Important Information for New Applications and projects in process

The Online Forms site will transition to a new system called ERM (Ethics Review Manager) in Queensland and Victoria. Online Forms will no longer be used to create or submit new ethics and research governance applications (HREA, SSA or LNR). Use of ERM will start on 16 July 2018.

What is ERM used for?
ERM is a paperless information management system for completion, submission and storage of documentation for:
- Human Research Ethics Application (HREA) form
- Victorian Specific Module (VSM)
- Site Specific Assessment (SSA) form
- Victorian Low and Negligible Risk (LNR VIC) application form *(only for sites that have nominated to use it)*
- All post-approval forms (e.g. amendment, progress report, safety report)

ERM allows secure digital signature of applications, and is an efficient way to share information with the research project team and the research office.

Research offices will use ERM to process ethics and research governance applications, and to communicate with applicants.

What is the timeline?

29 June 2018	Final date to **create** a new application form (HREA, SSA or LNR) using Online Forms (available until 5.00pm).
9 July 2018	Final date to **submit** an application form, further information response or post-approval report using Online Forms (available until 5.00pm).
13 July 2018	Final date for **research office to upload** all applications into AU RED (until 5.00pm).
16 July 2018	**ERM** starts!

Is ERM training available for research applicants?

Yes, training will be available on an ongoing basis. Click here to register your interest in an ERM information session for applicants (e.g. researchers, trial coordinators, ethics submission specialists) and sponsors/CROs.

ERM is exciting news for Victoria and Queensland, but what about National Mutual Acceptance (NMA)?

All of the Australian states and territories are committed to supporting NMA, and ERM is designed accordingly. Victoria and Queensland will be linked in ERM. More information will be provided regarding other states and territories prior to the ERM launch.

I already have an Online Forms account – will I need to create a new ERM account?

If you have submitted a Victorian or Queensland Online Forms application in the past, you will automatically have an ERM account on 16 July 2018. Your new ERM account will have the same login details as your old Online Forms account (and your password can be reset if you've forgotten it).

I'm planning to submit an application using Online Forms soon – what will happen to it?

Submit your application using Online Forms before 9 July 2018 and your research office will begin to process it using their AU RED system. If the application is not approved in AU RED by 13 July 2018, the research office will finish processing it in ERM after 16 July 2018.

I'm planning to submit an application soon after 16 July 2018, what should I do to prepare my application?

You can either:
Start your new application in ERM from 16 July 2018
or
Create your application before 29 June 2018 using Online Forms. On 16 July 2018, login to ERM and create a new application, then copy and paste each field from the Online Forms application into the ERM application and upload all supporting documents.

I've started an application in Online Forms but won't be submitting it anytime soon – will it be lost?

No applications will be lost! They will still be there in Online Forms. You can create a new application in ERM after 16 July 2018 and then copy and paste from the Online Forms application into the ERM one.

My ethics application will be submitted using Online Forms before 9 July 2018 but the SSA won't be submitted by then – what should I do about the SSA?

When you log into ERM after 16 July 2018, you will be able to create site specific assessment (SSA) form(s) for your research project. Each SSA can then be submitted to the site research governance officer (RGO) using ERM.

What about the old applications I've saved in Online Forms?

Online Forms will remain live for the foreseeable future, but only as an archive (you won't be able to create/submit new applications, but you can refer back to old ones). You can download past application forms and supporting documents and save them to a local drive.

I'm going to submit a multi-site ethics application – should I contact the Central Allocation System (CAS)?

The ERM system does not have CAS. For submitting a multi-site ethics application from 16 July 2018, you will **not** be required to book a multi-site application with CAS to obtain a HREC Reference Number - simply use ERM to complete and submit the application. The HREC Reference will be generated automatically when you submit.

Staff at the Coordinating Office will still be here to provide advice and answer your questions, and you can contact us if you need help with ERM.

I'm due to submit an annual report in July – should I use ERM for that?

ERM will be used to fill in and submit all post approval report forms, including annual reports, amendments and safety reports. Guidance on how to do this will be provided closer to the ERM launch. The Victorian reporting forms currently in use (the "orange forms") will be in ERM.

What if I need to report something urgently during the changeover period?

To report an urgent safety event between 9 – 15 July 2018, or weekend of 20 – 22 July 2018, please contact your research office directly.

Can I use ERM to submit an application to a private hospital's ethics committee?

ERM in Victoria is designed for public health organisations. Please contact us (details below) regarding submission to a private hospital.

Help!

If you have any questions, please contact the Coordinating Office for Clinical Trial Research at the Victorian Department of Health and Human Services. Email us or phone us on 03 9096 7394.