Health and Disability Ethics Committees

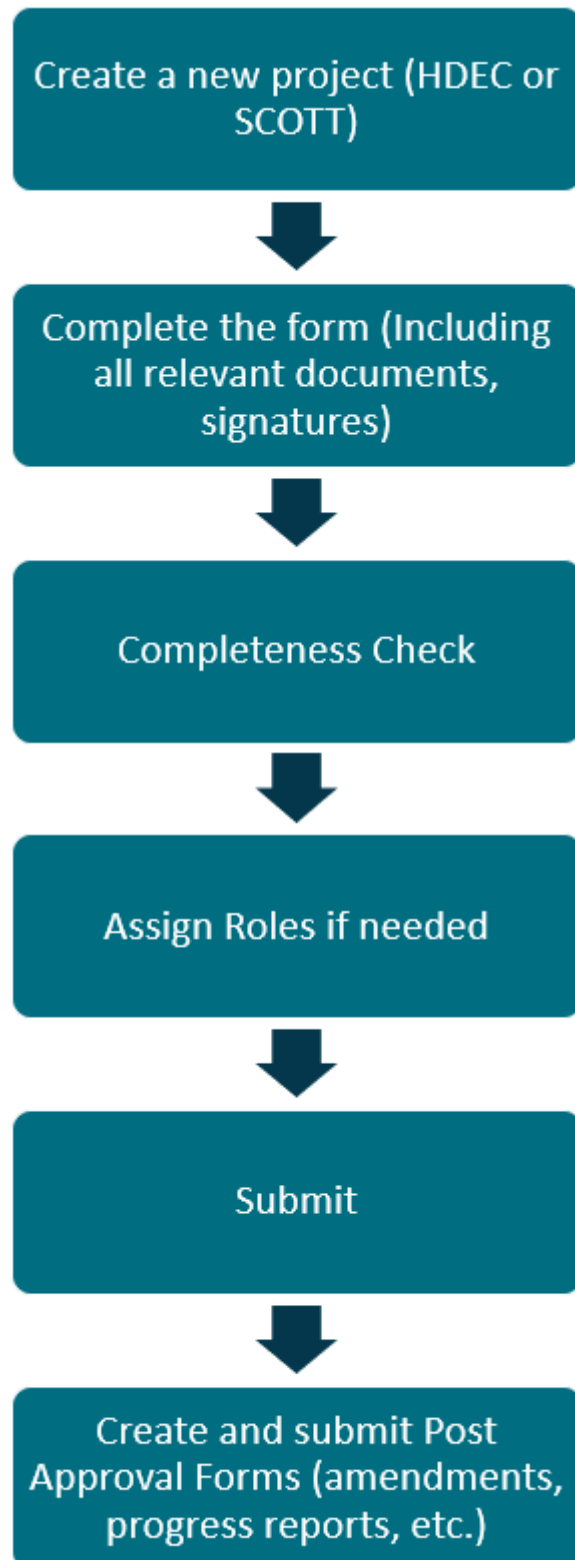# ethics rm
User Manual

I would like to…

Overview of Ethics Review Manager (Ethics RM) – HDEC or SCOTT applications

Create a new project (HDEC or SCOTT)

↓

Complete the form (Including all relevant documents, signatures)

↓

Completeness Check

↓

Assign Roles if needed

↓

Submit

↓

Create and submit Post Approval Forms (amendments, progress reports, etc.)

1.   Create an account in Ethics RM

Ethics RM is a website that enables users to complete and submit applications to the Health and Disability Ethics Committees (HDECs) and the Standing Committee on Therapeutic Trials (SCOTT).

Go to Ethics RM (https://nz.forms.ethicalreviewmanager.com)
Click Log in on the top right corner of the page (the Log in button allows you to create an account).

Click the green New User button.

Enter your details, choose a password and click Register after reading and accepting the Terms of Conditions and Privacy Policy. Passwords must be 10+ characters long (but no longer than 64) and must contain both upper and lowercase letters as well as at least one special character and number.

You will receive an activation email to your specified email address. Please check your spam folder if the email does not appear in your inbox.

Click the link to finish activating your account. You may now log in with your email address and password.

2. Log in to my Ethics RM account, and manage my account details or recover my account

Logging in and out

If you have registered for Ethics RM or have previously had an Online Forms account (Online Forms was the previous online system used by HDECs) then:

Go to Ethics RM (https://nz.forms.ethicalreviewmanager.com)
Click Log in on the top right corner of the page.
Enter your email address and password.
Click Log in.

This will automatically bring you to the Work Area, the main screen for Ethics RM. Your name and email address appear at the top right of the screen.

To log out of Ethics RM at any stage, click your name and email address at the top right of the screen and click 'Logout'
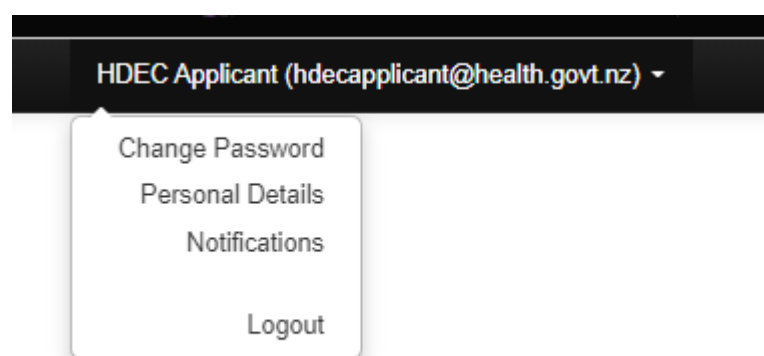
Manage account details

Click your name and email address on the top right of the screen.

From there you can select Change Password, Personal Details to view or change your account details, and Notifications as well as Logout.

Notifications brings up information directly related to you and your projects. This information also appears under the Notifications tile of your Work Area.

Account recovery/issues

If you cannot remember your password, please click Forgotten Password when you access the Log in screen.

Please enter the email address you use for Ethics RM and click 'Reset Password'.

Follow the instructions sent in your email to reset a new password. This will allow you to log in with your new password.

If you are having further issues with your account, please contact Technical Support (page 48). It is important to note that the Secretariat is unable to help with account queries. Instead, support for technical issues is managed by Infonetica.

3. Create, Edit or Delete Contacts

Your personal contact database is designed to help you if you are filling out many forms and often refer to a contact multiple times.

Create

To add a contact, click Contacts on the top left of the page:

- click New Contact

- enter their details then click Save.

Edit/Delete

Existing contacts can be edited by clicking Change Details. Enter or adjust details then click Save.

If you wish to delete a contact, click the Delete button.

When completing a form contacts can be loaded into the appropriate question by clicking the 'load' button and selecting the appropriate contact.

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Contacts

Search Contacts

	Title	First Name	Surname	Organisation	Address 1	City	Telephone	Email
Insert	Mx	HDEC	Example	HDEC				

Close

Forms   Work Area   Contacts   Help ▾   HDEC Applicant ▾

Contact loaded successfully into your form.

HDEC Application
Project Title: HDEC Application Example

Co-ordinating Investigator

Load   Add to contacts

H3. Please enter the CI's details.

