

Standard Principles for Operation

National Mutual Acceptance of Single Ethical and Scientific Review of Multi-centre Human Research Projects



Scope

These Standard Principles for Operation (Principles) describe the common principles for the National Mutual Acceptance of single scientific and ethical review of multi-centre human research projects (National Mutual Acceptance) in publicly funded health organisations.

The acceptance of scientific and ethical review of multi-centre human research projects will be referred to as National Mutual Acceptance.

The Principles are designed to inform the process of single ethical review for multi-centre human research projects. These principles should be applied to all types of research, with due consideration, for the differences in the ethical and governance review processes for the research.

These Principles provide general guidance for investigators, trial coordinators, sponsors, Contract Research Organisations (CRO) and other parties undertaking human research projects within public health organisations. Scientific and ethical review should be in accordance with the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007).

For more detailed operating procedures in each State or Territory, the relevant jurisdictional websites should be referred to and are available in the Fact Sheet and at Appendix 3.

For queries regarding these Principles, or the processes for ethical approval and site authorisation of multi-centre human research projects nationally, please contact the relevant jurisdiction listed on the Fact Sheet and in Appendix 3.

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Glossary

ACT	Australian Capital Territory
AHEC	Australian Health Ethics Committee
AHREC	Aboriginal Health Research Ethics Committee
Code	Code of Practice - Exposure of Humans to Ionizing Radiation for Research (2005) published by ARPANSA
CPI	Coordinating Principal Investigator
CRA	Clinical Research Associate
CRO	Contract Research Organisation
FSS-HREC	Forensic and Scientific Services - Human Ethics Committee
HREC	Human Research Ethics Committee
MOU	Memorandum of Understanding of single scientific and ethical review of multi-centre clinical trials
National Statement	National Statement on Ethical Conduct in Human Research (NHMRC)
NEAF	National Ethics Application Form
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
NSW	New South Wales
PI	Principal Investigator
PICF	Participant Information and Consent Form
Position Statement	Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products. NHMRC Australian Health Ethics Committee (AHEC)
Principles	Standard Principles for Operation
RGO	Research Governance Officer
SA	South Australia
SSA	Site Specific Assessment (includes research governance review/institutional authorisation)
SUSAR	Suspected Unexpected Serious Adverse Reaction
USADE	Unanticipated Serious Adverse Device Event
WA	Western Australia

Principle 01

National Mutual Acceptance of single scientific and ethical review of multi-centre research projects

Phased approach for implementation

1. Participation in National Mutual Acceptance (NMA) by individual States and Territories will be a phased process.

Initially New South Wales, Queensland, South Australia and Victoria are participating. Other jurisdictions will join when their systems are in place and communicated accordingly.

Investigators, trial coordinators, sponsors and CROs should check the relevant Government Health websites to confirm the status of participation in NMA.

2. NMA will provide the framework for single scientific and ethical review of multi-centre human research projects in publicly funded health organisations of participating jurisdictions.

There will be some exceptions to single scientific and ethical review and details can be found on jurisdiction health websites in the NMA Fact Sheet and in this document.

Multi-centre research

Under NMA multi-centre research means research to be conducted at more than one centre and would require more than one HREC review. Some examples can be found in Appendix 1.

Scope of research to be considered under the NMA

3. 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. This includes low and negligible risk research review by a full HREC using a national ethics form (e.g. NEAF).
4. The NMA single ethical review process applies to public health organisations; however, private health organisations may accept the review of a NMA proposal reviewed by a NHMRC certified HREC. Some jurisdictions may have certain requirements to provide ethical approval for private health organisations. Investigators should contact the respective State or Territory health department representatives and ensure these requirements are followed.
5. Participating jurisdictions are required to sign an inter-jurisdictional Memorandum of Understanding (MOU) to:
 - Enable publicly funded health organisations within their jurisdictions to accept the scientific and ethical review of a NHMRC certified reviewing HREC and ensure that

these organisations will not undertake any further review by the organisation's HREC, acknowledging there are some exceptions in jurisdictions;

- Apply a 60 calendar day (with stop-clock capability) benchmark¹ for scientific and ethical review and decision making by a certified reviewing HREC;
- Provide consistency of HREC review according to the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007);
- Ensure that a process of research governance review/institutional authorisation/site specific assessment (referred to collectively as SSA) is undertaken by a participating site at a publicly funded health organisation. A research governance process should be practiced at non-public health organisations as part of research governance responsibilities; and
- Ensure that a human research project does not commence at a site until approval from a certified reviewing HREC has been received and site authorisation has been endorsed at the site where the research is to be conducted.

