New Projects - Austin Health Sponsored Clinical Trials

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Content Owner	Office for Research	**Document Author**	Ethics, Integrity and Governance Operations Team

Contents

Overview

Austin Sponsored Clinical trials project is defined when the trial is funded by or the fund is administered by Austin Health (usually referred as 'Investigator initiated trial'. 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	
Study documents: 1. Protocol 2. PICF/S, using Austin Health Site PICF coversheet (in lieu of Austin Site PICFs) 3. Study files 4. Investigator CV 5. GCP training certificate 6. Investigator Brochure/Product Information 7. Data Safety Monitoring Board 8. Enrolment log 9. Screening log 10. Delegation log 11. Case report form 12. Adverse event tracker 13. Study budget (note required for in-kind support) 14. Fee form	**Registration** 15. Clinical trial notification 16. TGA notifications **Insurance, Indemnity, Agreements and legal documents:** 17. Agreements as deemed appropriate in consultation with Austin Health 18. *(for multi-site)* Medicines Australia CRG agreement, other applicable research agreements, e.g. service level agreement

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 that are additional to standard of care
4. Radiology	Required if your project uses imaging services that are additional to 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	1. Log onto ERM Application. 2. Create and complete the Human Research Ethics Application (HREA) from. • 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. • 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 from **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: • Coordinating Principal Investigator for multisite research. • Austin Health Site Principal Investigator for single site research.
Finalised your application	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. **For single-site Austin Health only projects:** No further steps are required. **For multi-site projects and where Austin Health is also a participating site:** • 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	1. Log into ERM Application. 2. Under HREA 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; Department of Radiology approval added in A-2.