Government of **Western Australia**
Department of **Health**

# WA Health
# National Mutual Acceptance Guidelines

Version 3.0

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# Contents

# 1. National Mutual Acceptance (NMA) Background

## 1.1 Aims

**The National Mutual Acceptance of ethical and scientific review for multi-centre human research projects conducted in public health organisations (NMA)** is the scheme that enables the single scientific and ethical review of multi-centre human research projects conducted in public health organisations (PHO) across **multiple** Australian jurisdictions.

Multi-centre research within **one** jurisdiction should be reviewed according to the relevant jurisdiction's requirements. In WA this is the WA Health Single Ethical Review scheme.

The NMA commenced in November 2013 for the review of multi-centre clinical trials, this was expanded to include all human research on 14 December 2015.

Western Australian (WA) public health organisations (WA Health) signed the NMA Memorandum of Understanding on 18 July 2017 and **will commence participation on 31 August 2017.**

The NMA aims to:

- enable PHOs of participating jurisdictions to accept a single ethical and scientific review of human research projects (these PHOs are known as **Accepting Organisations**)
- inform the ongoing development of the national system of single ethical and scientific review of multi-centre research.

Under the NMA, all multi-centre research projects being conducted at PHOs within the participating jurisdictions must be ethically and scientifically reviewed only once by a National Health and Medical Research Council (NHMRC) Certified reviewing HREC. **In WA Health this Certified reviewing HREC is known as the Lead HREC.** The exceptions are those research projects that require additional specialist review in some areas of research that apply in each jurisdiction. **In WA Health this additional reviewing HREC is known as the Specialist HREC** (which may or may not be certified).

## 1.2 Governance Review

A process of research governance review/institutional authorisation/site specific assessment (in NMA referred to collectively as site specific assessment [SSA], **in WA Health known as governance review**) must be undertaken by a participating PHO site. The human research project cannot not commence at a site until approval from a certified Lead HREC (and Specialist HREC, where relevant) has been received and site authorisation has been endorsed at the site where the research is to be conducted.

## 1.3 Participating Jurisdictions

Participating jurisdictions have signed a Memorandum of Understanding (MoU) which outlines agreed principles of participation and specific jurisdictional requirements.

Current participating jurisdictions include:

- Australian Capital Territory (ACT)
- New South Wales (NSW)
- Queensland (Qld)
- South Australia (SA)
- Victoria (Vic)
- Western Australia (WA).

Whilst the NMA Scheme applies to PHOs, private health organisations may accept the review of a NHMRC-certified Lead HREC. Some jurisdictions may have certain ethical review

requirements for private health organisations. Investigators should contact the relevant jurisdiction for more information.

## 1.4 Scope of Research Projects

The NMA scheme involves all human research projects for which an application must be made to a HREC for the purpose of being conducted at a PHO (this includes low and negligible risk research review by a full HREC using a national ethics form). Some human research projects however will be excluded from single ethical and scientific review.

**Human research** is defined in the NHMRC *National Statement on Ethical Conduct in Human Research 2007* (National Statement) 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.

## 1.5 Research Projects Exempted from NMA

Some human research projects are exempted from review under the NMA and will require review by specific HRECs. In WA Health these are known as **Specialist HRECs**.

### 1.5.1 National Exemptions

The following types of projects will be excluded from NMA because of jurisdiction-specific requirements:

- 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.
- Projects involving access to coronial material.
- First Time in Human (FTIH), Phase 0 and Phase 1 clinical trials (in ACT & SA only).

Refer to the *NMA Standard Principles for Operation* and *NMA Fact Sheet* for types of human research projects excluded from single ethical and scientific review under NMA.

### 1.5.2 WA Exemptions

For research conducted in Western Australia, projects involving the following will require Specialist HREC review in addition to the Lead HREC review:

1. 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.
2. All research projects that require access to coronial samples, data or information must be reviewed by the Coronial Ethics Committee, WA.

3. 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.

### 1.6 Retrospective Approval

There will not be retrospective inclusion of approved clinical trials under the NMA process that pre-date November 2013. However, additional sites from newly joined jurisdictions may be added to projects approved under the NMA process, by way of amendments. If a WA Health site is added as an amendment, the WA Specific Module must be submitted to the Lead HREC as part of the amendment review.

