

## New Projects - Approved by an external HREC

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<b>Content Owner</b>	Office for Research	<b>Document Author</b>	Ethics, Integrity and Governance Operations Team

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## Overview

National Mutual Acceptance (NMA) is a national system for mutual acceptance of scientific and ethical review of multi-centre human research projects conducted in publicly funded health services across jurisdictions. This allows a single ethical and scientific review for a multi-centre human research project can be provided across seven of the participating states/territories. This SOP applies if you have already received HREC Approval from another Australian publicly funded health service. The includes research meeting one or more of the definitions below:

- Directly or indirectly impacts on Austin Health patients (either in or outpatients)
- Uses Austin Health data
- Uses Austin Health resources
- Could impact on Austin Health's reputation

### Definition of Site:

When the research fits into one or more of the above categories, Austin Health is the site. Our business details cover all of Austin Health's campuses.

### Definition of Austin Health Co-ordinating Investigator:

Authorised person responsible on a day-to-day basis for the conduct of the study. This person is identified by Austin Health.

### Definition of Austin Health Site Principal Investigator (only required if different from Co-ordinating Investigator)

Austin Health Site Principal Investigator, a person who is suitably qualified, willing and able to take responsibility and have oversight of the project at Austin Health.

## Part A: Getting Your Documents Ready

*A-1: Preparing Project Documents for Human Research Ethics Submission (relevant templates available on the [Office for Research website](#))*

### Documents

#### Documents from the approval HREC:

1. HREC Approval letter/s
2. Protocol
3. Master PICF/S
4. Study files
5. Investigator Brochure/Product Information
6. Data Safety Monitoring Board
7. Enrolment log
8. Screening log
9. Delegation log
10. Case report form
11. Adverse event tracker
12. Clinical trial notification
13. TGA notifications

#### Austin site-specific documents:

14. Austin Site-specific Appendix to PICF
15. Site-specific study files
16. Site investigator CV
17. GCP training certificate
18. Site study budget (**not required if in-kind support**)
19. Fee form

#### Insurance, Indemnity, Agreements and legal:

20. Medicine Australia HREC and/or Standard form of Indemnity (*commercially sponsored projects*)
21. Clinical Trials Certificate of Currency AUD 10 million for any one occurrence and in the annual aggregate
22. Medicines Australia CTRA (or MTAA equivalent), including SEBs approval letter (if required)
23. Other agreements, as deemed appropriate in consultation with Austin Health

*A-2: Austin Department Approval (only required if Austin Health is a site; relevant templates available on the [Office for Research website](#))*

### Document type

### Notes

- | Document type                 | Notes  |
|-------------------------------|--|
| 1. Health Information Service | Required if your project need to access medical records  |
| 2. Pharmacy                   | Required if your project uses drugs that need to be dispensed by pharmacy  |
| 3. Pathology                  | Required if your project uses blood tests, regardless of whether it is additional or part of standard of care.               |
| 4. Radiology                  | Required if your project uses imaging services, regardless of whether it is additional or part of standard of care.          |
| 5. Nuclear Medicine/PET       | Required if your project includes procedures additional to standard of care  |
| 6. Medical Physicist Report   | Required if your project includes any ionising radiation, regardless of whether it is additional or part of standard of care |
| 7. Allied Health              | Required if your project uses Allied Health services that are not part of the project team.                                  |

## Part B: Submitting your documents for review

### *B-1: Getting your Austin Site-Specific Assessment (SSA) Authorisation*

Action	Description
Submit via the ERM	<ol style="list-style-type: none"> <li>1. Log into <a href="#">ERM</a> Application.</li> <li>2. Under HREA form, click “<b>Sub-form</b>”. Choose the “<b>Site Specific Assessment (SSA)</b>” from the form type.</li> <li>3. Click create and complete the SSA form.</li> <li>4. Upload all the documents from <b>A-1 and A-2</b>.</li> <li>5. Obtain electronic signatures from Austin Health Site Principal Investigator and their Head of Department (or delegate) on the SSA.</li> </ol>
Finalised your application	Submit Austin Health SSA.

## Part C: Version Control

Document History	
Version	Summary of Changes
1.1	Hyperlinks to the Resources for Researchers webpage and the ERM incorporated; Updated Clinical Trial Certificate of Currency; Department of Radiology approval added in A-2.
1.2	Updated notes regarding Departmental Approvals – Pathology and Radiology