# Applicant user guide to ERM

Ethical Review Manager (ERM)



Health and Human Services

To receive this publication in an accessible format phone 9096 7394 or email <u>multisite.ethics@dhhs.vic.gov.au</u>

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## Contents

Glossary	5
Application Process flow	6
Section 1: Introduction	7
Create an account	7
ERM Forms	10
Section 2: Work Area	13
Actions	13
General	14
Folders	14
Projects	14
Actions Pane	
Form Status Table	16
Tab Functions	
ERM Reference Numbers	
Section 3: The HREA form	
Create an HREA	21
Complete the HREA	
Import an HREA	
Upload Documents	
Assign access to the HREA	
Applying Signatures	
Section 4: Submission and Review Process - HREA	
Submission	
Responding to a Query from the Research Office	
Ethics Committee Review Request	
Section 5: National Mutual Acceptance (NMA) applications	40
Section 6: Victorian Specific Module (VSM)	
Section 7: Victorian Low and Negligible Risk Application (LNR VIC)	43
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form	<b>43</b>
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form Complete the LNR VIC	<b>43</b> 43 44
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form Complete the LNR VIC Upload Documents	<b>43</b> 43 44 44
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form Complete the LNR VIC Upload Documents Assign access to the LNR VIC form	<b>43</b> 43 44 44 44
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form Complete the LNR VIC Upload Documents Assign access to the LNR VIC form Applying Signatures	<b>43</b> 43 44 44 44 45
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form Complete the LNR VIC Upload Documents Assign access to the LNR VIC form Applying Signatures Section 8: Submission and Review Process – LNR VIC	<b>43</b> 43 44 44 44 45 <b>48</b>
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form Complete the LNR VIC Upload Documents Assign access to the LNR VIC form Applying Signatures. Section 8: Submission and Review Process – LNR VIC Submission	
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form Complete the LNR VIC Upload Documents Assign access to the LNR VIC form Applying Signatures Section 8: Submission and Review Process – LNR VIC Submission Responding to a Query from the Research Office.	
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form. Complete the LNR VIC. Upload Documents. Assign access to the LNR VIC form Applying Signatures. Section 8: Submission and Review Process – LNR VIC . Submission Responding to a Query from the Research Office. Ethics Committee Review Request.	43 44 44 44 45 48 48 48 48 51
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form Complete the LNR VIC Upload Documents Assign access to the LNR VIC form Applying Signatures Section 8: Submission and Review Process – LNR VIC Submission Responding to a Query from the Research Office Ethics Committee Review Request Section 9: Site Specific Assessment (SSA)	
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form Complete the LNR VIC Upload Documents. Assign access to the LNR VIC form Applying Signatures. Section 8: Submission and Review Process – LNR VIC Submission Responding to a Query from the Research Office. Ethics Committee Review Request. Section 9: Site Specific Assessment (SSA) Create a SSA	
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form Complete the LNR VIC Upload Documents Assign access to the LNR VIC form Applying Signatures Section 8: Submission and Review Process – LNR VIC Submission Responding to a Query from the Research Office Ethics Committee Review Request Section 9: Site Specific Assessment (SSA) Create a SSA Creating SSAs for Sites.	
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form Complete the LNR VIC Upload Documents Assign access to the LNR VIC form Applying Signatures Section 8: Submission and Review Process – LNR VIC Submission Responding to a Query from the Research Office Ethics Committee Review Request. Section 9: Site Specific Assessment (SSA) Create a SSA Creating SSAs for Sites Upload Documents	
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form Complete the LNR VIC Upload Documents Assign access to the LNR VIC form Applying Signatures Section 8: Submission and Review Process – LNR VIC Submission Responding to a Query from the Research Office. Ethics Committee Review Request. Section 9: Site Specific Assessment (SSA) Create a SSA Creating SSAs for Sites. Upload Documents Assign access to the SSA form	43 44 44 44 45 48 48 48 48 51 51 54 55 57 58
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form Complete the LNR VIC Upload Documents Assign access to the LNR VIC form Applying Signatures. Section 8: Submission and Review Process – LNR VIC Submission Responding to a Query from the Research Office Ethics Committee Review Request. Section 9: Site Specific Assessment (SSA) Create a SSA Creating SSAs for Sites Upload Documents Assign access to the SSA form Applying Signatures.	
Section 7: Victorian Low and Negligible Risk Application (LNR VIC)         Create a LNR VIC form         Complete the LNR VIC         Upload Documents         Assign access to the LNR VIC form         Applying Signatures         Section 8: Submission and Review Process – LNR VIC         Submission         Responding to a Query from the Research Office.         Ethics Committee Review Request.         Section 9: Site Specific Assessment (SSA)         Creating SSAs for Sites.         Upload Documents         Assign access to the SSA form         Applying Signatures.         Section 10: Submission and Review Process – SSA	
Section 7: Victorian Low and Negligible Risk Application (LNR VIC)         Create a LNR VIC form         Complete the LNR VIC         Upload Documents         Assign access to the LNR VIC form         Applying Signatures         Section 8: Submission and Review Process – LNR VIC         Submission         Responding to a Query from the Research Office.         Ethics Committee Review Request.         Section 9: Site Specific Assessment (SSA)         Creating SSAs for Sites.         Upload Documents         Assign access to the SSA form         Applying Signatures.         Section 10: Submission and Review Process – SSA         Submission	43 44 44 44 45 48 48 48 48 51 51 54 55 57 57 58 58 62 62
Section 7: Victorian Low and Negligible Risk Application (LNR VIC)         Create a LNR VIC form.         Complete the LNR VIC         Upload Documents.         Assign access to the LNR VIC form.         Applying Signatures.         Section 8: Submission and Review Process – LNR VIC         Submission         Responding to a Query from the Research Office.         Ethics Committee Review Request.         Section 9: Site Specific Assessment (SSA)         Creating SSAs for Sites.         Upload Documents.         Assign access to the SSA form.         Applying Signatures.         Section 10: Submission and Review Process – SSA.         Submission         Responding to a Query from the Research Office.	43 44 44 44 45 48 48 48 48 51 54 54 55 57 58 58 58 62 62 63
Section 7: Victorian Low and Negligible Risk Application (LNR VIC) Create a LNR VIC form Complete the LNR VIC Upload Documents Assign access to the LNR VIC form Applying Signatures. Section 8: Submission and Review Process – LNR VIC Submission Responding to a Query from the Research Office Ethics Committee Review Request. Section 9: Site Specific Assessment (SSA) Create a SSA Creating SSAs for Sites. Upload Documents Assign access to the SSA form Applying Signatures. Section 10: Submission and Review Process – SSA Submission Responding to a Query from the Research Office. Responding to a Query from the Research Office.	43 44 44 44 44 45 48 48 48 48 51 54 54 54 55 57 57 58 58 62 63 63 66
Section 7: Victorian Low and Negligible Risk Application (LNR VIC)         Create a LNR VIC form         Complete the LNR VIC         Upload Documents         Assign access to the LNR VIC form         Applying Signatures         Section 8: Submission and Review Process – LNR VIC         Submission         Responding to a Query from the Research Office         Ethics Committee Review Request.         Section 9: Site Specific Assessment (SSA)         Create a SSA         Creating SSAs for Sites.         Upload Documents.         Assign access to the SSA form.         Applying Signatures.         Section 10: Submission and Review Process – SSA         Submission         Responding to a Query from the Research Office.	43 44 44 44 45 48 48 48 48 48 48 51 51 54 55 57 57 58 58 62 62 63 66 69
Section 7: Victorian Low and Negligible Risk Application (LNR VIC)         Create a LNR VIC form         Complete the LNR VIC         Upload Documents         Assign access to the LNR VIC form         Applying Signatures         Section 8: Submission and Review Process – LNR VIC         Submission         Responding to a Query from the Research Office         Ethics Committee Review Request.         Section 9: Site Specific Assessment (SSA)         Create a SSA         Creating SSAs for Sites.         Upload Documents         Assign access to the SSA form         Applying Signatures.         Section 10: Submission and Review Process – SSA         Submission         Responding to a Query from the Research Office         Responding to a Query from the Research Office         Responding to a Query from the Research Office         Section 10: Submission and Review Process – SSA         Submission         Responding to a Query from the Research Office         RGO Review Request.         Section 11: Minimal Dataset Form (MDF)         Section 12: Legacy Application Replacement Form (LARF)	43 44 44 44 45 48 48 48 48 51 54 54 55 57 58 58 58 62 62 63 66 69 72
Section 7: Victorian Low and Negligible Risk Application (LNR VIC)         Create a LNR VIC form         Complete the LNR VIC         Upload Documents         Assign access to the LNR VIC form         Applying Signatures         Section 8: Submission and Review Process – LNR VIC         Submission         Responding to a Query from the Research Office         Ethics Committee Review Request.         Section 9: Site Specific Assessment (SSA)         Create a SSA         Creating SSAs for Sites.         Upload Documents.         Assign access to the SSA form.         Applying Signatures.         Section 10: Submission and Review Process – SSA         Submission         Responding to a Query from the Research Office.	43 44 44 44 45 48 48 48 48 51 54 54 54 55 57 58 58 62 62 63 66 69 72 74

Complete a Sub-form – Ethics Amendment Request7	7
Allowing others to access post approval forms7	8
Applying Signatures7	8
Submission and Review	0
Section 15: Post Authorisation	1
Create a Sub-form	1
Complete a Sub-form – Site Governance Amendment Request	2
Allowing others to access post authorisation forms8	3
Applying Signatures	4
Submission and Review	5
Section 16: Other ERM features	6
Project Update	6
Cancel a Signature	8
Changing jobs	8
Transfer a Project	9
Transfer a Sub form	1
Duplicate a Project9	2
Duplicate a Form9	3
Delete a Form9	4
Edit Roles and Share9	5
Collaborators9	6
Contacts9	7
Correspondence	8
Archived documents10	1
Folders	2
Submission to non ERM Research Offices10	4
Help10	5

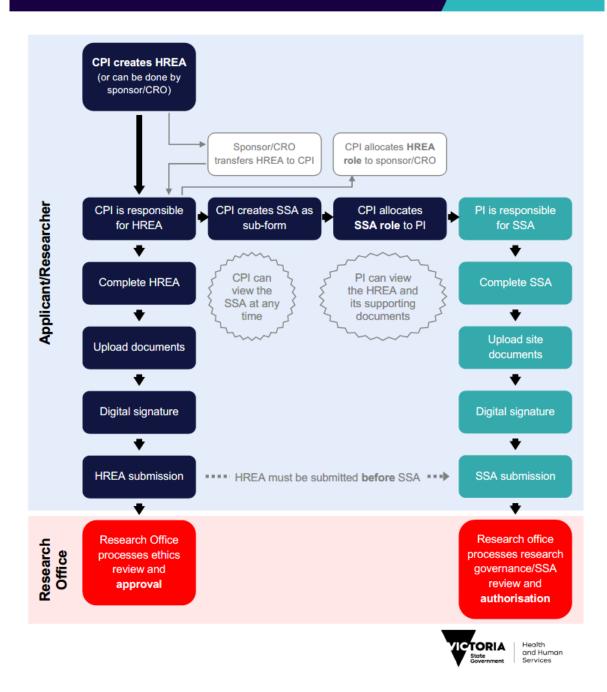
## Glossary

CPI	Coordinating Principal Investigator. Overall responsibility for the research
	project and submits the project for scientific and ethical review
CRO	Contract Research Organisation (may act as local sponsor for non-Australian
	entities)
CTN	Clinical Trial Notification
CTRA	Clinical Trial Research Agreement
СТХ	Clinical Trial Exemption
CV	Curriculum Vitae
FDA	Food and Drug Administration (in USA)
GCP	Good Clinical Practice
HREA	Human Research Ethics Application
HREC	Human Research Ethics Committee that has been certified under the NHMRC
	National Certification Scheme, and be a Certified Reviewing HREC under the
	NMA scheme
IB	Investigator Brochure
ICH-GCP	International Conference on Harmonisation – Good Clinical Practice
LARF	Legacy Application Replacement Form
LNR	Low and Negligible Risk application
MDF	Minimal Dataset Form
NHMRC	National Health Medical Research Council
NMA	National Mutual Acceptance (NMA) is a system for mutual acceptance of
	scientific and ethical review of multi-centre human research projects
	conducted in publicly funded health services across jurisdictions. Australian
	Capital Territory, New South Wales, Queensland, South Australia, Victoria and
	Western Australia participate in NMA
PI	Principal Investigator. Responsible for the project at a site
PICF	Participant Information Consent Form
QA	Quality Assurance application
RGO	Research Governance Officer
SSA	Site Specific Assessment
VSM	Victorian Specific Module

## **Application Process flow**

## Ethical Review Manager (ERM)

Ethics and Research Governance/SSA



## Section 1: Introduction

## Ethical Review Manager (ERM): https://au.forms.ethicalreviewmanager.com

#### About ERM

ERM is a paperless information management system for completion, submission and storage of:

- ethics applications
- research governance/site specific assessment (SSA) applications
- post-approval (ethics) forms
- post-authorisation (research governance) forms

ERM is used by research applicants (researchers, trial coordinators, sponsors, contract research organisations etc.). It is also used by research office administrators and ethics committee members to manage the review, processing and approval/authorisation of all applications.

The communication features of ERM ensure that the entire life-cycle of a research project can be managed within the ERM system.

ERM is used for all ethics and research governance/SSA applications to public health organisations in Victoria and Queensland. Some private health organisations also use ERM – for details, consult the organisation's research office.

#### Who uses Ethical Review manager (ERM)?

ERM can be used by anyone involved with an ethics or research governance/SSA application, including:

- Coordinating Principal Investigator (or delegate/s)
- Principal Investigators (or delegate/s)
- Sponsors/Contract Research Organisations/Trial Coordinators

ERM is a secure password-protected website. Each user must create their own private account.

#### Create an account

Go to the ERM website https://au.forms.ethicalreviewmanager.com

#### To Log in:

**Note:** Online Forms was the precursor to ERM. Online Forms account holders may already have an ERM account and can use the same login details.

For users with no previous Online Forms account:

- 1. Select New User
- 2. Enter the information and agree to the Terms and Conditions.
- 3. Click Register and a verification email is sent to the entered address

- 4. Select the activation link in the email
- 5. Click Log in
- 6. Log in with your email address and password

#### Log in

ERM Applications		Log in
ERM Applications	Contractions Contr	Log in
	Log n New User Forgotten Password	

- 1. Enter your email address and password
- 2. Select Log in

#### Forgotten password

When logging in as an applicant, if the password entered is incorrect an error message will appear

- Select Forgotten Password
- Enter the email address of the account to be signed into

	Forgotten Password	
A lir	k to reset your password will be emailed to you	
Email address		
	Reset Password	

- Select Reset Password
- An email will be sent with a link to change the password. Enter the new password and select

#### **Reset Password**

- A Message box will be displayed confirming the password change
- Select the link to return to the login page

Your password has successfully been reset, please click here to return to login page.

#### Changing password

- Log in with usual account details
- Select the account name located on top-right of browser

ERM Applications	Home Contacts Help •			Beta Test Mode	Ms Catherine Farrington
Work Area 🗸	Work Are	6			Change Password Personal Details
Home 24	General				Logout
Actions 🗸	Notifications	Signatures	Transfers	Shared	
Create Folder Delete Folder Create Project	24	0	0	23	

- Select Change Password
- A Change Password message box will be displayed Enter old and new password
- Select Change Password

Old Password	
New Password	
Confirm New Password	

#### Changing personal details

- Log in with usual account details
- Select the account name located on top-right of browser
- Select Personal Details
- A Change Personal Details message box will be displayed Enter changes to personal details
- Select Change Details

CI	nange Personal De	tails
	Title	
	Ms	
	First Name	
	Postcode	
	Country	
		T
	Unavailable	
	Change Details	

#### Log out

ERM Applicatio	NS Home Contacts Help ▼	Prof Major Researcher ▼
Work Area 🗸	Work Area	Change Password Personal Details
Home Notifications	General	Logout
0		

- Select arrow at right edge of account name
- Select Logout

## **ERM Forms**

	Work Area 🗸	,	HREA Sept	ember 17A			
Home	Notifications		Project Tree 🗸				
	Actions 🗸		HREA Septen	nber 17A	ect		
ំំំំំំំំំ	0	<	• HREA	`	> Main Form		
Project	Create Sub- form	Share	- O Ame	ndment Request	Sub Form		
1+	$\checkmark$	1	Site	Specific Assessment (SSA) VIC -	$\longrightarrow$	Sub Form	
Roles	Completeness Check	Submit	•	Complaint Report			
22	Θ	Ē	└──( ● Ame	indment Request			
Refresh	NMA Project	Print					
$\times$	4		Form Status	Review Reference	Application Type	Date Modified	NMA
Correspond	-		Not Submitted	N/A	N/A	02/10/2018 17:42	Project is not for NMA

- ERM is based on forms. The applicant creates a project and a main form simultaneously
- From the **main form**, the applicant can create **sub-forms** e.g. SSA form, Project Progress Report.
- From some sub-forms (SSA and LNR VIC SSA) further sub-forms can be created e.g. Site Progress Report, Complaint Report and Site Notification Form
- A summary of the forms available in ERM is displayed in the tables below.

#### Main Forms

There is only one main form for each project.

Form	Description
Human Research Ethics Application <b>(HREA)</b>	Ethics application form
Victorian Low/Negligible Risk Application Form (LNR VIC)	Ethics application form for low or negligible risk research in Victoria; used at selected organisations only
Quality Assurance Application Form <b>(QA)</b>	Application form for quality assurance or clinical audit in Victoria; used at selected organisations only
Minimal Dataset Form (MDF)	Proxy for an ethics application form; used when the ethics review was performed in a state/territory that does not use ERM; allows creation of SSA form(s) in ERM
Legacy Application Replacement Form <b>(LARF)</b>	Proxy for an ethics application form; used when an old project (approved before July 2018) is not in ERM nor reviewed under NMA; allows creation of Sub-form(s) in ERM for Victoria only

## Sub-forms for initial application

Form	Description
Victorian Specific Module (VSM)	Required as part of the ethics application when the HREA is utilised and the research project involves a site in Victoria; addresses Victorian legislation
Site Specific Assessment (SSA)	Research governance application form; one SSA is required for each site participating in a research project
Victorian Low/Negligible Risk Site Specific Assessment <b>(LNR VIC SSA)</b>	Research governance application form; one LNR VIC SSA is required for each site participating in a research project

## Sub-forms for post-approval

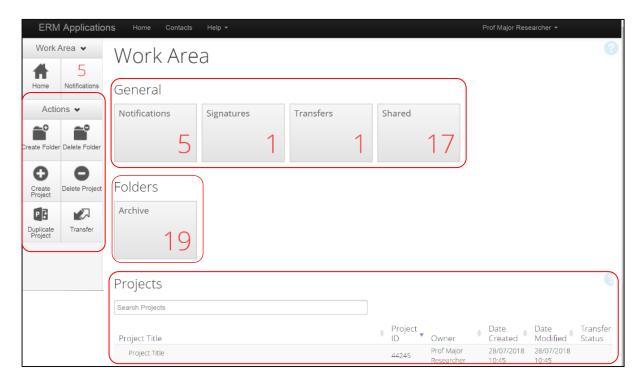
Form	Description
Ethics Amendment Request	Request ethical approval for a change to the design or conduct of a research project e.g. the protocol, PICF or change to personnel
Safety Report	Report a safety event to the reviewing ethics committee
Annual Safety Report	Report to the reviewing ethics committee on the safety profile of an interventional clinical trial
Serious Breach Report	Report a serious breach to the reviewing ethics committee
Suspected Breach Report	Report a suspected breach to the reviewing ethics committee
Project Progress Report	Report to the reviewing ethics committee on the progress of a research project (at least annually, may be more frequent if requested)
Site Closure Report	For a multi-site project, report the closure of one participating site to the reviewing ethics committee
Project Final Report	Report to the reviewing ethics committee on the progress of a research project at the time of its completion
Project Notification Form	Report to the reviewing ethics committee on any matters for which there is not a specific post-approval form available

## Sub-forms for post-authorisation

Form	Description
Complaint Report	Report a research project complaint to the site's research governance officer
Non-serious Breach/Deviation Report	Report a non-serious breach/deviation to the site's research governance officer
Site Audit Report	If requested by the site's research governance officer, provide a self- audit of the research project
Site Notification Form	Report to the site's research governance officer on any matters for which there is not a specific post-approval form available
Site Progress Report	Report to the site's research governance on the site's progress of a research project (at least annually, may be more frequent if requested)
Site Governance Amendment Request	Notify the research governance officer of either an amendment that has been approved by the reviewing ethics committee <b>or</b> a governance-only amendment that does not require ethical approval

## Section 2: Work Area

The Work Area is the ERM home page. The left side of the screen displays the Actions pane with function buttons below. The right of the screen displays an overview of projects in the user's ERM account.



## Actions

There are six action buttons under the Actions pane



Create a new project



Delete a project (only possible if the main form has not been submitted via ERM)



Create a bespoke folder for storage of projects



Delete a folder (only possible if the folder is empty)



Permanently transfer a project to a colleague



Duplicate an existing project

## General

There are four tiles in the **General** section. If the tile displays a red number, it may contain items that require attention.

Work A	١re	а					
General							
Notifications		Signatures		Transfers		Shared	
	5		1		1		17

**Notifications** - Contain messages that are sent to the user from the Research Office:

- $\circ\quad$  queries or request for information regarding an application
- Approval letters
- Messages automatically generated by ERM e.g. form updates
- Messages from other research team members/collaborators
  - the user has been assigned a level of access to a form
  - o a change in the access status of a form
  - an electronic signature has been requested
  - o a form has been signed electronically by the signatory

## Signature - Contain requests from colleagues to digitally sign an application i.e. a request for an electronic signature

- Transfers Contain requests to transfer a project to another ERM user
- Shared Contain information about forms and level of access another ERM user has shared with you

#### Folders

Displays bespoke folders for storage of projects.

## Projects

- Projects in the user's ERM account are listed under Projects
- To access a project begin typing the project's title in the **Search Projects** text box. Select a project from the list displayed

Work Area V	Work Area	
Actions 🗸	Notifications Signatures Transfers Shared	
Create Folder Delete Folder Create Project	3 0 0 7	
Delete Project	Folders	
	Old Applications Search Projects	
	Projects	
	Search Projects	
	Project Title         Ø         Project ID           Owner         Ø         Date Created         Ø         Date Modified           LNR December         \$0186         Ms Catherine Farrington         24/12/2018 10.02         24/12/2018 13.56	Transfer Status
	December Holidays 49968 Ms Catherine Parrington 12/12/2018 14:22 18/12/2018 17:39	

• The project will open under a Project Tree

Worl	rk Area 👻		HREA Sep	otember 17A			46664
	O otifications		Project Tree V	tember 17A	Project Tree		
Project Cre	Print C	Share	0 1	nendment Request ae Specific Assessment (ISBA) VIC - • Complaint Report			
	Recall		Form Status	mendment Request	Application Type	Date Modified	NMA
			Submitted	HREC/46664/VICTEST-2018-154992(v1)	Ethics Application	16/10/2018 11:12	Project is for NMA

## **Actions Pane**

There are eleven possible action buttons available under the Action pane on the left side of the screen. The actions are listed below:



Go to the Project overview



Create a Sub-form from the main form e.g. SSA



Enable collaborators to view, edit and manage the form



Enable collaborators to view, edit and manage the form



Identify mandatory questions within the form that require information to be entered



Submit the application to the reviewing organisation. Note: the reviewing organisation must be selected **within the form**, in order for the submission to be directed to that organisation.



Refresh



Record that the project falls within the National Mutual Acceptance (NMA) scheme. Information on NMA is available on the <u>Clinical Trials and Research</u> website.



Generate a PDF of the form



Communicate directly with the Research Office selected as the reviewing organisation within the form **only after** the form has been submitted



Import a HREA created on a different website e.g. hrea.gov.au, as an Xml file in to ERM

## Form Status Table

	ork Area 🐱	HREA Sept	ember 17A			466
Home P	3 Notifications	Project Tree V				
A	Actions 🛩	HREA Septer	abor 176			
Project C		O HREA	indment Request			
Roles C			Specific Assessment (SSA) VIC - Complaint Report			
		-	Site Notification Form			
$\times$	Import Xml	Form Status	Review Reference	Application Type	Date Modified	NMA
		Recalled	N/A	Ethics Application	17/10/2018 09:26	Project is for NMA
Correspond						

The Form Status table displays the current activity of the form

Form Status:	Description
Not Submitted	the application is still in progress and yet to be submitted
Submitted	the application has been submitted to the reviewing organisation
Recalled	the application has been recalled by the user to make changes. Only possible if the reviewing organisation has <b>not</b> started processing the application
Queried	the application has been queried by the Research Office for further clarification or edits
Validated	the application is ready for review by the ethics committee
Information Requested	the ethics committee has requested further clarification or information
Approved	the application has been approved by the reviewing ethics committee

#### **Review Reference:**

The unique identification code for a form and is generated when an application is submitted in ERM. It is composed of six parts -

#### 1 2 3 4 5 6 e.g. HREC/46664/VICTEST-2018-154992(v1)

	Component	Description	Examples
1	Application type	Identifies the type of application form	HREA, LNR VIC, MDF, SSA
2	ERM Project ID	The unique identification number for the research project	46664
3	Organisation/hospital code	The organisation/hospital to which this form was submitted	Austin, RCH, VICTEST
4	Year	Year of submission	Can change when a new form version is submitted in the following year
5	Submission number	System identifier for the particular submission of this form	154992
6	Version number	Version number to track submission history	v1 to v2 to v3

#### Application Type:

Identifies the type of application/form submitted e.g.