There will not be retrospective inclusion of approved research projects (i.e. non-clinical trials) under the NMA process that pre-date 14 December 2015. However, additional sites from newly joined jurisdictions may be added to projects approved under the NMA process, by way of amendments. If a WA Health site is added as an amendment, the WA Specific Module must be submitted to the Lead HREC as part of the amendment review.

## 2. Coordinating Principal Investigator and Principal Investigator Responsibilities

### 2.1 Coordinating Principal Investigator (CPI)

- Takes overall responsibility for developing the project in consultation with accepting sites (participating PIs) to ensure that the project design takes into consideration the different jurisdictional legislative requirements. As these will impact on whether a project can gain approval to be conducted at different sites across Australia. The *Jurisdictional Legislative Requirements* aims to provide an overview of the various legislative and administrative frameworks that currently exist in the Commonwealth and the participating jurisdictions that applies to the approval of human research under NMA. The document is not a substitute for legal advice.
- 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 Lead HREC (and Specialist HREC, where relevant) and passing on information from the HREC to the sponsor and the PI at each site conducting the research.
- Takes on the responsibilities as the PI at their own site (as outlined below).

### 2.2 Principal Investigator (PI)

- Takes responsibility at their own site for the conduct, management, monitoring and reporting of the research project.
- Is responsible for submitting the governance forms and documents for site authorisation and liaises with the site Research Governance Officer (RGO) throughout the life of the research project.
- 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 Lead HREC (and Specialist HREC, where relevant).

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

# 3. Lead Human Research Ethics Committees (HRECs)

## 3.1 Certified HRECs

Under NMA, the single ethical and scientific review of a multi-centre human research project is conducted by an appropriately NHMRC Certified HREC (Lead HREC) **sponsored by a PHO within a participating jurisdiction and certified in a relevant area of research**.

### 3.1.1 National Certification Scheme

The certification of HRECs pertains to the certification of their sponsoring institution. To be identified as a 'Certified Institution', the institution's ethical review process has undergone an independent assessment conducted by the NHMRC. Certification is dependent upon a satisfactory demonstration of institutional conformance with specified criteria which, in part, are based on the National Statement - including that the HREC is appropriately constituted, and that its institution's policies, processes and procedures meet an agreed national set of criteria. A *List of institutions with certified ethics review processes* is available from the NHMRC.

### 3.1.2 NMA Certified Lead HRECs

**Only Certified HRECs sponsored by PHOs in participating jurisdictions can be a Lead HREC under the NMA scheme.** The *HRECs, Research Governance (RG) Office, and Organisations* document provides participating Certified Lead HREC information. 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.

### 3.1.3 WA Health Certified HRECs

WA Health certified Lead HRECs, their contact details and categories include:

| HREC Name | Contact Details | Certification Categories |
|---|---|---|
| Child and Adolescent Health Service Human Research Ethics Committee (EC00268) | Princess Margaret Hospital for Children<br>GPO Box D184<br>PERTH WA 6840<br>P:08 9340 8221<br>E:pmhethics@health.wa.gov.au | Clinical trials phase I, II, III, IV<br>Clinical trials drugs and devices<br>Clinical interventional research other than clinical trials<br>Population health and/or public health<br>Qualitative research<br>Mental health<br>Paediatric research<br>Other health and medical research:<br>• Observational/non-clinical interventional. |
| Sir Charles Gairdner and Osborne Park Health Care Group Human Research Ethics Committee (EC00271) | Sir Charles Gairdner Hospital<br>Level 2, A Block<br>Hospital Avenue<br>NEDLANDS WA 6009<br>P:08 6457 2999<br>E:HREC.SCGH@health.wa.gov.au | Clinical trials phase I, II, III, IV<br>Clinical trials drugs and devices<br>Clinical interventional research other than clinical trials<br>Population health and/or public health<br>Qualitative research. |
| South Metropolitan Health Service Human Research Ethics Committee (EC00265) | Level 2, Education Building<br>Fiona Stanley Hospital<br>11 Robin Warren Drive<br>MURDOCH WA 6150<br>P: 6152 2064<br>E: SMHS.HREC@health.wa.gov.au | Clinical trials phase I, II, III, IV<br>Clinical trials drugs and devices<br>Clinical interventional research other than clinical trials<br>Population health and/or public health<br>Qualitative research<br>Mental health<br>Other health and medical research:<br>• Observational non-clinical research. |

### 3.1.4 WA Health Non-Certified HRECs

WA Health HRECs that are not Certified HRECs will not be involved in providing ethical review under the NMA scheme i.e. they will have no involvement with these projects. Their affiliated WA Health PHO will be an Accepting Organisation i.e. they will be required to accept the ethical review of a NMA Certified HREC. These organisations still retain the right not to conduct the project at their sites by not providing site authorisation, once a governance review has been conducted by the RG Office.

