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

FACT SHEET

National Mutual Acceptance (NMA) is the system of single scientific and ethical review of multi-centre human research projects across Australian jurisdictions (public health organisations only). Australian Capital Territory, New South Wales, Northern Territory, Queensland, South Australia, Tasmania, Victoria and Western Australia are current participants in NMA. The system has been in operation for review of multi-centre clinical trials since 1 November 2013; it was agreed to expand the system to include all human research commencing 14 December 2015.

Aims

(a) Enable Public Health Organisations of participating jurisdictions to accept a single ethical and scientific review of human research projects; and
(b) Inform the ongoing development of the national system of single ethical and scientific review of multi-centre research.

Under the National Mutual Acceptance agreement a multi-centre human research project is reviewed for ethical and scientific merit once only. There will be exceptions to some areas of research that will apply in each jurisdiction and these are listed in this document.

Reviewing Human Research Ethics Committees (HREC)

The single ethical and scientific review of a multi-centre human research project is conducted by an NHMRC Certified HREC of a participating jurisdiction and certified in a relevant area of research. A list of current Certified HRECs including the certification categories of each HREC can be found on the NHMRC website. The *HRECs, RGOs and Organisations* guidance document contains contact details for NMA and can be found on jurisdictional websites.

Applicants can apply to an NMA reviewing HREC as follows:

- Australian Capital Territory apply through REGIS: https://regis.health.nsw.gov.au
- New South Wales, apply through REGIS: https://regis.health.nsw.gov.au
- Northern Territory, the HREA may be prepared using the NHMRC portal https://hrea.gov.au/
- Queensland, apply through Ethics Review Manager: https://au.forms.ethicalreviewmanager.com/Account/Login?ReturnUrl=%2fHome%2fIndex
- South Australia, apply through Research GEMS: https://gems.sahealth.sa.gov.au/
- Victoria, apply through Ethics Review Manager: https://au.forms.ethicalreviewmanager.com/Account/Login?ReturnUrl=%2fHome%2fIndex
- Western Australia, apply through RGS: https://rgs.health.wa.gov.au/Pages/Home.aspx

Ethics application forms

A Human Research Ethics Application (HREA) form is required to be used for application to a certified HREC.

For studies in Victoria, the Victorian Specific Module must be completed in addition to the HREA.

For studies in Western Australia, the Western Australian Specific Module (WASM) must be completed in addition to the HREA.

For studies in NT, include the HREA (saved as both pdf and xml), the research protocol, PIS/CF, and Part D attachment to HREA NMA.

Low and Negligible Risk review pathway

NMA SOPs have previously required Low and Negligible Risk (LNR) research to be reviewed by a full HREC using a national ethics form (e.g. HREA).

Following consideration by the NMA Inter-Jurisdictional Working Group, it has been agreed to modify the NMA SOPs (and Fact Sheet) to support the acceptance of LNR research that has been reviewed using non-HREC levels of review, in accordance with the provisions in the *National Statement*.

The following statement has been developed following consultation with all States and Territories regarding their preferred process and stance.

Position Statement for all States and Territories except South Australia:

As with all NMA applications, projects meeting the Low or Negligible Risk (LNR) criteria for a non-HREC level of review according to the National Statement on Ethical Conduct in Human Research 2007 (updated 2018) (National Statement) will be reviewed under the NMA scheme only if they are submitted on the Human Research Ethics Application form (HREA).

An LNR project will be accepted under the NMA scheme if the project has been ethically reviewed using a non-HREC level of review described in the National Statement.

South Australia only:

Non-HREC levels of review will not be accepted for projects being submitted to South Australian public health organisations under NMA. Acceptable forms of review may include (i) review by a full NMA-participating HREC from another jurisdiction or (ii) re-review by a NMA-participating HREC from South Australia.

Guidance on NMA LNR review Process (excluding South Australia):

- Institutions with NMA-participating HRECs will have non-HREC levels of review that are consistent with the National Statement (5.1.20) for reviewing and approving LNR projects.
- As per the National Statement, those reviewing research at a non-HREC level must refer to an HREC any research they identify as involving more than low risk [5.1.21].
- In order to facilitate consistency in LNR review, referral may be made to the set of NMA-endorsed guidelines on LNR review, that are consistent with the National Statement (see NMA Standard Principles for Operation – Appendix 3).