- Ethics Application (the HREA)
- LNR application
- Quality Assurance
- SSA

#### Date Modified:

Displays the most recent date a form was updated

#### NMA:

Whether the research project/application will be reviewed under National Mutual Acceptance (NMA)scheme or not.

## **Tab Functions**

	Vork Area 👻		HREA Sep	tember 17A			4666
Home	3 Notifications		Project Tree 🗸				
Project	Actions	Share Submit		nther 17A endiment Request specific Assessment (SBA) VIC - • Complaient Report set Avolfaction Form endiment Request			
Correspond	Limport Xml		Form Status	Review Reference	Application Type	Date Modified	NMA
			Recalled	N/A	Ethics Application	17/10/2018 09:26	Project is for NMA

There are seven tabs that cover specific aspects of the application and its submission process

Tab	Explanation
Navigation	Application form is completed under Navigation tab
Documents	Displays all supporting documents that have been uploaded within the form Note: Documents are not uploaded under this tab; documents are uploaded within the relevant section of the form
Signatures	Shows a history of all digital signatures that have been applied to the form, and all signature requests
Collaborators	Displays members of the research team with access to the form; levels of access can be modified
Submissions	Shows a history of all submissions that have been made via ERM
Correspondence	Displays a record of the communication between the user and the reviewing organisation's research office
History	An auditable history of actions; if the form has been submitted, an archived version of the submission is available here.

Each tab is described below:

#### Navigation

- The Navigation tab displays the sections and associated questions within the form. Sections will become accessible or inaccessible depending on the information relative to the application
- Questions are hyperlinked (in blue) for quick navigation to the relevant section within the form

#	0		Form Status	<b>Review Reference</b>		Application Type		Date Modified		NMA	
Home	Notifications		Not Submitted	N/A		N/A		12/10/2018 16:43		Project is not for NP	Ah
	Actions 🗸		_	<u> </u>							
Project	Create Sub-	Share	Navigati	on Documents	Signatures	Collaborators	Submissions	Correspondence	History		
Roles	Completeness	Submit	HREA Section	westions							Show inactive \$
Refresh	S NMA Project	Print	ERM Module HREA Introduction	IRM Filter Questions							
Correspond	Import Xml		Project Team Disclosure of Interests	Project Team Disclosure of Interests							

#### Documents

• The Documents tab displays current supporting documents that have been uploaded in to a form. The details displayed indicate the document type, name, file name, version date and

number

Roles Completeness Check	Submit								
2 0		Form Status	Review Reference	Application	Type Da	ate Modified	NMA		
Rafreeh NMA Project	Print	Not Submitted	NA	N/A	12	/10/2018 16:43	Project	is not for NMA	
Correspond Import Xml		Navgato Documents	Documents	Signatures Collaborato	n Bubmasions Corr	espondence History			
		Туре		Document Name	File Name	Version Date	Version	Size	View
		Participant information and co	nsent form	PICFs Dec 2017	PICFs Dec 2017.docx	12/10/2018	1.0	474.6 KB	Download

#### Signatures

- Displays a history of all digital signatures that have been applied to the form and shows all signature requests
- Signatures are not applied in this tab. To sign a form, use the Navigation tab to access the relevant section for signature requests

	Vork Area • 2	~	HREA Septe	ember					46659
Home	Notifications		Project Tree 🛩						
Project Roles	Actions V Create Sub- form Completeness	Share		er pecific Assessment (SSA) VIC - ite Notification Form					
8		$\times$	Form Status	Review Reference	Application Type	Date Modified	NM	A	
NMA Project		Correspond	Not Submitted	N/A	N/A	17/10/2018 08:53	Pro	ject is not for NMA	
Import Xml			Navigati	on Documents Signa	tures Collaborators Submissions	Correspondence	History		
			Signatures						
			Note: There are no active	signatures on this form					
			Signature Reque	ests					
			Туре		Signatory Email	Requested Date	Status	Response Date	Action
			Co-ordinating Principal Inve	estigator/Researcher	abigail.cooper@dhhs.vic.gov.au	17/10/2018 08:54	Requested		Cancel

#### Collaborators

- Displays all members of the research team who have access to the application/form
- To view a collaborator's ERM email account, click on the collaborator's name and the email account will be displayed

Home	Notifications		Project Tree 🗸			
Project	Actions -	Share	HREA 09     HREA     She Specific As	sessment (SSA) VIC -		
Roles	Completeness Check	L Submit	Form Status	Review Reference	Date Modified	NMA
C2 Refresh	S NMA Project	Priot	Not Submitted	NA	24/01/2020 14:44	Project is not for NMA
Correspond	timport Xini			Navigation Documents Signatures	Collaborators Submissions Correspondence H	istory
			Collaborators			
			Name	Access		Edit Permissions
			Ms Abigail Cooper	abigail.cooper@dhhs.vic.gov.au	forms, Receive notifications	Edit Permissions
			Ms Catherine Farrington	Project Owner and Form Owner		Edit Permissions

• The form owner can edit the permissions for each collaborator only if the access level is assigned through the **Share** action

#### Submissions

- Displays the Review Reference e.g. HREC/46664/VICTEST-2018-154992(v1)
- Displays the current status of the application/form
  - Not Submitted / Submitted / Recalled / Queried / Approved
- The Committee that will review the application e.g. VICTEST1
- Under Pdf select Download to print form if required

nome	NORMERINA		Project Tree 🗸							
	Actions $\bullet$		O HREA S	eptember 17A						
Project	Create Sub-	Share	0 HR							
Roles	Print	Carrespond	-0	Site Specific Assessment (SSA) Vi	IC -					
import Xml	Recall		•	Amendment Request						
			Form Status	Review Reference		Applica	tion Type	Date Modified	NMA	
			Submitted	HREC/46664/VICTEST-20	18-154992(v1)	Ethics A	pplication	16/10/2018 11:12	Project is for NMA	
			ħ	lavigation Documents	Signatures Col	aborators Submissions	Correspondence	History		
			Submission	5						
			Review Referen	nce		Date	Status	Committee	Pdf	٦.
			HREC/46664/VICTE	IST-2018-154992(v1)		16/10/2018	Submitted	VICTest1	Download	

#### Correspondence

- Displays a record of the communication between the user and the reviewing organisation's research office
- It has no write/send message function

	Work Area 🛩		HREA Septem	ber 17A			46664
#	3 Notifications		Project Tree 🗸				
si a	Actions -	<b>V</b> Item	© HREA September 17	(Regard			
	Completions Check Check NMA Project	<b>4</b> ∎ 102		c Assessment (IERA) VIC - ant Report I Request			
$\simeq$	ځ		Form Status Stecaled	Review Reference	Application Type Ethon Application	Date Modified 17/10/2018 09:25	NMA Project in for NMA
	Instant See		Navgation	Documents Bignatures	Collaborators Butimessions	Correspondence History	
			Search correspondence				
			User Ms Catherine Parregton	1 Date 17/62016	<ul> <li>Message</li> <li>Phase see attached GOP certificate for Pr</li> </ul>		i Attachment
			Showing 1 to 1 of 1 antitian				First Previous 3 Next

• Use the **Correspond** button under the Actions pane to write and send a message to the Research Office only after a form has been submitted

#### History

• Displays an audit trail of the application form. The user actions are recorded including actions from the Research Office once an application/form has been submitted

• Attachments can be downloaded and viewed if an action includes submitting a form

	Actions 🗸			Site Notification Form			
Project	Create Sub-	Share		ndment Request			
			Form Status	Review Reference	Application Type	Date Modified	NMA
Roles	Completeness Check	Submit	Recalled	N/A	Ethics Application	17/10/2018 09:26	Project is for NMA
Refresh	S NMA Project	Print	Naviga	tion Documents Signatures	Collaborators Submissions	Correspondence History	]
Correspond	Import Xml		Form History				
			Date	ő User	A. Description		Attachment
			10:07	Ms Catherine Farrington	Description     Correspondence Sent		Download
			09:26	Ms Catherine Farrington	The form has been updat	ted	Download
			09:25	Ms Catherine Farrington	Form status changed from	m Submitted to Recalled	Download

#### **ERM Reference Numbers**

#### **Project ID:**

- Is the unique identification number for a research project
- Generated when you create a project in ERM
- Used to identify the research project

#### **Review Reference:**

- Is the unique identification code for a form submission
- Generated when you **submit the form** in ERM

V	Nork Area	~	HREA Sep	otember 17A					1 🛌	46664
Home	O Notifications		Project Tree 🗸					Project ID		
	Actions 🗸		O HREA Sep	tember 174						
Project	Create Sub- form	Share	• HREA							
Roles	Print	Correspond		Bile Specific Assessment (SSA) VIC -		Review R	eference	7		
Limport Xml	Recal			Amendment Request						
			Form Status	Review Reference			Application Type	Date Modified	NMA	
			Submitted	HREC/46664/VICTEST-2018-1	54992(v1)		Ethics Application	16/10/2018 11:12	Project is for NI	IA.
			Na	vigation Documents	Signatures	Collaborators	Submissions Corre	espondence History		

• Composed of six parts - ① ② ③ ④ ⑤ ⑥

#### e.g. HREC/46664/VICTEST-2018-154992(v1)

	Component	Description	Example
1	Application type	Identifies the type of application form	HREC - the HREA
2	Project ID	The unique identification number for the research project	46664
3	Organisation/hospital code	The organisation/hospital to which this form was submitted	VICTEST
4	Year	Year of submission	2018
\$	Submission number	Identifies the particular submission (version) of this form	154992
6	Version number	Version number	v1

## Section 3: The HREA form

## Create an HREA

- Log into ERM and go to the Work Area
- Select Create Project button under the Actions pane



- Enter the Project Title
- Select the jurisdiction where the application will be reviewed
- Select HREA from the Main Form options
- Select Create button to create the project

Create Project	×
Project Title (maximum 200 characters):*	
January Project	
Select Jurisdiction	
Victoria	
Main Form	
HREA •	
	Create

• The Project Tree will display the newly created project and HREA

tions 1	Vork Area V 9 Notifications			roject	Pro	ject Tree				
roject	Actions ~	Share	January Pro     HREA	ect		Project 1	Title			
2+ toles	Completeness	Submit	Form Status Not Submitted	Review Reference		Application Type		01/2019 14:11	NMA Project is	not for NMA
trosh	S NMA Project	Print	Nav	igation Documents	Signature	s Collaborators	Submissions Com	espondence H	istory	
espond	Import Xml		HREA							Sho
			Section ERM Module HREA Introduction	Questions ERM Filter Questions	NY .					
			Generate HREA document	Concerning LIDEA	pload HREC De	claration Declaration - CI/C	PI/Lead Declaration	on - Declaration - Al/Investigator	Declaration - Other	Generate HREA

## Complete the HREA

- Working under the **Navigation** tab, the ERM Filter Questions and Introduction are mandatory questions to be completed
- If the project involves a site in Victoria, a Victorian Specific Module (VSM) must be completed if certain features apply to the research project

	Actions •		Yes
Previous	) Next	<b>1</b> Navigate	Will this ethics application involve a site in Victoria?
Print	Documents	<b>Signatures</b>	Yes     No Select the features that are applicable to this research project:
Save	Share	Roles	Recruitment of adult research participants who do not have decision making capacity     Collection, use and/or disclosure of personal and/or health information     Removal of tissue or blood from a living or deceased adult or child, or performance of a post mortem     None of the above
Collaborators	Completeness Check	Submit	The Victorian Specific Module (VSM) is required. Create the VSM as a Sub-form of this HREA. Before submitting this HREA, upload the VSM below. Victorian Specific Module

- Refer to the <u>Victorian Specific Module (VSM)</u> section in the manual for detailed instructions on completing the VSM
- In Section 1 of the HREA Introduction, select the Acknowledge and Continue button to open the rest of the HREA to complete the application
- To save your work select the Save button under the Actions pane
- Selecting Previous and Next buttons will also save your work

## Import an HREA

If the HREA has already been completed on another website (NHMRC), the HREA form can be imported into ERM as an xml file.

- Details to obtain the xml file are available in ERM Frequently Asked Questions HREA section
- Create the project and HREA Main Form in ERM as previously described
- Complete the ERM Filter Questions and continue to 'HREA Introduction'
- Click on the Navigation
   Description
- Select Import Xml button
- An Import from Xml text box will be displayed
- Select Upload button

Import from >	ml
	ignatures will not be imported. Once the import is he application and click on the Completeness Check buttor equire your attention.
CAUTION: Importing th HREA.	XML file will overwrite ALL existing answers in your
Browse	$\frown$
	Upload
	Close

Actions .

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- The xml file will overwrite all existing answers in the HREA in ERM
- Signatures and documents will not be imported in the xml file therefore supporting documents will need to be uploaded in to the ERM HREA and signatures will need to be obtained again.

## **Upload Documents**

- Supporting documents to be included in the application are uploaded in Section 4 of the HREA
- Select Navigate button under the Actions pane to go to the Work Area
- In the bottom section of the HREA, select Upload
   to be directed to Attachments Q 4.1 for
   e.g. the Protocol to be uploaded to the HREA

	Actions 🗸		HREA
E		1	
Previous	Next	Navigate	Attachments
Print	Documents	Signatures	Q4.1 Attach the Project Description/Protocol to your HREA. *
E Save	<b>Share</b>	Roles	It is recommended that you use one of the templates provided in the HREA for your Project Description/Protocol.
5	~	<u></u>	Upload Document

- Press Upload Document
   Upload Document
   to attach the protocol from your local drive
- Other documents e.g. Participant Information Consent Form can be uploaded to the application by responding **Yes** to **Q 4.2**

	Actions 🗸		Q4.2 Are there any other relevant documents associated with conducting your research project?
Previous	) Next	◀ Navigate	<ul> <li>This may include attachment of:</li> <li>participant information and consent forms,</li> <li>questionnaires,</li> </ul>
Print	Documents	Signatures	<ul> <li>report forms,</li> <li>advertising materials,</li> <li>authorisations, approvals, letters of support or other clearances, and/or</li> <li>other project-related documentation specific to your institution and/or jurisdiction.</li> </ul>
E Save	Share	Roles	Consult with your institution's research/ethics office for advice on the necessary documentation.     Yes     No
S Collaborators	s Completeness Check	Submit	Attach any other relevant documents associated with conducting your research project. Optional
	ONBOR		<ul> <li>Ensure that you give meaningful and unique names to your files before uploading them.</li> <li>Enter the description in the document name field. The date and version fields are mandatory.</li> </ul>

- A drop-down list of Supporting Documents will be displayed
- Press Upload Document <sup>Upload Document</sup> to attach the selected
   Supporting Document from your local drive
- Uploaded documents will be displayed under their type, name, file name and version
- Multiple documents of the same document type can be added by selecting Upload Document multiple times
- Specify the version and date of each document to differentiate the documents within the same document type e.g. Sub-study PICFs

Туре	Document Name	File Name	Version Da	e Version	Size	View	Delete
Curriculum vitae	Dr Jones CV	Dr Jones CV.	docx 01/01/2018	1	12.5 KB	Download	Delete
Upload Document Participant informa Type	tion and consent form	ns Document Name	File Name	Version Date	Version Si	ze View	Delete

Curriculum vitae (CV) or resume of investigator/researcher Drug data sheet

Licence for dealing with a genetically modified organism GP/consultant information Institutional biosafety committee (IBC) approval Investigator brochure or reference safety information

Participant documentation e.g. diary, wallet card Participant information and consent form

Radiation: medical physicist's report Report forms Statistician comments

Western Australian specific module

Other project-related documentation

•

Form of indemnity

Invitation to participant Letter of support

NSW privacy form

Protocol (Tracked) Questionnaire Radiation: letter re standard care

Peer review

• Documents will also be displayed under the **Documents** tab and can be downloaded

2+	£+ 🔽 🚣		Form Status	Review Reference	Application 1	ype	Date Modified	NMA		
Roles	Completeness Check	Submit	Not Submitted	N/A	N/A		24/10/2018 16:46	Project	is not for NMA	
Refresh Correspond	Solution NIMA Project	Print	Navga Documents	Documents	Signatures Collaborators	Submissions	Correspondence History			
			Туре		Document Name	File Name	Version Date	Version	Size	View
			Participant information and	consent form	PICFs Dec 2017	PICFs Dec 2017.docx	31/12/2017	1.3	474.6 KB	Download
			Curriculum vitae		Dr Jones CV	Dr Jones CV.docx	01/01/2018	1	12.5 KB	Download

#### Assign access to the HREA

In ERM, the project owner can make the HREA available to others e.g. sponsors or colleagues. Using the **Roles+** function, the project owner assigns other research team members pre-defined levels of access to the HREA.

#### Give access

•

	ct <b>Rol</b> e	es+	Roles button	under the A	Actions	pane				
Ħ	Vork Area 🗸 9 Notifications		January Pro	oject						
ភំ	Actions ~	<b>\$</b> Share	January Project     HREA							
2+ Roles		Submit	Form Status	Review Reference		Application Ty	rpe	Date Modified 24/01/2019 14:		NMA Project is for NIMA
	S NMA Project	Print	Navigat	ion Documents	Signatures	Collaborators	Submissions	Correspondence	History	
Correspond	Import Xml			Questions						Sh
			ERM Module	ERM Filter Questions						

• A dropdown list will display the different levels of access to the HREA

HREA Share (read-only) – to view HREA including uploaded documents
HREA Share (read, write) – to view and edit the form
HREA Share (read, create subforms) – to view, create subforms (SSA)
HREA Share (read, write, submit) – to view, write and submit forms

HREA Share (read, write, submit)
HREA Share (read-only)
HREA Share (read, write)
HREA Share (read, create subforms)
HREA Share (read, write, submit)

• Enter the collaborator's email address and select the level of access

Share Roles				×
Sharing a form enables others to view/edit the same form depending on the level of	f access you give them. Please select the users you wish to share this form with:			
Collaborator email	HREA Share (read-only)	<b>H</b>		
Note: This form has not yet been shared with anyone	HREA Share (read-only) HREA Share (read, write) HREA Share (read, create subforms) HREA Share (read, write, submit)			
			Share Role	Close

- Select Share Role button
- Other research team members can be added using the  $\blacksquare$  button

#### If the collaborator does not have an ERM account

• A message will be displayed if the collaborator's email does not exist in ERM

Share Roles		
Sharing a form enables others to view/edit the same form depending on the level of acc	ess you give them. Please select the users you wish to share this form with:	
Multisite.ethics@dhhs.vic.gov.au	HREA Share (read-only)	• +

- Select the **Invite** button to invite the collaborator to create an ERM account
- This raises a green bar across the screen advising the collaborator has been successfully invited

User has been successfully invited.
Share ? ×
Sharing a form enables others to view/edit the same form depending on the level of access you give them. Please select the users you wish to share this form with:

• The collaborator will receive an email notification inviting them to share the project and a link to ERM to create an account. The collaborator should also notify the project owner when their ERM account has been activated

🖞 New 🛪 💭 Reply to All ㅋ 😕 Forward ㅋ 📄 ㅋ 👂 ㅋ 🌐 Display = 🔍 ㅋ 🚷 More ㅋ	
Please log in to ERM - Invitation from Ms Catherine Farrington donotreply to: Multisite ethics	27/02/2019 10:00 AM Show Details
Project Title: January Project Project ID: 50965	,
Ms Catherine Farrington would like to share the above project with you but it appears that your email is not in the system.	
Please go to <u>ERM</u> and select New User. Follow the prompts. Please inform Catherine when you have logged in so that they can share the project and assign your access permissions.	

- The project owner will need to repeat the steps to assign the collaborator access to the HREA as described in <u>Give access</u>
- Select Roles + button under the Actions pane

V	Nork Area 🐱		January F	Project					
Home	9 Notifications		Project Tree 🗸						
	Actions $\checkmark$		O January P	roject					
Project	Create Sub-	Share	• HRE/						
2+		<u></u>	Form Status	Review Reference	Application	Туре	Date Modified		NMA
Roles	Completeness Check	Submit	Not Submitted	N/A	N/A		24/01/2019 14:2	25	Project is for NMA
Refresh	S NMA Project	Print	Na	vigation Documents	Signatures Collaborators	Submissions	Correspondence	History	
$\times$	4								
Correspond	Import Xml		HREA						Sh
			Section	Questions					
			ERM Module	ERM Filter Questions					

#### Accept access

- The collaborator e.g. the PI will receive an email notification on their assigned role for the project
- The collaborator logs into ERM

• From the Work Area the collaborator selects Notifications tile

#	Vork Area • 1		Work Are	a		
Home	Notifications		General			
	Actions 👻		Notifications	Signatures	Transfers	Shared
reate Folder	Delete Folder	Create Project	1	1	0	0
elete Project	Duplicate	Transfer	Folders	)		

• Select the Message title to open the message

	V	17	אוז כמנופרווופ דמרוווקנטור נוזמוקפט צטטר וטרוז זוזמרפ מננפזג נט. אפמט, אורופ	NULL	January Project
	•		Ms Catherine Farrington has assigned you a role in their project	None	January Project
_					

• A Message text box will be displayed Select View Form

Project Short Title January Project Date 25/01/2019 16:14	
Date 25/01/2019 16:14	
Ms Catherine Farrington has assigned you a r project	role in their

- The project and form will be displayed. Supporting documents attached to the form can also be viewed
- The collaborator can edit and submit sub-forms e.g. the SSA for their site depending on the level of access assigned by the project owner

#### Manage access

- The level of access previously assigned to a research member can be modified in the following way if **Roles +** has been used
- Highlight the relevant form in the Project Tree and select the **Roles** + button under the Actions pane
- A **Share Roles** textbox will be displayed showing the form's level of access that has been assigned to the collaborator e.g. HREA read only
- Select Remove

Share Roles						×
Sharing a form enables others to vie	ewledit the same form depending on the level of acces	s you give them. Please select the use	rs you wish to share this form v	with:		
Collaborator email		HREA Share (read-only)		• 🛨		
Name	Role	Given on	Remove	Remove All Permissions		
Ms Amanda Walpole	HREA Share (read-only)	HREA	Remove	Remove		
			$\square$			
					Share Role	Close

- The Share Roles page stays to allow the level of access to be modified
- Enter the collaborator's ERM email address and new level of access e.g. read, create subforms
- Select Share Role

Share Roles				×
Sharing a form enables others to view/edit the same form depending on the level of access you give	e them. Please select the users you wish to share this form with:			
Collaborator entail	HREA Share (read-only)	FT.		
Note: This form has not yet been shared with anyone	HREA Share (read-only) HREA Share (read, write)			
	HREA Share (read, create subforms)			
	HREA Share (read, write, submit)			
			Share Role	Close

• The collaborator will receive an email notification informing them of the change in their access

## **Applying Signatures**

#### Declaration

The National Health and Medical Research Council **HREA** requires the applicant to enter the names of members of the research team who are signing the application.

- The Coordinating Principal Investigator is required to sign the Declaration for the HREA submission
- A declaration may be completed by each of the researchers/investigators
- Consult your institution's policy for guidance on whether all members must sign this application or whether the CPI can sign on behalf of the research team

	Actions 🗸		HREA
Previous	۲	1	
evious	Next	Navigate	Investigator Team Declarations
rint	Documents	Signatures	This declaration must be completed by each of the researchers/investigators or, where applicable, one member on behalf of the research team. Consult your institution's policy for guidance on whether all members must sign this application or whether one member can sign on behalf of the research team.
ave.	Share	Roles	<ul> <li>You can upload evidence of the other researchers/investigators' agreement to this declaration (e.g. a PDF of an email).</li> <li>You can have researchers/investigators sign this application after it is completed and printed (i.e. a vet link' signature).</li> <li>You can use the request signature feature to have other researchers/investigators completed their declaration within this application.</li> <li>You must identify which researchers/investigators will be providing evidence or wet link signatures. Upload any supporting documents and enter the</li> </ul>
Social Sectors	Completeness	Submit	relevant details for those researchers/investigators before requesting electronic signatures as this will lock the form.
			Indicate which members must sign this application Signature required by CPI Chief Investigator/Researcher Coordinating Principal Investigator/Researcher Lead Investigator/Researcher
			Principal Investigator     Associate/Assistant/Sub-/Co-Investigator/Researcher     Signature required by PI     Other
			This system requires you to enter the names of members who are signing this application. You must also indicate how the member will be signing, and upload any signature documents prior to requesting any electronic signatures. The application will be locked (read only) once you have signed/requested electronic signatures.

#### Signatures

The HREA form questions / information must be complete, <u>before</u> doing signatures Any change to the HREA form will invalidate signatures

The applicant must indicate how each member will be signing the application **before** requesting any electronic signatures.