### 3.1.5 WA Specialist HRECs

In WA the following Specialist HRECs must provide additional HREC review to the Certified Lead HREC's review if the project involves a WA Exemption:

- Department of Health WA Human Research Ethics Committee (EC00422) (WA Health)
- Coronial Ethics Committee WA (external to WA Health)
- Western Australian Aboriginal Health Ethics Committee (external to WA Health)

## 3.2 Selecting a Lead HREC

The process for the CPI selecting a Lead HREC under the NMA scheme is as follows:

1. The HREC must be a Certified HREC.
2. The Certified HREC must be sponsored by a PHO from a participating jurisdiction as listed in *HRECs, Research Governance (RG) Office, and Organisations*. The Certified HREC must be certified in the category of research related to the human research project.
3. The CPI must apply the following for each jurisdiction regarding the selection of a HREC:

- **Australian Capital Territory** - the choice of HREC is at the discretion of the applicant.
- **New South Wales** - the choice of HREC is at the discretion of the applicant.
- **Queensland** – selection is through the Central Co-ordinating Service online form.
- **South Australia** - applications should be to the certified HREC associated with the site at which the applicant is conducting the research and if this is not applicable, the selection of a suitable certified HREC is at the discretion of the applicant.
- **Victoria** – selection is through the Central Allocation System (Phone: (03) 9096 7395)
- **Western Australia** - applications should be to the certified HREC associated with the site at which the applicant is conducting the research and if this is not applicable, the selection of a suitable certified HREC is at the discretion of the applicant.

## 3.3 Ethics Application Forms

Under the NMA process, the Human Research Ethics Application (HREA) must be used for ethics applications. In addition to the HREA, some jurisdictions require an additional Module to be completed for projects being conducted in their jurisdiction:

- **New South Wales** – requires the *NSW Privacy Form* if applicable.
- **Victoria** - requires the *Victorian Specific Module*. 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.
- **Western Australia** requires the *WA Specific Module (WASM)*. Find further information in the *WA Health Research Authorisation Monitoring Form Guidelines.*

The CPI must sign the declaration section of the HREA. PIs are not required to sign the declaration as they will make a declaration in the SSA Form.

## 3.4 Master Participant Information and Consent Form

The NHMRC templates are the recommended Master Participant Information and Consent Forms (PICFs). Other Master PICFs may be acceptable (refer to Lead HREC websites).

The CPI is responsible for submission of the Master PICF to the Lead HREC (and Specialist HREC, where relevant) following appropriate consultation with participating sites.

**A Site Master 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 in the *NMA Standard Principles for Operation*. However, it should be noted that a Lead HREC (and Specialist HREC, where relevant) is not required to accept Catholic wording on a PICF if it is deemed not appropriate for that particular research project.

The PIs are responsible for the submission of **Site PICFs**, based on the Master PICFs (with site specific details inserted), to the relevant Research Governance (RG) Offices as part of site authorisation.

## 3.5 Ethics Checklist

The *Ethics checklist* should be completed by the CPI and included with every new research project submitted to a NMA Lead Certified HREC within the jurisdictions of NSW, Qld, SA and Vic. **It is not required for WA Health HRECs,** though may be used as a guide for documents that may be require submission to the Lead HREC.

# 4. Jurisdictional IT Systems for Ethics Applications

Each participating jurisdiction is responsible for:

- making available IT infrastructure for use by PHOs and Certified HRECs to enable administration of mutual acceptance of single ethics review.
- assisting consolidation of national research project activity information, cross-border application tracking and nationwide reporting by using a system which complies with relevant national e-health and interoperability standards.

The following IT systems are currently utilised by each jurisdiction to adhere to the NMA requirements:

- WA Health's Research Governance Service (RGS): WA
- Infonetica's AU RED/Online Forms: ACT, NSW (will adopt REGIS in 2018), Qld, SA, Vic.