Scope of research

The scope of NMA is all human research.

Human Research is defined in the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007, p7) *as* research conducted with or about people, or their data or tissue.

'Clinical trial' is defined as interventional research involving a drug/device trial, radiation therapy, surgery, treatment or diagnostic procedure and studies associated with ongoing activities relating to trials that have been conducted. This may include post-trial activities such as observational research and evaluation of a trial, developing a registry and other post-marketing surveillance activities.
This includes commercially sponsored, collaborative groups and investigator initiated clinical trial research.

HREC monitoring and reporting

The reviewing HREC will have oversight of the human research project and ensure that it complies with all ethical, scientific and safety requirements, as appropriate. Investigators and/or the research project's sponsor will be required to provide regular progress reports, other required reports and safety reports to the reviewing HREC. Refer to *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016).

The NMA *Monitoring and Reporting Framework* and *Monitoring and Reporting Tables* outline the requirements for each participating jurisdiction including local site reporting requirements and can be found on jurisdictional websites.

Site Specific Assessment (SSA)

The National Mutual Acceptance scheme provides for ethical and scientific approval only. Each participating Public Health Organisation must undertake a site specific assessment (SSA) of a multi-centre human research project and be authorised in compliance with the relevant jurisdictional standard operating procedures.

Each jurisdiction will have a SSA form for use within that jurisdiction.

Types of human research projects excluded from single ethical and scientific review under NMA – participating jurisdictions

For research conducted in the Australian Capital Territory

- Phase 0 and Phase I (first time in human) clinical trials will not be accepted under the single ethical review system for institutions under the ACT public health system and must be reviewed by ACT Health HREC
- All human research projects requiring access (including linkage) to territory data collections owned or managed by the ACT Government must be reviewed by the ACT Health HREC
- All human research projects involving persons in custody in the ACT and/or staff of ACT Justice Health require review by the ACT Health HREC
- Research studies involving access to coronial material must be reviewed by the ACT Health HREC
- Approval from the ACT Health HREC is required where the research project involves research in, or concerning:
    - The experience of Aboriginal and Torres Strait Islander peoples of the ACT as an explicit focus of all or part of the research;
    - Data collection explicitly directed at Aboriginal and Torres Strait Islander peoples of the ACT;
    - Aboriginal and Torres Strait Islander peoples of the ACT, as a group, are to be examined in the results;
    - The information has an impact on one or more Aboriginal and Torres Strait Islander communities of the ACT; or
    - Aboriginal and Torres Strait Islander health funds, from the ACT, are a source of funding.

For research conducted in New South Wales

All human research projects involving persons in custody in NSW and/or staff of NSW Justice Health require review by the NSW Justice Health HREC.

Approval from the Aboriginal Health and Medical Research Council Ethics Committee is required where the research project involves research in, or concerning, NSW and any one of the following applies:

- The experience of Aboriginal people is an explicit focus of all or part of the research;
- Data collection is explicitly directed at Aboriginal people;
- Aboriginal peoples, as a group, are to be examined in the results;
- The information has an impact on one or more Aboriginal communities; or
- Aboriginal health funds are a source of funding.

All human research projects requiring access (including linkage) to statewide data collections owned or managed by NSW Health or the Cancer Institute (NSW) may be reviewed by the NSW Population and Health Services Research HREC.

Early Phase Clinical Trials (EPCTs) (definition provided on NSW OHMR website, but includes Phase 0 (first time in human) and Phase 1 clinical trials) will not be accepted under the NMA scheme for clinical trials for New South Wales Public Health Organisations, except in the following circumstances:

- EPCTs involving adult participants will be required to be submitted to the Bellberry Ltd HRECs;
- For EPCTs involving paediatric participants:
    - Where the lead site is located in NSW, these applications will be required to be submitted to the Sydney Children's Hospitals Network HREC;

- Where the lead site is located in other NMA jurisdictions, approvals will be accepted from a certified HREC hosted by a specialist paediatric health organisation operating under the NMA scheme,

In addition to any research governance (site specific assessment) requirements.

For research conducted in Northern Territory

Please refer to the requirements at the Menzies School of Health Research website – NMA application process, and complete the requested documents:

- Cover letter describing the study and its NT context including naming the NT sites and NT co-investigators.
- Ethics application that was previously approved by the lead NMA-certified HREC, including all supporting documents e.g. HREA, protocol, PIS/CF
- Approval letter from lead NMA-certified HREC; and correspondence from lead HREC acknowledging ethical oversight of NT sites if applicable and if not included on original approval letter
- Part D attachment to HREA NMA – Aboriginal and Torres Strait Islander Research.