Using a combination of signature methods, electronic signatures should be sought LAST as the application/form will be locked once an electronic signature request has been made Multiple electronic signatures can occur

There are three signature methods available:

- If a wet ink signature is preferred, select 'Wet ink after printing' to sign after the HREA is completed
- If a document is used to endorse agreement, select 'Upload other evidence' to reflect investigator's agreement then attach the evidence e.g. a PDF of an email

- For electronic signature select 'Electronic signature' and use the ERM 'Request Signature / Sign' function to electronically sign the declaration within the application using ERM
  - \* Signatories must have an ERM account to provide an electronic signature

	Actions 🛩	2	HREA
Previous	() Next	✔ Navigate	INCA
-	0	0	Declaration - CI/CPI/Lead Investigator
Print	Documents	Signatures	Coordinating Principal Investigator/Researcher
Save	Share	Roles	I, (inset name) certify that:
Collaborator	s Completeness Check	Sutmit	<ul> <li>conversion</li> &lt;</ul>

The HREA form owner may request signatures as follows:

- 1. To use Wet ink signature
- Select Wet ink sign after printing

Coordinating Principal Investigator/Researcher	
I, (insert name)	
<ul> <li>certify that:</li> <li>All information in this application and supporting documentation is correct and as complete as possible;</li> <li>I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;</li> <li>I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisation policies;</li> </ul>	onal
<ul> <li>All relevant financial and non-financial interests of the project team have been disclosed; and</li> <li>In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance arrangements specified in this application and those associated with the student's educational program.</li> </ul>	ce with the
Q4.7 How will the Coordinating Principal Investigator/Researcher agree to these terms?	
<ul> <li>You can use the ERM 'request/sign' function to electronically sign this application.</li> <li>Select 'Upload other evidence' to upload and attach other evidence, such as an email.</li> <li>Select 'Sign after printing' if you intend to sign the HREA after it is printed (i.e. 'wet ink' signature).</li> </ul>	
Electronic signature (in place of HREA 'sign on screen')	
Upload other evidence     Wet ink sign after printing	
Sign here:	
Date:	

- 'Wet ink sign after printing' creates a signature section (at bottom of screen)
- Using the **Print button** from the Actions Pane, print this section and obtain the
  - signature from the CPI / PI. Save to your local drive as a pdf
- Navigate to last section of the HREA to find Upload
- Upload then opens Q 4.2 to attach the Declaration page
- Select 'Yes' to other relevant documents and select 'Other project-related documentation'
- Select **Upload document** Upload Document to attach the signature document to the HREA
- The uploaded signature document will be displayed with the document and file name and versions

<ul> <li>Other project-related docu</li> </ul>	mentation						
Other project-related documentation	specific to your institution	n and/or jurisdiction					
Туре	Document Name	File Name	Version Date	Version	Size	View	Delete

- 2. To Upload other evidence to attach an email copy / letter to indicate agreement
- Select 'Upload other evidence'

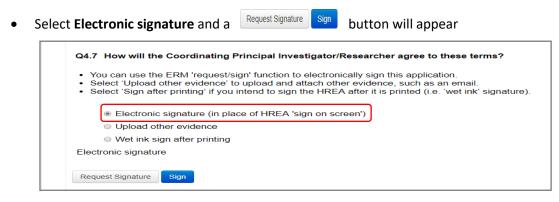
• :	You can use the ERM 'request/sign' function to electronically sign this application. Select 'Upload other evidence' to upload and attach other evidence, such as an email. Select 'Sign after printing' if you intend to sign the HREA after it is printed (i.e. 'wet ink' signature
	<ul> <li>Electronic signature (in place of HREA 'sign on screen')</li> <li>Upload other evidence</li> </ul>
	Wet ink sign after printing oad signature

- Select **Upload Document** Upload Document to attach the signature document from your local drive
- The Signature document will be displayed with document and file names and versions

<ul> <li>Select '</li> </ul>	Upload other evidence' to upload	tion to electronically sign this application. and attach other evidence, such as an er sign the HREA after it is printed (i.e. 'we	mail.				
0 E	lectronic signature (in place of HF	REA 'sign on screen')					
• U	pload other evidence						
● W	/et ink sign after printing						
Upload sig	Inature						
Туре	Document Name	File Name	Version Date	Version	Size	View	Delete
Signature	Signature for Professor Smith	Signature for Professor Smith.docx	19/08/2018	1	12.5 KB	Download	Delete

3. To request an Electronic Signature

Investigator, select Request Signature



• To request an electronic signature from the Coordinating Principal Investigator / Principal

• The system performs a completeness check to highlight any incomplete sections that need to be completed. Each incomplete item will be displayed as a link to the relevant section

Request Signature

button

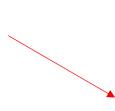
• When all required sections of the HREA have been completed select **Request Signature** 

Request Signature

•	Enter the signatory's	s ERM email	address and	message an	d select <b>Request</b>
	Enter the signatory s		addi C55 ana	message an	a sciect negacot

Request a signature	×
Enter the email address of the person you want to sign	this form
Email Address	
Enter a message (Optional, max 800 characters)	
	Request Close

• The requested signatory will receive an email notification with the signature request, a message and link to ERM Log in/Signatures page



You have received a signature request from Ms Jane Citizen with a message. Could you please sign this HREA? To view your outstanding signature requests, click on the following link:

http://au.forms.ethicalreviewmanager.com/Signatures/Index

- The signatory logs into ERM •
- From the Work Area the signatory selects Notifications or Signatures tile to open the request

1	Work Area 🐱	Work Are	12		
<b>#</b>	1	VVOIK AIE	a		
Home	Notifications	General			
	Actions 🕶	Notifications	Signatures	Transfers	Shared
reate Folde	r Delete Folder Create Project	1	1	0	0
O elete Projec	t Duplicate Transfer	Folders		)	

Requested Date 🚽

12/12/2018 15:38 New requests are highlighted

Work Area 🐱	Signatures							
Home Notifications	Search Signatures							
Tromoadoria	Scarch Signatures							
	Туре	+ 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	View Form
	Head of Supporting Department	October 24	Ms Catherine Farrington		19/11/2018 12:20		Invalidated	View Form

Under the **Action** tab, select **View Form** to review the application .

For endorsement of the application, select Sign •

button under the Actions pane

Actions 🗸		HREA		
	$\bigcirc$	1		
Previous	Next	Navigate		Read access only.
Print	Sign	Reject	ERM Filter Ques	tions
	$\square$		In which jurisdiction	will your ethics application be submitted for review?
Completeness			Queensland	t Health
Спеск			Victoria	
			<ul> <li>Mater</li> </ul>	
			Project Title	CHANGES TO THIS FIELD WILL UPDATE THE TITLE FOR THE ENTIRE PROJECT
			October 22	

A Sign Form text box is displayed
 The signatory enters their ERM log in details to sign the form
 Select Sign Sign button

Sign Form		×
	n details in order to sign this form:	
Username	Password	
		Sign Close

• The Status has changed from Requested to Signed

۷	Nork Area 🐱	Signatures							
Ħ	13								
Home	Notifications	Search Signatures							
		Туре	+ 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	12/12/2018 15:55	Signed	View PD
		Head of Supporting Department	October 24	Ms Catherine Farrington		19/11/2018 12:20		Invalidated	View Fo

• The applicant receives an email notification indicating the signature request has been accepted by the signatory i.e. the form has been signed



*To request multiple signatures - when the applicant / form owner requests authorisation from other investigators* 

- Repeat the signatory process for electronic signatures from other research members if required e.g. Principal Investigator if indicated on the Investigator Team Declarations in the HREA
- Once the signature process is complete the form is locked

	Actions 🗸		HREA	585
	€	1		
Previous	Next	Navigate	This form has been locked through signatures/requests	
Print	Documents	Signatures	Declaration - CI/CPI/Lead Investigator	9
Unlock	Share	Roles	Coordinating Principal Investigator/Researcher	0
Collaborator	Completeness	Submit	I, (insert name)       Protessor xx         certity that: <ul> <li>All information in this application and supporting documentation is correct and as complete as possible;</li> <li>There iread and addressed in this application and supporting documentation is correct and as complete as possible;</li> <li>There iread and addressed in this application and view and ipplications, regulations, research guidelines and organisational policies;</li> <li>All information in on-financial interests of the project team have been disclosed, and</li> <li>The capacity of a supervisor, as applicable, I have reviewed this application and view and exploration and supporting documents specified on and the supervisor is application and these associated with the structure's document agricultation and is application and view and exploration and view and exploration and view application and view reviewed this application and view and exploration and view and exploration and view and exploration and view and exploration and view reviewed this application.</li> <li>Select Upload other evidence is upload and tatch other evidence, such as an email.</li> <li>Select Upload other evidence is upload and tatch other evidence, such as an email.</li> <li>Select Upload other evidence is upload and tatch other evidence, such as an email.</li> <li>Select Upload other evidence.</li> <li>Upload other evidence.<td></td></li></ul>	

- The form can be unlocked for further editing by selecting the **Unlock** button under the Actions pane
- The form must open for the **Unlock** action button to be available
- A Unlock form text box is displayed noting this action will
   <u>unlock form text box is displayed noting this action will
   Performing
   Performing
   Performing
  </u>
- Select **Confirm** to unlock the form
- The form is unlocked for editing

Unlock Form	×
Performing this action will invalidate any signat	ures on the form. Are you sure?
	Confirm Cancel

			Form unlocked	
€	€	1	INCA	10.
evious	Next	Navigate	Declaration - CI/CPI/Lead Investigator	0
Print	Documents	D Signatures	Coordinating Principal InvestigatoriResearcher	0
lave	Share	2+ Roles	I, (insert name) Professor xx	
Se aborators	Completeness Check	Submit	<ul> <li>All information in this application and supporting documentation is correct and as complete as possible;</li> <li>I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;</li> <li>I have finalimisted myself with, considered and addressed in this application regiven to relevant guidelines;</li> <li>I have finalimisted myself with, considered and addressed in this application, regiven to relevant financial and non-financial interests of the project team have been disclosed, and</li> <li>In the capacity of a supervisor, as applicable. I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.</li> </ul>	
			Q4.7 How will the Coordinating Principal Investigator/Researcher agree to these terms?	

- Complete the edits in the form
- Repeat the signatory process for electronic signatures from research team members
- The application is ready for submission

## Section 4: Submission and Review Process - HREA

In ERM the submission and review processes are similar for all forms.

For the initial application submission ensure the form is complete and all documents are uploaded

#### and signatures completed.

To note, as the project title <u>cannot</u> be changed once approved, ensure the title is correct before submitting or resubmitting the application.

#### **Submission**

- Navigate to the Actions pane and select the Submit
- The system performs a completeness check to highlight any incomplete sections.

If complete, the form is ready to be submitted

• Select the **Submit** button

Submit	
Complete: Your form is complete and ready to submit	
	Submit

button

• The system will automatically submit the application to the HREC/ethics review body selected in **Q 4.3** of the HREA

Application type	HREC - the HREA
	TREC - LIE TREA
ERM Project ID	46664
Organisation/hospital code	VICTEST
Year	2018- year of submission
Submission number	154992 - submission version number
Version number	v1

- Following the submission, a unique identification code is generated. It is composed of six parts - e.g. HREC/46664/VICTEST-2018-154992(v1)
- The Form Status of the application becomes Submitted

#### Recall an application

Any changes made to the submission will INVALIDATE all electronic signatures and will require all signature requests again

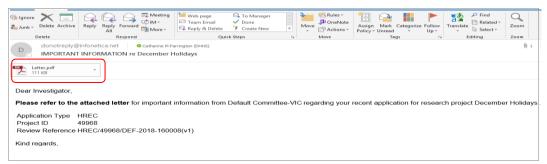
- Once the application has been submitted, a recall option becomes available
- The form can be recalled until the submission is actioned by the Research Office
- The recall removes the submitted application from the Research Office's ERM account
- Select the **Recall** button under the Actions Pane to recall the submission and make any changes / additions
- Select the Submit

button again. The application will be resubmitted.

## Responding to a Query from the Research Office

If an application is queried by the Research Office for further clarification or changes, additions e.g. supporting documents:

• The applicant is advised via an ERM email of important information regarding their application



 A 'Query – Ethics Application' letter (pdf) from the Research Office will include details for further information to be provided via ERM

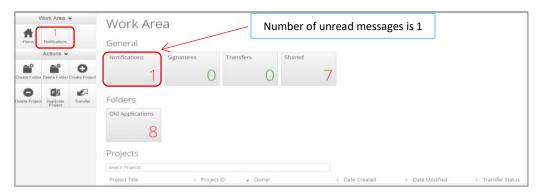
	Committee-VIC Human Research Ethics Committee
	QUERY - ETHICS APPLICATION
14 December 2018	
Dear ,	
Project Title Project ID	December Holidays 49968
<b>Review Reference</b>	HREC/49968/DEF-2018-160008(v1)
Local Reference Nun	iber
(HREC). The applicatio	g an ethics application to Default Committee-VIC Human Research Ethics Committee in has been assessed and it is not of a satisfactory standard for ethical review. Some n order for the application to proceed for review by the HREC.
Information to be Pro	vided
Change answer to que	stion 4.2 and upload PICF,
Upload Protocol	
Edit Questionnaire.	
Submission	
	uested information via ERM as soon as possible, in order for your ethics application to
	application form in ERM and revise the supporting documentation as specified above ing documentation, ensure that:
For changes to support	
· all version dates	and/or version numbers are updated es copy is uploaded to ERM.
all version dates     a tracked-chang Please submit the requi	

#### To access the **Query**

• In the Work Area, click on the **Notifications** tile

the revisions / additions as requested

The form will be unlocked to allow the applicant to complete

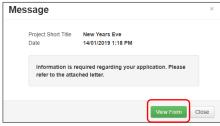


• Select the Message title to open and view the message

Notif	ic	ations					
Search							
Start		End					
Display		) 100 no	otifications				
	Pl	ease note that only the specified number of notifications will show after searching.					
		Search					
- ÷	¢	Message		Attachment	Project Short Title	\$ Time ,	,
	-	Your January Project has been upgraded		None	January Project	14/02/2019	×
	•	Dr Bernice Davies has requested a signature from you		None	February Project	07/02/2019	ж
		Your form has been signed by Ms Abigail Cooper		None	Jan Project	07/02/2019	×
		Dr Bernice Davies changed your form share access to: Read. Write. Submit		None	March Project	04/02/2019	×
	-	Dr Bernice Davies has assigned you a role in their project	<b>×</b>	None	February Project	01/02/2019	×
	-	Information is required regarding your application. Please refer to the attached lette	er.	Ø	New Years Eve	14/01/2019	×

• A Message box will be displayed allowing the user to view the form

	11100	ouge
Press <b>View Form</b> to be directed to the relevant form		Project Short Title Date
		Information is re



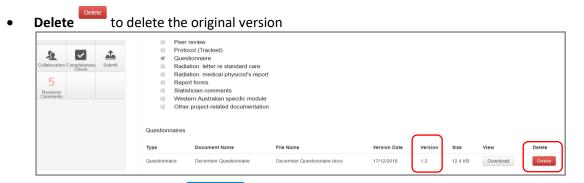
• The form will open under the Navigation tab

Work Area 🐱		December Holidays								
Home 1 Notifications			Project Tree V							
	Actions -		O December He	adays						
Project	Create Sup-	3 Reviewer Comments	O HREA							
<	2+	~	Form Status	Review Reference		Application Type		Date Modified		NMA
Share		Completeness Check	Queried	N/A		Ethics Application		13/12/2018 14:25		Project is not for NMA
Submit	Refresh	S NMA Project	Navio	ation Documents	Signatures	Collaborators	Submissions	Correspondence	History	
Print	Correspond	import Xml	HREA							u :
			Section ERM Module HEEA Introduction Project Overview Project Team Disclosure of Interests Restrictions Evaluations Location Methods Participants	Cuestions ERM filter Questions Inhoduction   HECC Directory Project Overview Project Team Concessure of Inferests Restrictions Evaluations Location Idethods Participants						

- Select Reviewers Comments under the Actions pane
- A text box will be displayed of the Overall Reviewer Panel Comments (e.g. 3 comments)

	Supporting document requiring e	Previous Comments
Comment	Date Added	Submission
Please edit the questionnaire.	14/12/2018 at 09:16 AM	Latest Submission
This application will not be reviewed until you provide a protocol.	14/12/2018 at 09:15 AM	Latest Submission
This project requires a participant information and consent form. Please provide it.	14/12/2018 at 09:14 AM	Latest Submission

- Select a comment to be directed to the relevant section in the form i.e. to **Q 4.2 Are there any** other relevant documents associated with conducting your research project?
- As the query requires a new version of a document, the original version should be deleted, and the new version uploaded into the form. Deleted/previous document versions are automatically archived. See <u>Archived documents</u> for further information on how to access archived documents.



• Select **Upload Document Upload Document** to upload the revised (new) version of the document with the correct version number and date

• Previous document versions are archived in **Submitted Documents** and viewed in the **Project** 

#### Overview screen

Work Area ~ 18 Home Notifications	Project Overview - Jan Project
	Call Project:     FIEA     Bas Specific Assessment (SBA) V/C - Administrator Use Only     Gas Pacific Assessment (SBA)
	Forms Bubmitted Documents Transfers History
	Submitted Documents Search forms documents
	Form Reference         0         Form name         0         Status         0         Type         0         Name         0         Version         0         State         0         Version           HREA         HREA         87692019         State         PHetocid         State         State         Download

• The HREA now includes the latest version ready for resubmission

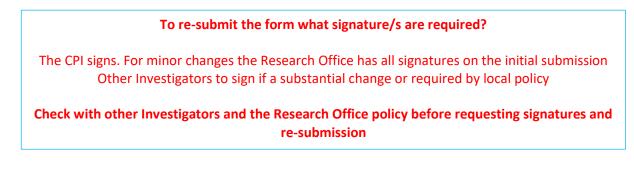
		Type Questionnaire	Document Name December Questionnaire	File Name December Questionnaire.docx	Version Date 31/12/2018	Version 1.3	Size	View	Delete
			-					15	
		Questionnaires	Questionnaires						
		00	er project-related documentatio	51					
			stern Australian specific modul er project-related documentatio						
eviewer mments									
			tistician comments						
5			diation: medical physicist's repo port forms	л					
Check	Submit		diation: letter re standard care	<del></del>					
	Submit		estionnaire						
0 🗸	<u> </u>								

• Continue to complete the other queries as instructed in the **Overall Reviewer Panel Comments** as above



- Once the revisions / additions have been completed, the form and / or supporting documents can be resubmitted
- The system will automatically search for a completed electronic signature if 'Electronic signature' was selected in **Q 4.7** of the HREA in the previous submission
- If the CPI is not required to complete the Declaration page, proceed to **Q 4.7** of the HREA

• Select **Wet ink sign after printing.** This will reset the signature method to enable the system to resubmit the application



• In the Actions pane select the Submit button to resubmit

	Actions ~			orm of indemnity							
Ø	( )	1		cence for dealing with a genet P/consultant information	ically modified organ	ism					
E		7		stitutional biosafety committee	(IBC) approval						
Previous	Next	Navigate	In In	vestigator brochure or referen	ce safety information						
-	D.	D	In In	vitation to participant							
-	Ø	-	E Le	atter of support							
Print	Documents	Signatures		SW privacy form							
IIID				articipant documentation e.g. c							
	<	<b>2</b> +		articipant information and cons	ient form						
Save	Share	Roles		eer review rotocol (Tracked)							
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52	$\checkmark$			adiation: letter re standard car	e						
Collaborators	Completenes	Submit		adiation: medical physicist's re							
-			E Re	eport forms							
5			St St	atistician comments							
Reviewer				estern Australian specific mod							
			. Ot	ther project-related documents	ation						
			Participant in	formation and consent forms							
			Туре		Document Name	File Name	Version Date	Version	Size	View	Delete
			Participant infor	rmation and consent form	PICFs Dec 2017	PICFs Dec 2017.docx	01/12/2018	1.1	474.6 KB	Download	Delete
				_							
			Upload Docum	nent							
			Questionnair	es							
			Туре	Document Name	File Name		Version Date	Version	Size	View	Delete
			Questionnaire	December Questionnaire	December Ques	tionnaire.docx	31/12/2018	1.3	12.4 KB	Download	Delete

- The Research Office will receive the submission
- The application is assigned to a HREC meeting
- Following the HREC review there may be an information request from the Ethics Committee

## **Ethics Committee Review Request**

Clarification or requests for further information from the reviewing Ethics Committee to the applicant must be managed through ERM

• The applicant is advised via an ERM email of important information regarding the application

So Junk Delete Arc	All More -	<ul> <li>✓ Validation Work</li> <li>◯ To Manager</li> <li>☑ Team Email</li> <li>✓ Done</li> <li>♀ Reply &amp; Delete</li> <li>✓ Create New</li> </ul>	↓ ₩ove	🟥 Actions -	Policy - Unread	gorize Follow • Up •	Find P Find ■ Related → Related → Select →	Zoom
Delete	Respond	Quick Steps	E.	Move	Tags	5	Editing	Zoom
Letter.pdf	Ply@infonetica.net Catherine MF							₿1 M
Dear Investigat	or,							
Please refer to	the attached letter for important	information from Default Committ	ee-VIC reg	arding your	recent application	for researc	ch project Decembe	er Holidays.
Application Typ								
Project ID	49968							
Review Refere	nce HREC/49968/DEF-2018-1608	B3(v2)						
Kind regards,								

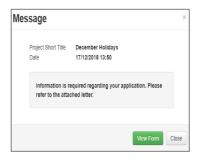
•	A 'Request For Further Information' letter (pdf) from the HREC will include details for further information to be provided via ERM	Defaul Conmittee VICHuman Research Ethics Committee REQUEST FOR FURTHER INFORMATION
•	The form is <b>unlocked</b> to allow the applicant to complete the requests as outlined in the attached letter	<text><text><text><text><text><text><text><text><text><text><text><text><text><text><text><text><text></text></text></text></text></text></text></text></text></text></text></text></text></text></text></text></text></text>
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## Respond to a request for further information from the Ethics Committee

- Depending on the request, the applicant can amend the HREA and add new documents
- Log in to ERM account
- In the Work Area, click on the Notifications tile
- Select the Message title to open and view the message

Work Area 🗸	Notifications
# 2	Search
Home Notifications	Start End
	Display
	Please note that only the specified number of notifications will show after searching.
	Information is required regarding your application. Please refer to the attached letter.     a December Holdays 17/12/2018

A Message box will be displayed allowing the user to view the form
 Press View Form View Form to be directed to the relevant form



• The HREA, will open under the Navigation tab

	Work Area		December Holidays								
Home	1 Notifications		Project Tree 🗸								
	Actions •		O December Ho	lictaves							
Project	Create Sub-	3 Reviewer Comments	• HREA								
<	2+	~	Form Status	Review Reference	Application Type	Date Modified	NMA				
Share	Roles	Completeness Check	Queried	N/A	Ethics Application	13/12/2018 14:25	Project is not for NMA				
<b>£</b> Submit	Refresh	S NMA Project	Navigi	tion Documents Signature	s Collaborators Submissi	ons Correspondence History					
Print	Correspond	import Xml	HREA								
			Section ERM Module HREA Introduction Project Overview Project Team Disclosure of Interests Restrictions Evaluations Location	Carestions ERM Filter Carestions Introduction   IntEC Directory Project Conview Project Toram Disclosure of Interests Restructions Location Location Location							

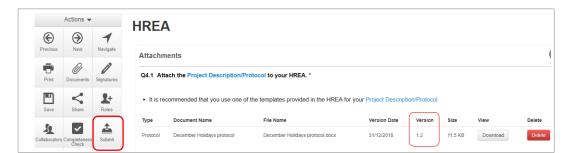
- Select **Reviewers Comments** under the Actions pane
- A text box will be displayed of the Overall Reviewer Panel Comments

Overall Reviewer Panel Comments		ж
Comment	Date Added	Show Previous Comments  Submission
The questionnaire is too complex. Please simplify it so that participants will be able to understand.	17/12/2018 at 13:48 PM	Latest Submission
The protocol is nice but needs more detail about the methodology.	17/12/2018 at 13:46 PM	Latest Submission
		Close

- Select a comment e.g. a comment requesting more information in the protocol, to be directed to the relevant section in the form i.e. **Q 4.1 Attach the Project Description/Protocol to your HREA**
- The request requires a new version of a protocol. The original version should be deleted, and the new version uploaded into the form. Deleted/previous document versions are automatically archived. See <u>Archived documents</u> for further information on how to access archived documents.
- Select Delete
- to delete the original version

	Actions 🛩		HRE	1								
	€	1		-								
Previous	Next	Navigate	Attachn	nents								
÷	0	0										
Print	Documents	Signatures	Q4.1 Att	Attach the Project Description/Protocol to your HREA. *								
	<	1+	• It is re	commended that you use one of	the templates provided in the HREA for	your Project Descript	ion/Protocol.					
Save	Share	Roles	Туре	Document Name	File Name	Version Date	Version	Size	View	Delete		
SQ ollaborators	Completeness Check	Submit	Protocol	December Holidays protocol	December Holidays protocol.docx	01/12/2018	1.1	11.5 KB	Download	Delete		
5												
Reviewer			1000000000		mente associated with conducting w							

- Select **Upload Document** to upload the revised (new) version of the protocol with the correct version number and date
- The HREA now includes the latest version ready for resubmission



- Continue to complete the other requests as instructed in the **Overall Reviewer Panel Comments** as above
- In the Actions pane select the **Submit** button to resubmit
- The reviewing Research Office will receive the resubmission

## **Approved Applications**

- Applicants are informed of decisions by the HREC via email using ERM. If the application has been approved, the form is locked
- Log on to ERM and click on Notifications tile
- A formal approval letter from the HREC can be downloaded by the applicant
- If the application review outcome is **not approved**, applicants are also informed via email through ERM.