## 4.1 Submission Process for a WA Health Lead HREC

If the project is being reviewed by a Certified WA Health Lead HREC the CPI should:

**RGS**

- **Follow Quick Start Guide for New User process to:**
- **Sign up to RGS & Create a new project -** select 'inter-jurisdictional sites' and 'National Mutual Acceptance single ethical review'.
- **Complete Sites Tab** for all Australian sites under the NMA Lead HREC review.
- **Complete Members Tab** for all investigators listed on ethics application form. Can appoint a CPI Delegate.
- **Complete Declarations Tab** (as relevant).
- **Complete Project Details Tab** - in the Project Header nominate the WA Health Lead HREC (and Additional WA Health Specialist HREC if applicable).
- **In Forms & Documents Tab** - add and complete the WA Specific Module (WASM) and add any other additional ethics documents into RGS.

**HREA**

- **Complete the HREA** on the NHMRC's website, print as pdf and upload it into RGS as a document.

**Modules**

- **If relevant complete the** *Victorian Specific Module* or *NSW Privacy Form* and upload into RGS as a document (links available on **RGS**).

**RGS**

- Follow **Quick Start Guide for New User** process to:
- **In Forms & Documents Tab** - submit WASM and ethics documents to the relevant WA Health Lead HREC (and Additional WA Health Specialist HREC if applicable). Specialist HRECs outside WA Health will require separate applications outside RGS.
- **In Forms & Documents Tab** - WA Health PIs must complete and submit the governance forms and documents to WA Health RG Offices, for site authorisation at WA Health sites.

**Online Forms**

- **For sites outside WA Health** - Once ethical approval is received, the CPI must use **Online Forms** to create a Minimal Dataset Form (MDF), upload copy of HREA and supporting documents, create SSA(s) and transfer each SSA to the site Principal Investigator.

## 4.2 Submission Process for an External Lead HREC

If the project is being reviewed by a Certified Lead HREC external to WA Health the CPI should:

**RGS**

- **Follow Quick Start Guide for New User process to:**
- **Sign up to RGS & Create a new project -** select 'inter-jurisdictional sites' and 'National Mutual Acceptance single ethical review'.
- **Complete Sites Tab** for all Australian sites under the NMA Lead HREC review.
- **Complete Members Tab** for all investigators affiliated with or accessing identifiable data from WA Health sites. Can appoint a CPI Delegate.
- **Complete Declarations Tab (as relevant).**
- **Complete Project Details Tab -** in the Project Header select Lead HREC outside WA Health (and Additional WA Health Specialist HREC if applicable).
- **In Forms & Documents Tab -** add and complete the WA Specific Module (WASM) and print as PDF to send to External Lead HREC. Do not submit it at this time.

**Online Forms**

- **Complete the** HREA on the **Online Forms** website, and upload the WASM and any other additional ethics documents.

**Modules**

- **If relevant complete the** *Victorian Specific Module* or *NSW Privacy Form* and upload into RGS as a document (links available on **RGS**) and upload into Online Forms.

**RGS**

- **Once ethical approval is received and an Additional WA Health Specialist HREC is involved**, follow **Quick Start Guide for New User** to:
- **In Forms & Documents Tab** - the **CPI** must upload the approved ethics documents (including the HREA and Lead HREC approval letter) to ethics.
- **In Forms & Documents Tab** submit WASM and ethics documents to the relevant Additional WA Health Specialist HREC. Specialist HRECs outside WA Health will require separate applications outside RGS.
- **In Forms & Documents Tab** - WA Health PIs must complete and submit the governance forms and documents to WA Health RG Offices, for site authorisation at WA Health sites.

**RGS**

- **Once ethical approval is received and no Additional WA Health Specialist HREC is involved**, follow **Quick Start for New User** to:
- **In Forms & Documents Tab** - the **CPI or PI** must upload the approved ethics documents (including the HREA and Lead HREC approval letter) to ethics.
- **In Forms & Documents Tab** submit WASM and ethics documents to the WA Health RG Office affiliated with a WA Health site involved with the project.
- **In Forms & Documents Tab** - WA Health PIs must complete and submit the governance forms and documents to WA Health RG Offices, for site authorisation at WA Health sites.