Note as per Section 38 of the HDEC Standard Operating Procedure the **CI must be professionally based, in whole or in part, in New Zealand.**

For international studies a local investigator must be nominated as the CI for the New Zealand arm of the study.

Title

Mx

First Name

HDEC

Surname

Example

Organisation

HDEC

Alternatively, if you enter the details manually on the form, they can be saved by using the 'Add to contacts' button.

4.   Create a new project

A project consists of:

- one main form (which can be an HDEC Application, Tissue Bank Application or a SCOTT Application)

- any number of post approval forms submitted after approval (sometimes referred to as 'Sub forms' within EthicsRM).

In the Work Area of Ethics RM, click the Create Project button on the left side.
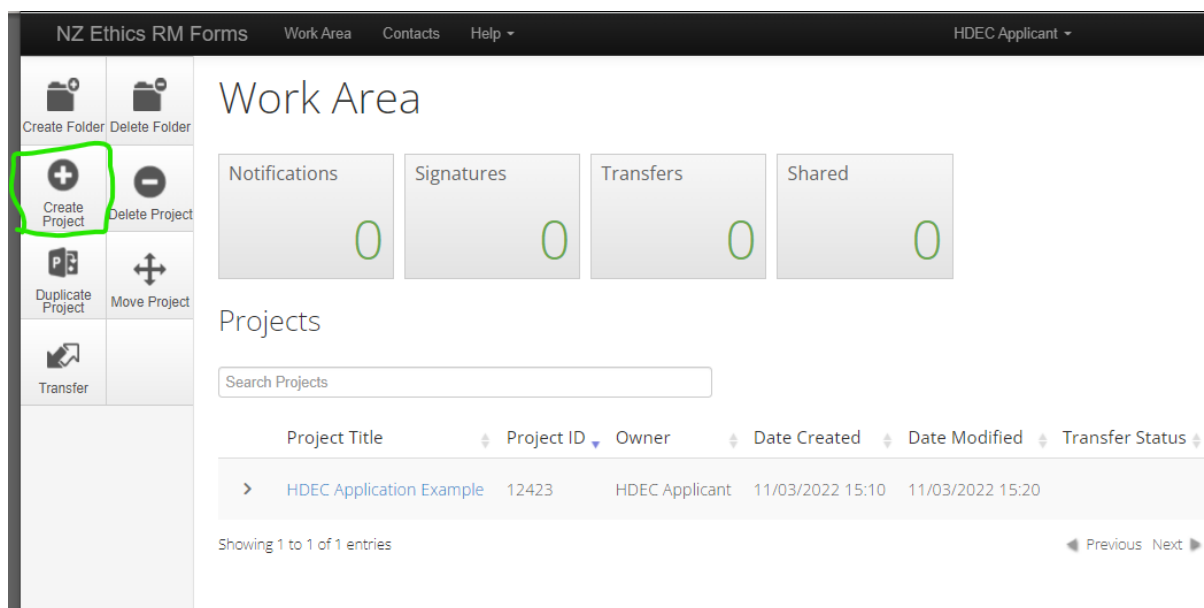
Enter your Project Title and select which application you wish to make from the options under Form.

It is important to note that Project Titles **cannot** be amended once created.

Please ensure that you name the project as you wish it to appear in Ethics RM. In some circumstances a project may have a title, and a full formal title. If relevant, the full formal title of the study may be entered on the application form but is not required for all studies to be different from the project title. The full formal title is what displays on HDEC letters.

Click Create when you have finalised your project title and have the correct form selected.

Create Project ✕

Project Title* (Max 200 characters)

HDEC Example 2

Form*

HDEC Application ⌄

Create   Close

Your new project will appear on the screen with a title (left) and Project ID (right). This can be found also under your Work Area if you have to navigate off this screen.

Only the project owner currently has access to this form until further collaborators are added. For specific instructions please see Section 9 – Allocate Roles (page 29) and set up email notifications for a project.

The project tree will currently only contain the chosen application form. Post approval items will appear under this form after these items are submitted in future. Later you will also be able to view this by clicking Project on the left side to see the Project Overview.

The row beneath the project tree allows you to see if an action is required on the form, its status, review reference, application type and date and time it was last edited.

Project tabs

Navigation tab – selecting this tab gives you an overview of the sections of the form you have created for the project. The tick box in the top right corner of the form allows you to only see sections currently inactive based on the answers in the form.

Inactive questions are not the same as incomplete questions, because the form removes or adds some questions based on your answers. Therefore, you may not need to complete every section of the form.

More information about using the navigation tab to complete your application is provided in the next chapter (page 16).

Documents tab – selecting this tab shows which documents are currently attached to the form. This tab provides a view-only of the documents, which means that it does not allow you to upload or change any documents attached, but you may choose to download the documents individually or in bulk (as a single PDF) by using the 'view selected' button.

Signature requests tab – selecting this tab shows which signatures are active on the form (under the heading 'Signatures', as well as which requests are pending (under the heading 'Signature Requests').

Collaborators tab – selecting this tab shows the name and type of access linked to each collaborator added to the form. The project owner may edit permissions for existing collaborators here. New collaborators can be added through the Roles function (page 29).

Submissions tab – selecting this tab gives you a timeline of the submission of the form. Each time it is submitted, it will appear here. If a form is invalidated or Provisionally Approved by an HDEC, it will require to be resubmitted. This tab allows you to see whether this has been submitted more than once and when. PDFs of previous invalidated submissions (marked 'Archived') may be downloaded here.

Correspondence tab – selecting this tab allows you to directly send a message to the Secretariat. Message history (both received and sent) will display here with timestamps. You can also send correspondence using the 'Correspond' button on the left-hand side of the window.

You will receive a notification in Ethics RM to alert you when there is a response.

Notifications

Search [ ]

Received after [ ]   Received before [ ]

Display [slider]   100 notifications

Please note that only the specified number of notifications will show after searching.

[Search]

		Message		Attachment	Project Short Title	Date
☐ ✔ ⚑		Correspondence received		None	HDEC Example 2	13:01

Clicking on a notification will display a shortcut to the form associated with the correspondence. Click View Form to go to the form the message has been received for.

Message   ✕

Project Short Title	**HDEC Example 2**
Date	**18/03/2022 13:01**

Correspondence received

◄ ─── ►

[View Form]   [Close]

| Navigation | Documents | Signatures | Collaborators | Submissions | Correspondence | History |

Correspondence   [New Correspondence]

[Search correspondence...]

User	Date	Message		Attachment
Review user	18/03/2022	Reply from Secretariat		
HDEC Applicant	18/03/2022	Message to Secretariat		

File attachments can be sent via correspondence but please **do not send additional or missed documents that were not included in your submission.** These cannot be reviewed or included in approval letters.

History tab – selecting this tab shows the full history of the submission, including actions and decisions by both the project owner and the Secretariat. See page 31 for more information on the History tab.

5. Complete the form

The 'Navigation' tab is available on all forms (HDEC, SCOTT, Tissue Bank and Post Approval Sub forms). It allows you to navigate through the form by Questions under each Section. Inactive questions are not displayed unless you tick Show Inactive Sections. Active questions automatically display, clicking on them will take you directly to that question in the form. Certain questions are activated or deactivated depending on your answers to the questions in the form, so not all pages of the form will be active, and it is important you answer everything accurately to generate all relevant questions.