# Section 5: National Mutual Acceptance (NMA) applications

NMA is a national system for mutual acceptance of scientific and ethical review of multi-centre human research projects conducted in publicly funded health services across jurisdictions. Single ethical and scientific review for a multi-centre human research project can be provided across six participating states/territories.

If the application is to be reviewed under the NMA scheme, this needs to be recorded in ERM for reporting purposes.

- When completing the HREA, select Yes to Q 4.6 Will this application be reviewed under the National Mutual Acceptance scheme?
- Navigate

# back to the Actions pane and select NMA Project

	Work Area		January Pro	oject			
fame	9 Notifications		Project Tree 🗸				
	Actions $\checkmark$		January Project				
noject	Create Sub-	< Share	• Jan Kalay Project				
2+		<u>±</u>	Form Status	Review Reference	Application Type	Date Modified	NMA
Roles	Completeness	Submit	Not Submitted	N/A	N/A	24/01/2019 14:25	Project is not for NMA
C	8	÷					
efresh	NMA Project	Print	Navigati	on Documents Signatures	Collaborators Submissions	Correspondence History	
Tespond	t Import Xml		HREA				Sho
			Section G	Questions			
			ERM Module	ERM Filter Questions			
			HREA Introduction	Introduction HREC Directory			
			Project Overview	Project Overview			

- A NMA Project text box will be displayed
- The Form Status Table will be updated to 'Project is for NMA'

# Section 6: Victorian Specific Module (VSM)

For each project that utilises the HREA form and has a site in Victoria, the **Victorian Specific Module (VSM)** must be completed if certain research features of the project apply as indicated in the HREA – ERM Filter Questions. In these instances, the VSM is mandatory when the HREA is used. It addresses Victorian legislative requirements.

O

The VSM is submitted to the reviewing HREC as part of the ethics application.

#### In ERM:

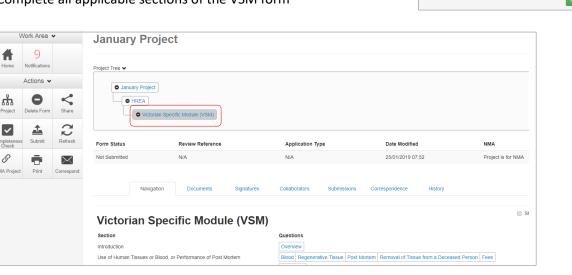
- The VSM is created as a sub-form of the HREA
- Under the Actions pane select Create Sub-form Create Sub-form button

V	Vork Area 👻		January Proj	ect			
Home	9 Notifications		Project Tree 🗸				
Project	Actions V	Share	January Project     HREA		HREA highlighted		
1+	~	<u></u>	Form Status	Review Reference	Application Type	Date Modified	NMA
Roles	Completeness Check	Submit	Not Submitted	N/A	N/A	24/01/2019 14:25	Project is for NMA
<b>C</b> Refresh	Ø NMA Project	Print	Navigation	Documents	Signatures Collaborators Submissions	Correspondence History	
$\times$	4						
Correspond	Import Xml		HREA				Sh
			Section Que	estions			
			ERM Module ER	M Filter Questions			

A Create Sub-form text box will be displayed
 Select the Vistorian Specific Medule (VSNA) from the d

Select the Victorian Specific Module (VSM) from the drop-down list Select **Create** 

- The VSM will appear in the Project Tree as a sub-form of the HREA
- Complete all applicable sections of the VSM form



- In the VSM, select **Print** is generate a pdf and save to your local drive
- Return to the HREA (highlight in Project Tree) and go to the **ERM Filter Questions** section



V	Vork Area 👻	6	January Pro	piect						
Home	9 Notifications		Project Tree 🗸							
	Actions 👻		<ul> <li>January Project</li> </ul>							
Project	Create Sub-	Share	O HREA	an Specific Module (VSM)						
Roles	Completeness Check	Submit	Form Status	Review Reference		Application T	ype	Date Modified		NMA
<b>Q</b> Refresh	Ø NMA Project	Print	Not Submitted	N/A		N/A		24/01/2019 14	25	Project is for NMA
orrespond	Simport Xml		Navigat	ion Documents	Signatures	Collaborators	Submissions	Correspondence	History	
			HREA							St
				Questions ERM Filter Questions	)					

• Select **Upload Document** Upload Document to upload the pdf of the VSM

	Actions •		
Previous	) Next	Navigate	Is the Coordinating Principal Investigator the contact person for this application?  * Yes
Print	Documents	) Signatures	* 105 No
Save	Share	L+ Roles	A multi-site application must be shared with the Principal Investigator (or their delegate) at each site included in the ethics application.
St.	Completeness Check	Submit	Have you shared this form with colleagues at each site?
			Will this ethics application involve a site in Victoria?
			© No
			Select the features that are applicable to this research project:
			Recruitment of adult research participants who do not have decision making capacity     Collection, use and/or disclosure of personal and/or health information     Removal of tissue or blood from a living or deceased adult or child, or performance of a post mortem     None of the above The Victorian Specific Module (VSM) is required. Create the VSM as a Sub-form of this HREA. Before submitting this HREA, upload the VSM below. Victorian Specific Module
			Upload Document

• The VSM is attached to the HREA as a supporting document

	Actions 👻									
Previous	) Next	✔ Navigate	Have you shared this form with	colleagues at each site?						
Print	Documents	) Signatures	Will this ethics application invol	ve a site in Victoria?						
Save	Share	Roles	<ul> <li>Yes</li> <li>No</li> </ul>							
St. Collaborators	Completeness Check	Submit	Collection, use and/	research participants who or disclosure of personal a blood from a living or dec	o do not have decision making ind/or health information beased adult or child, or perfo	ormance of a post m		HREA, uplo	ad the VSM belo	w.
		ſ	Victorian Specific Module	Document Name	File Name	Version Date	Version	Size	View	Delete
		l	Victorian specific module (VSM)	VSM January 2019	VSM January 2019 docx	01/01/2019	1.1	80.8 KB	Download	Delete

- When the HREA is complete and all supporting documents are uploaded (including the VSM) and signatures obtained, Submit the HREA
- Return to the VSM in the Project Tree and **Submit** the VSM
- If edits to the VSM are requested by the reviewing HREC, the Research Office will unlock the form
- Complete the edits and select Submit

# Section 7: Victorian Low and Negligible Risk Application (LNR VIC)

For a single-site low and negligible (LNR) research project, the LNR VIC application form may be utilised instead of the HREA. A Victorian Specific Module is not required for project utilising the LNR VIC application form.

Some reviewing HRECs may not accept the LNR VIC; always discuss the research project with the reviewing organisation's Research Office before creating an ethics application for a low risk research project.

## Create a LNR VIC form

- Log into ERM and go to the Work Area
- Select Create Project button under the Actions pane

Work Area •	Work Area		
Home Notifications	General		
Actions 🐱	Notifications Signatures Transfers Shared		
Create Folder	3 1 1 17		
Create Project	Folders		
P 🗄 🔊 📈	Archive		
Duplicate Transfer Project	19		

- Enter the Project Title
- Select Victoria as the reviewing jurisdiction
- Select LNR VIC from the Main Form options
- Select Create button to create the project

Create Project	×
Project Title (maximum 200 characters):*	
LNR January	
Select Jurisdiction	
Victoria •	
Main Form	
LNR VIC •	
	Create Close

The Project Tree will display the newly created project and LNR VIC

	Vork Area	~	LNR Jan							
ൺ	10 Notifications Actions ~	Share	Project Tree V UNR Jan UNR VIC							
~	<u>+</u>	2	Form Status	Review Reference		Application Type		Date Modified		ММА
ompleteness Check	Submit	Refresh	Not Submitted	N/A		N/A		29/01/2019 10:25		Project is not for NMA
S IMA Project	Print	Correspond	Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence	History	
			LNR VIC							. 1
			Section	Questions						
			Introduction	Organisation						
			Research Project Research Team	Project Details Research Team	]					

## Complete the LNR VIC

- Working under the 'Navigation' tab, the **Introduction** section provides a drop-down list of HRECs that will accept the LNR VIC form. Review this section before completing the form. If your organisation is not listed, contact your research office for guidance.
- Continue to complete each section relevant to your application

## **Upload Documents**

- Sections with the form allow supporting documents e.g. protocol, questionnaire to be uploaded into the form
- Other supporting documents can be uploaded by selecting **Supporting Documents** Supporting Documents located in the last section of the LNR VIC
- Press **Upload Document** <sup>Upload Document</sup> to attach the selected Supporting Document from your local drive
- Uploaded documents will be displayed under their type, name, file name and version
- Multiple documents of the same document type can be added by selecting <sup>Upload Document</sup> multiple times
- Specify the version and date to differentiate the documents within the same document type

	Actions •		LNR	VIC						
E	€	1		VIC						
Previous	Next	Navigate	Suppor	rting Documents						
-	Ø	1ª		<b>J</b>						
Print	Documents		Upload	any other supporting docu	ments					
m	<	50	Туре	Document Name	File Name	Version Date	Version	Size	View	Delete
Save	Share	Collaborators	Other	Signature document	Signature document.docx	01/01/2019	1.1	12.5 KB	Download	Delete
ompleteness	s Submit		Upload [	Document						

## Assign access to the LNR VIC form

In ERM, the project owner can make the LNR VIC form available to other research team members. Using the **Roles +** function, the project owner assigns other collaborators pre-defined levels of access to the LNR VIC form.

Select Roles + button under the Actions pane

	10 Notifications		LNR Jan     LNR VIC							
		$\square$	Form Status	Review Reference		Application Type		Date Modified		NMA
Project	Create Sub- form	Roles	Not Submitted	N/A		N/A		29/01/2019 11:01		Project is not for NMA
ompleteness Check	Submit	Refresh	Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence	History	
S NMA Project	Print	Correspond	LNR VIC							
			Section Introduction	Questions Organisation						

- A dropdown list will display the different levels of access to the LNR VIC form
- Continue to follow the steps as described in Section 3: The HREA form <u>Give access</u> and to manage access

## **Applying Signatures**

### Declaration

The Coordinating Principal Investigator is required to sign the Declaration page for the LNR VIC submission if the ethics application is multi-site otherwise the Principal Investigator is required to sign for a single site application.

- A declaration may be completed by each of the researchers/investigators
- Consult your institution's policy for guidance on whether all members must sign this application or whether the CPI can sign on behalf of the research team

	Actions ~		LNR VIC
Previous	() Next	1 Navigate	
			Statement
Print	Documents	Signatures	Declaration of Coordinating Principal Investigator
E Save	Share	Collaborators	I certify that:     All information is correct and as complete as possible.     I have had access to and read the National Statement on Ethical Conduct in Human Research (NHMRC, 2007) and the research will be conducted in accordance with the Mational Statement.
Completeness Check	Submit		<ul> <li>I have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these.</li> <li>I will immediately report to the HREC/non-HREC review body anything which might warrant review of the research, including serious or unexpected adverse effects on participants, compaints, proposed changes in the protocol; and unforseen events that might affect continued ethical acceptability of the project.</li> <li>I have attempted to identify all the risks related to the research that may arise in conducting this research and acknowledge my obligations and the rights of participants.</li> <li>I will not continue the research if ethical approval or site authorisation is withdrawn and wall comply with any special conditions required by the HREC/non-HREC review body, cooperate with monitoring requirements (at a minimum annual progress reports and a final report will the provided to the HREC/non-HREC review body).</li> <li>I have the experipriate qualifications, training, experience and facilities to conduct the research and to deal with any emergencies and contingencies related to the research that may arise.</li> </ul>

	Actions 🗸		LNR VIC	501
Previous	) Next	✓ Navigate	This form has been locked through signatures/requests	Veraler
Print	Documents	Signatures	Statement	9
Unlock	< Share	Collaborators	Declaration of Principal Investigator I certify that:	
Completeness	Submit		<ul> <li>All information is correct and as complete as possible.</li> <li>I have had access to and read the <i>National Statement</i> on <i>Ethical Conduct in Human Research</i> (NHMRC, 2007) and the research will be conducted in accordance with the <i>National Statement</i>.</li> <li>I have neural legislation and regulations, and the research will be conducted in accordance with these.</li> <li>I have complete as participants: composite changes in the protocol, and unforsen events that might affart continued theiral acceptability of the project.</li> <li>I have attempted to identify all the risks related to the research that may arise in conducting this research and acknowledge my obligations and the rights of participants.</li> <li>I will incontinue the research including service is stellar to the HREC/non-HREC revew body.</li> <li>I have attempted to identify all the risks related to the research that may arise in conducting this research and acknowledge my obligations and the rights of participants.</li> <li>I will not continue the research including service is stellawing the HREC/non-HREC revew body.</li> <li>I have the appropriate qualifications, training, experience and facilities to conduct the research and to deal with monotring requirements (at a minimum annual progress reports and a final report will be provided to the HREC/non-HREC revew body.</li> <li>I have the appropriate qualifications, training, experience and facilities to conduct the research and to deal with any emergencies and contingencies related to the research that may arise.</li> </ul>	1

An electronic signature is obtained using ERM.

The signatory must have an **ERM** account to provide an electronic signature An electronic signature should be sought LAST as the application/form will be locked once the electronic signature request has been made.

### The LNR VIC form owner may request signatures as follows:

#### To use Wet ink signature

- Using the **Print** button from the Actions pane, print the Declaration page and obtain the signature from the CPI/PI. Save to your local drive as a pdf
- Navigate to last section of the LNR VIC to find Additional Documents
- Supporting Documents opens to attach the Declaration page
- Select **Upload document** Upload Document to attach the signed Declaration page to the LNR VIC
- The uploaded signed Declaration page will be displayed with the document, file name and version

	Actions 🛩			R VIC						
I		1								
Previous	Next	Navigate	Supp	oorting Documents						
Print	0 Documents	Signatures	Uploa	ad any other supporting documents						
	<	52	Туре	Document Name	File Name	Version Date	Version	Size	View	Delete
Save	Share	Collaborators	Other	Signature for Professor Smith	Signature for Professor Smith.docx	01/01/2019	1	12.5 KB	Download	Delete
~	<u>t</u>		Uploa	ad Document						
Completeness Check	Submit									

#### To Upload other evidence - to attach an email copy / letter to indicate agreement

- Navigate to last section of the LNR VIC to find Additional Documents
   Supporting Documents
- **Supporting Documents** opens to attach the signature document
- Continue as described above to **Upload** the pdf document to the LNR VIC

#### To request an Electronic Signature

- Select Request Signature
   Request Signature
   button
- The system performs a completeness check to highlight any incomplete sections that need to be completed
- When all sections have been completed, select Request Signature
- Enter the signatory's ERM email address and select Request

Request a signature		
Enter the email address of the person you want to sign th	is form	
Email Address		
Enter a message (Optional, max 800 characters)		
	Request	Clos

- The signatory will receive an email notification for a signature, a message and a link to ERM Log In page
- The signatory logs in to ERM

• From the Work Area the signatory selects Signatures tile to open the request

Work Area 🐱	Work Area
<b>1</b> 0	Work/Wed
Home Notifications	General
Actions 🗸	Notifications Signatures Transfers Shared
Create Folder Delete Folder Create Project	10 2 1 25
Delete Project Duplicate Project Transfer	Folders
·	Requested

- New requests are highlighted
- Under the Action tab, select View Form View Form to review the application

Work Area 🐱	Signatures						
# 10	0						
Home Notifications	Search Signatures						
	Туре	Project Title	Requesting User	Message	Requested Date	Response Date Status	Action
	Principal Investigator	LNR December	Ms Catherine Farrington	Can you please sign this LNR form so I can submit	24/12/2018 10:52	Requeste	d View Form
					<u> </u>		

• For endorsement of the application, select **Sign** button under the Actions pane

Actions	~	LNR VIC	5018
Previous Next	Navigate	A Read access only.	
Print Sign	× Reject	Information	Ø
	. alter	Guidance	
pleteness Check		The Victorian Low and Negligible Risk Ethics Application Form (LNR VIC) can be used for a low/negligible risk research project in Victoria only.	
UTINES.		Some reviewing Human Research Ethics Committees (HRECs) or ethics review bodies do not accept the LNR VIC. At these organisations, the Human Research Ethics Application (HREA) form must be used for all ethics applications.	
		Entries Apparation (Intel A) which must base to use of the expension approximation. Before completing the LNR VIC, consult with the research office of the organisation that hosts the reviewing HREC or ethics review body.	
		All research must be conducted in compliance with the National Statement on Ethical Conduct in Human Research (NHMRC, 2007).	
		Level of Risk	P
		HREC or ethics review body to which this application will be submitted [Administrative Use Only] *	0

- A Sign Form text box is displayed. The signatory enters their ERM log in details to sign the form
   Select Sign Sign button
- The applicant receives an email notification indicating the signature request has been accepted
- Repeat the signatory process for electronic signatures from other members if required e.g. Associate Investigator if indicated in the Research Team in the LNR VIC
- Once the signature is complete the application is ready for submission

## Section 8: Submission and Review Process - LNR VIC

Initial application submission – ensure the Form is complete and all documents are uploaded and signatures completed

## Submission

Navigate to the Actions pane and select the Submit

button

• The system performs a completeness check to highlight any incomplete sections If complete, the form is ready to be submitted

• Select the Submit Submit button

Submit		X
Complete: Your form is complete and ready to submit		
	Submit	Close

- The system will automatically submit the application to the HREC/ethics review body selected in the 'Introduction' section of the LNR VIC form
- Following submission, a unique identification code is generated.
   It is composed of six parts e.g. LNR/61791/DEF-2020-202467 (v1)

Application type ERM Project ID Organisation/hospital code Year Submission number	LNR 61791 DEF 2020- year of submission 202467 - submission version number
Submission number	202467 - submission version number
Version number	v1

## Recall an application

Any changes made to the submission will INVALIDATE all electronic signatures and will require all signature requests again

- Once the application has been submitted, a recall option becomes available
- The form can be recalled until the submission is actioned by the Research Office
- The recall removes the submitted application from the Research Office's ERM account
- Select the **Recall** button under the Actions Pane to recall the submission and make any changes / additions
- Select the **Submit** button again. The application will be resubmitted

## Responding to a Query from the Research Office

If an application is queried by the Research Office for further clarification or changes, additions (e.g. supporting documents):

• The applicant is advised via an ERM email of important information regarding their application

gnore 🔀 📼	Reply Reply Forward All	02 Meeting S© IM ~ ⊡∎ More ~	ERM Training Team Email Reply & Delete	G To Manager ✓ Done 爹 Create New		Move	Assign Mark Policy * Unread	Categorize F	ollow Transla		Zo
Delete	Respond		Qu	lick Steps	5	Move	Tag	35	- G	Editing	Zo
D donotreply@i	nfonetica.net		arrington (DHHS)								
Letter.pdf 112 KB	-										
Dear Investigator,											
Dear Investigator, Please refer to the a	attached letter for	r important	information from	n Default Commi	ttee-VIC	regarding your	recent applica	tion for re	esearch proj	ect LNR Jan	iuary
Please refer to the a	NR	rimportant	information from	n Default Commi	ttee-VIC	regarding your	recent applica	tion for re	esearch proj	ect LNR Jan	luary
Please refer to the a Application Type L Project ID 5	NR 0365			n Default Commi	ttee-VIC	regarding your	recent applica	tion for re	esearch proj	ect LNR Jan	luary
Please refer to the a	NR 0365			n Default Commi	ttee-VIC	regarding your	recent applica	tion for re	esearch proj	ect LNR Jan	iuary
Please refer to the a Application Type L Project ID 5	NR 0365			n Default Commi	ttee-VIC	regarding your	recent applica	tion for re	esearch proj	ect LNR Jan	iuary

 A 'QUERY-ETHICS APPLICATION' letter (pdf) from the Research Office will include details for further information to be provided via ERM

	9 January Dear ,
The form will be <b>unlocked</b> to allow the applicant to complete the	Project Project
revisions / additions as requested	Review   Local Re Thank yo

	Your Logo Here
Default	Committee-VIC Human Research Ethics Committee
	QUERY - ETHICS APPLICATION
Ľ	
9 January 2019 Dear	
Project Title	LNR January
Project ID	60365
Review Reference Local Reference Num	LNR/50385/DEF-2019-161972(v1) ber
(HREC). The application	g an ethics application to Default Committee-VIC Human Research Ethics Committee thas been assessed and it is not of a satisfactory standard for ethical review. Some order for the application to proceed for review by the HREC.
Information to be Prov	vided
Please amend the Partic	sipant Information and Consent Form to include the duration of the study.
Submission	
	ested information via ERM as soon as possible, in order for your ethics application
	rting documentation as specified above. For changes to supporting documentation
Please revise the suppo ensure that:	
ensure that: • all version dates	and/or version numbers are updated es copy is uploaded to ERM.
ensure that: • all version dates • a tracked-change Please submit the reque considered at the next H	es copy is uploaded to ERM. ested information using ERM by 16 January 2019 in order for the application to be IREC meeting. If a response is submitted after this date, your ethics application will
ensure that: • all version dates • a tracked-change Please submit the reque considered at the next H allocated to a later meet	es copy is uploaded to ERM. ested information using ERM by 16 January 2019 in order for the application to be IREC meeting. If a response is submitted after this date, your ethics application will

### To access the **Query**

•

• In the Work Area, click on the **Notifications** tile

Work Area V	Work Area
Home Notifications Actions ~ Create Folder Delete Folder Create Project	General     Signatures     Transfers     Shared       8     0     0     11
Delete Project Project Transfer	Folders Old Applications
	Projects Bearch Projects
	Project Title         0         Project ID         v         Owner         0         Date Created         0         Date Modified         0         Transfer State           UNR January         \$0365         Ms Catherine Farrington         07/01/2019 14:43         09/01/2019 14:53         09/01/2019 14:53

• Select the Message title to open and view the message

Work Area 🐱	Notifications			
# 9	Search			
Home Notifications	Start End			
	Display 100 notifications 100 notifications Please note that only the specified number of notifications will show after searching.			
	Search			
	• • Message	Attachment 0	Project Short Title	0 Time
	💼 🛩 🎓 Information is required regarding your application. Please refer to the attached letter.	Ø	LNR January	14:59

- A Message box will be displayed allowing the user to view the form
- Press View Form View Form to be directed to the relevant form

Me	ssage		×
	Project Short Title Date	LNR January 09/01/2019 14:59	
	Information is refer to the attac	equired regarding your application. Please ched letter.	
		View Form C	llose

• The LNR VIC form will open under the **Navigation** tab.

Selec	ct <b>Rev</b>	iewe	rs Comments	Reviewer Comments UNC	ler the	Actions	pane			
Home	Work Area		LNR January							
Project	Actions ~	1 Reviewer Comments	Project Tree    LNR January  LNR VIC  LNR VIC  LNR VIC	SSA - Administrator use on	ly .					
Share	Completeness	Submit	Form Status	Review Reference		Application Type		Date Modified		NMA Project is not for NMA
Refresh	S NMA Project	Print	Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence	History	PEOPERATE TO TO TANKA
Correspond			LNR VIC Section Infroduction Research Project Research Team	Questions Organisation Project Details Research Team						

A text box will be displayed of the Overall Reviewer Panel Comments

Overall Reviewer Panel Comments			×
	PICF requires edits		Show Previous Comments
Comment		Date Added	Submission
Please include duration of study.		09/01/2019 at 14:56 PM	Latest Submission
			Close

- Select the comment to be directed to the relevant section in the form i.e. to Participant Consent
   Q 5.1
- As the query requires a new version of a **document**, the original version should be deleted, and the new version uploaded into the form. Previous document versions are automatically archived.
- Select Delete

### to delete the original version

Processor     Processor       Image: Processor     Processor       Image: Processor     Signatures       Image: Processor     Signatu	Processor     Processor       Image: Processor     Processor       Image: Processor     Signatures       Image: Processor     Signatu	Actions ~								
Price     Price     Price       Price       Price	Image: Constant	( )	-							
Print     Documental     Signatures       Save     State     Cataboration       Save     Save     Save       A     1       S.1(a) How well informed consent be obtained and recorded?	Print     Decement     Signature       Image: State and the state of project involve information of participants / state and the state of project involve information of participants / state and the state of project involve information of participants / state and the state of project involve information of participants / state and the state of project involve information of participants / state and the state of project involve information of participants / state and the state of project involve information of participants / state and the state of project involve information of participants / state and the state of project involve information of participants / state and the state of project involve information of participants / state and the state of project involve information of participants / state and the state			Participant Consent						
Image         Containants         Image         No           Image         Am         5.1(a) How will informed consent be obtained and recorded?	Base         Base         Collaborators         Image: No           Image: No         Image: No         Image: No         Image: No           <			5.1 Will the research project involve i	informed consent of participa	ants?				
	Upload Participant Information and Consent Form (PICF)									
			1 Reviewer Comments	5.1(a) How will informed consent be	obtained and recorded?					
			Next	Next Navgate Document Signatures Share Collaborators	Image     Image       Next     Image       Documents     Signatures       Signatures     Signatures       Signatures     Containcrators       Signatures     Image       Subarres     Image       Decements     Image       Subarres     Image       Subarres     Image       Image     Image       Subarres     Image	Image: Space of the space o	Image: Space with the space with t	Image: Space with the second of the secon	Image: Second	Image: State with the second secon

• Select **Upload Document** <sup>Upload Document</sup> to upload the revised (new) version of the document with

the correct version number and date

	Actions ~		LNR VIC							
€	$\bigcirc$	1								
evious	Next	Navigate	Participant Consent							5
Print	Documents	Signatures	5.1 Will the research project involve i	nformed consent of participa	nts?					
Bave	Share	Collaborators	⊛ Yes ⊜ No							
✓ bleteness heck	Submit	1 Reviewer Comments	5.1(a) How will informed consent be a	obtained and recorded?						
			Upload Participant Information and Co							
			Туре	Document Name	File Name	Version Date	Version	Size	View	Delete
			Participant information and consent form	Master PICF January 2018	Master PICF January 2018.docx	09/01/2019	1.2	473.2 KB	Download	Dekte

- Continue to complete other queries if instructed in the Overall Reviewer Panel Comments
- Once the revisions / additions have been completed, the form and / or supporting documents can be resubmitted

- Select the **Submit** button under the **Actions** pane to resubmit the revised application
- The Research office will receive the submission
- The application is assigned to a HREC meeting
- Following the HREC review there may be an information request from the Ethics Committee.