¹ Sixty calendar days are allowed for the single scientific and ethical review of an application. Where a valid application is received, the clock starts on the submission closing date for the HREC meeting at which an application will be reviewed. The clock stops when a request for further information or clarification is requested from the applicant. The clock recommences when the requested information or clarification has been received. The clock is stopped when the HREC provides a final decision.

Principle 02

Transition to National Mutual Acceptance

1. The initiative for interstate mutual acceptance of single scientific and ethical review between New South Wales Ministry of Health, Queensland and Victorian Health Departments operated from October 2011. It was superseded by NMA in November 2013.
2. Clinical trials that have previously been granted ethical approval under the interstate mutual acceptance process will continue under those prior arrangements.
3. There will not be retrospective inclusion of approved clinical trials under the NMA process. However, additional sites from newly joined jurisdictions may be added to projects approved under the NMA process, by way of amendments.
4. The expansion of NMA to all human research projects commenced on 14 December 2015 and will apply in States and Territories that are signatories to the national MOU. There will not be retrospective inclusion of approved research projects (non-clinical trials) that pre-date 14 December 2015.

Principle 03

Types of human research projects excluded from single scientific and ethical review

For research conducted in Australian Capital Territory Health

- 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) must be reviewed by the NSW Population and Health Services Research HREC.

For research conducted in the Northern Territory:

Phase 0 (first time in human) and Phase 1 clinical trials will not be accepted under the single ethical review for clinical trials for Northern Territory public health system institutions. Where a Certified HREC from another jurisdiction has provided prior

approval for a Phase 0 or Phase 1 clinical trial application, these applications will be re-reviewed ethically by the appropriate HREC in the Northern Territory in addition to any research governance/specific assessment/institutional authorisation requirements.

Approval from the appropriate NT HREC is required where the research project involves research in, or concerning:

- The experience of Aboriginal and Torres Strait Islander people as an explicit focus of all or part of the research;
- Data collection explicitly directed at Aboriginal and Torres Strait Islander people;
- Aboriginal and Torres Strait Islander people, as a group, are to be examined in the results;
- A significant number of the population are likely to be of Aboriginal and Torres Strait Islander origin;
- The information has an impact on one or more Aboriginal and Torres Strait Islander communities; or
- Aboriginal and Torres Strait Islander health funds are a source of funding.

For research conducted in Queensland

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

Research studies that specifically target Aboriginal and Torres Strait Islander peoples must be reviewed by ethics committees closest to the communities that are involved in the research.

For research conducted in South Australia

Phase 0 (first time in human) and Phase 1 clinical trials will not be accepted under the single ethical review for clinical trials for South Australian public health organisations. Where a Certified HREC from another jurisdiction has provided prior approval for a Phase 0 or Phase 1 clinical trial application, these applications will be re-reviewed ethically by the appropriate HREC in South Australia in addition to any research governance/site specific assessment/institutional authorisation requirements.

Approval from the Aboriginal Health Research Ethics Committee (AHREC), South Australia, will 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 safety'; 'cultural health'; and 'language and culture' are used in the description and design of the project indicating that the project has important health implications; or

- South Australian Aboriginal and Torres Strait Islander health funds are a source of funding.