The form does not need to be completed in one session as there is a save button you can click at any time.

Clicking 'Navigate' in the form brings you back to the project main screen.

For guidance on the HDEC form screening questions please refer to the Appendix (on page 50).

To fill out the form, click the first question available for you to fill out. From there, you can proceed with filling in the form. If there are multiple pages, you may click Previous or Next on the left-side menu, as well as Previous Page and Next Page at the bottom of each page.

Click Save on the left-side menu if you wish to Save your progress at any time and navigate out of the form. You may return to certain sections using the Navigation tab from the project main screen.

Upload documents

Questions within the form will prompt you when you need to upload documents in relevant sections. These will be attached to the form and appear under Documents tab for your reference (and re-download if required).

You will need to upload one document at a time if multiple attachments are required.

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Please refer to the Committee's requirements in the HDEC Standard Operating Procedures (SOPs) for documents that are considered mandatory for your submission. While the form should prompt for all that are required, you remain responsible for ensuring you have attached everything required as per the Committee's requirements. Your submission may be considered invalid if mandatory documents are missing due to an error in submission.

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Previous   **Next**

Navigate   **View as PDF**

Documents   **Signatures**

Save   **Roles**

Collaborators   **Completeness Check**

Submit

A3. Protocol number (if applicable):

If this protocol has a unique identifier, please enter this below.

Upload Protocol document.

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Protocol	Protocol	Protocol.docx	11/03/2022	1	57.9 KB	Download	Delete

A4 Please provide the dates on which you plan to commence and conclude your study in New Zealand.

6.   Check for Completeness

It is important to check for completeness before you submit to make sure you have answered all the questions in the form.

While in the form or selecting the submission in the project tree in the main page of the project, click Completeness Check from the menu on the left of the screen to identify missing information from your application. Any outstanding items will be listed. You can select the highlighted questions to go to that section to complete them. Any sections that require signatures will also show up as incomplete if they are not yet signed.

You have the option to submit anyway, but we do not recommend this as a form is considered incomplete and will not be validated if it is missing sections. This will cause delays for your submission.

Once the application is complete, the check for completeness will say 'Your form is complete and ready to submit'.

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Completeness Check

Incomplete: Please complete the following questions

- A2. Formal study title:
- Planned commencement date:
- Planned conclusion date:
- A5. Please indicate your review preference.
- A6. Closed meeting request.
- A7. Is this application related to one or more previous applications for HDEC review?
- A8. Scientific basis

7. Requesting a Signature and signing a form

What is a Signature?

Electronic signatures replace an 'ink' signature as evidence of authorisation for the Coordinating Investigator (CI), Sponsor, and Locality on forms generated on the Ethics RM system. This avoids the need to take or post paper copies of forms to the various individuals who need to authorise the application forms.

The persons authorising the form must have an Ethics RM account.

You can view current and pending signatures under the Signatures tab in the project.

How to request a Signature

The application form will prompt you to request signatures at the end. Please ensure the form has been completed **before** any signatures are requested. EthicsRM locks the form when signatures are requested and changing answers will invalidate any pending requests or completed signatures. If this occurs the signatures will need to be re-obtained.

By default, the CI and Primary Contact Person signatures are required. If you are the CI or Primary Contact Person you may sign the form yourself by clicking the 'sign' button, otherwise click 'request'.

CI Declaration

This button may be used by the Coordinating Investigator to sign the form.

If you are not the Coordinating Investigator please select the 'Request' button.

Request Signature | Sign

If your study requires authorisation from a Sponsor or Locality, please indicate this when prompted. The signature button will appear, and requests can be sent.

Sponsor Authorisation ⊙ 0

Does your study require authorisation from a **commercial sponsor?**

Note this is only required for the initial submission. If you are responding to a provisional approval and have already received authorisation you may change your answer to 'no'.

- ● Yes, my study requires authorisation from the sponsor now
- ○ No, my study has received authorisation
- ○ No, my study does not have a sponsor

This button may be used to send a request to the study sponsor.

Note: If the sponsor representative is unable to view the 'Sign' button this may be a browser issue - please ensure they are using a modern browser e.g. Chrome or Firefox as Internet Explorer and Edge are not supported.

[Request Signature]

[Add Another Signature]

If you require locality authorisation at a later date, please indicate this. A sub form may be created at any time with additional signature requests.

Locality Authorisation ⊙ 0

ⓘ

Please indicate whether your study requires locality authorisation.

Locality authorisation is required before a study commences but is **not required before** the HDEC review process and may be entered in the system later with a sub-form. Please see the ERM FAQ.

For information on localities please see the help button.

If you have obtained locality authorisation and are submitting a **response to provisional approval** please select "Locality authorisation for this study has been obtained in a previous submission". Any signatures will be preserved on the original submission.

- ○ Yes, my study is ready for locality authorisation now
- ● No, my study requires locality authorisation at a later date
- ○ No, my study does not require locality authorisation
- ○ Locality authorisation for this study has been obtained in a previous submission

Locality authorisation can be requested at any time by creating the appropriate sub-form. Please ensure the recipient has read access on **this form** using the 'Roles' button. For more information please see the ERM FAQ.

What Signing involves

When you have sent a request, the form will indicate this with a timestamp.

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CI Declaration

This button may be used by the Coordinating Investigator to sign the form.

If you are not the Coordinating Investigator please select the 'Request' button.

Request Signature | **Sign**

Signature Request: Signature requested from hdecapplicant@health.govt.nz on 11/03/2022 16:18

The recipient will receive an email notification and a notification in Ethics RM and the signature request will appear on their 'signatures' tile on the main work area. As previously noted, this person must have an Ethics RM account.

M Forms   Work Area   Contacts   Help ▾   HDEC Applicant ▾

Work Area

Notifications	Signatures	Transfers	Shared
1	1	0	0

How to sign a form

The signatures tile will contain a list of any previous and current requests.

Signatures

Search signatures

Type	Project Title	Project ID	Requesting User	Message	Requested Date	Response Date	Status	Action
Coordinating Investigator	HDEC Example	12425	Mr HDEC Applicant	[Optional message to CI]	11/03/2022 16:18		Requested	View Form

Showing 1 to 1 of 1 entries

Clicking 'view form' will take you to the application form. If the signature request came from the main form you will have automatic read-only access. If the signature came from a sub form you will need to contact the requestor so they can give you read access. If the 'view form' button is greyed out, please contact the requestor to check the roles and permissions.

When you have finished reviewing the application you have the option to sign it or reject it.

HDEC Application

Project Title: HDEC Example

Version: [

🔒 Read access only.

Screening Overview

Purpose of Form

This form will help determine whether HDEC review is required and if so, what review pathway the study will go through. The questions are based on the rules from section three of the Standard Operating Procedures (SOP) for Health and Disability Ethics Committees (HDEC). You can find a copy of the SOP at https://ethics.health.govt.nz/operating-procedures

Guidance is provided to help answer the questions. If you answer the questions correctly and you do not require HDEC review, the system will generate and send you an 'out of scope' letter from HDEC that states why HDEC review is not required.

If you answer the questions correctly and require HDEC review, the form will direct you to the

Rejecting the form will return it to the requestor along with the reason why you cannot yet authorise the study (eg, an incorrect or misleading answer).