## 4.3 Submission Process for Previous NMA approval with WA added as Amendment

RGS

- **Follow Quick Start Guide for New User to:**
- **Sign up to RGS & Create a new project -** select 'inter-jurisdictional sites' and 'National Mutual Acceptance single ethical review'.
- **Complete Sites Tab** for all Australian sites under the NMA Lead HREC review.
- **Complete Members Tab** for all investigators affiliated with or accessing identifiable data from WA Health sites. Can appoint a CPI Delegate.
- **Complete Declarations Tab (as relevant).**
- **Complete Project Details Tab -** in the Project Header select Lead HREC outside WA Health (and Additional WA Health Specialist HREC if applicable).
- **In Forms & Documents Tab -** add and complete the WA Specific Module (WASM) and print as PDF to send to External Lead HREC. Do not submit it at this time.

RGS

- **Once ethical approval is received and no Additional WA Health Specialist HREC is involved**, follow Quick Start for New User to:
- **In Forms & Documents Tab** - the **CPI or PI** must upload the approved ethics documents (including the HREA and Lead HREC approval letter) to ethics.
- **In Forms & Documents Tab** submit WASM and ethics documents to the WA Health RG Office affiliated with a WA Health site involved with the project.
- **In Forms & Documents Tab** - WA Health PIs must complete and submit the governance forms and documents to WA Health RG Offices, for site authorisation at WA Health sites.

# 5. Ethical and Scientific Review by Lead HRECs

## 5.1 Full HREC Review

The scope of NMA includes any form of human research. This includes low and negligible risk research which must be reviewed by a full HREC using a national ethics form (e.g. HREA). HREC review must be conducted in according to the NHMRC *National Statement on Ethical Conduct in Human Research 2007*.

## 5.2 Timeliness of Review and Reporting

A 60 calendar day (with stop-clock capability) benchmark[1] for scientific and ethical review and decision making by a certified Lead HREC must be applied. A similar timeframe is recommended for governance review by a RG Office. Participating jurisdictions are required to contribute to national NMA annual reports on the number of projects and timeliness of review by both HRECs and RG Offices.

WA HRECs and RG Offices from Health Service Providers (HSPs) and the Department of Health will be required to provide these statistics to the WA Department of Health for collation for each fiscal year. The RGS and local information technology (IT) systems will used to extract data for these reports.

## 5.3 Jurisdictional Legislative Requirements

The Lead HREC must take into consideration the different jurisdictional legislative requirements when reviewing a project. As these will impact on whether a project can gain approval to be conducted at different sites across Australia. The *Jurisdictional Legislative Requirements* aims to provide an overview of the various legislative and administrative frameworks that currently exist in the Commonwealth and the participating jurisdictions that it applies to for the approval of human research under NMA. The document is not a substitute for legal advice.

The areas of legislation that may have to be considered apply to:

1. Clinical Trial Notification (CTN) and Clinical Trial Exemption (CTX) Schemes
2. Consent
3. Embryo Research
4. Financial Accountability
5. Gene Technology
6. Ionising Radiation
7. Privacy and Confidentiality
8. Record Keeping
9. Removal and Use of Human Tissue
10. Risk Management
11. Jurisdictional Data Collections

## 5.4 Duration of Scientific and Ethical Approval

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 project.

[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 (application) closing date (ACD) for the HREC meeting at which an application will be reviewed. The clock stops when a request for further information or clarification (AIR) 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.

### 5.5 HREC Approval Letters

HREC approval letters should clearly:

- List all organisations (or sites) that have been approved through single ethical review.
- State the HREC approval date.
- Specify the date on which the CPI submits to the Lead 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.
- Specify the duration of ethical approval.

### 5.6 HREC Insurance

Each participating jurisdiction is responsible for ensuring that it has appropriate insurance for the purpose of participating in the NMA i.e. for the purpose of conducting ethical review of multi-centre clinical trials and other research projects.

## 6. HREC Monitoring and Reporting

The Lead HREC will have oversight of the human research project and ensure that it complies with all ethical, scientific and safety requirements, as appropriate. Investigators will be required to provide regular progress reports, other required reports and safety reports to the Lead HREC (and Specialist HREC, where relevant) in accordance with each jurisdiction's requirements based on the NHMRC *Safety monitoring and reporting in clinical trials involving therapeutic goods 2016*.