## Ethics Committee Review Request

Clarification or requests for further information from the reviewing Ethics Committee to the applicant must be managed through ERM

• The applicant is advised via an ERM email of important information regarding the application

File Message Q	Tell me what you want to do										
ignore ►	Reply Reply Forward All Respond	► ERM Training     ♀ To Manager       □ Team Email     ✓ Done       ♀ Reply & Delete     ♀ Create New       Quick Steps     ■		Assign Mark Categorize Follow Policy - Unread Up - Tags	÷ ⊸ Select *	Zoom Zoom					
donotreply@	r INFORMATION re LNR Januar	arrington (DHHS)			N						
Dear Investigator, Please refer to the attached letter for important information from Default Committee-VIC regarding your recent application for research project LNR January. Application Type LNR											
,	50365 LNR/50365/DEF-2019-16199	3(v2)									

- A 'REQUEST FOR FURTHER INFORMATION' letter (pdf) from the HREC will include requests for further information to be provided via ERM
- The form is **unlocked** to allow the applicant to complete the requests as outlined in the attached letter

	Your Loop Here
	L
De	fault Committee-VIC Human Research Ethics Committee
(	REQUEST FOR FURTHER INFORMATION
10 January 2019 Dear	
Project Title Project ID Review Refere	LNR January 5936 Nee LNR503050E7-2019-161998(v2)
(HREC). The ap The information	britting an ethics application to Detaul Committee-ViC Human Research Ethics Committee stoation was reviewed by the HMEC # their meeting on HMEC meeting date provided in the HMIcs application was not sufficient for the HMEC to make a decision on the
	ith acceptability of your proposed research project. The HREC therefore requests further rding the research project.
Information to I	be Provided
TDe	Comment
Upload protocol	The protocol requires more internation about how the results will be analysed.
Resubmission	
Please provide t progress.	he requested information via ERM as soon as possible, in order for your ethics application to
Please revise th ensure that	e supporting documentation as specified above. For changes to supporting documentation,
<ul> <li>all version</li> <li>a tracked</li> </ul>	n dates and/or venion numbers are updated -changes copy is uploaded to ERM.
Please resubmit	using ERM by 24 January 2019 in order for the application to be considered at the next HREC
	Page 1 of 2

## Respond to a request for further information from the Ethics Committee

- Depending on the request, the applicant can amend the LNR VIC form and add new documents
- Log in to ERM account
- In the Work Area, click on the Notifications tile
- Select the Message title to open and view the message

	Work Area 🐱	Notifications			
1	9	Search			
Hom		Start End	/		
		Display			
		Dearch			
		🗉 🔍 🖉 Message	Attachment	Project Short Title	Time
		📋 🖌 🍺 Information is required regarding your application. Please refer to the attached letter.	0	LNR January	08:46

•	A message box will be di	splayed allowing the user to view the form
	Press View Form View Form	to be directed to the relevant form

Me	essage		×
	Project Short Title Date	LNR January 10/01/2019 08:46	
	Information is r refer to the atta	equired regarding your application. Please ched letter.	
		View Form	Close

The LNR VIC, will open under the Navigation tab

	Work Area 👻	•	LNR January				
ff.	8		-				
Home	Notifications		Project Tree 🗸				
	Actions 🐱		C LNR January				
Project	Create Sub	2 Reviewer Comments	O LNR VIC	- Administrator use only			
< Share	Completeness Check	Submit	Form Status	Review Reference	Application Type	Date Modified	NMA
C	8	-	Information requested	N/A	LNR Application	09/01/2019 16:45	Project is not for NMA
Refresh	NMA Project	Print					
$\times$			Navigation	Documents Signatures	Collaborators Submissions	Correspondence History	
orrespond							
			LNR VIC				Sh
			Section	Questions			
			Introduction	Organisation			

- Select **Reviewers Comments** under the Action pane •
- A text box will be displayed of the Overall Reviewer Panel Comments

Overall Reviewer Panel Comments		
		Show Previou
Comment	Date Added	Submission
The protocol requires more information about how the results will be analysed.	10/01/2019 at 08:44 AM	Submission 2
Please include duration of study.	09/01/2019 at 14:56 PM	Submission 1

Select the comment relating to the Ethics Committee request to be directed to the relevant •

section in the form i.e. Project Details Q 1

- The request requires a new version of a protocol. The original version should be deleted, and the • new version uploaded into the form. Previous document versions are automatically archived.
- •

Select **Delete** to delete the original version

	Actions 🛩									
Previous	(Next	<b>↓</b> Navigate	1.10	Research aims, methodology a	ind significance					
Print	Documents	Signatures								
Save		Collaborators	1.11 /	Anticipated start date for the re	search project					
Completeness Check	s Submit	2 Reviewer Comments	1.12	Anticipated finish date for the r	esearch project					
	Upload protocol									
			Туре	Document Name	File Name	Version Date	Version	Size	View	Delete
			Protoco	ol January protocol	January protocol.docx	01/01/2019	1.1	11.6 KB	Download	Delete

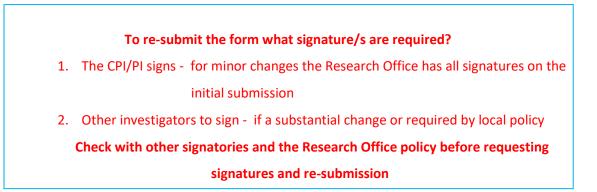
Select **Upload Document** to upload the revised (new) version of the protocol with the • correct version number and date

The LNR VIC now includes the latest version ready for resubmission

	Actions 🛩											
Previous	() Next	Navigate										
Print	Documents	<b>D</b> Signatures	1.10	Resear	rch aims, methodology ar	nd significance						
Save	Share	Collaborators										
Completeness	Submit	2 Reviewer Comments	1.11	Anticip	ated start date for the res	earch project	(					
	1.12 Anticipated finish date for the research project				(							
	Upload protocol											
			тур	,	Document Name	File Name	ſ	Version Date	Version	Size	View	Delete
			Prot	DCOI	January protocol	January protocol.docx		10/01/2019	1.2	11.6 KB	Download	Delete

Continue to complete other requests if instructed in the Overall Reviewer Panel Comments

Note amending a form and/or adding a new document will invalidate any electronic signatures.



In the Actions pane select the **Submit** button to resubmit ٠

The reviewing Research Office will receive the resubmission

## **Approved Applications**

- Applicants are informed of decisions by the HREC via email using ERM. If the application has been approved, the form is locked
- Log on to ERM and click on Notifications tile
- A formal approval letter from the HREC can be downloaded by the applicant If the application review outcome is **not approved**, applicants are also informed via email through ERM.

## Section 9: Site Specific Assessment (SSA)

The Victorian SSA form is used to address governance at a public health organisation in Victoria. It is the responsibility of the site Principal Investigator to complete the Victorian SSA form for their site, and to submit the form to the site Research Governance Officer (RGO).

## Create a SSA

• From the HREA or LNR VIC, select Create Sub-form button under the actions pane

1	Nork Area 🐱		Jan Project							
Home	10 Notifications		Project Tree 🗸							
Project	Actions 🗸	Share	Jan Project     HREA	)						
2+	~	1	Form Status	Review Reference		Application Type		Date Modified		NMA
Roles	Completeness Check	Submit	Not Submitted	N/A		N/A		30/01/2019 12:13		Project is not for NMA
Refresh	S NMA Project	Print	Navigatio	n Documents	Signatures	Collaborators	Submissions	Correspondence	History	
$\ge$	4									
Correspond	Import Xml		HREA							
			ERM Module E	RM Filter Questions troduction HREC Directory						

- A Create Sub-form box will be displayed
- Select the jurisdiction
- Select SSA VIC from the drop-down list
- Select Create button

Select Jurisdiction Victoria	Victoria	Create Sub-form		×
	elect the sub-form that you would like to apply to this form	Select Jurisdiction		
Select the sub-form that you would like to apply to this form		Victoria •		
	Site Specific Assessment (SSA) VIC 🔹	Select the sub-form that you would like to apply to	o this form	
Site Specific Assessment (SSA) VIC v		Site Specific Assessment (SSA) VIC	T	

• The Project Tree will display the newly created SSA

	Work Area	*	Jan Project							
Home	10 Notifications	3	Project Tree V							
	Actions <b>、</b>		• Jan Project							
Project		Create Sub-	HREA     Site Sp	ecific Assessment (SSA) V	IC -					
Share	Roles	Completeness Check	Form Status	Review Reference		Application Type		Date Modified		NMA
1	3	8	Not Submitted	N/A		N/A		30/01/2019 12:40		Project is not for NMA
Submit	Refresh	NMA Project								
•	$\ge$		Navigatio	n Documents	Signatures	Collaborators	Submissions	Correspondence	History	
Print	Correspond									
			Site Specifi	c Assessme	ent (SSA)	VIC				
			Section	Questions						
			Introduction	Information Project		Site Addition				

• Information from the HREA will not automatically populate the SSA

## **Creating SSAs for Sites**

The SSA for a site is created by either the HREA (or LNR VIC) project owner or by assigning this role to the site PI.

The creation and management of site SSAs in **ERM** should be determined by the CPI / delegate. Both options (i) and (ii) are described below:

- (i) HREA project owner
- The HREA project owner creates the SSA as sub-form of the HREA and becomes the SSA form owner
- The HREA / SSA owner may start the SSA then assign responsibility for its completion and submission to the site PI
- In the Introduction section of the SSA form, complete question Q 1.4 to enter the name of the • site/organisation

Select **Roles+** button under the Actions pane

	Actions 🗸		Site Specific Assessmer	nt (SSA) VIC - Albur	v Wodonga	Health
۲		1			y mouonga	louitii
Previous	Next	Navigate	Location Information		Name of site	
Print	Documents	Signatures	1.4 Name of site/organisation	Albury Wodonga Health		¥
E	Share	Roles				
<u>.</u>	~	<u></u>				
Collaborators	Completeness Check	Submit				

A Share Roles text box will be displayed

Enter the collaborator's (site PI) email address and select SSA Sharing

This level of access includes all of the following:

- o read
- o write
- o create subforms e.g. Site Notification Form
- o receive notifications

Share Roles			×
Sharing a form enables others to view/edit the same form depending on the level of acc	ess you give them. Please select the users you wish to share this form with:		
Collaborator email	SSA Sharing v	Ŧ	
Note: This form has not yet been shared with anyone	oon onanny		
			Share Role Close

- Other research team members can be added using the  $\blacksquare$  button
- Select Share Role button •
- The collaborator e.g. the site PI will receive an email notification about their assigned role in the • project
- The collaborator logs into ERM and follows the steps as described in Assign access to the HREA

• The project (HREA) and SSA will be displayed in the Project Tree

	Work Area 🛩	Jan Project				
ff.	9					
Home	Notifications	Project Tree 🗸				
	Actions 🛩	O Jan Project				
ATT Project	Delete Form	O HREA				
			ecific Assessment (SSA) VIC - Administrator U	se Only		
<	<u>+</u>					
Share	Roles Complet Cher	Ress Form Status	Review Reference	Application Type	Date Modified	NMA
1	2 8	Not Submitted	N/A	N/A	01/02/2019 10:23	Project is not for NMA
Submit	Refresh NMA Pr	oject				
÷	$\sim$	Navigatio	n Documents Signatures	Collaborators Submissions	Correspondence History	
Print	Correspond					
		Site Specifi	c Assessment (SSA	VIC		
		one opecin				
		Section	Questions			

- Using Roles + allows the collaborator to also view the HREA form and supporting documents. All documents uploaded to the ethics application by the CPI are automatically available when the CPI has shared the SSA (using Roles +) with the site PI
- Complete the SSA form

### (ii) Assigning Role to Site PI

- The HREA is allocated to the PI/delegate using **Roles +** allowing the PI access to the HREA to create their own SSA

1	Work Area 👻		January Pr	oject			
Home	10 Notifications		Project Tree 🗸		HREA highlighted		
	Actions 🛩		S January Proje	a –		1	
Project	Create Sub-	Share	• HREA				
2+	~	<u>_</u>	Form Status	Review Reference	Application Type	Date Modified	NMA
Roles	Completeness Check	Submit	Not Submitted	N/A	N/A	19/02/2019 14:16	Project is for NMA
Refresh	S NMA Project	Print	Naviga	tion Documents	Signatures Collaborators Submissions	Correspondence Histor	y
$\sim$	古						
Correspond	Import Xml		HREA				Sho
			Section	Questions			
			ERM Module	ERM Filter Questions			

- A Share Roles text box will be displayed
- Enter the collaborator's (site PI) email address and select HREA Share (read, create subforms)

Share Roles		
Sharing a form enables others to viewledit the same form depending on th	ne level of access you give them. Please select the users you wish to share th	his form with:
Collaborator email	HREA Share (read, create subforms)	• +

- Select Share Role Share Role
- The collaborator will receive an email notification about their assigned role in the project
- The collaborator logs into ERM and follows the steps as described in Assign access to the HREA
- The project (HREA) will be displayed in the Project Tree
- Select the **Create Sub-form** button under the Actions pane
- A Create Sub-form text box will be displayed Select Site Specific Assessment (SSA) VIC Select Create

Create Sub-form	×
Select Jurisdiction	
Select the sub-form that you would like to apply	to this form
Site Specific Assessment (SSA) VIC	•
	Create Close

• The SSA will be displayed in the Project Tree

	Work Area	~	January	Projec	ct						
-	30 Notifications		Project Tree 🕶			_					
Project	Actions •	Create Sub-		REA	Assessment (BSA) VIC						
Share	Replace	Completeness	Form Status		Review Reference		Application 7	ype	Date Modified	1	NMA
Submit	2 Refresh	P NMA Project	Not Submitted		N/A		N/A		25/02/2019 11	26	Project is for NMA
Print	Correspond			Navigation	Documents	Bignatures	Collaborators	Submissions	Correspondence	History	
			Site Sp	ecific /	Assessme	nt (SSA)	VIC				U 9
			Section Introduction		Questions Information Project	Location Ethics R	site Addition				

• Complete the SSA form

## **Upload Documents**

All site specific supporting documents are uploaded to the SSA when completing the relevant question in the form. See table below for examples of document types.

Section	Questions (hyperlink)		Document Example
Site Research Team	Documents		Curriculum Vitae, GCP training certificates
Recruitment	Participant Details	Q 4.1	Site specific PICF
Regulation	Research Agreement	Q 5.2	Clinical Trial Research Agreement (CTRA)
Other Documents	Other Documents	Q 7.1	Signature document, Departmental forms

• Example – Site specific PICF

	Actions 🛩		Site Specific Assessment (SSA) VIC -
Previous	() Next	Navigate	
Print	Documents	Signatures	Participant Details 4.1 What does the research project involve at this site?
E Save	Share	Roles	Recruitment of participants     Access to records     Use of samples
ollaborators	Completeness Check	Submit	4.1(a) Target number of participants at this site
			4.1(b) Recruitment procedure at this site Include information about any dependent or unequal relationships, and participant reimbursement.
			Upload participant information and consent form (PICF) Upload Document

- Press Upload Document Upload Document to attach the site specific PICF from your local drive
- Uploaded documents will be displayed under their type, name, file name and version
- Multiple documents of the same document type can be added by selecting Upload Document multiple times
- Specify the version and date to differentiate the documents within the same document type

Upload participant information ar	nd consent form (PICF)						
Туре	Document Name	File Name	Version Date Ve	ersion	Size	View	Delete
Participant information and consent form	PICFs Dec 2017(site specific version)	PICFs Dec 2017(site specific version).docx	31/12/2017 1.	1	269.6 KB	Download	Delete
Upload Document							

• Documents will also be displayed under **Documents** tab and can be downloaded

Share	Roles	Completeness Check	L							
1	3	S	Form Status	Review Reference	Application Type	Date Modified		NMA		
Submit	Refresh	NMA Project	Not Submitted	N/A	N/A	01/02/2019 14:07		Project is fo	r NMA	
ē.	$\times$									
Print	Correspond		Navigation	Documents Signatures	Collaborators Submissions	Correspondence	History			
			Documents							
			Documents Type	Document Name	File Name		Version Date	Version	Size	View
				Document Name Dr Jones CV	File Name Dr Jones CV/docx		Version Date 01/02/2018	Version	Size	View

## Assign access to the SSA form

In ERM, only the **SSA form owner** can make the SSA available to other research team members using the **Roles+** function.

- Select the Roles+ button under the Actions pane
- Enter the collaborator's email address and select SSA Sharing.
   Select Share Role button

Share Roles				×
Sharing a form enables others to view/edit the same form depending on the level of acc	tess you give them. Please select the users you wish to share this form with:			
Collaborator email	SSA Sharing	• 🕂		
Note: This form has not yet been shared with anyone	SSA Sharing			
			Share Role	Close

- The collaborator will receive an email notification regarding access to the project
- The collaborator logs in to ERM and follows the steps as described in Assign access to the HREA
- The collaborator will be able to view and edit the SSA

## **Applying Signatures**

#### Declaration

The Principal Investigator (PI) is required to sign the Declaration by Principal Investigator page in the

SSA form for endorsement of the project at the site.

• For departments directly involved in the research project **(SSA Q 3.3)**, the department head is required to sign the Declaration by Head of Department

Signature of I	Head of Department
• A Head of Dep	artment may delegate responsibility to an appropriate staff member
	must not approve their own research on behalf of their department. If an investigator is also Head of Department, certification must be a to whom the Head of Department is responsible.
Who is providing	r sinnature?
	Department
<ul> <li>Head of</li> </ul>	Department's Delegate
Name	
Department	
Declaration by	Head of Department
certify that:	
<ul> <li>I have discus</li> <li>All investigate</li> <li>There are su</li> </ul>	In research project application named above, so this research project, and the resource implications for this department, with the Principal Investigator, or shalanders from my department involved in the research project have the skills, trianing and appendix on the state research project being samed or values skills treasurement project to be considured at this site.

• For any department that is providing support or services to the research project, the supporting department head is required to sign the Declaration by Head of Supporting Department

Site Sp	ecific Assessment (SSA) VIC -
Signature o	of Head of Supporting Department
A supporting team.	g department is any department that is providing support or services to the research project, but which does not have any member(s) on the resea
<ul> <li>A Head of S</li> </ul>	Supporting Department may delegate responsibility to an appropriate staff member.
Who is provid	ding signature?
= Head	d of Supporting Department
< Head	d of Supporting Department's Delegate
Namo	
Department	
Declaration b	by Head of Supporting Department
I certify that:	
<ul> <li>I am able t</li> </ul>	Id the project details in this SSA. To perform the investigations/services indicated. cussed this research project with the Principal Investigator.
Request Signat	ture Tapa

#### Signatures

The SSA form questions / information must be complete, <u>before</u> requesting signatures. Any change to the SSA form will invalidate signatures.

Using a combination of signature methods e.g. wet ink signatures, attaching other evidence, electronic signatures should be sought LAST as the form will be locked once electronic signature requests have been made. Multiple electronic signatures can occur.

\* Signatories must have an ERM account to provide electronic signature

### The SSA form owner / user may obtain signatures as follows:

## To use Wet ink signature

- Using the **Print button** from the Actions Pane, print the relevant Declaration page and obtain the signature from the PI /Head of Department /Supporting Head of Department. Save to your local drive as a pdf
- Navigate to Section **Other Documents** of the SSA to find [Other Documents]
- Other Documents opens to Q 7.1 of the SSA form to attach the Declaration page
- Select **Upload document** Upload **Document** to attach the Declaration page to the SAA form

	Actions 🗸		Site Specific Assessment (SSA) VIC - Administrator Use Only				
ſ		1	one opecine Assessment (SOA) vio - Administrator Ose Only				
Previous	Next	Navigate	Supporting Documents				
Print	Documents	Signatures	7.1 Are any other supporting documents provided (in addition to the documents already uploaded within this SSA)?				
E Save	Share	L+ Roles					
Sec. Collaborators	Completeness Check	Submit	Upload Document				

#### To attach other evidence to indicate agreement

- Navigate to Section 'Other Documents' of the SSA to find Other Documents'
- Other Documents opens to Q 7.1 of the SSA form to attach the signature document
- Select Upload Document Upload Document to attach the signature document from your local drive to the SSA form
- Other supporting documents can also be uploaded in this section

#### To request an Electronic Signature

• To request an electronic signature from the Head of Department, Supporting Head of

Actions 🛩		Site Specific Assessment (SSA) VIC - Administrator Use Only
• •	1	Site Specific Assessment (SSA) VIC - Administrator Ose Only
revious Next	Navigeta	Signature of Head of Department
Print Documents	Signatures	A Head of Department may delegate responsibility to an appropriate staff member.
Save Share	Roles	<ul> <li>An investigator must not approve their own research on behalf of their department. If an investigator is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible.</li> </ul>
aborators Completeness	Submit	Who is providing signature?

• Enter the signatory's ERM email address and select Request

Request a signature	×
Enter the email address of the person you want to sign this for	
Email Address	
Enter a message (Optional, max 800 characters)	
Req	est Close

- The requested signatory will receive an email notification for a signature
- The signatory logs into ERM
- From the Work Area the signatory selects Signatures tile to open the request
   ERM Applications
   Home
   Contacts
   Help -

Work Area 🐱		Work Area
#	1	WUIK AIEd
Home	Notifications	General
,	Actions 👻	Notifications Signatures Transfers Shared
reate Folder [	Delete Folder Create	
elete Project	Duplicate Tran	E a la la seconda de



- New requests are highlighted
- Under the Action tab, select View Form View Form to review the SSA form
- The ethics application cannot be viewed unless the **HREA** Project/Form Owner has used the **Roles+** function from the **SSA** to share the SSA form with the signatory
- For endorsement of the SSA application, select **Sign** button under the Actions pane

Actions V	Site Specific Assessment (SSA) VIC -
Previous Next Navigate	Read access only.
Print Sign Reject	Signature of Head of Department
	A Head of Department may delegate responsibility to an appropriate staff member.
Completeness Check	<ul> <li>An investigator must not approve their own research on behalf of their department. If an investigator is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible.</li> </ul>
	Who is providing signature?   Head of Department Head of Department's Delegate  Department Department Department Department I certify that: I have discussed this research project application named above. I have discussed this research project application named above. I have discussed this research project application named above. I have discussed this research project application named above. I have discussed this research project application named above. I have discussed this research project application named above. I have discussed this research project application named above. I have discussed this research project application named above. I have discussed this research project applications for this department, with the Principal Investigator. I have discussed this research project being carried out using such resources. I support this research project being carried out using such resources.

A Sign Form text box is displayed
 The signatory enters their ERM log in details to sign the form
 Select Sign Sign button

Please enter your logii	details in order to sign this form:	
Usemame	Password	

- The applicant receives an email notification indicating the signature request has been accepted by the signatory i.e. the form has been signed
- Repeat the signatory process for electronic signatures for other signatories
- All signatures must be obtained before the SSA can be submitted to the site Research Governance Officer
- Once the signature is complete the application is ready for submission

# Section 10: Submission and Review Process - SSA

Ensure the SSA form is complete and all site documents are uploaded and **signatures completed**. When the SSA is submitted, the site Research Governance Officer (RGO) automatically has access to all documents uploaded to the main(ethics)form when the ethics application has been submitted via ERM to a Victorian or Queensland HREC. This means that only site governance documents should be uploaded to the SSA form and submitted for authorisation.

button

## **Submission**

Navigate to the Actions pane and select the Submit

The system performs a completeness check to highlight any incomplete sections If complete, the form is ready to be submitted

Submit	×	:
Complete: Your form is complete and ready to submit		
	Submit Close	

- Select the Submit Submit button
- The system will automatically submit the application to the site/organisation selected in **Q 1.4** of the SSA
- Following the submission, a unique identification code is generated.
   It is composed of six parts e.g. SSA/60889/VICTEST-2020-201446(v1)

Application type	SSA
Project ID	60889 – ERM project number
Organisation/hospital code	VICTEST
Year	2020- year of submission
Submission number	201446 - submission version number
Version number	v1
Version number	v1

### Recall an application

Any changes made to the submission will INVALIDATE all electronic signatures and will require all signature requests again

- Once the SSA application has been submitted, a recall option becomes available
- The form can be recalled until the submission is actioned by the Research Office
- This action removes the submitted application from the Research Office's ERM account
- Select the **Recall** button under the Actions Pane to recall the submission and make any changes / additions
- Check that any electronic signatures are completed

Select the **Submit** button. The application will be resubmitted

V	Work Area 🐱	December Ho	idays			
Homs Project	6 Nestfications Actions ~		: Assessment (BEA) V/C - Administrator Us c Assessment (BEA) V/C - ]	e Cniy		
S MA Project		this form for review	Review Reference	Application Type	Date Modified 28/12/2018 14:01	NMA Project is not for NMA
		Navigation	Documents Signatures	Collaborators Bubmissions	Correspondence His	itory
		site specific i	Assessment (SSA)			
		Introduction	Information Project Location Ethics I	Review Site Addition		
		Site Research Team	Team Documents Impact Conflict of	Interest		
			Dates Departments and Services Sur	nmary		
		Site Impact				
		Participants	Recruitment Co-enrolment Standard			
		Participants Regulation	Recruitment Co-enrolment Standard Sponsor Research Agreement Indem	Care Admissions nity and Insurance TGA Notification Safe	¢γ	
		Participants	Recruitment Co-enrolment Standard		ty .	

