

Signature requests and submission process in ERM

The requestor must first determine which signatories are providing 'wet ink' signatures and/or electronic signatures.

A signatory must have an ERM account to sign an application/form electronically.

If a combination of signature methods is used, **electronic signatures should be sought last** as the application/form becomes locked once an electronic signature request has been made.

Wet ink signatures

Steps

1. The requestor completes the application including the attachment of all relevant documents
2. In the HREA form **Q 4.7**, select wet ink sign as the signature method

Custom print this page by selecting the **View as PDF**  button found under the Actions pane and obtain the required signature. Scan the page and save to your local drive

Q4.7 How will the Coordinating Principal Investigator/Researcher agree to these terms?

- You can use the ERM 'request/sign' function to electronically sign this application.
- Select 'Upload other evidence' to upload and attach other evidence, such as an email.
- Select 'Sign after printing' if you intend to sign the HREA after it is printed (i.e. 'wet ink' signature).


Electronic signature (in place of HREA 'sign on screen')

Upload other evidence

Wet ink sign after printing

Sign here:


Date:

3. The signed page is attached to the HREA in **Q 4.2** under **Other project-related documentation**
Select **Upload Document**  to attach the signed page from your local drive
4. An **Upload Document** button is available when the 'Upload other evidence' signature method e.g. an email copy or letter to indicate agreement is selected

The uploaded signature document will be displayed with the document and file name and version

Other project-related documentation


Other project-related documentation specific to your institution and/or jurisdiction

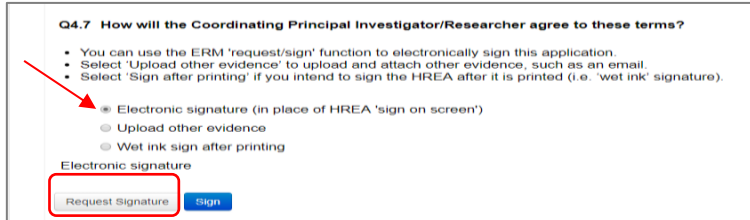
Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Other project-related documentation	CPI signature	CPI signature.pdf	19/08/2018	1	155.5 KB		

5. In a **SSA** form, the Declaration page is printed  and signed by the signatory. The page is scanned, saved and uploaded in **Q 7.1 Supporting Documents**.

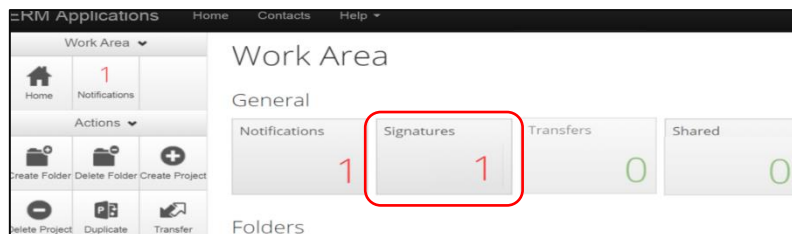
Electronic signature request

Steps

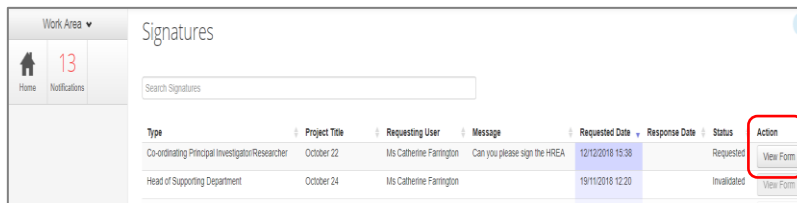
1. The Requestor selects 'Electronic signature' as the signature method and a   button will appear. Select **Request Signature**





2. A **Request a Signature** pop up box is displayed. Enter the signatory's ERM email address and select **Request**
3. The signatory will receive an email notification of the signature request with a link to the ERM Work Area. Select the **Notifications** or **Signatures** tile to open the request



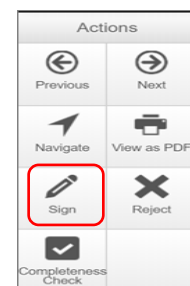
4. New requests are highlighted  and select **View Form** to review the application.



Type	Project Title	Requesting User	Message	Requested Date	Response Date	Status	Action
Co-ordinating Principal Investigator/Researcher	October 22	Ms Catherine Farrington	Can you please sign the HREA	12/12/2018 15:38		Requested	
Head of Supporting Department	October 24	Ms Catherine Farrington		19/11/2018 12:20		Invalidated	

5. Select **Previous / Next** to move through the form or **Navigate** to access an overview of the form and uploaded supporting documents.

For endorsement of the application, select **Sign**



6. A **Sign Form** textbox is displayed.


The signatory enters their ERM log in details and selects **Sign** 

7. The Requestor receives an email notification advising that the signature has been applied, i.e. the form is signed.

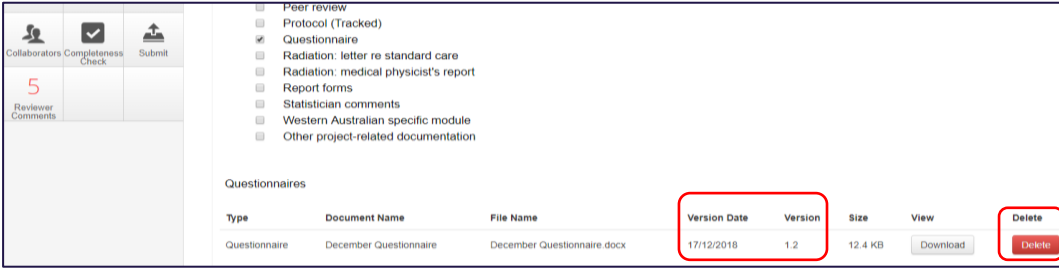
Submission process in ERM

Ensure the form is complete with all supporting documents uploaded and signature requests completed.

Steps

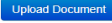
1. Navigate to the Actions pane and select the **Submit**  action button
2. Following submission, a unique identification code is generated e.g. HREC/74950/VICTEST-2021-257683(v1)
3. The applicant will be advised by the Research Office if the application requires further clarification, edits to documents or additions. The form will be unlocked.
4. If the query requires a new version of a particular document, the original version should be deleted, and the new version uploaded into the form.

5. Select the **Delete**  button to delete the original



The screenshot shows the ERM interface with a list of documents. The 'Delete' button is highlighted in red. The table below shows the document details:

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Questionnaire	December Questionnaire	December Questionnaire.docx	17/12/2018	1.2	12.4 KB	Download	Delete

6. Select the **Upload Document**  to upload the revised (new) version of the document from your local drive with the correct version number and date
7. Check with the Research Office if CPI/PI signatures are required again
8. Once the revisions/additions have been completed, the form is ready for resubmission

9. Select the **Submit**  button to resubmit

Authorised by the Coordinating Office for Clinical Trial Research

Department of Jobs, Precincts and Regions
121 Exhibition Street Melbourne Victoria 3000
Telephone 0408 274 054
© Copyright State of Victoria,
Department of Jobs, Precincts and Regions 2021

Except for any logos, emblems, trademarks, artwork and photography this document is made available under the terms of the Creative Commons Attribution 3.0 Australia license.

This document is also available in an accessible format at multisite.ethics@ecodev.vic.gov.au