For research conducted in Tasmania

- Phase 0 (first time in human) and Phase 1 clinical trials will not be accepted under the single ethical review system for institutions under the Tasmanian public health system. Where a Certified HREC from another jurisdiction has provided prior approval for a Phase 0 or Phase 1 clinical trial application, these applications will undergo ethical and scientific review by Tasmanian HREC. Applications will be subject to standard research governance/site specific assessment/institutional authorisation requirements.
- All human research projects requiring access (including linkage) to Tasmanian data collections owned or managed by the State Government must be reviewed by the Tasmanian HREC.
- All human research projects involving persons in custody in Tasmania and/or staff of the Department of Justice require review by the Tasmanian HREC.
- Research studies involving access to coronial material must be reviewed by the Tasmanian HREC.
- Approval from the Tasmanian HREC is required where the research project involves research in, or concerning:
 - The experience of Aboriginal and Torres Strait Islander people as an explicit focus of all or part of the research;
 - Data collection explicitly directed at Aboriginal and Torres Strait Islander people;
 - Aboriginal and Torres Strait Islander people, 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; or
 - Aboriginal and Torres Strait Islander health funds are a source of funding.

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 clinical trials, where Aboriginality is a key determinant or is explicitly directed at Aboriginal people, must be reviewed by the Western Australian Aboriginal Health Ethics Committee. That is, where the clinical trial 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 clinical trials that require access to coronial samples, data or information must be reviewed by the Coronial Ethics Committee, WA.

All clinical trials 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.

Principle 04

Submission for scientific and ethical review

Coordinating Principal Investigator (CPI) and Principal Investigator (PI) responsibilities

Coordinating Principal Investigator

- Takes overall responsibility for developing the HREC application in consultation with accepting sites (participating PIs).
- Takes overall responsibility for the research project and submits the project for scientific and ethical review;
- Is responsible for the ongoing communication with the reviewing HREC and passing on information from the HREC to the sponsor and the PI at each site conducting the research; and
- Takes on the responsibilities as the PI at their own site (as outlined below).

Principal Investigator

- Takes responsibility at their own site for the conduct, management, monitoring and reporting of the research project;
- Is responsible for submitting the site specific assessment documents for site authorisation and liaises with the site Research Governance Officer (RGO) throughout the life of the research project; and
- Is responsible for relevant communication with and reporting to the CPI with respect to all information related to the research that requires submission to the reviewing HREC.

The CPI and PI may delegate some responsibilities to research staff to manage communication during the project.

CPI Declaration on the National Ethics Application Form (NEAF)

1. The CPI must sign the declaration section of the NEAF. PIs are not required to sign the declaration as they will make a declaration in the SSA form.
2. Single ethical approval will be provided through NMA; however, a human research project cannot commence until authorisation is provided by the participating site. The PI is responsible for obtaining this authorisation. The site Chief Executive or a delegate (as determined by that organisation) will have the responsibility for providing authorisation for the commencement of a human research project at their site.

Reviewing HRECs

3. The single scientific and ethical review of a multi-centre human research project is to be conducted by an appropriately NHMRC Certified HREC (reviewing HREC) in a participating jurisdiction.
4. The **HRECs, RGOs and Organisations** NMA document lists participating jurisdiction HREC information. There are different areas of certified review. The majority of reviewing HRECs are certified to review adult research projects. Some HRECs are certified to review paediatric research projects and some are certified to review both adult and paediatric research projects. This document is available on jurisdictional websites (refer to Appendix 3).

How to submit an ethics application in each jurisdiction

5. Applications by the CPI for ethical review of multi-centre human research projects are to be made as follows:
 - In Queensland, through the Central Co-ordinating Service website at http://www.health.qld.gov.au/ohmr/html/regu/cen_coord_serv.asp
 - In Victoria, through the Central Allocation System by phone: 03 9096 7395
 - In Australian Capital Territory and New South Wales and the Northern Territory, the choice of HREC is at the discretion of the applicant.
 - In South Australia and Western Australia, applications should be to the certified HREC associated with the site at which the applicant is conducting the research project and if this is not applicable, the researcher should identify a suitable HREC.
 - In Tasmania, through the Tasmanian HREC, once certified; prior to certification of the Tasmanian HREC, at the discretion of the applicant.

Principle 05

Ethics application forms

1. A National Ethics Application Form (NEAF or an updated form) is to be used for submission of a research proposal to a reviewing HREC for scientific and ethical review.
2. Each jurisdiction, through the reviewing HREC, will have its own requirements in relation to requested changes to information in the ethics application form.