The Lead HREC (and Specialist HREC, where relevant) and the site conducting the human research project is responsible for monitoring the ongoing conduct and safety of approved research as stated in the NHMRC *National Statement on Ethical Conduct in Human Research 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 2012*.

The NMA *Monitoring and Reporting Framework* is intended as a guide for HRECs, organisations, researchers and other parties participating in NMA. It is designed to assist understanding of monitoring and reporting processes involved in ethical review and research governance of human research. It provides an overview of monitoring and reporting and sets out the responsibilities of researchers, HRECs and institutions.

The NMA *Monitoring and Reporting Tables* is a guide for investigators (CPI and PI), HREC Coordinators and Research Governance Officers (RGOs). They provide information on the reporting requirements for multi-centre human research projects taking place in States and Territories. They cover the reporting requirements related to:

- Safety
- Amendments
- Complaints
- General
- Pre and Post approval/authorisation requirements.

## 6.1 Annual Progress Reports

Annual or more frequent progress reports to the Lead HREC (and Specialist HREC, where relevant) should be provided by the CPI/Delegate 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 Lead HREC (and Specialist HREC, where relevant).

An annual progress report will be due on the anniversary date of the Lead HREC approval (not on the anniversary date of site authorisation or project commencement).

The CPI/Delegate is responsible for submitting a collated annual progress report to the Lead HREC (and Specialist HREC, where relevant). The CPI/Delegate should submit reports to the reviewing HREC(s) by the required date. If a site PI/Delegate has not provided the CPI/Delegate 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.

### 6.1.1 Reporting Process for a WA Health Lead HREC

The *WA Health Annual Progress Report* must be used by the CPI/Delegate if a WA Health Lead HREC approves the project. A copy of the report should be sent to the WA Health Specialist HREC (if relevant). WA Health PIs/Delegates must submit a copy to WA Health RG Offices.

### 6.1.2 Reporting Process for an External Lead HREC

The CPI/Delegate will be required to contact the External Lead HREC and provide reporting on the External Lead HREC's Annual Progress Report form. The *WA Health Annual Progress Report* must be completed by the CPI/Delegate if a WA Health Specialist HREC is involved. WA Health PIs/Delegates must also use this form to provide Annual Progress Reports to the WA Health RG Offices (all sections should be completed by the PI/Delegate).

## 6.2 Amendments

Modification of an approved human research project must be submitted to the Lead HREC (and Specialist HREC, where relevant) 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.

In cases of immediate safety concerns (Urgent Safety Measure) not covered under usual monitoring or a risk to participant safety, the Lead HREC should receive a report from the responsible investigator as soon as possible. The Lead HREC can then be fully informed and an ethical decision made, before a formal amendment process occurs.

A HREC amendment must not be implemented at a site until ethical approval is provided and the RG Office at the site has been consulted and has confirmed that site authorisation is current.

A RG Office should provide a timely response to PIs/Delegates regarding the amendment, to avoid undue delay of the amendment to the project at the site.

### 6.2.1 Amendment Process for a WA Health Lead HREC

The *WA Health Amendment Form* must be used by the CPI/Delegate if a WA Health Lead HREC approves the project. A copy of the form should be sent to the WA Health Specialist HREC (if relevant). Once the HREC amendment has been approved, the WA Health PIs/Delegates should submit the form and ethics approval letter to the WA Health RG Offices (any additional 'Governance' related amendments can be added at this time) for review and site authorisation.

### 6.2.2 Amendment Process for an External Lead HREC

The CPI/Delegate will be required to contact the External Lead HREC and submit the Amendment on the External Lead HREC's Amendment Form. The *WA Health Amendment Form* must be completed by the CPI/Delegate if a WA Health Specialist HREC is involved. Once the HREC amendment has been approved, the WA Health PIs/Delegates should complete and submit the *WA Health Amendment Form* and ethics approval letter to the WA Health RG Offices (any additional 'Governance' related amendments can be added at this time) for review and site authorisation.

## 6.3 Extension of HREC Approval

Extension of the HREC approval period may be requested and the Lead HREC and WA Health Specialist HREC (if relevant) 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 Lead HREC in the relevant jurisdiction. WA Health HRECs will follow current WA Health policy.