For research conducted in Queensland

Research studies involving access to coronial material must be referred to the Forensic and Scientific Services Human Ethics Committee (FSS-HEC) for ethical and legal approvals.

For research conducted in South Australia

Phase 0 and Phase 1 clinical trials will be exempt from single ethical review in South Australia.
Approval from the Aboriginal Health Research Ethics Committee (AHREC), South Australia, will also be required where:

- The experience of South Australian Aboriginal and Torres Strait Islander people is an explicit focus of all or part of the research; or
- Data collection is explicitly directed at South Australian Aboriginal and Torres Strait Islander people; or
- Where it is proposed to separately identify South Australian Aboriginal and Torres Strait Islander people in the results; or
- The information has an impact on one or more South Australian Aboriginal and Torres Strait Islander communities; or
- The geographic location of the research is such that a significant number of the population are likely to be of Aboriginal and Torres Strait Islander origin (based on 4.7.6 of the National Statement, 2007); or
- Where terms such as ‘resilience’; ‘well-being’; ‘cultural safely’; ‘cultural health’; and ‘language and culture’ are used in the description and design of the project indicating that the project has important health implications for South Australian Aboriginal and Torres Strait Islander people; or
- South Australian Aboriginal and Torres Strait Islander health funds are a source of funding.

For research conducted in Tasmania

All human research projects will be accepted under the single ethical review for clinical trials in a Tasmanian publicly funded health service, where the HREC providing the ethical review is certified appropriately for the category of research in which the HREC approval is sought.

For research conducted in Victoria

Research studies involving access to coronial material must be referred to the Victorian Institute for Forensic Medicine HREC.

Research studies involving persons in custody require review by the Justice HREC of Victoria.

For research conducted in Western Australia

All research projects, where Aboriginality is a key determinant or is explicitly directed at Aboriginal people, must be reviewed by the Western Australian Aboriginal Health Ethics Committee (WAAHEC). That is, where the project involves the following categories:

- Aboriginality is a key determinant;
- data collection is explicitly directed at Aboriginal people;
- Aboriginal people, as a group, will be examined in the results;
- the information has an impact on one or more Aboriginal communities; or
- Aboriginal health funds are a source of funding.

All research projects that require access to coronial samples, data or information must be reviewed by the Coronial Ethics Committee, WA.

All research projects that require the use and disclosure of personal information from the Department of Health data collections or data linkage must be reviewed by the Department of Health WA HREC.

Jurisdiction contacts and websites

Australian Capital Territory
Research Ethics and Governance Office
Phone: 02 5124 7968
Email: ethics@act.gov.au
Web: https://www.health.act.gov.au/research/research-ethics-and-governance

New South Wales
The Office for Health and Medical Research
Email: moh-researchethics@health.nsw.gov.au
Website: https://www.medicalresearch.nsw.gov.au/national-mutual-acceptance/

Northern Territory
NT Health Research Governance Office
Phone: 08 8922 7764
Email: nthealth.rgo@nt.gov.au
Website: https://health.nt.gov.au/data-and-research/nt-health-research

Queensland
Research, Ethics and Governance; Health Innovation, Investment and Research Office
Phone: 07 3708 5071
Email: hiiro_reg@health.qld.gov.au
Website: www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

South Australia
Office for Research
Phone: 08 8226 4235
Email: health.humanresearchethicscommittee@sa.gov.au
Website: www.sahealth.sa.gov.au/researchethics

Tasmania
Research Governance Office, Clinical Quality Regulation and Accreditation
Tasmania Department of Health
Phone: 03 6166 0395
Email: research.governance@health.tas.gov.au
Website: https://www.health.tas.gov.au/research

Victoria
Coordinating Office for Clinical Trial Research
Phone: 0408 274 054
Email: multisite.ethics@safercare.vic.gov.au
Website: https://www.clinicaltrialsandresearch.vic.gov.au

Western Australia
Research and Innovation Office
Department of Health WA
Phone: 08 9222 4222
Email: RIO.DOH@health.wa.gov.au
Website: https://rgs.health.wa.gov.au/Pages/Home.aspx