

New Projects - Commercially Sponsored Projects

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Overview

Commercially Sponsored project is defined when a project is funded by an Australian arm of an International Pharmaceutical and/or Biotechnology company, or an Australian Clinical Research Organisation (CRO) or an Australian Private Company. 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
- Requests our Research Partners to act as local Sponsor, where the project uses Austin health patients, data, resources and/or impacts Austin Health’s relationship.

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 the Pharmaceutical and/or Biotechnology Company or CRO.

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](#))

From Sponsor	From Austin Principal Investigator
<p>Study documents:</p> <ol style="list-style-type: none"> 1. Protocol 2. PICF/S 3. Investigator Brochure/Product Information 4. Data Safety Monitoring Board 5. Enrolment log 6. Screening log 7. Delegation log 8. Case report form 9. Adverse event tracker 10. Fee form <p>Registration</p> <ol style="list-style-type: none"> 11. Clinical trial notification 12. TGA notifications <p>Insurance, Indemnity, Agreements and legal documents:</p> <ol style="list-style-type: none"> 13. Medicine Australia HREC and/or Standard form of Indemnity 14. Clinical Trials Certificate of Currency AUD 10 million for any one occurrence and in the annual aggregate 15. Medicine Australia CTRA (or MTAA equivalent), including SEBs approval letter (if required) 16. Other agreements, as deemed appropriate in consultation with Austin Health 	<p>Study documents:</p> <ol style="list-style-type: none"> 1. Study files 2. Austin PICF coversheet 3. Investigator CV 4. GCP training certificate 5. Site study budget <p>Insurance, Indemnity, Agreements and legal documents:</p> <ol style="list-style-type: none"> 6. Other applicable research agreements, e.g. service level agreement 7. Austin Health Agreement Cover letter

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
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 Human Research Ethics Application Submitted

Action	Description
Submit via the ERM	<ol style="list-style-type: none"> 1. Log onto ERM Application. 2. Create and complete the Human Research Ethics Application (HREA) from. <ul style="list-style-type: none"> • Click on “Create Project” button. • Fill in the project title and jurisdiction. Choose the “Human Research Ethics Application (HREA)” from the main form type. • Click create and complete the HERA form. 3. Create and complete the Victorian Specific Module (VSM) from. <ul style="list-style-type: none"> • Under the HREA form, click “Sub-form”. Choose the “Victorian Specific Module (VSM)” from the form type. • Click create and complete the VSM form. 4. For single site project, upload all the documents A-1 and A-2 to ERM. 5. For multi-site project, upload all the documents from A-1 (Study documents) to ERM. 6. Send the HREA to be signed electronically from: <ul style="list-style-type: none"> • Coordinating Principal Investigator for multisite research. • Austin Health Site Principal Investigator for single site research.
Finalised your application	<ol style="list-style-type: none"> 1. Submit your ERM application before the cut-off date. Please note that we no longer accept email submissions. If you have trouble accessing ERM, please contact research@austin.org.au for assistance. <p>For single-site Austin Health only projects: No further steps are required.</p> <p>For multi-site projects and where Austin Health is also a participating site:</p> <ul style="list-style-type: none"> • Submit your Austin Health Site-Specific Assessment (SSA) Authorisation application (instructions in B-2 below). • For noting: SSA review can occur in parallel with HREC review, this is part of our streamlining strategy.

B-2 Getting your Site-Specific Assessment (SSA) Authorisation

Action	Description
Submit via the ERM	<ol style="list-style-type: none"> 1. Log into ERM Application. 2. Under Austin Health form, click “Sub-form”. Choose the “Site Specific Assessment (SSA)” from the form type. 3. Click create and complete the SSA form. 4. Upload all the documents from A-1 (Registration, Insurance, Indemnity, Agreements, and legal documents) and A-2. 5. Obtain electronic signatures from Austin Health Site Principal Investigator and their Head of Department (or delegate) on the SSA.
Finalised your application	Submit Austin Health SSA (only for multi-site projects where Austin is a site), noting you are encouraged to submit your SSA application together with your HREC application.

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 Trials Certificate of Currency; Department of Radiology approval added in A-2.
1.2	Updated notes regarding Departmental Approvals – Pathology and Radiology