Reject Signature ✕

Please enter your login details in order to reject this form:

| Username | Password |

Reason:

Reason - (Max 800 characters)

Reject   Close

To sign the form, click the sign button, agree to the declaration and enter your username and password.

Sign Form ✕

Please enter your login details in order to sign this form:

hdecapplicant@health.govt.nz   ••••••••••••••••••

Sign   Close
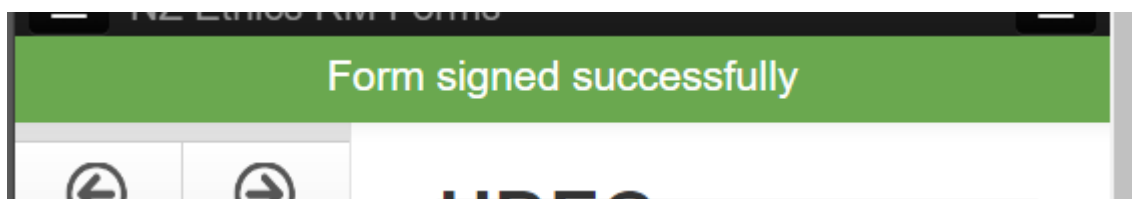
A confirmation message will display and returning to the signature tile will show the request has been approved. A PDF of the form you signed will be kept on record and may be accessed here.

Signatures

Search signatures

Type	Project Title	Project ID	Requesting User	Message	Requested Date	Response Date	Status	Action
Coordinating Investigator	HDEC Example	12425	Mr HDEC Applicant	[Optional message to CI]	11/03/2022 16:18	11/03/2022 16:25	Signed	View PDF

Showing 1 to 1 of 1 entries

The form owner will receive a notification the form has been signed and a timestamped record of it will be retained on the application under the signatures tab.

Signatures

Type	Signatory Email	Signed Date	Validity
Coordinating Investigator	hdecapplicant@health.govt.nz	11/03/2022 16:25	Valid

Signature Requests

Type	Signatory Email	Requested Date	Status	Response Date	Action
Coordinating Investigator	hdecapplicant@health.govt.nz	11/03/2022 16:18	Signed	11/03/2022 16:25	Cancel

Signature validity

Signatures only need to be obtained once. If the form is submitted and invalidated or unlocked as part of a provisional approval, Ethics RM creates an archived version of the form in its current state and then unlocks a new copy of it for editing. The signatures on this copy will be invalidated but **do not** need to be re-obtained in order to submit and the original signatures preserved on the archived original submission are still valid for HDEC's purposes. Please note, the signatory process is likely to be revised in a future software update, but this requires working with our software vendor.

8.   Submit a form

Once you have completed the form, uploaded the relevant documents and obtained all mandatory signatures, you can submit your application to HDEC or SCOTT.

You can do this by either clicking Submit after doing a completeness check, or by clicking the Submit button on the left-side menu.
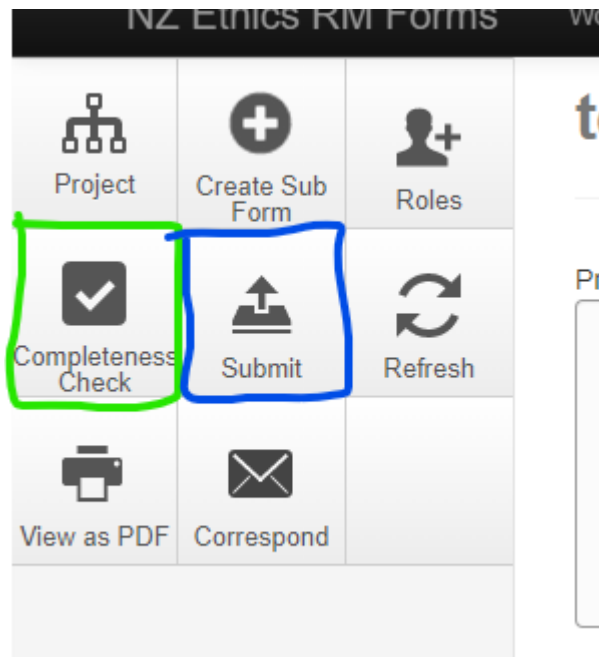
Once you have submitted your form, you will be taken to a confirmation screen that confirms your submission as complete.

Submission Message

Thank you for submitting your form. It has been successfully received.

What happens next?

<u>If your study is out of scope for HDEC review</u>, you will receive an automatically generated out of scope letter.

Please note that this does not mean that your study has HDEC approval or that it does not require ethics approval - only that it does not require HDEC approval.

<u>If your study is within scope for HDEC review</u>, the HDEC Secretariat will assess your application and, if valid, assign it to either the full or expedited review pathway.

If your study requires full Committee review, you will receive a letter from the HDEC Secretariat providing the time and date of the Zoom meeting at which your application will be reviewed by HDEC. Study investigators are encouraged to attend these meetings.

If your study can be reviewed via the expedited review pathway, your application will be reviewed online by two HDEC members rather than in a full Committee meeting. Study investigators will not be present for this review.

If your study is not validated, you will be asked to update the information in your application before it can be assigned to a review pathway.

[Back to Project]   [Print Submission to PDF]

9. Frequently asked questions about submissions

Can I change my form after submitting?
No, you may not make changes to an application between submission and approval; however, you may recall or withdraw your study if you would like to make substantial amendments to your application.

I submitted my form then realised some documents are missing, how can I add them?
No documents can be added or amended after submission.

The form will need to be recalled (or withdrawn if it has been validated by the HDEC Secretariat). This can be done with the 'recall' button that will appear on the action menu after submission.

It is the responsibility of the applicant and coordinating investigator to ensure all documents are uploaded with the correct version numbers and dates <u>before submission</u>.

The HDEC Secretariat **cannot add additional documents or amend approval letters** for studies that have been validated and assigned for review**.**

Which HDEC committee has my application been submitted to?
New HDEC applications submitted for review have the option to be reviewed 'as soon as possible' or by a specific committee. Please indicate your preference in the application form. If you select a specific HDEC committee, the form will ask for a reason (eg, resubmission of a previously declined study the HDEC committee is familiar with).

'As soon as possible' will be assigned to the next available HDEC committee meeting with a pending agenda and an available timeslot.