## Responding to a Query from the Research Office

If an SSA application is queried by the Research Office for further clarification or changes, additions (e.g. supporting documents):

• The applicant is advised via an ERM email of important information regarding their SSA application

donotreply@infonetica.net  Catherine M Farmgton (0+H5) IMPORTANT INFORMATION re New Years Eve
Letter.pdf
Dear Investigator,
Please refer to the attached letter for important information from Default Committee-VIC regarding your recent application for research project New Years Eve.
Application Type SSA
Project ID 50227
Review Reference SSA/50227/DEF-2019-161533(v1)
Kind regards,

- A 'REQUEST FOR INFORMATION' letter (pdf) from the Research Office will include details for further information to be provided via ERM
- The form will be *unlocked* to allow the applicant to complete the revisions / additions as requested

	Your Logo Here
RESE/	ARCH GOVERNANCE / SITE SPECIFIC ASSESSMENT (SSA)
	REQUEST FOR INFORMATION
fr	om Default Committee-VIC Research Governance Officer
2 January 2019	
Dear,	,
Project Title	New Years Eve
Project ID Review Refer	50227 ence SSA/50227/DEF-2019-161533(v1)
	submitting a research governance/SSA application to Default Committee-VIC . The application seed by the research governance officer (RGC) and it is not of a satisfactory standard. Some quired.
Information to	be Provided
Please add site	contact details to the PICF.
Submission	
	e SSA form in ERM and revise the supporting documentation as specified above. For changes ocumentation, ensure that:
	on dates and/or version numbers are updated d-changes copy is uploaded to ERM.
	the requested information via ERM as soon as possible, in order for your research IA application to progress.
	roject cannot commence at this site until research governance/SSA authorisation has been
granted.	
-	ny further information, please contact the RGO via the ERM 'Correspond' button or 1234 5678

### To access the Query

• In the Work Area, click on the Notifications tile

Work Area ~	Work Area
Home Notifications	General
Actions 🛩	Notifications Signatures Transfers Shared
Create Folder Delete Folder Create Project	2 0 0 7
Delete Project Dupiscate Project Transfer	Folders
	Old Applications
	Projects
	Bearch Projects
	Project Title    Project ID
	December Holidays 49968 Ms Catherine Parrington 13/12/2018 14:22 13/12/2018 14:25

• Select the Message title to open and view the message

Work Area 🐱	Notifications		3
Home 9	Search		
Home Homeations	Start End		
	Display 100 notifications Please note that only the specified number of notifications will show after searching.		
	Sterch		
	Message	Attachment      Project Short Title     Time	e 🗸
	😑 🖌 🎽 Information is required regarding your application. Please refer to the attached letter.	New Years Eve 13:1	9 🗙

• A **Message** box will be displayed allowing the user to view the form

Reviewer Comments

• Press **View Form** to be directed to the relevant form

Mes	sage		×
	-		
	Project Short Title	New Years File	
	Date	02/01/2019 13:19	
		quired regarding your application	. Please
	refer to the attac	hed letter.	
		Viev	v Form Close

- The SSA form will open under the Navigation tab
- Select Reviewers Comments

under the Action pane

	Work Area	÷	New Y	ears Eve							
Home	8 Notifications		Project Tree								
Project	Actions V	1 Reviewer Comments		HREA     Site Specific	Assessment (8SA) VI	C -					
Share	Roles	Completeness Check	Form Status			Review Reference	A	pplication Type	Date Mo	dified	NMA
<b>L</b> Submit	Refresh	P NMA Project	Partial applic	ation received		N/A	S	SA Application	02/01/20	19 13:13	Project is not for NMA
Print	Correspond			Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence	History	
			Site S	Specific A	ssessme	ent (SSA)	VIC				Sho
			Section Introduction		Questions Information Project		Review Site Addition				

• A text box will be displayed of the Overall Reviewer Panel Comments

Overall Reviewer Panel Comments			~
Overall Reviewer Panel Comments	PICF requiring edits		^
Comment		Date Added	Show Previous Comments
Site contact details are missing from PICF.		02/01/2019 at 13:16 PM	Latest Submission
			Close

• Select the comment to be directed to the relevant section in the SSA form, e.g. to Q 4.1 Participant Details

As the query requires a new version of a document, the original version should be deleted and • the new version uploaded into the form. Previous document versions are automatically archived.

ele			Delete	to delete the	original vers	ion					
	¢		-	Site Specific As	ssessment (S	SSA) VIC -					
	Previous	Next	Navigate	Participant Details							$\mathbf{\mathcal{P}}$
	Print	Documents	Signatures	4.1 What does the research proje	ect involve at this site?						
	E Save	Share	St- Roles	<ul> <li>Recruitment of particip</li> <li>Access to records</li> <li>Use of samples</li> </ul>	pants						
	Collaborators	Completeness Check	Submit	4.1(a) Target number of participa	ants at this site						
	Reviewer Comments			4.1(b) Recruitment procedure at Include information about any dep		s, and participant reimbursement.					
	Upload participant information and consent form (PICF)						$\square$				
				Type Participant information and consent	PICFs Dec 2017(site specific	File Name PICFs Dec 2017(site specific	Date 31/12/2018	Version	Size 269.6	View	Delete

• Select **Upload Document** Upload **Document** to upload the revised (new) version of the document with

the correct version number and date

The SSA form now includes the latest version ready for resubmission •

Actions 🛩	~	4.1 What does the research pro	ect involve at this site?						
Pravious Next	<b>√</b> Navigata	Recruitment of particip Access to records							
Print Documents	Signatures	Use of samples							
Save Share	Roles	4.1(a) Target number of participa	ants at this site						
Collaborators	on Submit	<ol> <li>4.1(b) Recruitment procedure at Include information about any de</li> </ol>		s, and participant reimbursement					
1 Reviewer Comments		Upload participant information ar	nd consent form (PICF)						
		Туре	Document Name	File Name	Version Date	Version	Size	View	Delete
		Participant information and consent form	PICFs Dec 2017(site specific version)	PICFs Dec 2017(site specific version).docx	01/01/2019	1.2	269.6 KB	Download	Delete

- Once the revisions / additions have been completed, the form and / or supporting documents can be resubmitted
- In the Actions pane select the Submit button to resubmit ٠

1	Work Area	•	New Years Ev	e				
<b>H</b> ome	8 Notifications		Project Tree 🗸					
<b>f</b> roject	Actions V	1 Reviewer Comments	New Years Eve     HREA     Site Specifi	ic Assessment (SSA) VIC -				
< Share	L+ Roles	Completeness Check	Form Status	Review Reference	Application Type	Date Modified	NMA	
<b>L</b> Submit	Refresh	O NMA Project	Partial application received	N/A	SSA Application	02/01/2019 13:13	Project is not for NMA	
Print	Correspond		Navigation	Documents Signatures	Collaborators Submissions	Correspondence History		
	Site Specific Assessment (SSA) VIC							
			Introduction	Information Project Location Ethics Re				

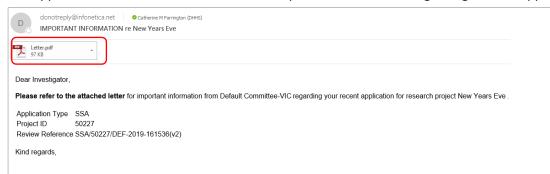
- The Research Office will receive the submission
- The SSA application is assessed by the Research Governance Officer (RGO)
- Following the assessment there may be an information request from the RGO •

## **RGO Review Request**

Clarification or requests for further information from the RGO to the applicant must be managed

through ERM

• The applicant is advised via an ERM email of important information regarding the SSA application



- A 'REQUEST FOR INFORMATION' letter (pdf) from the RGO will include requests for further information to be provided via ERM
- The SSA form is unlocked to allow the applicant to complete the requests as outlined in the attached letter

	Your Logo Here
RESEAR	RCH GOVERNANCE / SITE SPECIFIC ASSESSMENT (SSA)
fror	REQUEST FOR INFORMATION n Default Committee-VIC Research Governance Officer
2 January 2019	
Dear ,	
Project Title Project ID Review Referen	New Yeas Eve 6027 ce SSA/50227/DEF-2019-191536(v2)
	omitting a research governance/SSA application to Default Committee-VIC. The application ed by the research governance officer (RGO) and additional information is required.
	ore information about the funding source.
Submission	
Please alter the S	SA form in ERM as specified above. For changes to supporting documentation, ensure that:
	dates and/or version numbers are updated changes copy is uploaded to ERM.
	requested information via ERM as soon as possible, in order for your research application to progress.
The research proj granted.	ject cannot commence at this site until research governance/SSA authorisation has been
If you require any	further information, please contact the RGO via the ERM 'Correspond' button or .
Yours sincerely,	

### Respond to a request for further information from the RGO

- The applicant can amend the SSA and add new documents if requested by the RGO
- Log into ERM account
- In the Work Area, click on the Notifications tile
- Select the Message title to open and view the message

Notif	ications		
Search			
Start	End		
Display	100 notifications		
	Please note that only the specified number of notifications will show after searching.		
	Search		
÷	+ Message	Attachment      Project Short Title	🕴 Time  🗸
	Information is required regarding your application. Please refer to the attached letter.	New Years Eve	14/01/2019

- A message box will be displayed allowing the user to view the SSA form
- Press View Form to be directed to the relevant section in the SSA form

les	sage		×
	Project Short Title Date	New Years Eve 02/01/2019 15:26	
	Information is n refer to the attac	equired regarding your application. Please ched letter.	
		View Form	Close

- The SSA will open under the Navigation tab
- Select **Reviewers Comments** under the Actions pane

	Work Area	*	New Years Ev	e						
<b>H</b> ome	8 Notifications		Project Tree 🗸							
roject	Actions •	2 Reviewer Comments	New Years Eve     HREA     Site Specific	ic Assessment (SSA) Vie	0.4					
<b>\$</b> hare	Roles	Completeness Check	Form Status	Review	Reference	Applica	tion Type	Date Modified	1	NMA
1 ubmit	Refresh	Ø NMA Project	Information requested	N/A		SSA Ap	plication	03/01/2019 05	2.41	Project is not for NMA
Print	Correspond		Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence	History	
			Site Specific		ent (SSA)	VIC				🗎 Shi
			Introduction		Location Ethics R	eview Site Addition				

• A text box will be displayed of the Overall Reviewer Panel Comments

Overall Reviewer Panel Comments		×
Comment	Date Added	Show Previous Comments
Please provide more information about the funding source.	02/01/2019 at 15:24 PM	Latest Submission
		Close

• Select a comment e.g. comment requesting more information about the funding source, to be directed to the relevant section in the form i.e. **Q 6.1 Type(s) of funding** 

	Actions 🗸		Site Specific Assessment (SSA) VIC -
۲		-	Site Specific Assessment (SSA) Vio -
Previous	Next	Navigate	Funding
Print	0 Documents	Signatures	6.1 Type(s) of funding
Save	Share	Roles	Commercially sponsored Sponsored, other (e.g. collaborative group) External (e.g. NHMRC) Internal/Departmental
<u>Se</u>		Submit	Other
2	Completeness Check	Gubhit	Other funding
Reviewer Comments			Source Philanthropic funds raised from 2018 charity event AU\$ 1000000

- Enter the requested information as instructed in the **Overall Reviewer Panel Comments**
- Continue to complete other requests if necessary

### To re-submit the form what signature/s are required?

- 1. The PI signs. For minor changes the Research Office has all signatures on the initial submission
- 2. Other signatories to sign if a substantial change or required by local policy

Check with other signatories and the Research Office policy before requesting signatures and re-submission

In the Actions pane select the **Submit** button to resubmit ٠

The reviewing RGO will receive the resubmission ٠

## **Authorised Applications**

- Applicants are informed of decisions by the RGO via email using ERM. If the application has been authorised, the form is locked
- Log on to ERM and click on Notifications tile ٠
- A formal authorisation letter from the RGO can be downloaded by the applicant •
- If the application review outcome is not authorised, applicants are also informed via email ٠ through ERM.

# Section 11: Minimal Dataset Form (MDF)

When the ethical review of a research application is in a jurisdiction that does not use ERM, a Minimal Dataset Form (MDF) is used to create the SSA form for sites in Victoria and Queensland. It is a proxy form that is created **once only** for the research application.

The site Principal Investigator uses ERM to complete the SSA and submit to the site Research Governance Officer.

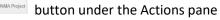
- The CPI / delegate logs onto ERM
- Select Create Project button under the Actions pane to create a new Main Form

	Create Project	~
	Project Title (maximum 200 characters):*	
Enter the Project Title, jurisdiction and select <b>MDF</b> from the Main	MDF January Select Jurisdiction	
Form drop-down list	Victoria • Main Form	
Select Create button	MDF  Please Select INR VIC	
	Logacy Application Bonlacomont Form V/C	ose
		Enter the Project Title, jurisdiction and select MDF from the Main Form drop-down list Select Create button

• The MDF will appear in the Project Tree

V	Vork Area	~	MDF January	/				
Home	15 Notifications		Project Tree 🗸					
	Actions 🛩		MDF January					
Project	Create Sub-	Share						
<b>~</b>	<u> </u>	2	Form Status	<b>Review Reference</b>		Application Type		
mpleteness Check	Submit	Refresh	Not Submitted	N/A		N/A		
S MA Project	Print	Correspond	Navigatio	n Documents	Signatures	Collaborators	Submissions C	D
			MDF					
			Section			G	uestions	
			Minimal Dataset Form			1	Minimal Dataset Form	

- Complete the questions in the MDF
- Enter the unique ethics reference number indicating where the ethics application was reviewed and approved e.g. HREC/19/CAL/123
- Select the Navigate button to move back to the Project Tree and select the NMA Project



A NMA Project text box is displayed
 Select 'Project is NMA' and Save Save

For further information on NMA see <u>NMA research governance/SSA application</u> on the **Clinical trials and research** webpage

- Select **Upload Document** Upload Document to upload a copy of the HREA reviewed by the NMA HREC into the MDF
- Select the relevant supporting documents e.g. Copy of ethics approval letter, Master PICF, protocol associated with the ethics application.

	Actions 🗸		
Previous	) Next	<b>↓</b> Navigate	Upload the HREA reviewed by the NMA HREC outside Queensland, Mater or Victoria.
Print	Documents	Signatures	Select <b>all</b> supporting documents reviewed as part of the ethics application.
Save	Share	Collaborators	<ul> <li>Advertising material</li> <li>Case report form</li> <li>Evidence of Clinical Trial Notification (CTN)</li> <li>Copy of ethics approval</li> <li>Curriculum vitae (CV) or resume of investigator/researcher</li> <li>Drug data sheet</li> <li>Form of indemnity</li> <li>Licence for dealing with a genetically modified organism</li> <li>GP/consultant information</li> <li>Institutional biosafety committee (IBC) approval</li> <li>Investigator brochure or reference safety information</li> <li>Invitation to participant</li> <li>Letter of support</li> </ul>
			<ul> <li>NSW privacy form</li> <li>Participant documentation e.g. diary, wallet card</li> <li>Participant information and consent form</li> </ul>

• Select **Upload Document** Upload Document to upload the PICF, protocol and other relevant documents from your local drive.

Ensure the Victorian Specific Module (VSM) is selected if a VSM was submitted as part of the ethics application. The CPI should provide a copy of the WORD document of the VSM that was submitted to the reviewing HREC.

Save	Share	S Collaborators	<ul> <li>Victorian specific module (VSM)</li> <li>WA specific module</li> <li>Any other documentation relevant to the ethics application</li> </ul>
ompleteness Check	Submit		<ul> <li>Attach any other relevant documents associated with conducting your research project.</li> <li>Ensure that you give meaningful and unique names to your files before uploading them.</li> <li>Enter the description in the document name field. The date and version fields are mandatory.</li> </ul>
			Participant information and consent form Upload Document Project Description/Protocol Upload Document
			Victorian specific module (VSM) Upload Document

- Select **Submit** button under the Actions pane. The **Submit** action is a systems action and does not submit the form to a HREC
- The site RGO will have access to the uploaded ethics documents in the MDF when the site SSA is submitted
- From the MDF the CPI / delegate creates the SSA as a sub-form

Work Area 🐱	<b>MDF</b> January					
Home 15 Notifications	Project Tree 🛩					
Actions •	MDF January     MDF					
mpleteness Check	Form Status	Review Reference		Application Type		
VA Project Print Correspond	Navigation	Documents	Signatures	Collaborators	Submissions	с
	Section Minimal Dataset Form				uestions Iinimal Dataset Form	

Select the jurisdiction and Site Specific Assessment (SSA)
 Select Create button
 Victoria

Create Sub-	form		>
Select Jurisdiction			
Victoria	*		
Select the sub-form that	at you would like to apply	to this form	
Site Specific Assess	nent (SSA) VIC	*	

- The CPI / delegate selects the **Roles** + keep button under the Actions pane to enable the site PI access to the SSA for its completion and submission to the site RGO
- Enter the collaborator's (site PI) ERM email address and select SSA Sharing
   Select Share Role

haring a form enables others to view/e	edit the same form depending on the level	of access you give them. Please select the users you wish to share this form with:		
Collaborator email		SSA Sharing	• +	
Note: This form has not yet been sha	and with anyone	SSA Sharing		
Hote. This form has not yet been she	area war anyone			

• The site PI will receive an email notification and logs into ERM to complete and submit their SSA.

# Section 12: Legacy Application Replacement Form (LARF)

The Legacy Application Replacement Form (LARF) is required for a Victorian-only research project when the original ethics application was not in the previous database system used by research offices (AU RED). It cannot be used for NMA research projects.

The LARF is not an ethics application form; it is a proxy form that allows sub-forms e.g. post approval forms to be created in ERM. Only **one** LARF is required for the research application.

## Consult the reviewing organisation's research office before creating a LARF to confirm whether the form is required.

- The CPI / delegate logs onto ERM
- Select **Create Project** button under the Actions pane to create a new Main Form
- Enter the Project Title, jurisdiction and select Legacy Application Replacement Form from the main form drop-down list Select Create button

Create Project	×
Project Title (maximum 200 characters):*	
LARF January	
Select Jurisdiction	
Victoria •	
Main Form	
Legacy Application Replacem 🔹	
	_
Create	ise

The LARF will appear under the Project Tree

uub- Share Rofresh	Form Status	-		Application Type		Date Modified		NMA
ub- Share	C Legacy Ap	pplication Replacement Form VIC	2	Application Type		Date Modified		NMA
ub- Share	C Legacy Ap	pplication Replacement Form VIC	2	Application Type		Date Modified		NMA
		Review Reference		Application Type		Date Modified		NMA
·····	Not Submitted	N/A		N/A		06/02/2019 17:00		Project is not for NM
Correspond	Naviga	ation Documents	Signatures	Collaborators	Submissions	Correspondence	History	
	Legacy App	plication Repl	lacemen	t Form VIC		ions		
		Correspond Navig	Correspond Navigation Documents	Correspond Navigation Documents Signatures	Correspond Navigation Documents Signatures Cottaborators  Legacy Application Replacement Form VIC section	Correspond           Navigation         Documents         Signatures         Collaborators         Submissions           Legacy Application Replacement Form VIC         Section         Quests	Correspond           Navigation         Documents         Signatures         Collaborators         Submissions         Correspondence           Legacy Application Replacement Form VIC         Section         Questions         Section         Section	Correspond         Navigation         Documents         Signatures         Collaborators         Submissions         Correspondence         History           Legacy Application Replacement Form VIC           Guestions

- Complete the questions in the LARF

Select the **Submit** button under the Actions pane

- The form will be submitted to the organisation that reviewed the original application
- From the LARF the CPI / delegate creates a new sub-form

	Work Area 🐱	LARF Ja	inuary				
Home	15 Notifications	Project Tree 🗸	-				
Project	Actions V Create Sub- form	© LARF J	anuary	)			
÷	÷ 🖂	Form Status	Review Reference	App	ication Type	Date Modified	NMA
Print	Correspond	Approved	LARF/51368/VICTEST-2019-1645	36(v1) Lega	cy Application Replacement	06/02/2019 17:08	Project is not for NM
			Navigation Documents	Signatures Collaborators	Submissions Correspondence	History	
		Legacy	Application Repla	acement Form V	IC		Show Ins
		Section Legacy Application	- D		Questions Details of Original Applicatio		

• Select the jurisdiction and appropriate post-approval form e.g. Amendment Request

	Create Sub-form ×
Select Create	Select the sub-form that you would like to apply to this form Amendment Request VIC
	Create Close

- The CPI / delegate selects the **Roles** + k button under the Actions pane to share the LARF with other research team members
- Enter the collaborator's email address and select Post Approval/Authorisation Subforms

#### Select Share Role

Share Roles	×
Sharing a form enables others to view/edit the same form depending on the level of access you give them. Please select the users you wish to share this form with:	
Collaborator email Post Approval/Authorisation Subforms	
Note: This form has not yet been shared with anyone	
	Share Role Close

- Complete the questions in the post-approval form
- Sign the post -approval form
- Submit the post-approval form

# Section 13: Quality Assurance (QA) Application Form

The Quality Assurance (QA) VIC form can be used for the submission of the following types of projects:

- clinical audit
- quality assurance
- evaluation activities
- a project that involves the potential for no more than negligible risk

Consult with the organisation's Research Office before creating the QA application. The Research Office will advise whether the QA form is the right choice for the project.

- The applicant logs into ERM
- Select Create Project button under the Actions pane to create a new Main Form

•	Enter the Project Title, jurisdiction and select Quality Assurance
	(QA) VIC from the main form drop-down list
	Select Create

Create Projec	ж	
Project Title (maximum 2	200 characters):*	
QA January		
Select Jurisdiction		
Victoria	¥	
Main Form		
Quality Assurance (QA	N) VIC 🔻	

- The QA form will appear under the Project Tree
- Complete the questions in the QA form
- The Supporting Documents section will enable supporting documents e.g. a

Questionnaire to be uploaded into the application

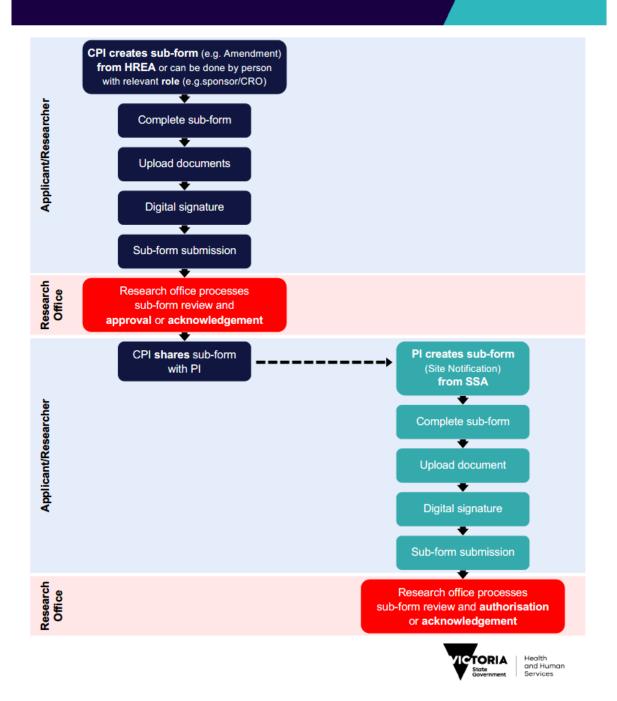
	Actions 🛩		Quality Assurance (QA) VIC
Previous	() Next	1	Quality Assurance (QA) VIC
Previous	Next	Navigate	Supporting Documents
Print	Documents	Signatures	Are there any other supporting documents for the project?
ED Save	Share	Collaborators	* Yes ● No
	±.		Select the documents
Check	Submit		Advertising material Case report form Case report form Case report form Case report form Case mapping the sphere of the sphere of support The sphere of sphe

- Select Upload Document
   Upload Document
- Select Submit button under the Actions pane to submit the application to the reviewing organisation.

