**Purpose**

Interstate Mutual Acceptance will establish ethical and scientific review of multi-centre clinical trials in public health organisations in New South Wales, Queensland and Victoria. Other States and Territories may participate in the future.

Primary Aims:

- Enable public health organisations of participating jurisdictions to accept a single ethical and scientific review of multi-centre clinical trials; and
- Inform the ongoing development of a national system of single ethical and scientific review of multi-centre research.

Expected outcomes:

- Decreased duplication of ethical review;
- Decreased timelines for ethics approval, thereby;
  - Increasing access to new treatments for patients sooner, leading to improved health outcomes;
  - Increasing the attractiveness of Australia as a location for clinical trials; and
  - Increased cooperation between participating jurisdictions, researchers, industry and NHMRC.

**Functions**

Interstate Mutual Acceptance will:

- Provide single ethical review of multi-centre clinical trials conducted within public health organisations in participating jurisdictions;
- Provide single ethical and scientific review of multi-centre clinical trial applications on behalf of public health organisations in participating jurisdictions, by National Health and Medical Research Council (NHMRC) registered Human Research Ethics Committees (HRECs) that are certified by NHMRC to review clinical trials;
- Allow public health organisations to accept the ethical and scientific review, of an NHMRC certified HREC, for clinical trials being conducted at institutions in participating jurisdictions so that studies will not be reviewed by another HREC;
Accommodate current mechanisms for single ethical and scientific review of participating jurisdictions, including existing central allocation of applications in Victoria and Queensland;

Ensure that each participating jurisdiction’s NHMRC certified HRECs are indemnified with respect to reviewing multi-centre clinical trials;

Require the sponsor of commercially sponsored clinical trials to continue to provide indemnity to the NHMRC certified HREC;

Require research governance to remain the responsibility of participating sites, using existing state-based systems of site specific assessment; and

Allow exception for those studies needing specialist HREC review under jurisdictional requirements, as per Exceptions for specialist HREC review

**Exceptions for specialist HREC review**

Some multi-centre clinical trials will require review by a specialist HREC regardless of whether or not they have been, or are to be, reviewed by a Certified HREC. These include the following for each of the jurisdictions.

**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 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 approval.
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.

Membership

Jurisdictions

All Australian jurisdictions may be a signatory to the Memorandum of Understanding (MOU) in relation to mutual acceptance of ethical and scientific review of multi-centre clinical trials in public health organisations.

Participating jurisdiction parties and party representatives shall be listed in Appendix A of the MOU and may be amended as agreed by all jurisdictions from time to time.

Each participating jurisdiction party representative will have equal representation in the decisions regarding the MOU.

Participating jurisdiction public health organisations shall be listed in Appendix B of the MOU and may be amended as agreed by all jurisdictions from time to time.

Reviewing HRECs

Each participating jurisdiction’s Human Research Ethics Committees (HRECs) must be registered with the NHMRC and certified by NHMRC to review clinical trials.

Participating NHMRC certified HRECs are listed in Appendix C of the MOU and may be amended as agreed by participating jurisdictions from time to time.

A reviewing HREC will accept an ethics application (NEAF) that is in keeping with the categories of research to which NHMRC certification applies. The reviewing HREC may or may not be a participating site in the clinical trial.

Operational principles

Administration for clinical trial ethics applications and research governance in public health organisations must utilise the Australian Research Ethics Database (AU RED).

The operations of a certified HREC and its manner of conducting its ethical and scientific review are a matter for the HREC, provided that the certification standards and jurisdictional requirements are met.
Certified HRECs within its jurisdiction are indemnified with respect to the certified HREC’s decisions in reviewing multi-centre clinical trials that are to be conducted at public health organisations in participating jurisdictions.

There will be mechanisms established to address legislative differences related to ethical review of human research. Guidance will be provided for reviewing HRECs on legislative requirements for each respective participating jurisdiction, if applicable (see National & State Statutory and Administrative Frameworks for Ethical Review of Multi-centre Studies).

Monitoring and complaints handling will be in line with jurisdictional processes laid out in the Research Ethics and Governance – Monitoring and Reporting Framework.

**Application to a reviewing HREC**

An applicant applying to a certified reviewing HREC, to undertake single ethical and scientific review of a multi-centre clinical trial, should follow either of the following process:

- In New South Wales it will be at the discretion of the applicant to select an HREC; or
- In Queensland through the Central Co-ordinating System (CCS) for HRECs; or
- In Victoria through the Central Allocation System (CAS) for HRECs.

Ethics application administration and processes will be according to standard operating procedures of the respective jurisdictions.

**The role and responsibilities of investigators.**

A Coordinating Principal Investigator (or Coordinating Investigator) may submit an ethics application to an NHMRC certified HREC in any one of the participating jurisdictions.

Depending on the jurisdiction in which the HREC application is to be submitted, the responsibilities of investigators conducting the research will be in accordance with the standard operating procedures of that jurisdiction.

In particular, the role and responsibilities of the Coordinating Principal Investigator (or Coordinating Investigator) with respect to the HREC application and post HREC approval monitoring and reporting will vary according to the jurisdiction in which the HREC application is made and as specified in the individual jurisdiction’s standard operating procedures.

Investigators will be responsible for providing reports (e.g. progress/final reports, adverse event/serious adverse event/SUSAR reports and other safety reports) for submission to the HREC according to individual jurisdiction’s standard operating procedures.
Compliance with monitoring responsibilities of the HREC approving the research will be guided by the relevant State or Territory reporting requirements.

**Research Governance – Site Specific Assessment**

Public health organisations will authorise commencement of research by conducting a site-specific assessment of all multi-centre clinical trials at a participating institution in compliance with the relevant jurisdictional standard operating procedures.

**Roles and responsibilities – sites**

The Public Health Organisation at each research site will continue to have the responsibility to ensure that research is compliant with legislative requirements, the monitoring framework and local governance policies.

**Performance of mutual acceptance**

Participating jurisdictions will uniformly report data regarding Interstate Mutual Acceptance from AU RED according to an agreed format and for agreed time periods and this will be shared with participating jurisdictions.

Participating jurisdictions may report data regarding Interstate Mutual Acceptance from AU RED as a collective for purposes of informing relevant stakeholders. Jurisdictions will agree on the content and frequency of such reporting.

Individual jurisdictions may report on their own jurisdiction’s activity and AU RED data as determined by that jurisdiction for the purposes of informing their jurisdiction’s government or other stakeholders.