Those that requested a specific committee will be assigned by the secretariat to the HDEC committee requested.
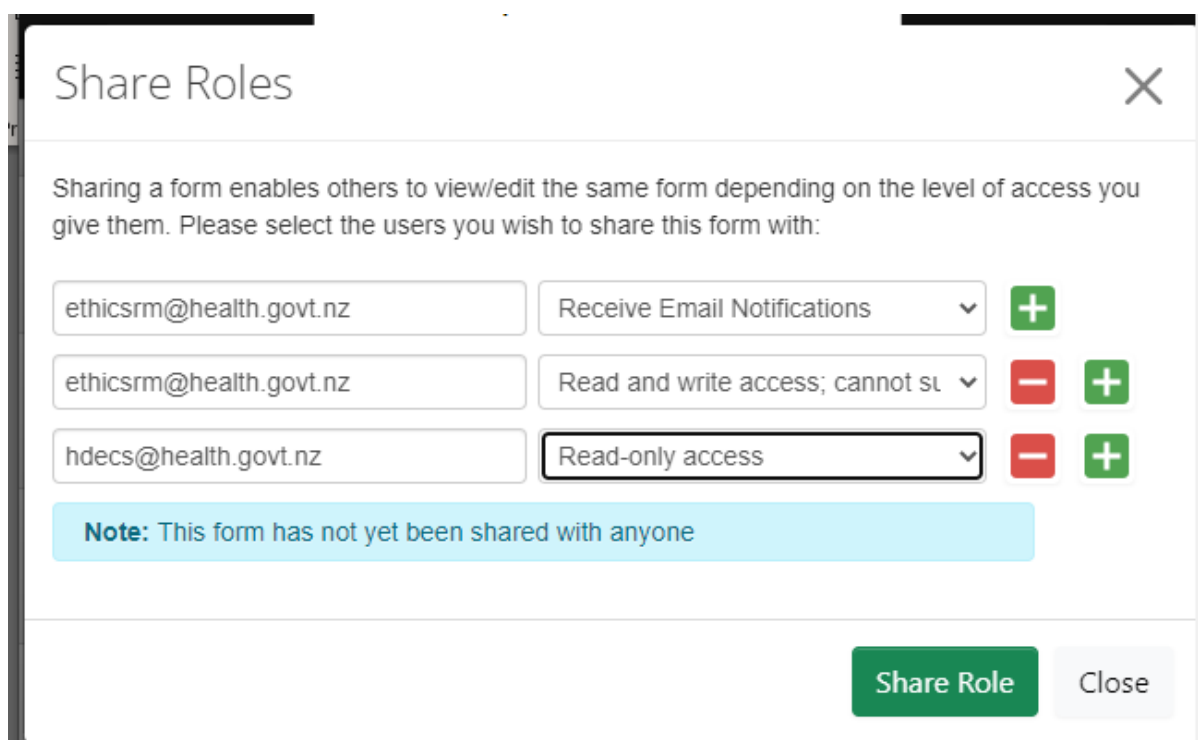
10. Allocate Roles and set up email notifications for a project

What are Roles?

Roles are a function where you can extend this access and add collaborators to your project and grant various permissions.

By default, only the **project owner** has ownership and permission to view and edit the project.

To add a Role to this project, click the Roles button on the left side of the window. Enter the email of the person you wish to invite to see this project under Collaborator email. This person must have a registered Ethics RM account. Select what access you wish to grant and click the green + sign to add the role. Repeat this as many times as you require, and you can assign multiple roles to a single user.

Click Share Role once you have added the collaborators.

You do not need to add the Secretariat to a role for them to be able to see or access your application after you submit.

A project owner can remove or edit permissions in future using the Collaborators tab or the Roles button again.

Receiving email notifications

Email notifications are automatically sent to the project owner. If additional users need to be notified, ensure you assign them 'Email Notifications' when allocating roles to these users.

11.   Transfer a project to another user

You can transfer a project if you would like to give somebody else full and permanent control of the project.

Once the form has been accepted by the recipient, you will no longer be the owner of the form and the person to whom the form was transferred will become the new project owner.

How to Transfer a project

Go to the Work Area.

Click on the Transfer button on the left-side of the window.

Enter the email address of the user you wish to transfer your project to. (Note that they must have an existing Ethics RM account for this to be valid.)

Enter a message to accompany the transfer request if you wish.

Select the project you wish to transfer. You may do this for multiple projects at a time.
Click Transfer.

While the transfer request is pending the applications will remain in your work area.

Work Area

Notifications	Signatures	Transfers	Shared
6	0	0	0

Projects

Search Projects

	Project Title	Project ID	Owner	Date Created	Date Modified	Transfer Status
>	MDF Test	12444	HDEC Applicant	14/03/2022 14:57	14/03/2022 14:57	
>	HDEC Example 2	12424	HDEC Applicant	11/03/2022 15:23	15/03/2022 11:15	Transfer Requested
>	HDEC Application Example	12423	HDEC Applicant	11/03/2022 15:10	11/03/2022 16:14	Transfer Requested

Showing 1 to 3 of 3 entries   ◀ Previous Next ▶

How to accept a Transfer

Applications that have been transferred to you will appear on the main work area under the Transfers tile.

Work Area

Notifications	Signatures	Transfers	Shared
72	0	4	1

Transfers

Transfer Id	Project Title	From User	To User	Message	Requested Date	Response Date	Status	Action
629	HDEC Example 2	HDEC Applicant	You		18/03/2022 11:16		Requested	View Project
628	HDEC Application Example	HDEC Applicant	You		18/03/2022 11:16		Requested	View Project

Click 'View Project' to be taken to the application. From here the application may be reviewed and the transfer accepted or declined by using the action menu to the left.
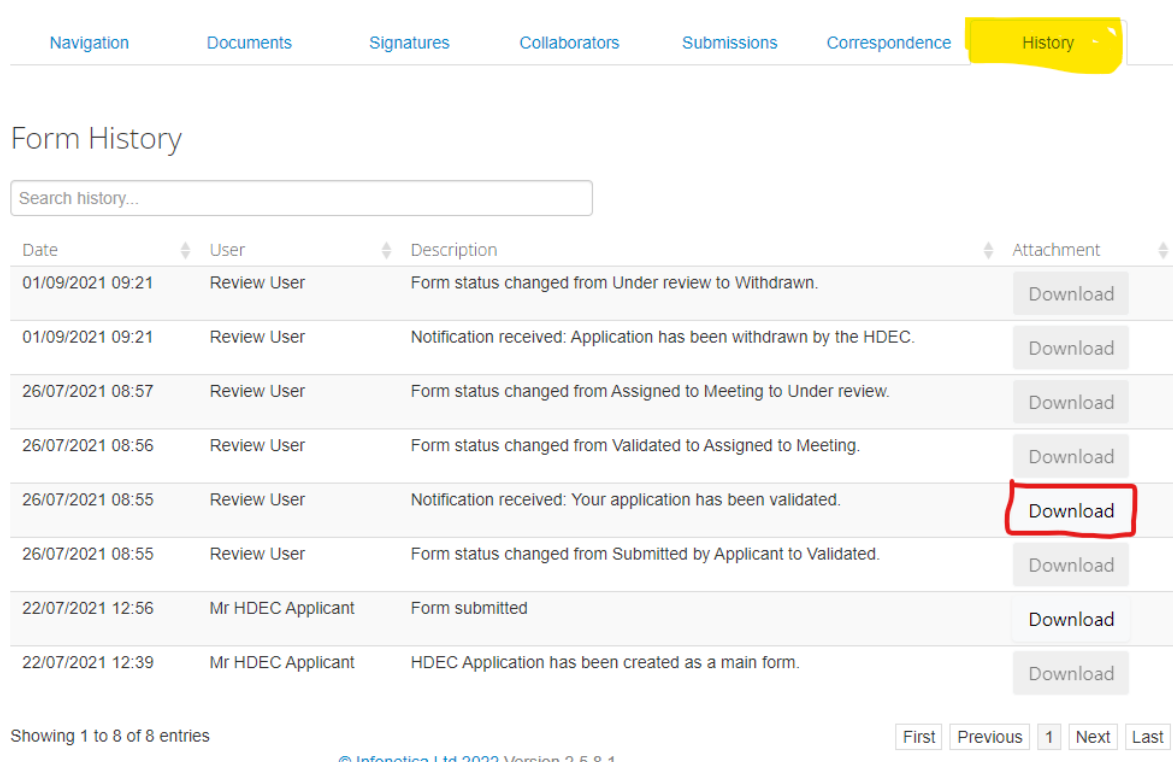
12. Follow the progress of my submission and view letters from HDECs/SCOTT

There are two ways to keep track of an application's progress, via the history tab and via EthicsRM notifications.