# Section 14: Post Approval

# Ethical Review Manager (ERM)

Post-approval and Post-authorisation



Once a research project has been ethically approved, any change to its design or conduct must be approved by the reviewing HREC or ethics review body.

Post approval information should also be submitted to the reviewing organisation.

In ERM, Post Approval forms are created as sub-forms from the original ethics application (HREA) to request amendments and provide information / reports relating to the research project as required by the reviewing HREC.

#### Sub-forms for post approval

- Ethics Amendment Request
- Project Notification Form
- Project Progress Report
- Project Final Report
- Site Closure Report

## Create a Sub-form

Select Create

- The CPI / delegate logs in to ERM
- Select the project title to display the project under the Project Tree and highlight the HREA
- Select **Create Sub-form** button under the Actions pane to create a new sub-form
- Select the jurisdiction and the sub-form e.g. Ethics Amendment Request VIC

•	The Ethics Amendment Request VIC form will be displayed under the Project Tree

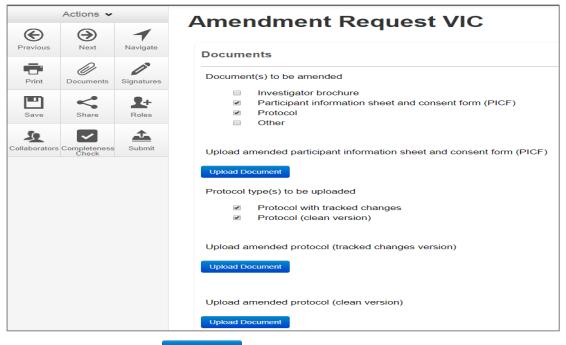
Work	Area 🗸	Project Tree 🗸						
Home	36 Notifications				H			
Project	Duplicate	Form Status	Review	v Reference	Date	Modified	NMA	
Delete Form	m Share	Not Submitted	N/A		22/04	/2020 15:45	Project is	not for NMA
Roles	Transfer Form	Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence	History
Completene Check	ss Submit	Ethics A	mendme	nt Reque	est VIC			🕑 Show
~	~	Section		Questions				

Create Sub-form ×
Select Jurisdiction
Victoria
Select the sub-form that you would like to apply to this form
Ethics Amendment Request VIC
Create
Close

- Safety Report
- Annual Safety Report
- Serious Breach Report
- Suspected Breach Report

# Complete a Sub-form – Ethics Amendment Request

- Complete the questions in the form, in this example the Ethics Amendment Request form
- Depending on the amendment category, new versions of documents e.g. PICF, protocol can be attached to the amendment form



- Select Upload Document Upload Document to attach the amendment documents from your local drive
- Specify the version and date

	Actions 🗸			tor brochure								
Previous	) Next	Navigate	<ul><li>Participa</li><li>Protocol</li><li>Other</li></ul>	nt information sheet a	and consent form (PICF)							
Print	Documents	<b>D</b> Signatures	Upload amended pa	articipant information	sheet and consent form (	PICF)						
m	~		Туре	E	Document Name	File Name		Version Date	Version	Size	View	Delete
Save	Share	Roles	Participant information a	and consent form	Master PICF January 2018	Master PICF Jar	nuary 2018.docx	01/02/2019	1.5	473.2 KB	Download	Delete
5		£	Upload Document									
_	Completeness Check		Protocol type(s) to b	e uploaded								
				with tracked changes (clean version)								
			Upload amended pr	otocol (tracked chang	ges version)							
			Туре	Document Name	File Name	1	Version Date	Version	Size	View		Delete
			Protocol (Tracked)	Study XYZ tracked	Study XYZ tracke	d.docx	01/02/2019	1.5	11.5 KB	Down	load	Delete
			Upload amended pr	rotocol (clean version)	)			_				
			Type Docu	iment Name	File Name	Version Date	Versio	n Size	v	liew	Del	ete
			Protocol Study	/ XYZ	Study XYZ.docx	01/02/2019	1.5	12.5 K	в	Download	D	elete

• Documents will also be displayed under the Documents tab and can be downloaded

2	8	•	Form Status	<b>Review Reference</b>	Application 1	Type Date Mod	lified	NMA		
lefresh	NMA Project	Print	Not Submitted	N/A	N/A	07/02/201	19 13:40	Project	t is for NMA	
respond			Navigation	Documents	Signatures Collaborators	Submissions Correspondence	e History			
				$\square$						
			Documents							
			Documento							
			Туре		Document Name	File Name	Version Date	Version	Size	View
					Document Name Master PICF January 2018	File Name Master PICF January 2018 docx	Version Date 01/02/2019	Version	Size 473.2 KB	View
			Туре	ent form						

# Allowing others to access post approval forms

Using Roles +, allows other research team members access to a post approval form.

• Highlight the post approval form e.g. Ethics Amendment Request in the Project Tree

Work	Area 🗸	Project Tree 😽						
Home	36 Notifications			ment (SSA) VIC -				
Project	Duplicate Form		Ethics Amendment F					
•	~	Form Status	Review	v Reference	Date	Modified	NMA	
Delete Form	Share	Not Submitted	N/A		22/04	/2020 15:45	Project is	not for NMA
Roles	Transfer Form	Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence	History
Completeness Check	s Submit		mendme		est VIC			🗷 Show I
~	~	Section		Questions				

- Select Roles + button under the Action pane
- Enter the collaborator's ERM email address and select Post Approval/Authorisation Subform
- Other collaborators can be added by selecting 🗄 button

		Share Roles						×
		Sharing a form enables others to viewiedit the same form depending on the level of access you give them. Please select the users you wish to share this form with:						
•	Select <b>Share Role</b>	Collaborator email			Post Approval/Authorisation Subforms		• 🛨	
		Name	Role	Given on	Post Approval/Authorisation Subforms	Remove	Remove All Permissions	
		Dr Bernice Davies	SSA Sharing	Site Specific Assessment (SSA) VIC	- Administrator Use Only	Remove	Remove	
							Share Role Clo	ose

- The collaborator receives an email notification on their assigned role in the project
- The collaborator at the site can view the amendment form and associated documents

## **Applying Signatures**

The Coordinating Principal Investigator is required to sign the Declaration page to indicate the information is complete and correct. To request an electronic signature:

In the Declaration section, select Request Signature Request Signature button



- The system performs a completeness check to highlight any incomplete sections
- Enter the signatory's ERM email address and message • Select Request

Request a signature	×
Enter the email address of the person you want to sign this form	
Email Address	
Can you please sign the amendment form	
	)
Request	Close

- The requested signatory will receive an email notification for a signature, a message and link to ٠ ERM Login/Signatures page
- The signatory logs into ERM •
- From the Work Area the signatory selects Signatures tile to open the request ٠

V	/ork Area ╺	Work Are			
<b>#</b>	1	VVOIK AIE	d		
Home	Notifications	General			
	Actions 🐱	Notifications	Signatures	Transfers	Shared
Create Folder	Delete Folder Create Project	1	1	0	0
<b>O</b> Delete Project	Duplicate Transfer	Folders			1

New requests are highlighted. Select **View Form** to review the amendment form ٠

Work Area 🐱	Signatures					3
<b>1</b> 0	8					
Home Notifications	Search Signatures					
					Requested	Response
	Туре	Project Title	Requesting User	Message		Date Status Action
	Principal Investigator	LNR December	Ms Catherine Farrington	Can you please sign this LNR form so I can submit	24/12/2018 10:52	Requested View Form

For endorsement of the amendment, select **Sign** button under the Actions pane

	Actions •		Amendment Request VIC
	$\Theta$	1	Amenument Request vio
Previous	Next	Navigate	Read access only.
Print	<b>D</b> Sign	X Røject	Guidance
			Amendment
Check			Once a research project has been ethically approved, any change to its design or conduct must be approved by the reviewing Human Research Ethics Committee (HREC) or ethics review body.
			This Amendment Request must be completed and submitted to the reviewing HREC or ethics review body.
			An amendment to a research project may also impact research governance/site specific assessment (SSA). The Research Governance Officer (RGO) at each affected site must be notified of the amendment by the site Principal Investigator (PI), in order to determine if research governance/SSA amendment is required.
			An amendment must not be implemented at a site until the HREC or ethics review body has granted approval of the amendment and (if applicable) the site RGO has granted authorisation of research governance/SSA amendment.

• A Sign Form text box is displayed

The signatory enters their ERM log in details to sign the form

Select Sign Sign button

Sign Form			×
Please enter your login details i	n order to sign this form:		
Username	Password		
		Sign	Close

- The applicant receives an email notification indicating the signature request has been accepted, i.e. the form has been signed
- The form is ready for submission

### Submission and Review

- Navigate to the Actions pane and select the Submit <sup>≜</sup> button
- The system performs a completeness check to highlight any incomplete sections. If complete the form is ready to be submitted
- Select **Submit** button
- The post approval form will be received by the reviewing organisation's Research Office.
   How to respond to queries and requests from the Research Office is described in <u>Submission and</u> <u>Review Process</u>

# Section 15: Post Authorisation

Post Authorisation forms provide information / reports relating to a research project to the site Research Governance Officer (RGO).

In ERM, Post Authorisation forms are sub-forms created from the Site Specific Assessment (SSA).

Sub-forms for post authorisation

- Complaint Report
- Non-serious Breach / Deviation Report
- Site Audit Report
- Site Governance Amendment Request
  - To notify the RGO of an amendment that has been approved by the reviewing ethics committee or
  - To notify the RGO of a governance-only amendment that does not require ethical approval
- Site Notification Form
- Site Progress Report

### Create a Sub-form

- The PI / delegate logs in to ERM
- Select the project title to display the project under the Project Tree and highlight the SSA for your organisation
- Select Create Sub-form button under the Actions pane to create a new sub-form e.g. Site Governance Amendment Request Select Create

Create Sub-form		×
Select the sub-form that you would like to apply to this form Site Governance Amendment Request		
	Create	Close

• The Site Governance Amendment Request form will be displayed under the Project Tree

Work	Area 🐱	O HREA 0	3								
<b>H</b> ome	36 Notifications	HREA     Site Specific Assessment (SSA) VIC -									
Actio	ons 🗸		Site Governance	e Amendment Reque	est -						
Project			Ethics Amendment F	Request VIC -							
Project	Duplicate Form	Form Status	Review	v Reference	Date	Modified	ММА				
Delete Form	Share	Not Submitted	N/A		22/04/	22/04/2020 16:17		not for NMA			
Delete Form											
Roles	Transfer Form	Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence	History			
~	<u>±</u>							<b>e</b> 5			
Completenes: Check	s Submit	Site Gov	/ernance	Amendr	nent Requ	est					
~	~	Section		Questions							

# Complete a Sub-form – Site Governance Amendment Request

The steps for completing a Site Governance Amendment Request will depend upon which ethics committee reviewed the amendment request. Either (i) or (ii) apply:

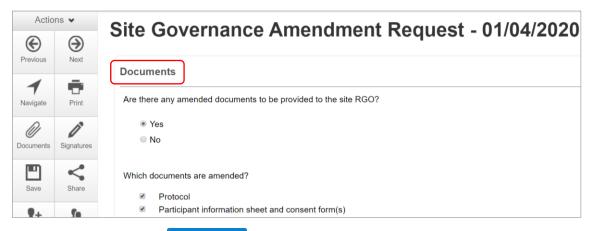
- (i) If the amendment request was submitted to an ethics committee in Victoria, ensure the Ethics Amendment Request form owner (CPI / delegate) has assigned the site PI/ delegate access to the ethics amendment submission and documents. See <u>Allowing others to access</u> <u>post approval forms</u>
- In the Project Tree, select the Ethics Amendment Request VIC form
- From the Documents tab, the amendment submission can be downloaded by selecting the Print



Associated documents can be downloaded by selecting **Download** and saved to your local drive

Work A	Area 🖌	Form Status	Review	Reference	Date Modified	NMA		63	445 🕜
#	25	Not Submitted	N/A		22/04/2020 18:05	Project is no	t for NMA		
Home	Notifications	_							
Actio	ons 🗸	Navigation	Documents	Signatures Collabor	ators Submissions	Correspondence	History		
Project	Share	Documents							
~	1	Туре		Document Name	File Name	Version Date	Version	Size	View
Completeness Check	Submit	Participant information a	nd consent form	PICF Master December 2019	PICF Master December 201	9.docx 31/12/2019	1	11.9 KB	Download
3	5	Protocol		December Holidays protocol	December Holidays protocol	.docx 31/12/2019	1	11.5 KB	Download
Refresh	NMA Project						_	· · · ·	
•	$\times$						Downloa	ad All as Pdf	
Print	Correspond			© Infone	tica Ltd 2020 Version 2.2.8.4				

- Return to the Site Governance Amendment Request form in the Project Tree
- Upload a copy of the:
  - Ethics Amendment Request to the reviewing ethics committee (PDF copy of the amendment submission)
  - Amendment approval from the reviewing ethics committee (PDF copy of amendment approval letter/certificate)
- Other documents if relevant, e.g. the protocol, Master PICF and Site PICF can be uploaded in the
   Amended Documents section under Documents



- Select **Upload Document** to upload the relevant documents from your local drive
- Specify the version and date
- Continue to complete the form
- (ii) If the amendment request was submitted to an ethics committee outside of Victoria, the
   Minimal Dataset Form (MDF) is used to enable the Site Governance Amendment Request
   form to be completed
- In the Project Tree, select the site SSA for your organisation

Select the Create Sub-form action to create a Site Governance Amendment Request form

Work	Area 🕶	MDF23						
Home	36 Notifications	Project Tree 🗸						
Acti	ons 🛩	MDF23				/		
ភំ	<b>P</b>		Ē					
Project	Duplicate Form		Site Specific Assess	ment (SSA) VIC - Be	ndigo Health			
0	0							
Delete Form	Create Sub- form	Form Status	Revie	w Reference	D	ate Modified	NM	A
<	2+	Not Submitted	N/A		2:	3/04/2020 15:33	Pro	ect is for NMA
Share	Roles							

- Upload a copy of the:
  - Amendment submission to the reviewing HREC (PDF copy provided by the CPI/delegate)
  - Amendment approval from the reviewing HREC (PDF copy of approval letter/certificate provided by the CPI/delegate)
- Other documents if relevant, e.g. the protocol are uploaded as described in (i)
- Continue to complete the form.

### Allowing others to access post authorisation forms

Using **Roles +** allows other research team members access to a post authorisation form

• Highlight the post authorisation form e.g. Site Governance Amendment Request in the Project Tree

Home Actio	Area ✓ 36 Notifications ons ✓		A Site Specific Assess	e Amendment Reque	- 181			
Project	Duplicate Form	Form Status		v Reference	Date M	Nodified	NMA	
Delete Form	Share	Not Submitted	N/A		22/04/	2020 16:17	Project is	not for NMA
<b>L</b> + Roles	Transfer Form	Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence	History
Completeness Check	Submit	Site Gov	ernance	Amendn	nent Requ	est		<b>e</b> 5
~	~	Section		Questions				

- Select Roles + button under the Action pane
- Enter the collaborator's ERM email address and select Post Approval/Authorisation Subform

Share Roles					26
Sharing a form enabl with:	les others to view/edit the same	form dependin	g on the level of ac	cess you give them. P	ease select the users you wish to share this form
Collaborator email		Post Approval/Au	thorisation Subforms	· 🛨	
Name	Role		Given on	Remove	Remove All Permissions

- Select Share Role
- The collaborator receives an email notification on their assigned role in the project
- The collaborator at the site can view the Site Governance Amendment Request and associated documents

# **Applying Signatures**

The Principal Investigator is required to sign the declaration page to indicate the information is

complete and correct. To request an electronic signature:

In the Declaration section, select the Request Signature Button

Actions 🗸		Site Governance Amendment Request - 01/04/2020
۲	$\bigcirc$	Site Governance Amendment Request - 01/04/2020
Previous	Next	Declaration
<b>7</b> Navigate	Print	Declaration of Principal Investigator
0		The information provided is complete and correct.
Documents	Signatures	The project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved).
L Save	Share	The project is being conducted in compliance with the <i>National Statement on Ethical Conduct in Human Research</i> (NHMRC, 2007) and <i>Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods</i> (NHMRC, 2016), or as amended.
2+	5	Request Signature Sign

• The system performs a completeness check to highlight any incomplete sections

• Enter the signatory's ERM email address and message Select **Request** 

Request a signature							
Enter the email address of the person you want to sign this form							
Email Address							
Can you please sign the Site Governance Amendment Request form							
Request	Close						

- The requested signatory will receive an email notification for a signature, a message and link to ERM Login/Signatures page
- The signatory logs into ERM

ERM Applic

• From the Work Area the signatory selects the Signatures tile to open the request

	Work Area 🐱	Work Are	2		
Home	1 Notifications	General	a		
	Actions 🗸	Notifications	Signatures	Transfers	Shared
ate Folde	er Delete Folder Create Project	1	1	0	0
elete Proje	ct Duplicate Transfer	Folders		)	

- New requests are highlighted. Select **View Form** View Form to review the Site Governance Amendment Request form
- For endorsement of the form, select **Sign** button under the Actions pane
- A Sign Form text box is displayed

The signatory enters their ERM log in details to sign the form

Select Sign Sign button

- The applicant receives an email notification indicating the signature request has been accepted, i.e. the form has been signed
- The form is ready for submission

## Submission and Review

- Navigate to the Actions pane and select the Submit button
- The system performs a completeness check to highlight any incomplete sections. If complete the form is ready to be submitted
- Select **Submit** button
- The post authorisation form will be received by the organisation's RGO.
   How to respond to queries and requests from the RGO is described in <u>Submission and Review -</u> <u>SSA</u>.

Sign Form		×
Please enter your login deta	ils in order to sign this form:	
Username	Password	
		Sign Close

# Section 16: Other ERM features

# Project Update

A notification to update a project will appear when there has been a modification to a form or a process within ERM. This ensures access to the most recent version of forms used in ERM.

- Only the project owner may update a project
- Approved forms retain the version they were approved in
- Forms and sub-forms that have been submitted or under review will also be updated
- Forms with electronic signatures applied but not submitted should be **updated after submission** otherwise updating will invalidate electronic signatures

#### How to update to a newer version

- Print and save a copy of any unsubmitted forms before the project is updated to ensure no data is lost
- The Update prompt is viewed by the project owner at the top of the form
- The project owner clicks on the **Update** link

HREA		
	Note: There is a newer version of the project. Update	
Team Member Details		

- A pop-up message displays information about electronic signatures on <u>unsubmitted</u> forms which will be invalidated if a project is updated
- Select the **Update** button to update the project

Update Project	×
Note: This will update all the forms within this project. Any electronic signatures on unsubmitted forms will be invalidated – NOTE updating does not invalidate signatures on submitted forms	
Update Description	
There is a newer version available.	
Update	Close

- Notification of the project update will appear in the Notifications tile
- From the Work Area select the Notifications tile. Select the relevant message

Notif	ications			
Search				
Start	End			
Display	Please note that only the specified number of notifications will show after searching.			
	Search			
•	🕈 Message	$\frac{\mathbb{A}}{\mathbb{V}}$	Attachment	Project Sho
	Your May HREA has been upgraded		None	May HREA

• A Message box will be displayed informing the project owner of the upgrade

Message	
Pacatal De N. Desse 15	
on to Hearing to a	
	-226

- If the completion of a form is in progress, select the **Completeness Check** button under the Actions pane to check if additional data entry is required as the new version may introduce additional guestions into the form
- An Update prompt is also seen by collaborators and form owners should advise the project owner of any need to delay the Update e.g. if the form owner is working on a form with unsubmitted electronic signatures

Note: There is a newer version of the project. (Please contact the project owner to update this form).

### When should the project be updated?

- Before you request electronic signatures
- After a form has been submitted and validated by the Research Office
- When the project has been released back to the applicant for edits after the submission
- After form approval

#### What are the steps in a multi-site project?

- The project owner should advise all form owners of when the project update will occur
- Form owners should advise the project owner if the Update needs to be delayed
- Print and save a copy of any un-submitted forms before the project is updated
- The project owner updates the project

#### How to find the form version

- The form version appears at the top right-hand corner of the screen when the form is open
- The most recent date a form has been edited is displayed under **Date Modified** below the Project Tree

# **Cancel a Signature**

A **Request Sent** message is displayed at the top of the screen whenever an electronic signature has been made. The form is locked through signature requests. To cancel a signature:

Move to the Signatures tab and select the Cancel butto

<sup>b</sup> button under the **Action** heading

	Work Area	~	HREA 30				60
Home	21 Notifications		Project Tree 🗸				
Project	Actions V Duplicate Form	Create Sub-	HREA 30     HREA     Sile Specifi	Assessment (BSA) VIC - Administrator Use Only			
Share		Transfer Form	Form Status	Review Reference	Date Modified	NMA	
	<u>±</u>	8	Not Submitted	N/A	06/01/2020 12:47	Project is not for NMA	
Completenes Check		NMA Project		Navigation Documents Signatures	Collaborators Submissions Correspondence	History	
Print	Correspond						
			Signatures				
			Note: There are no active signa	tures on this form			
			Signature Requests	5			_
			Туре	Signatory Email	Requested Date	Status Response Date	Action
			Principal Investigator	amanda.walpole@dhhs.vic.gov.au	06/01/2020 12:48	Requested	Cancel

- The form is now unlocked and signatures invalidated. The **Status** has changed from Requested to Recalled
- The signatory will also receive a notification email regarding the signature cancellation
- If a Principal Investigator has signed <sup>Sign</sup> their own form directly, their signature can also be cancelled
- To cancel the signature, open the relevant form at any question and select the **Unlock** button under the Actions pane

	Actions 🗸		Site Specific Assessment (SSA)	VIC - Administrator Use Only
E	$\overline{}$	1	Site Specific Assessment (SSA)	vio - Administrator Ose Only
Previous	Next	Navigate	E This	s form has been locked through signatures/requests
Print	Documents	Signatures	Site Dates	
Unlock	<b>Share</b>	Roles	3.1 Anticipated start date for the research project at this site	
Collaborators	Completeness	Submit	3.2 Anticipated finish date for the research project at this site	

- An Unlock Form text box will be displayed. Select Confirm
- The signature has been cancelled (invalidated) and the form is unlocked.

# Changing jobs

If an applicant changes jobs or moves to another organisation but remains a collaborator on certain projects, the applicant can continue to access their projects in ERM but will need to have their ERM account details updated. Contact <u>Infonetica Helpdesk</u> to update the account details and email. If a project owner is leaving the project permanently, the project should be transferred to another collaborator in the research team.

# **Transfer a Project**

The project owner can use the **Transfer** function to permanently transfer a project to another ERM user. This may be when a Sponsor creates an HREA application then transfers it permanently to the CPI or when the project owner intends to leave the project and transfers project responsibilities to another collaborator in the research team.

If the current project owner is unable to be contacted, contact <u>Infonetica Helpdesk</u> for further assistance to permanently transfer a project.

 $\sim$ 

- From the Work Area, select the **Transfer** button from the Actions pane
- A Transfer Projects text box is displayed noting loss of future access to the project
- The project owner enters the ensuing project owner's ERM email address
- Enter a message to the new project owner (optional)
- Select the correct project from the list
- Select Transfer button
- All forms are locked pending the transfer
- The new project owner will receive an email notification regarding the transfer of the project

Plea	se note that you will los	e all access to this project.
Email	Address	
Enter	a message (optional)	
	52902	March 25 project
0	53715	Test Practice 1
	55579	21st HREA
	55663	June MDF
	55998	July HREA
	57465	September HREA (2)
	57470	september mdf (3)
	57570	HREA September
0	57730	September MDF
	57840	September LARF
	57937	MDF
-	58064	HREA 16 September

#### Cancel a transfer request

The project owner can cancel the transfer request if the request has **not** been accepted by the new project owner.

