

Submitting Amendment requests for approved projects

Date Effective	19 April 2022	Revision Due Date	19 April 2023
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Contents

- Overview1**
- Part A: Amendments when Austin Health is the led HREC1**
 - A-1 Getting your amendment request submitted1**
 - A-2 Austin Department Approval (only required if Austin Health is being added as a site as part of the amendment)2**
- Part B: Amendments for projects approved by an External HREC3**
 - B-1 Getting your Austin Site-Specific Assessment (SSA) Amendment Authorised3**
- Part C: Version Control3**

Overview

Projects with active Ethics approvals may go through research amendment(s) throughout the lifespan of the research. Such amendments may include change of sites and research personnel, update on study documents, update on existing research agreements as well as amendment of research protocol which would not result in significant alteration on the original research aim(s), purpose and/or scope of the research.

Research amendments must be reviewed and approved by relevant Ethics Committee prior to implementation. It is the responsibility of Co-originating Principal Investigator to ensure that amendment requests are submitted, and approvals are obtained prior to implementing any changes.

Part A: Amendments when Austin Health is the lead HREC

A-1 Getting your amendment request submitted

Action	Description
Document preparation	<ol style="list-style-type: none"> 1. For any documents to be updated due to the amendment, e.g. out-facing documents, study files, protocol, Investigator brochures, etc., provide a copy of both tracked and clean versions based on the lasted approved version. 2. Ensure updated version controls are included within the updated documents as well as in the file names. 3. For any new documents to be produced due to the amendment, only a clean copy is required. Please ensure corrected version controls are included within the new documents as well as in the file names. 4. Ensure relevant Austin Site Department Approvals are in place, if applicable. See A-2. 5. Provide a completed Fee From (available on the Office for Research website).
Submit via the ERM	<ol style="list-style-type: none"> 1. Log into ERM Application. 2. Under HREA form, click “Sub-form”. Choose the “Ethics Amendment Request” from the form type.

3. Click create and complete the form.
4. Upload all applicable documents mentioned above in “Document preparation”.
5. Send the amendment form to be signed electronically from:
 - Coordinating Principal Investigator for multisite research.
 - Austin Health Site Principal Investigator for single site research.

1. Submit your ERM amendment at any time. Please note that we no longer accept email submissions. If you have trouble accessing ERM, please contact research@austin.org.au for assistance.

Finalised your application

For single-site Austin Health projects or multisite where Austin Health is only providing Ethical Review: No further steps are required.

For multi-site amendments where Austin Health is the lead HREC and a site:

- Submit your Austin Health Site-Specific Assessment (SSA) Authorisation application (instructions below).
- **For noting:** SSA review can occur in parallel with HREC review, this is part of our streamlining strategy.

Finalising your Austin led SSA application (multisite only)

1. Log into [ERM](#) Application.
2. Under the Austin Health “**Site Specific Assessment (SSA)**” from. Choose the “Site Amendment” from the form type.
3. Click and create and complete the “Site Amendment” form.
4. Upload all applicable documents from A-1 above.
5. Obtain electronic signatures from Austin Health Site Principal Investigator and their Head of Department (or delegate).
6. Submit SSA amendment form at the same time so both approvals can be given in parallel.

A-2 Austin Department Approval (only required if Austin Health is being added as a site as part of the amendment; 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: Amendments for projects approved by an External HREC

B-1 Getting your Austin Site-Specific Assessment (SSA) Amendment Authorised

Action	Description
Document preparation	<ol style="list-style-type: none"> 1. Receive and upload into ERM your lead HREC ethics approval letter & documentation 2. For any Austin Site-Specific documents to be updated due to the amendment, e.g. out-facing documents, study files, site agreements, etc., provide a copy of both tracked and clean versions based on the lasted approved version. 3. Ensure updated version controls are included within the updated documents as well as in the file names. 4. For any new documents to be produced due to the amendment, only a clean copy is required. Please ensure corrected version controls are included within the new documents as well as in the file names. 5. Ensure relevant Austin Site Department Approvals are in place, if applicable. See A-2.
Submit via the ERM	<ol style="list-style-type: none"> 1. Log into ERM Application. 2. Under the Austin Health “Site Specific Assessment (SSA)” form. Choose the “Site Amendment” from the form type. 3. Click and create and complete the “Site Amendment” form. 4. Upload all applicable documents. 5. Obtain electronic signatures from Austin Health Site Principal Investigator and their Head of Department (or delegate).
Finalised your application	<ol style="list-style-type: none"> 1. Submit Austin Health SSA amendment form.

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.