History Tab

In the History tab of your project, you can monitor the progress of your application through the key stages in the review process and view decisions from HDECs and SCOTT.

Letters from the HDECs, such as validation letters and decision letters, can also be viewed and downloaded here. If a letter is attached to an event the 'Download' button will be visible and the letter may be viewed here.

Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence	History

Form History

Search history...

Date	User	Description	Attachment
01/09/2021 09:21	Review User	Form status changed from Under review to Withdrawn.	Download
01/09/2021 09:21	Review User	Notification received: Application has been withdrawn by the HDEC.	Download
26/07/2021 08:57	Review User	Form status changed from Assigned to Meeting to Under review.	Download
26/07/2021 08:56	Review User	Form status changed from Validated to Assigned to Meeting.	Download
26/07/2021 08:55	Review User	Notification received: Your application has been validated.	Download
26/07/2021 08:55	Review User	Form status changed from Submitted by Applicant to Validated.	Download
22/07/2021 12:56	Mr HDEC Applicant	Form submitted	Download
22/07/2021 12:39	Mr HDEC Applicant	HDEC Application has been created as a main form.	Download

Showing 1 to 8 of 8 entries

First   Previous   1   Next   Last

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Notifications Tile

Work Area

Notifications	Signatures	Transfers	Shared
72	0	4	1
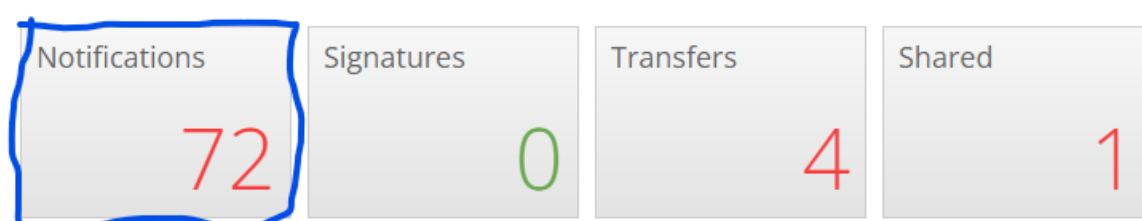
The notifications tile will update whenever an action is taken on your study. A paperclip icon indicates a letter is attached to the notification. Clicking it will display the letter.

☐ ✔ ⚑	Application recalled		None	Test app example	02/08/2021
☐ ✔ ⚑	Application Submitted		None	Test app example	02/08/2021
☐ ✔ ⚑	Your application has been validated		📎	Full submission test 10	26/07/2021
☐ ✔ ⚑	Your application has been validated		📎	Full submission test 8	26/07/2021
☐ ✔ ⚑	Your application has been validated		📎	Full submission test 11	26/07/2021
☐ ✔ ⚑	Your application has been validated		📎	Full submission test 5	26/07/2021
☐ ✔ ⚑	Your application has been validated		📎	Full submission test 12	22/07/2021

Attachment   ✕

Dear Mr HDEC Applicant

Re: Ethics ref: 2021 FULL 0094

   Study title: Full submission test 5

This letter is to confirm receipt of this application for HDEC review, which was originally submitted on day/month/year.

Arrangements for HDEC review

Your application has been assigned for HDEC review by the HDEC-Full Review pathway.

HDEC: Committee Name

Time: Time of Meeting

Meeting date: day/month/year

Download   Close

None

13. Recall an application submitted for HDEC review

Please note the recall option is only enabled if the application is pending registration by the review body (ie, the submission is awaiting the committee secretariat to validate the application). If your application has been successfully recalled you may amend the form, upload/amend your supporting documents and request signatures (if required) prior to re-submitting the application.

If you are not able to recall your application because it has been registered by the Secretariat and you would like to withdraw your application, you need to send correspondence to the Secretariat in Ethics RM requesting this.

To recall your submission, click the Recall button on the left-side of the window. Only a project owner or a user with 'Full write' access can perform this action.

Any kind of form that requires submission and validation can be recalled, but only before it is validated.

14. Duplicate or Delete a Project

The Work Area allows a project owner to duplicate the information in an application into a new project or to delete an entire project. This is useful if an application is declined as it may be duplicated and amended instead of beginning a new blank application.

Duplicate a project
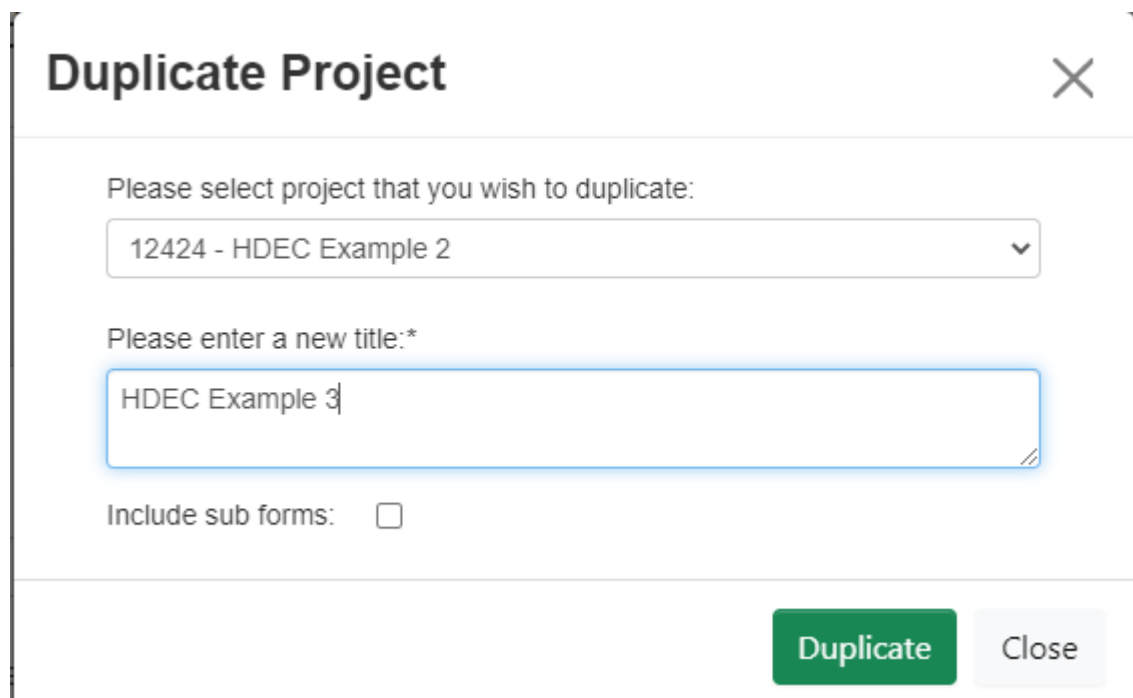
Click 'Duplicate Project' from the left side of the Work Area.