Additional forms to be reviewed by the HREC are required as follows:

- For studies in Victoria, the Victorian Specific Module must be completed and the CPI must submit this form in addition to the NEAF. Note that each Victorian participating site must also submit a Section 4 Use of Ionising Radiation Form for that site if radiation is involved in the project.
- For studies in Western Australia, the Western Australian-Specific Module must be completed in addition to the NEAF.
- For research proposals in the ACT, the ACT-Specific Module must be completed in addition to the NEAF.

Principle 06

Master participant information and consent form

1. The NHMRC templates are the recommended Master Participant Information and Consent Forms (PICFs). Other Master PICFs may be acceptable (refer to HREC websites).
2. The CPI is responsible for submission of the Master PICF to the reviewing HREC following appropriate consultation with participating sites.
3. A PICF with site-specific wording may be submitted by a participating site, via the CPI, and must be based on the Master PICF with addition of specific site requirements or policies relating to the conduct of the research. The Site Master PICF should be on the letterhead of the site with an appropriate footer, referencing the Master PICF and version. For sites which function in accordance with the Catholic Health Australia's "Code of Ethical Standards for Catholic Health and Aged Care Services in Australia" 2001 ("the Catholic Code") a recommended Catholic statement is available at Appendix 2. . However, it should be noted that a Reviewing HREC is not required to accept Catholic wording on a PICF if it is deemed not appropriate for that particular research project.

Principle 07

Notification of a HREC decision and post approval of a human research project

Duration and conditions of scientific and ethical approval

1. Scientific and ethical approval for human research projects will be for up to a five year period or rolling approval for the life of the study.

HREC approval letters

2. HREC approval letters should clearly:
 - List all organisations (or sites) that have been approved through single ethical review;
 - State the HREC approval anniversary date;
 - Specify the date(s) on which the CPI submits to the reviewing HREC, a progress report which includes reporting from all approved sites;
 - List documents, with version identification, associated with the research project that was reviewed and approved by the reviewing HREC;
 - Indicate that the research cannot commence until site authorisation has been endorsed by the participating site;
 - The duration of ethical approval.

Annual/progress reports

3. Annual or more frequent progress reports to the reviewing HREC should be provided by the CPI to maintain the approval for the designated approval period. HREC approval will be contingent upon receipt of an annual (or more frequent) report to the reviewing HREC.
4. An annual progress report will be due on the **anniversary date of HREC approval** (not on the anniversary date of site authorisation or trial commencement).
5. The CPI is responsible for submitting a collated annual progress report to the reviewing HREC. The CPI should submit reports to the reviewing HREC by the required date. If a site PI has not provided the CPI with the appropriate annual report information, it will be at the discretion of the reviewing HREC whether to suspended ethical approval at that participating site until a report is submitted.

Amendments

6. Modification of an approved human research project must be submitted to the reviewing HREC as an amendment. This may include, but is not limited to, a change to the protocol or an approved document or addition of a new site.
7. In cases of immediate safety concerns not covered under usual monitoring or a risk to participant safety, the reviewing HREC should receive a report from the responsible investigator as soon as possible. The reviewing HREC can then be fully informed and an ethical decision made, before a formal amendment process occurs.

8. A HREC amendment must not be implemented at a site until ethical approval is provided and the RGO at the site has been consulted and has confirmed that site authorisation is current.
9. A site RGO(s) should provide a timely response to PIs regarding the amendment, to avoid undue delay of the trial.

Extension of HREC approval

10. Extension of the HREC approval period may be requested and the reviewing HREC must be consulted for information on the process and period of the extension. In some jurisdictions, a new ethics submission, review and scientific and ethical approval will be required. The process to be followed will depend on the decision of the reviewing HREC in the relevant jurisdiction.

