

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

**Australian Capital Territory (ACT)**
**New South Wales (NSW)**
**Northern Territory (NT)**

**Queensland (QLD)**
**South Australia (SA)**
**Tasmania (TAS)**

**Victoria (VIC)**
**Western Australia (WA)**

## 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 Australian Capital Territory, New South Wales, Northern Territory, Queensland, South Australia, Tasmania, Victoria and Western Australia 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* (NHMRC, 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* (NHMRC, 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 The NMA initiative superseded that interstate system.

## Further Information

For jurisdictional details, refer to the *NMA Factsheet*.

For details on the ethics application process in each state or territory, visit the relevant State/Territory Department websites.

## Making an Application

### Application Form

Applications for scientific and ethical review must be prepared using the Human Research Ethics Application (HREA) form:

- **QLD & VIC** ERM website https://au.forms.ethicalreviewmanager.com/
- **NSW & ACT** REGIS website https://regis.health.nsw.gov.au/
- **SA** Research GEMS website https://gems.sahealth.sa.gov.au/
- **WA** RGS website https://rgs.health.wa.gov.au/Pages/Home.aspx
- **NT** The HREA application may be prepared using the NHMRC portal https://hrea.gov.au/
- **TAS** Refer to QLD, VIC, NSW, ACT, SA, NT and WA above

For research projects in:

**VIC** a Victorian Specific Module (VSM) must be completed
**WA** a WA Specific Module (WASM) must be completed via the RGS
**ACT** specific forms must be completed
**NT** specific forms must be completed and further ethical and scientific review may be triggered

### Submission

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

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.

Refer to: NMA research governance matrix

### Exclusions

Certain multi-centre research projects are excluded from NMA 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 involving access to coronial material
- First Time in Human or Patient (FTIH/FTIP) and Phase 1 clinical trials (in NSW, ACT, NT and SA only).

NMA-excluded projects will be reviewed under local jurisdictional arrangements. Contact jurisdiction(s) for 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.

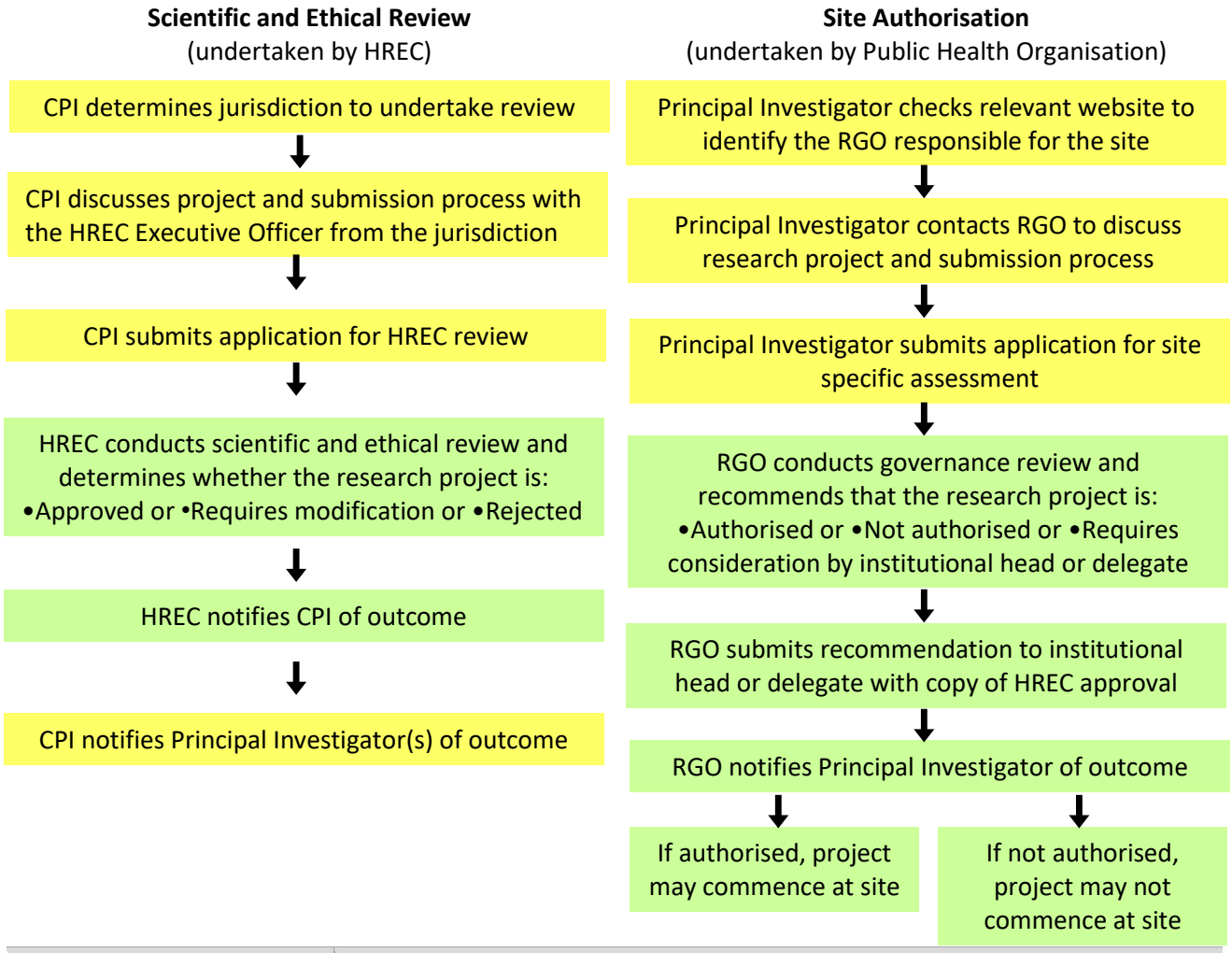
Site authorisation is one aspect of research governance. Public Health Organisations undertake site specific assessments (SSAs) for all multi-centre human research projects that are to be conducted at a site under their control, in compliance with the relevant jurisdictional standard operating procedures.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

## Overview

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| **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. |