Select from the drop-down menu for the project you would like to duplicate.

You will be required to select a new project title.

There is a tick that allows you to include Sub Forms. This is unlikely to be needed, especially if a project is being duplicated for resubmission.

Click Duplicate.

Delete a project

Click 'Delete Project' from the left side of the Work Area.

Select from the drop-down menu which project you would like to delete.

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Delete Project

X

Please select project that you wish to delete:*

MDF Test	⌄
MDF Test	
HDEC Example 2	
HDEC Application Example	

Delete   Close

Click Delete. After a confirmation prompt the project will be removed from your work area. Once a project has been deleted it **cannot be recovered.**

Project deleted successfully

Work Area

Notifications	Signatures	Transfers	Shared
6	0	0	0

Projects

Search Projects

	Project Title	Project ID	Owner	Date Created	Date Modified	Transfer Status
>	HDEC Example 2	12424	HDEC Applicant	11/03/2022 15:23	15/03/2022 11:15	Transfer Requested
>	HDEC Application Example	12423	HDEC Applicant	11/03/2022 15:10	11/03/2022 16:14	Transfer Requested

Showing 1 to 2 of 2 entries

◀ Previous Next

Note that a project cannot be deleted if it is under review. It must be recalled or withdrawn first to be deleted.

15. Manage Projects in the Work Area

This section lists all the available categories you can store your projects in. This is similar to directories in a computer filing system.

In addition to Create Projects, Delete Project, Duplicate Project and Transfer, there are other options for your Work Area to manage or sort your projects.

Users can create folders by clicking Create Folder to sort their projects into categories or even archive old projects if they wish.

These are user-customisable folders that may be named anything. Delete folder will delete a folder.

Move Project allows you to move projects into folders, however they may also be 'dragged and dropped'.

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Work Area

eate Project

ove Project

Notifications	Signatures	Transfers	Shared
6	0	0	0

Project Folders

All Projects	Completed Trials	Site X	Sponsor Y
3	1	0	0

Projects

Search Projects

	Project Title	Project ID	Owner	Date Created	Date Modified
>	HDEC Example 2	12424	HDEC Applicant	11/03/2022 15:23	15/03/2022 11:15
>	HDEC Application Example	12423	HDEC Applicant	11/03/2022 15:10	11/03/2022 16:14

If a folder contains projects it cannot be deleted and the projects must first be moved.

Delete Folder   ✕

Please select the folder that you wish to delete:

Completed Trials ⌄

This folder contains submissions and cannot be deleted.

Delete   Close

16. Create and submit a Post Approval Form

What is a Post Approval Item?

A 'post approval item' is an item submitted for HDEC review after a study has been approved. In EthicsRM post approval items are labelled 'sub forms' and are attached to their 'parent form' (the initial HDEC/SCOTT application).

Examples of post approval items include:
- substantial amendments
- annual progress reports
- protocol deviations or violations
- notifications of conclusion of study
- final reports.

Substantial vs Minor Amendments

As per the HDEC SOPs, an amendment to an approved study only requires HDEC review if it is substantial. Applicants may make minor amendments to an approved study at any time without approval from or notification to the HDEC.

SUBSTANTIAL AMENDMENTS	MINOR AMENDMENTS
Significant amendments are required to be submitted for HDEC review. Examples of these include: - Significant changes to the design/methodology of the study. - Significant changes to the type and/or number of procedures undertaken by participants. - Changes relating to the safety of physical or mental integrity of participants, or to the risk/benefit assessment for the study. - Significant changes to study documentation (such as participant information sheets). - The appointment of a new CI. - Any significant change to the study protocol or the information provided in the application for approval. - Notification of urgent safety measures taken to protect participants from a significant, immediate hazard to their health and safety. - Temporary halts to the study due to safety concerns. - Substantial protocol deviations. - Early termination of a study.	Minor amendments are not required to be submitted for HDEC review. Examples of these include: - Minor or administrative changes to study documentation. - Updated versions of the Investigator's Brochure (where the study involves a new medicine). - Changes to the research team (including lead/principal investigators at particular localities) other than the appointment of a new Co-ordinating Investigator. - Changes in funding arrangements, except where these may alter the ability of participants to access publicly-funded compensation in the event of injury. - Changes in arrangements for recording or analysing study data, or for storing or transporting samples. - The extension of the study beyond the expected end date given in the application form, except where this is related to other changes that are substantial. - Routine closure of a site. - Addition of a new site.

How to create and submit a Post Approval Form

Select the project from your Work Area you wish to make a Post Approval Form for. Only the project owner or those with 'Full Write' access can create and submit a Post Approval Form.

Once in the project, click the Create Sub Form button on the left-side of the window.

Select which kind of form you require from the drop-down menu.

Click Create.

Your Post Approval Form will now show up in the project tree under the application. Like applications, Post Approval Forms can be saved and completed at a later time by clicking the Save button before navigating away.

To fill in the form, click the available question under the Navigation tab. Answer all questions and submit documents once completed. For specific instructions please see Section 8 – Submit a Form (page 26).

Click Completeness Check to ensure you have completed the form.

Click Submit when your form is complete.

17. Manage or add a locality

Before a study commences at a given locality in New Zealand, it must be authorised by that locality in Ethics RM. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Locality authorisations are not mandatory prior to submission – you may add a new locality at any time. You do not need to submit a Post Approval Form for HDEC review advising HDECs of the addition of a new locality. If locality approval has been obtained before submitting to HDEC, there is an option in the application form for the locality to sign.

Additions of localities can be viewed in the project tree along with other Sub Forms such as Post Approval Forms.

Add locality after HDEC approval

To do this click on the study that requires an additional signature and then select the 'Create Sub Form' button.
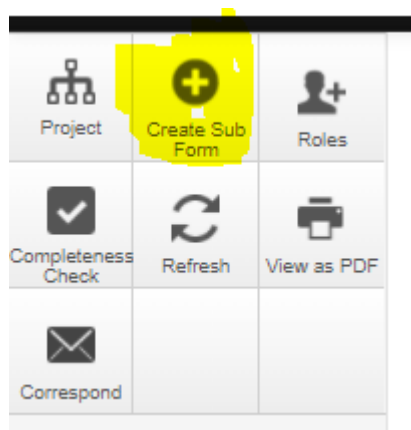
Select the appropriate Sub Form depending on the signature requested (locality or individual investigator/sponsor representative) and click create.
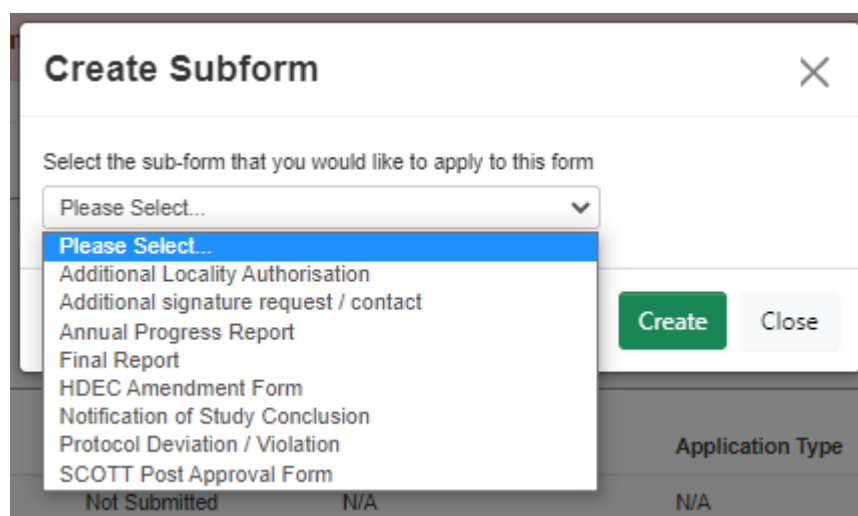
The Sub Form has been created and will be attached to the application.