• In the Project Overview screen display under the **Transfers** tab, select the **Cancel** button

Work Area V R 21 Home Notifications	Project OV	erview - H					
	Transfers Transfer Id 3160	From User You	Forms To User Ms Amanda Walpole	Butwritted Documents Transf Requested Date 271;22019 12:39	ers History Status Requested	Response Date N/A	Action

• A message indicating the transfer request has been successfully cancelled will be displayed

				uest cancelled successfu				
Home 21	Project Tree ¥							
	HREA 27     HREA     Site Sp	ecific Assessment (SSA)	VIC - Administrator Use Only					
			Forms	Submitted Documents	Transfers	History		
	Transfers							
	Transfer Id	From User	To User	Requested Date		Status	Response Date	Action
	3160	You	Ms Amanda Walpole	27/12/2019 12:39		Requested	N/A	Cancel

#### Accept a transfer

- The new project owner will receive an email notification to log into their ERM account
- In the Work Area, select the **Transfers** tile

Work Area 🐱		Work Are	2			
Home	30 Notifications		General	d		
	Actions $\checkmark$		Notifications	Signatures	Transfers	hared
Create Folde	r Delete Folder	Create Project	30	2	2	34
Delete Project			Folders			
			ERM for research offices	Archived projects	ERM demos for A pplicants	Test for project tr ansfer
			16	90	2	0

• A list of all transfers will be displayed. In the relevant message line, select **View Project** to open the project as read only

Transfe	rs						
Search Transfer	5						
Transfer Id	Project Title	From User	0 To User 0	Message	🕴 Requested Date 💡 Response Dat	e ( Status (	Action
2861	HREA 16 September	Ms Catherine Farrington	You	This project has been permanently transferred to you. Thank y	/ou 02/10/2019 12:03	Requested	View Project
107	TEST for HREA	Prof Matt Happy	You	All yours	26/07/2018 10:51	Requested	View Project
				Showing 1 to 2 of 2 entries			

• To accept the transfer, select the **Accept Transfer** button from the Actions pane

Home 30 Notifications Actions •	Project Tree V	stember			
Project Completeness Refresh	• HREA	Specific Assessment (SSA) VIC -			
Accept Accept project transfer Print	Form Status	Review Reference	Application Type	Date Modified	NMA
	Not Submitted	N/A	N/A	02/10/2019 11:44	Project is not for NMA
Correspond		Navigation Documents	Signatures Collaborators 5	Submissions Correspondence History	
	HREA				Show Inactive Sections
	Section	Questions			

• An Accept Transfer text box is displayed

Accept Transfer	×
Are you sure that you want to perform this action?	
	Yes No

• Select **Yes** to accept the transfer

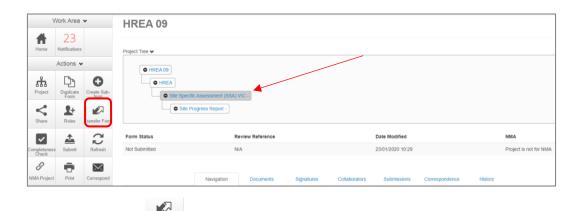
					Transfer	r accepted succ	essfully			
-	14 Notifications		Project Tree 🛩							
	Actions $\checkmark$		Test Practice 1							
n Project	Completeness Check	C2 Refresh	O HREA	: Assessment (SSA) VIC -						
~	x	÷								
Accept Transfer	Reject Transfer	Print	Form Status	Review Re	eference	Applica	tion Type	Date Modifie	d	NMA
			Information requested	NA		Ethics A	pplication	17/04/2019 1	125	Project is not for NIAA.
			Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence	History	
			HREA							Show inactive Section

- Ownership of the project is transferred including all sub-forms e.g. SSAs and associated documents. The new owner can access the project from their Work Area.
- The new owner can assign other research members pre-defined levels of access to the project and forms

# Transfer a Sub form

A form owner can transfer sub forms e.g. SSAs to another collaborator independently from the main project.

For the form transfer to be successful the form must first be shared with the intended new owner. Use **Roles +** to allow the new form owner to also view the HREA (*look up the project branch*).



- Select **Transfer Form** <sup>Transfer Form</sup> button under the Actions pane
- A Transfer Form To Another User text box will be displayed
- Select the **Transfer Sub Forms** checkbox to include other subforms that are associated with the form e.g. a Site Progress Report

Transfer Form To Another User	×
amanda.walpole@dhhs.vic.gov.al	
Transf	er Close

- Select Transfer
- A **Transfer successful** Transfer successful message will be displayed at the top of the screen.
- The collaborator will receive an email notification informing them of the transfer with a link to ERM and becomes the new form owner including the owner of any associated subforms
- The new form owner is shown under the **Collaborators** tab

- The new form owner can assign other collaborators access to the form using the Share function
- The collaborators can only view the HREA if the Project Owner assigns access from the HREA

using the **Roles +** function

### **Duplicate a Project**

In ERM, an existing project can be duplicated regardless of whether the project has been submitted or not. Subforms can also be duplicated in this process.

• From the Work Area select Duplicate Project

Work Area 🐱	Work Area					
<b>1</b> 21	WORK ALEA					
Home Notifications	General					
Actions 🐱	Notifications	Signatures	Transfers	Shared		
Create Folder Delete Folder Create Project	21	0	0	24		
Delete Project Duplicate Project	Folders					
	Old Applications	Approved project				
	8	2				

Duplicate Project

60889 - HREA 08

clude sub forms:

elect a Jurisdicti

HREA 09

Please select project that you wish to

- A Duplicate Project textbox will be displayed
- Select the project to be duplicated
- Enter a new title for the project and delete the previous project's ID number
- Select Include sub forms (SSAs) if subforms are also to be duplicated
- Select Duplicate
  - The duplicate project with the new title will be displayed under **Project Title**

Work Area 🗸	Work Area		
Home Notifications	General		
Actions 🗸	Notifications Signatures Transfers	Shared	
Create Folder Delete Folder Create Project	23 0 (	24	
Delete Project	Folders		
	Old Applications Current projects 2		
	Projects		
	Search Projects		
	Project Title	🔍 Project ID 🚽 Owner	Date Created     Date Modified
	HREA 09	60952 Ms Catherine Farrington	09/01/2020 11:08 09/01/2020 11:09
	HREA 08	60889 Ms Catherine Farrington	07/01/2020 12:40 07/01/2020 12:44

- If subforms have been duplicated, information in the form is also duplicated but will require certain details to be re-entered e.g. Project title and name of site/organisation
- The duplicate function will not copy documents (protocol, PICFs), signatures and permissions (Roles+, Share) that have been assigned to the original project

 Upload supporting documents and assign other members of the research team pre-defined levels of access to the duplicated project using the Roles + or Share function.

# **Duplicate a Form**

Subforms can be duplicated using a similar duplicate function and can be useful for duplicating SSAs. The duplicate function will copy all answers in the form but **not** copy documents e.g. site PICFs, signatures and permissions assigned to the original subform. As the SSA site/organisation name will also be duplicated it is important to amend these details for each duplicated SSA.

• In the Project Tree highlight the subform to be duplicated

Dh

Select D	uplicat	<b>Form</b> button under the Actions pane	
1	Work Area 🐱	HREA 29	
Home	21 Notifications	Project Tree 🖌	
	Actions 🗸	C HREA 29	
Project	Duplicate Form	(Internal Control Assessment (ISSA) V/C - Administrator Use Only	
0	< 1		

Site Specific Assessment (SSA) VIC

- A **Duplicate Form** textbox will be displayed
- Select number of duplicates required e.g. 2
- Select Duplicate

C S

 $\times$ 

• The duplicated subforms will be displayed in the Project Tree

Duplicate Form	×
Duplicate the current sub form with data.	
Number of duplicates required: 2	
Warning! This process can take a while.	
	Duplicate Close



• Select the duplicate SSA then select the **Location** hyperlink to be directed to **Q 1.4 Name** of site/organisation

nome	recations		Project Tree 🗸					
Project	Actions V	Delete Form	HREA 29     HREA     Site Spi	iscific Assessment (BSA) VIC - Administrator Use C				
Create Sub- form	Share	Roles	Site Sp	ecific Assessment (SSA) VIC - Administrator Use O	nly			
Transfer Form	Completeness Check	Submit	Form Status	Review Reference		Date Modified		
~	6	-	Not Submitted	N/A		03/01/2020 14:52		
Refresh	NMA Project	Print		Navigation Documents	Signatures Collaborat	ors Submissions	Correspondence	History
Correspond								
			Site Specifie section Introduction	C Assessment (SSA)				

• Select the relevant site/organisation name from the drop-down list



• The correct site/organisation will be displayed with the SSA in the Project Tree

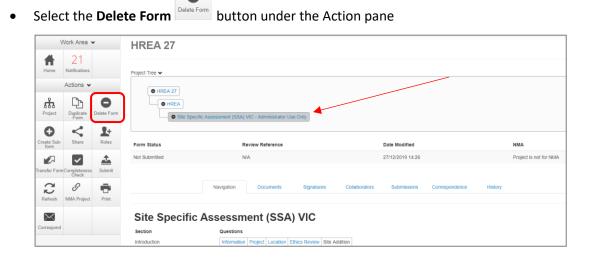
V	/ork Area 🐱	HREA 29	
Home	21 Notifications	Project Tree 🗸	
Project	þ.	Form	
Create Sub- form		Site Specific Assessment (SSA) VIC - Albury Wodonga Health     Site Specific Assessment (SSA) VIC - Administrator Use Only	*

• Upload supporting documents and assign other members of the research team pre-defined levels of access to the duplicated form using the **Roles +** or **Share** function.

### Delete a Form

The applicant can delete a subform if it has been created unnecessarily and can only be performed if the form has **not** been submitted.

• In the Project Tree highlight the subform which needs to be deleted



•	A <b>Delete Form</b> text box is displayed	Delete Form	×	
		Delete form Site Specific Assessment (SSA) VIC?		
•	Select <b>Delete</b> to delete the form	Delete Clo	se	

- The subform can still be deleted if an electronic signature request has been made.
  - If the form has been signed by the signatory, open the form and select the Unlock button under the Actions pane.

ſ

An Unlock Form textbox is displayed. Select Confirm.



The form becomes unlocked and all signatures are invalidated. The **Delete Form** button under the Actions pane is now available.

ii. If the form has not been signed (**Status** is Requested), see **Cancel a Signature** for further details.

# Edit Roles and Share

A collaborator's level of access to a form can be changed in two ways depending on whether



#### Roles +

- Highlight the relevant form in the Project Tree and select the Roles + button under the Actions pane
- A **Share Roles** textbox will be displayed showing the form's level of access that has been assigned to the collaborator e.g. HREA read only
- Select Remove

Share Roles						
Sharing a form enables others to vie	ew/edit the same form depending on the level of acces	s you give them. Please select the us	ers you wish to share this form w	ith:		
Collaborator email		HREA Share (read-only)		• 🖶		
Name	Role	Given on	Remove	Remove All Permissions		
Ms Amanda Walpole	HREA Share (read-only)	HREA	Remove	Remove		
					Share Role	Close

- The Share Roles page stays to allow the level of access to be modified
- Enter the collaborator's ERM email address and new level of access e.g. read, create subforms
- Select Share Role

Share Roles			3
Sharing a form enables others to view/edit the same form depending on the leve	of access you give them. Please select the users you wish to share this form with:		
Collaborator email	HREA Share (read-only) HREA Share (read-only)	• 🛨	
Note: This form has not yet been shared with anyone	HREA Share (read, write) HREA Share (read, create subforms)		
	HREA Share (read, write, submit)	Share Role	Close

• The collaborator will receive an email notification informing them of the change in their access level

#### Share

- Highlight the relevant form in the Project Tree and move to the Collaborators tab
- Select the Edit Permissions button to modify the collaborator's access level

Home	Notifications		Project Tree 🕶									
	Actions $\bullet$		O HREA 09									
noject.	Create Sub-	<b>\$</b> Share	HREA     Site Specific	c Assessment (SSA) V	IC -							
Roles	Completeness Check	submit	Form Status	Re	view Reference			Date Modified			NMA	
<b>C</b> Refresh	P NMA Project	Print	Not Submitted	N	A.			24/01/2020 14:44			Project is not for NMA	
<b>X</b> respond	Contract Xrel			Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence	History		
			Collaborators									
			Name		Access							Edit Permissions
			Ms Abigail Cooper		Read, Write, Subm	t, Share, Create all s	ub forms, Receive no	tifications				Edit Permission
			Ms Catherine Farrington		Project Owner and	Form Owner						Edt Permission

- An Edit Permissions textbox will be displayed. Deselect the permissions and select Save
- The collaborator will receive a message in the **Notifications** tile (under the Work Area) informing them of the change in their access level.

## Collaborators

The form owner can use the **Collaborators** action button to edit permissions for each collaborator only if the access level is assigned through the **Share** action

• Select the Collaborators action button

Actio	ns 🗸			
Previous	) Next	Project Team		ĺ
<b>1</b> Navigate	Print	Q1.9.1 Title	Load	Add to contacts
		Prof		
0 Documents	Signatures	Q1.9.2 First Name		
<b>P</b>	~	Amanda		
Save	<b>Share</b>	Q1.9.3 Surname/family name		
2+	5	Walpole		
Roles	Collaborators	Q1.9.4 Email Address		

• A list of current collaborators for the form will be displayed

Deselect or select the new levels of access

Name Ms Catherine Farrington Ms Amanda Walpole	Access Project Owner and Form Owner Read, Write, Submit, Share, Create all sub forms, Receive ordifications	Edit Permissi Edit Permission
Farrington	Read, Write, Submit, Share, Create all sub forms, Receive	Permission
Ms Amanda Walpole		<b>E</b> -0
	Trainford for	Permissio
Edit Permi	ssions - Ms Amanda Walpole	

Submit

Share
 Create all sub forms
 Receive notifications

• Select Save

•

Select Edit Permissions

Save Close

### Contacts

The **Contacts** area can be used to save and edit contact details for project team members. Details saved in **Contacts** can be used to populate all ERM forms.

#### Add a Contact

• Select Contacts above Work Area



• Select + Add Contact

Work Area 🐱	Contacts	+ Add Co	ntact			 
Home 18	Search Contacts					
	Title   First Name Abigail	Surname Cooper	Organisation	Address 1	0 City 0 Telephone	Delete Delete

- A **New Contact** textbox will be displayed to enter the new details
- Select Save button

New Contact	
Title	
First Name	
Last Name	
Organisation	
Organisation	
Qualification	
	Save

• New contact details will be displayed under Contacts

ERN	M Applicatio	ns Home	Contacts H	elp 👻					Prof Major Researcher 👻		
Work	Area 🐱	Conta	cts	+ Ad	d Contact						(
<b>#</b>	0										
Home	Notifications	Search C	Contacts								
		Title 🕴	First Name 🕸	Surname 🕴	Organisation 🕴	Address 1 🕴	City	Telephone 🕴	Email	¢	Delete
		Prof	Major	Researcher	Best Place		Best Town	03 8888 8888	major.researcher@google.com		Delete

• Contacts can also be added when completing a form

Select Add to contacts
 Add to contacts
 button

	Actions •	8	HREA	5
Previous	) Next	1 Nevigate		
Print	Documents	Signatures	Team Member Details  National Statement 1.1 (e) states:  Research that has ment isconducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research "	
Save	Share	L+ Roles	<ul> <li>resultability in the search team you should ensure there is appropriate and sufficient expertise to undertake all the research activities.</li> <li>Ensure that you list who is undertaking the research activities and default their expertise. Journalistations and competence in the following section.</li> <li>Where research will involve team members who are currently unknown (e.g. a future class of students) this should be recorded in the Project.</li> <li>Description-Protocol and the supervisor should complete this section of the HERA as the researcher/investigator.</li> </ul>	
Se Collaborator	s Completeness Check	Submit	Please refer to the information icon 🊯 and read the guidance for Q1.9.1-Q1.9.13 prior to completing the questions in the following section.	
			Project Team	
			Q1.9.1 Title	Save Con
			Doctor Q1.9.2 First Name	
			John	

• The details will be saved in the Contacts area for future use in other forms

#### Insert Contact in a form

- Contact details can be inserted automatically when completing Team Member Details in a form
- Select Load Load button

	Actions 🛩			
Previous	) Next	- Navigate	Please refer to the Information icon 👔 and read the guidance for Q1.9.1-Q1.9.13 prior to completing the questions in the following section.	
Print	Documents	<b>D</b> Signatures	Project Team	0
Save	Share	Roles	Q1.9.1 Title	:ts
Collaborators	Completeness	Submit	Doctor Q1.9.2 First Name	
			John	
			Q1.9.3 Sumame/family name Smith	

- A Contacts text box will be displayed to insert the relevant contact
- Select **insert** button

Search Contacts							
	Title	First Name	Surname	Organisation	Address 1	City Telephone	0 Email
Insert	Doctor	John	Smith				
Insert	Professor	David	Jones				

Contact details will be successfully loaded into the form

	Actions ~		Add Another Remove
I	( )	1	
Previous	Next	Navigate	Load Add to contacts
-	Ø	0°	Project Team
Print	Documents		Q1.9.1 Title
	<	2+	Professor
Save	Share	Roles	Q1.9.2 First Name
2	~	<u></u>	David
Collaborators	Completenes: Check	s Submit	Q1.9.3 Surname/family name
			Jones
			Q1.9.4 Email Address

# Correspondence

#### To the Research Office

The applicant can use the **Correspond** function to communicate with the reviewing organisation's Research Office and should be used **after** a form has been submitted to the reviewing organisation. **Correspond** must **not** be used to respond to a query or information request.

Select the **Correspond** button from the Actions pane to open communication with the designated Research Office.

- A Correspond text box will display where the message will be delivered to
- Enter message details and attach documents if required

Correspond	×
Note: This message will be delivered to members of VICTest1.	
Ploase enter a message	
Choose Files No file chosen	
	Send Close

- Select Send
- A record of the correspondence can be accessed in the **Correspondence** tab

V	Nork Area 👻		January Project	ct							5
Home	19 Notifications		Project Tree ♥								
Project	Actions ~	Share	January Project     HREA								
2+	~	<u>±</u>	Form Status	Review Reference		Application Ty	pe	Date Modified		NMA	
Roles	Completeness Check	Submit	Not Submitted	N/A		N/A		14/02/2019 09:06		Project	is for NMA
C2 Refresh	© NMA Project	Print	Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence	History		
Correspond	timport Xml		Correspondence	+ Ne							
			Search correspondence								
			User		0 Date	0 Me	ssage			1	Attachment
			Ms Catherine Farrington		14/02/2019	See	attached CV for Dr Jone	rs -			Ø

#### From the Research Office

- At times the Research Office may use their Correspondence function to communicate with the applicant. It is <u>not</u> used by the Research Office to query or request clarification relating to an application
- The applicant will receive an email notification regarding the new correspondence with a link to the relevant project. Click on the link provided

<b>⊞</b> 90 <b>↑↓</b> •	Correspondence regarding HREA 06 - Message (HTML)	×
File Message Help HPE Content Manager	Q Tell me what you want to do	
Thu 3001/2020 3:20 PM donotreply@infonetica.net Correspondence regarding HREA 06 © Catherine Farrington (DHHS)		
Dear Catherine, Project Title: HREA 06 Project ID: 60871 Application: HREA		
The VICTest1 research office has sent correspo the review of your application.	ndence to you in ERM. The correspondence contains important information regarding	
To view your correspondence, click on the follow link: https://au.forms.ethicalreviewmanager.com		
This is a system-generated email. Please do no	t reply.	

• Select the Correspondence tab to display a Correspondence list

	Work Area	~	HREA 06							
Home	26 Notifications		Project Tree 🗸							
	Actions 🗸		O HREA 06							
Project	Create Sub-	Share	• HREA							
2+	•	$\times$	Form Status		Review Refere	ice				Date Modified
Roles	Print	Correspond	Submitted		HREC/60871/V	CTEST-2020-198801	(v1)			07/01/2020 08:5
mport Xml	Recall				Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence
			HREA	Questions						

### • Select the relevant message

١	Work Area	~	HREA 06						
Home	26 Notifications		Project Tree 🗸						
	Actions 🗸		HREA 06						
Project	Create Sub-	Share	• HREA						
2+	•	$\times$	Form Status	Review Refer	ence				Date Modified
Roles	Print	Correspond	Submitted	HREC/60871/	/ICTEST-2020-198801	(v1)			07/01/2020 08:5
oport Xml	Recall			Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence
			Correspondence		+ New Corre				
			Search correspondence						
			User	Date	Mes	sage	<b></b>		
			Review user	30/01/2020	Hi Cath	erine, Thanks for submit	ting your application. It lo		

• A Correspondence Message textbox will display details of the message

Correspondence Message	×
Date 30/01/2020 2:19 PM	
H Catherine, Thanks for submitting your application. It looks great! The committee are really looking forward to reviewing it at their meeting! from your friendly research office	
Note: No correspondence attachments	
	Close

# Archived documents

When an application requires resubmission with new document versions, deleted documents are automatically archived in ERM. Archived documents can be accessed in the Project Overview screen

• Highlight the project title in the Project Tree and move to the Submitted Documents tab

Project (	Overvie	w - HREA	80										
Project Tree 🗸													
		nt (SSA) VIC - Administrati	or Use Only										
Vict	torian Specific Modu	le (VSM)											
				Forms	Submitted Documents	Transfers	History						
						Transfers	Thistory						
Submitted Do	ocuments						т накогу						
Submitted Do							i navor y						
		Submission Date	Status     Sta	Туре		]	Name	<ul> <li>Version</li> </ul>	¢ Size	0	View	0	Archive
Search forms docume	ents	Submission Date 17/01/2020	Status     Archived	Type Protocol		]		Version 1	§ Size 11.5 K		View	•	Archive
Search forms docume Form Reference	ents	•				]	Name			(B		¢	
Search forms docume Form Reference HREA	<ul> <li>Form name</li> <li>HREA</li> </ul>	17/01/2020	Archived	Protocol	FORMATION AND CONSENT F	]	Name     December Holidays protocol	1	11.5 K	(B	Download	¢	

- The **Status** for current document versions is <u>Submitted</u> and previous/deleted versions are now <u>Archived</u>
- When the application has been approved, the Status of the submitted documents is Approved
- Select **Download** Download button to view an archived document

Project C	)verviev	w - HREA	08								
Project Tree 🛩											
	Specific Assessmen vrian Specific Modul	nt (SSA) VIC - Administrato	x Use Only								
				Forms	Submitted Documents	Transfers	History				
Submitted Do	ocuments										
Submitted Dt											
Search forms documer	its										
		Submission Date	Status ()	Туре		]	0 Name	0 Version	🖌 Size 🍦	View	Archived
Search forms documer		Submission Date     17/01/2020	Status () Submitted	Type Protocol		]6	Name     December Holidays protocol version 2	Version     2	<ul> <li>Size 0</li> <li>11.6 KB</li> </ul>	View	0 Archived
Search forms documer Form Reference	0 Form name			Protocol	FORMATION AND CONSENT FC						
Search forms documen Form Reference HREA	Form name     HREA	17/01/2020	Submitted	Protocol	FORMATION AND CONSENT FC		December Holidays protocol version 2	2	11.6 KB	Download	

• Other collaborators with assigned access can also view archived documents

# **Folders**

All applications are listed together in the Work Area home page. Folders can be created to organise applications accordingly.

Select Create Folder button under the Action pane



• A **Create Folder** text box will be displayed Enter Folder title e.g. Approved project

Create Folder	×
Folder Title (maximum 40 characters):* Approved projects	
	Create Close

- Select Create
- A new Folder tile (Approved project) is displayed in the Work Area under Folders

#	Work Area ▾	Work Are	а					
Home	Notifications	General						
	Actions 🗸	Notifications	Signatures	Transfers	Shared			
Create Folde	r Delete Folder Create Project	19	0	0	15			
O Delete Projec	t Duplicate Project	Folders				New Folder tile		
		Old Applications	Approved project					
		Projects Search Projects						
		Project Title	Projec					Transfer Status
		QA January LARF January	51369		ine Farrington		6/02/2019 18:05 6/02/2019 17:31	

- Applications listed under **Projects** can be moved to the new folder using 'drag and drop'
- Select the Folder tile to display the list of projects moved to the Folder

Work Area 🐱	Work Area
Home Notifications	General
Actions 🗸	Notifications Signatures Transfers Shared
reate Folder Delete Folder Create Project	19 0 0 15
elete Project Duplicate Project Transfer	Folders
	Old Applications Approved project 1
	Projects QA January \$1369 Ms Catherine Farrington 06/02/2019 18:05 06/02/2019 18:05
	Search Projects
	Project Title    Project ID
	QA January 51369 Ms Catherine Farrington 06/02/2019 18:05 06/02/2019 18:05
	LARP January 51368 Ms Catherine Parrington 06/02/2019 17:00 06/02/2019 17:31

• Select a project to display the application and associated forms

	Work Area 🗸	•	Approved project Projects						
<b>H</b> ome	19 Notifications		Search Projects						
	A -41		Project Title	φ	Project ID 🗸	Owner 🕴	Date Created	φ	Date Modified
	Actions 🗸		QA January		51369	Ms Catherine Farrington	06/02/2019 6:05:20 PM		06/02/2019 6:05:22 PM
Create Project	Delete Project	Duplicate Project	MDF January Showing 1 to 2 of 2 entries		51345	Ms Catherine Farrington	06/02/2019 12:13:53 PM		06/02/2019 12:30:53 PM
Rename	Hove Project	Transfer					2019 Version 2.0.5.1 tions   Privacy Policy		

### **Other Folder Actions**



Create a new project



Delete a project (only possible if the main form has not been submitted via ERM)



Delete a folder (only empty folders can be deleted)



**Permanent** transfer of a project to another user e.g. Sponsor creates the HREA and transfers it permanently to the CPI



Duplicate an existing project. Includes all forms in the project but **not** any attached supporting documents



Rename the tiles under Folders and enter a new name for the tile



Move a Project filed in **Folders** to the **Work Area.** The Project will be listed with other current projects under **Project Title** 

# Submission to non ERM Research Offices

For a submission to a HREC that does not use ERM e.g. Private hospital HREC, the HREA can be completed and printed as a pdf.

- Leave the last question in the ERM Filter Questions section (*Select the Committee that your ethics application will be submitted to*) blank
- Leave **Q 4.3** (Select the Organisation that hosts the HREC) blank
- Select the Print button under the Actions pane to generate a pdf of the form. Save the document to your local drive
   Do not select Submit.

# Help

#### To access ERM

http://au.forms.ethicalreviewmanager.com/Account/Login

For assistance

Infonetica Helpdesk:

02 9037 8404

helpdesk@infonetica.net

Coordinating Office for Clinical Trial Research: 03 9096 7394

multisite.ethics@dhhs.vic.gov.au