FREQUENTLY ASKED QUESTIONS

Reintroduction of Ethics Review Manager (ERM)

Discovery & Innovation Unit | Austin Health

These FAQs have been developed to support Austin Health's research community with the reintegration of ERM into our ethics and governance submission process.

What is Austin Health's new ethics and governance submission process?

From Monday 24 August, all new project approval requests must first be entered into Ethics Review Manager (ERM) before being registered in Research Architect (RA).

Instead of entering extensive project information into multiple systems, researchers will now:

1. create and submit their application in ERM, including the Human Research Ethics Application (HREA), Victorian Specific Module (VSM), Site Specific Assessment (SSA) and supporting documents
2. record the ERM reference number
3. register the project in RA using the streamlined form called "**Research Application** "and include the ERM reference number
4. identify the Austin Health departments required to support the project, and
5. submit the registration and receive confirmation from RA.

The Discovery & Innovation Unit (DIU) will retrieve the application and documents from ERM and manage approval workflows and communications through RA.

The revised process reduces duplicate data entry while maintaining Austin Health's governance and reporting requirements, as well as those required under the National Mutual Acceptance scheme.

What projects need to be added to ERM?

- All new projects submitted after 11.59pm on 23 August 2026 (single or multisite)
- All multisite projects that have ethics approval or site governance authorisation that will require **any** action by Austin Health HREC or DIU for site governance authorisation
- Note: single site projects that have HREC approval or site governance approval prior to 11.59pm on 23 August 2026 will not be required to transition to ERM (until further notice), however, a PI/delegate can elect to create a HREA if they so choose.

Who will add the projects to ERM?

This will be a joint effort:

- The PI/delegate is responsible for submitting new projects from 24 August 2026.

- The DIU team will assist with all Austin Sponsored projects already in the Approval workflow, but not yet approved, (i.e., projects already submitted into RA on or before 11.59pm 23 August 2026, but not yet approved for Ethics or Site Governance)
    - DIU will draft the VSM and HREA then DIU will notify PI/delegate ready for review then PI/delegate will confirm for accuracy and obtain PI signature then DIU will approve in ERM for the researcher
    - Please note DIU are unable to process the SSA in these instances. The SSA is completed by the researcher/delegate
- The PI/delegate is responsible for identifying projects that have ethics approval or site governance authorisation and require any action item where documentation in the project record is required.

What will happen to projects unapproved in ERM as of 23 August 2026?

The DIU will conduct an audit of ERM and take the following action:

- If the project can be located in RA and has Austin Health approval/authorisation then DIU will approve the record in ERM.
- If the project cannot be located in RA it will be assumed as unapproved or no longer required then DIU will take no action in ERM.
- If the project is identified by the PI/delegate then please contact DIU via email including the parent case number or Lead HREC approval number, full title and ERM number then DIU will locate and update in ERM.

The project has an ERM entry, but the researcher did not do an SSA in ERM for Austin Health?

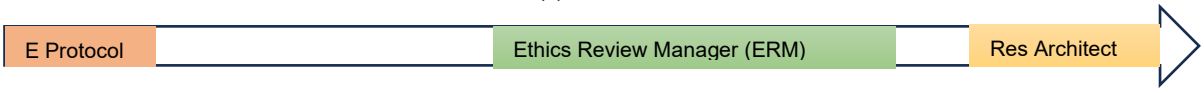
In this case, the PI/delegate can add an SSA for Austin Health then inform DIU via email including the parent case number or Lead HREC approval number, full title and ERM number then DIU will approve the SSA.

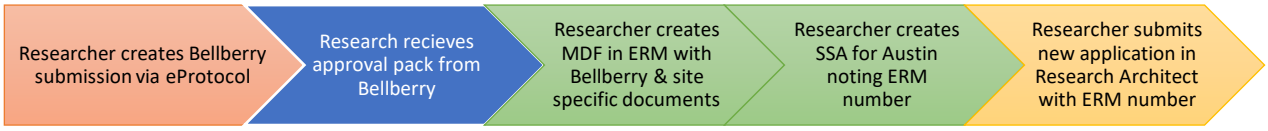
What is required when a HREC external to NMA is used? (i.e., Bellberry as the HREC)

Please note the advice below is from Safer Care Victoria.

For industry sponsored clinical trials that are reviewed by Bellberry

- These projects do not fall within the NMA scheme
- Participating sites can decide to accept the Bellberry review in line with their own governance requirements
- An MDF can be created on ERM to support sites that want to use ERM for their SSA





ERM submission types

Minimum data form (MDF)

A simplified ERM application pathway intended for projects that require institutional registration and oversight but **do not require a full governance review within ERM**. Austin Health will accept this pathway for:

- projects that are single site AND already ethics and governance approved at Austin Health in RA
- projects that have already received ethics approval through another institution (i.e., Bellberry) and Austin Health has a site governance role, or
- projects in which Austin Health staff are participating in a study being conducted elsewhere and no Austin Health participants, data, tissue, facilities, or resources are being used.

Please do not use the MDF pathway if:

- An NMA HREC is the reviewing HREC (including Austin Health HREC); and
- the submission in ERM is performed after 23 August 2026 AND you do not already have ethics and/or governance approval

Human Research Ethics Application (HREA)

The Human Research Ethics Application (HREA) is the national ethics application form used to seek Human Research Ethics Committee (HREC) review and approval of research involving humans used by National Mutual Accepting HREC's. The HREA captures detailed information about the study design, participant population, consent processes, privacy and confidentiality arrangements, risks and benefits, data management, and ethical considerations.

Non NMA HRECs may use an alternative ICT portal with an alternative format HREA.

- Please check with Austin Health if they will accept a non NMA HREC review and approval.
- Please note Austin Health will accept a Bellberry approval so as long as Austin Health is listed on the relevant HREC approval letter.
- The Sponsor is responsible for ensuring all participating sites are aware of the approval pathway undertaken, and what those sites will accept.

Researchers should use either the ERM HREA for NMA HREC approvals, or the Bellberry ICT portal for Bellberry HREC approval when their project requires review by an HREC, including:

- clinical trials

- clinical research involving patients, participants, carers, or members of the public
- research involving access to identifiable or re-identifiable personal information
- research involving human tissue, biological samples, or genetic data
- qualitative research involving interviews, focus groups, surveys, or observations where HREC review is required
- multi-site research requiring ethical review through the National Mutual Acceptance (NMA) scheme or another certified HREC process, and
- student or investigator-initiated research involving human participants.

Researchers should not use the HREA when:

- the activity is a Quality Assurance, Quality Improvement, Audit, Evaluation, or Service Development activity that does not constitute research
- the project is exempt from HREC review under local policy
- the submission is for governance review only and ethics approval has already been granted by another HREC, and
- the project only requires institutional registration through an MDF (when the project has been approved in RA prior to 23 August 2026 or approved by Bellberry external to ERM HREA).

Further reading

- For more information about the new ethics and governance submission process and how to reintegrate ERM into your workflow, please visit the 'How do to clinical research at Austin Health' page on The Pulse. You'll find document submission guides, templates and more.

Decision making for pathway from 24 August 2026