## 6.4 Safety Reporting

Safety reporting (i.e. Serious Breach, Significant Safety Issues, SUSAR or USADE, Annual Safety Report and updated Investigator Brochure) is the responsibility of the Sponsor, CPI and PIs and submission of appropriate safety reports should be guided by the NHMRC *Safety monitoring and reporting in clinical trials involving therapeutic goods 2016*. For guidance on safety reporting refer to the *Monitoring and Reporting Tables* for NMA.

### 6.4.1 Safety Reporting Process for a WA Health Lead HREC

The *WA Health Safety Form* must be used by the CPI/Delegate if a WA Health Lead HREC approves the project. A copy of the form should be sent to the WA Health Specialist HREC (if relevant). This form should also be used by WA Health PIs/Delegates to report to WA Health RG Offices when this reporting is required (guidelines are contained within the form).

### 6.4.2 Safety Reporting Process for an External Lead HREC

The CPI/Delegate will be required to contact the External Lead HREC and submit the Safety Report on the External Lead HREC's Safety Form. The *WA Health Safety Form* must be completed by the CPI/Delegate if a WA Health Specialist HREC is involved. The *WA Health Safety Form* should also be used by WA Health PIs/Delegates to report to WA Health RG Offices when this reporting is required (guidelines are contained within the form).

## 6.5 Complaints

The complaints process should be guided by jurisdictional policies and procedures. For guidance on reporting of complaints refer to the *Monitoring and Reporting Tables* for NMA.

### 6.5.1 Complaints Reporting Process for a WA Health Lead HREC

The *WA Health Research Complaint Form* must be used by the complainant if a WA Health Lead HREC approves the project. If the complaint relates to the whole project it should be submitted to the Lead HREC and the WA Health Specialist HREC (if relevant) should be advised by the CPI/Delegate of the complaint and outcome. If the complaint relates to a specific WA Health site the complainant should submit the form to the relevant WA Health RG Office.

### 6.5.2 Complaints Reporting Process for an External Lead HREC

The complainant will be required to contact the External Lead HREC and submit the complaint using their processes if it relates to the whole project. If the complaint relates to a specific WA Health site the complainant should submit the *WA Health Research Complaint Form* to the relevant WA Health RG Offices.

### 6.6 Final Report

The PI/Delegate must submit a final report to the relevant RG Office when a site is closed. The CPI/Delegate is responsible for submitting a final report to the Lead HREC (and Specialist HREC, where relevant) when the whole project is closed (i.e. all sites covered by the ethical review are closed).

#### 6.6.1 Final Reporting Process for a WA Health Lead HREC

The *WA Health Final Report* must be used by the CPI/Delegate to close a project if a WA Health Lead HREC approves the project. A copy of the report should be sent to the WA Health Specialist HREC (if relevant). WA Health PIs/Delegates must submit the *WA Health Final Report* to WA Health RG Offices when closing the WA Health sites.

#### 6.6.2 Final Reporting Process for an External Lead HREC

The CPI/Delegate will be required to contact the External Lead HREC and provide reporting on the External Lead HREC's Final Report form when closing the project. The *WA Health Final Report* must be completed by the CPI/Delegate if a WA Health Specialist HREC is involved. WA Health PIs/Delegates must submit the *WA Health Final Report* to WA Health RG Offices when closing the WA Health sites.

## 7. Site Authorisation

### 7.1 Governance Review

The NMA scheme provides for ethical and scientific approval only. Each participating PHO will continue to undertake a governance review (also called SSA) of all multi-centre human research projects conducted at sites under their control and provide site authorisation in compliance with the relevant jurisdictional standard operating procedures (SOPs). These SOPs should be read in conjunction with the *NMA Standard Principles for Operation*.

### 7.2 Governance Application Forms

Each jurisdiction will have a governance application form for use within that jurisdiction. This may be either a SSA Form or Access Request Form as applicable.

#### 7.2.1 WA Health Governance Forms

In WA Health, depending on whether the PI is conducting the project at a site or accessing WA Health participants, their data or tissue, they will complete respectively either a:

- WA Health Site Specific Assessment (SSA) Form and Budget Form; OR
- WA Health Access Request Form.

Find further information in the *WA Health Research Authorisation and Monitoring Forms*. All WA Health governance forms must be submitted to WA Health RG Offices via the RGS.

#### 7.2.2 External Jurisdiction's Governance Forms

Jurisdictions external to WA Health have their own SSA Forms. Information regarding these forms can be found at Online Forms.

**This document can be made available in alternative formats on request for a person with a disability.**