Monitoring of approved human research project

11. The reviewing HREC and the site conducting the human research project is responsible for monitoring the ongoing conduct and safety of approved research as stated in the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007). For further information, reference can be made to the NHMRC *Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research* at: http://hrep.nhmrc.gov.au/uploads/files/Framework_for_Monitoring.pdf
12. The *Monitoring and Reporting Tables* for NMA should be referred to and are available on participating jurisdiction websites (see Fact Sheet and Brochure). The *Monitoring and Reporting Tables* are a guide for CPIs, PIs, reviewing HRECs and Research Governance Officers (RGOs) involved in multi-centre human research projects.
13. Safety (adverse events, SUSARs/USADEs) reporting is the responsibility of CPI and PIs and submission of appropriate safety reports should be guided by the *NHMRC Australian Health Ethics Committee (AHEC) Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products (Position Statement)*.
14. For safety (adverse events, SUSARs/USADEs) reporting refer to the *Monitoring and Reporting Tables for NMA* on jurisdictional websites (at Appendix 3).

Principle 08

Requirements for a multi-centre human research project involving use of ionising radiation

1. The reference document for research involving the use of ionising radiation is the '*Code of Practice - Exposure of Humans to Ionizing Radiation for Research (2005)*' published by ARPANSA (2005) (Code). The Code applies to research involving humans who are exposed to ionising radiation which is additional to that received as part of normal clinical management.
2. In Victoria, state-specific guidelines for research involving the use of ionising radiation can be accessed by sending the Coordinating Office an email: Multisite.ethics@dhhs.vic.gov.au.
3. Other jurisdictional websites may be referred to for guidelines and further information on research involving the use of ionising radiation.

Appendix 1

Definition and examples of multi-centre research for NMA

Multi-Centre Research

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

Some examples:

- The study is at your centre and in **public** hospitals of other jurisdictions participating in NMA.
- The study is to be carried out at more than one centre within different jurisdictional Health districts (relevant in some jurisdictions only) in Mental Health, Community Dental Services, etc.

Multi-centre research not included in NMA

Multi-centre research within **one** jurisdiction (State or Territory) should be reviewed according to the relevant jurisdiction's requirements.

Appendix 2

Catholic recommended wording

If the research project involves a site which functions in accordance with the Catholic Health Australia's "Code of Ethical Standards for Catholic Health and Aged Care Services in Australia" 2001 ("**the Catholic Code**"), then this must be addressed, particularly with respect to the type of research and Patient Information Sheet/Consent Form content. The investigator must contact the relevant institution(s) for specific advice, especially relating to the content of the Patient Information Sheet/Consent Form.

The Catholic Code is available at the [Catholic Health Australia](#) website.

Catholic statement recommended for use by HRECs

The following statement was developed through the deliberations of the Catholic Health Australia working group representing Catholic hospital ethicists and clinicians. This is recommended for use by any human research ethics committee seeking to provide clear communication to potential research participants of child-bearing age and is consistent with Catholic teaching.

**Patient Information and Consent Form Statement where pregnancy must be avoided:
Recommended Template for Catholic Institutions**

The effects of *[Name of investigational product]* on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project. If you are male, you should not father a child or donate sperm for at least *[number]* months after the last dose of study medication.

Both male and female participants must avoid pregnancy during the course of the research and for a period of *[number]* months after completion of the research project. You should discuss effective methods of avoiding pregnancy with your study doctor.

[For female participants] If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

[For male participants] You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary.

Appendix 3

Jurisdictional Contact Details

Australian Capital Territory

Research Office

Web: <http://healthresearch.anu.edu.au/human-research-ethics-committee.html>

New South Wales

The Office for Health and Medical Research

Website: <http://www.health.nsw.gov.au/ethics/Pages/default.aspx>

Email: researchethics@doh.health.nsw.gov.au

Northern Territory

Royal Darwin Hospital and Flinders University

Email: lewis.campbell@gmail.com

Queensland

Health and Medical Research Unit

Website: http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

South Australia

Operational Service Policy Unit

Website: www.sahealth.sa.gov.au/researchethics

Email: Health.HumanResearchEthicsCommittee@sa.gov.au

Tasmania

Office of the Chief Medical Officer

Email: john.milbourne@dhhs.tas.gov.au

Victoria

Coordinating Office for Clinical Trial Research

Website: <http://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research>

or <http://www2.health.vic.gov.au/about/clinical-trials-and-research/health-and-medical-research>

Western Australia

Research Development Unit, Office of the Chief Medical Officer

Website: www.health.wa.gov.au/researchdevelopment/home/multi_centre.cfm