Please note: You will need to go onto the **main study form** and use the **Roles** button to grant at least read-access to the person you sent the request to. Failure to complete this step will mean they will only be able to view the Sub Form and not the main application itself.

18. Submit a Response to Request for Further Information (Provisional Approval)

Submissions that receive a Provisional Approval decision from the HDECs must submit a response within 90 days to the request for further information, as outlined in the decision letter.

When a submission receives a Provisional Approval decision, the form submitted becomes unlocked and is now able to be edited by you. This will 'invalidate' any signatures on the form, but sponsor and locality signatures do not need to be obtained again. The coordinating investigator and applicant will need to re-sign the response.

Tracked change versions of documents are required when responding to further requests so the HDECs can view what changes have been made. Nothing in the original submission should be changed, and this response is considered in addition to the originally submitted documents. It is encouraged that a cover letter be submitted outlining all the changes requested and your response.

Responding to a Provisional Approval for an Application submission

Under Navigation, select the question in section H titled 'Response to Provisional Approval'.

Upload all documents that were requested to be amended or provided.

Response to Provisional Approval

If your study receives a provisional approval the HDEC may request updated documents. Please upload both clean and tracked changes versions of any documents here by selecting the box below.

It is strongly encouraged to include a cover letter responding to each of the HDECs points provided in the provisional approval letter.

If you are submitting the study for the first time please do not check the box and continue with the form. The box may be unselected if clicked in error.

☑ Respond to Provisional Approval

Please upload your response to provisional approval documents here.

For ease of use version numbers and dates **are not mandatory** and the system will accept these. If these details are required on approval letters please ensure they are accurate *before* submitting.

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Response to PA Document	Peer Review	Peer Review.docx	18/03/2022	1	36.8 KB	Download	Delete
Response to PA Document	PIS	PIS.docx	10/03/2022	2	34.1 KB	Download	Delete

Upload Document

Click Completeness Check to ensure all sections are answered.

Click Submit once complete.

Responding to a Provisional Approval for a Post Approval Form submission

Under Navigation, select the question to open and edit the form.

Go to the Upload Documents section of the form.

Upload all documents that were requested to be amended or provided.

Click Completeness Check to ensure all sections are answered.

Click Submit once complete.

Note: Unlike the application form, Post Approval forms do not have a dedicated section for responding to requests for further information. The document upload section of the Post Approval form is appropriate to upload your response. The documents already uploaded should not be deleted.

19. Contact someone for help/support

HDEC queries

Please see our [General](#) and Ethics RM frequently asked questions (page 51) first to see whether your query can be answered. The Secretariat cannot provide technical support for account or login issues but can help with HDEC-related queries and any issues with the forms. For queries about a specific submission, please use the correspondence function in Ethics RM.

Please provide your ethics reference when contacting us and allow for 5-7 working days for a response:

Email (general queries about HDEC process): hdecs@health.govt.nz
Email (Ethics RM HDEC queries): ethicsrm@health.govt.nz

Phone: 0800 4 38442 (0800 4 Ethic)
(from outside New Zealand: +64 4 819 6877)

Technical Support

Technical support for Ethics RM is available from Infonetica's IT help desk:

Tel: 0800 634 758 or +64 4 9747675 Assistance is available from **12.01pm to 6pm NZT Mon to Fri** (The Helpdesk is situated in Sydney, Australia).

E-mail: helpdesk@infonetica.net

If the line is busy or if you are calling out of hours please email them at helpdesk@infonetica.net using the [Helpdesk Request template](#) so that they can attend to your issue sooner. Otherwise, stay on the line and leave a detailed message after the voicemail.

Please provide your:
- Country – NZ
- Full Name and email address used for login
- Title of project and Project ID (URL and screenshots of the full screen are also useful)
- Short message describing the issue. Please include:
    - full page screen shots
    - copy/paste the URL from the address bar of your browser
      (eg, https://nz.forms.ethicalreviewmanager.com/Project/Index/234207)
    - email address that you used to login into the system (eg, Mr Test Applicant (applicant@test.net))
    - Identifying details of your project and details of the issue you are experiencing
- If you wish to locate the owner of a study, please provide:
    - Project title
    - HDEC/SCOTT reference number.

Please keep your contact details up to date in Personal Details (top right hand corner) so that you can help them help you.

20. Manage my migrated project from Online Forms

My study was not migrated over, how do I find it?

If your study does not appear when you log on, please contact the project owner and ask to be added to the project as a collaborator. If you are unsure who the project owner is or believe it is yourself and the study is not showing, please email ethicsrm@health.govt.nz with the study title or reference and the Secretariat will identify the project owner.

Can I create post approval forms for my migrated study?

Yes. All migrated studies are compatible with the new post approval forms. Please see the standard guidance on creating post approval forms on page 40.

My migrated study was declined, how do I reapply?

As the HDECs introduced the new application form with the launch of ERM on 1 September 2021, the old forms are unfortunately incompatible and unable to be duplicated. You will need to create a new application. Although many of the questions have changed and new questions have been introduced to align with the 2019 National Ethical Standards many of the answers can be copied and pasted onto the new form.

How do I find signatures/authorisations from the old system?

Any signatures given on a project have been attached to the application's migration form. To find these click on the study from the main work area, scroll down to the navigation area and click on the 'Authorisation Report' tab.

The following information for each signature will be displayed:

This report can be downloaded or printed by using the 'View as PDF' button on the action menu.

How do I submit a response to provisional approval for my migrated study?

Migrated forms are considered read-only and therefore cannot be unlocked to respond in the usual method for Ethics RM. Please email your response to Provisional Approval to HDECS@health.govt.nz.

Appendix

21. Filling out the HDEC Application Form

Completing the screening questions of the first two pages of the HDEC form will activate more of the form if your project is determined to be in scope for HDEC review. You must read and agree to the Disclaimer to display the scope/pathway of your project and proceed with the rest of the form or out of scope acknowledgement.

Full vs Expedited HDEC Review

The one HDEC form is used for all applications, regardless of review type (full/expedited). The answers you provide in the screening questions will determine whether the application will be reviewed via the full or expedited pathway.

An application assigned to the full review pathway is reviewed at an HDEC committee meeting. The committee has 35 calendar days from the close of agenda to review the application and make a final decision. This timeframe may be suspended once for up to 90 calendar days when the committee requires additional information in order to make a final decision.

An application assigned to the expedited review pathway is reviewed by a subcommittee comprised of the Chair and up to two other members. This does not involve a physical meeting of the committee. A final decision must be made within 15 calendar days. This timeframe may be suspended once for up to 90 calendar days when additional information is required in order to make a final decision.

To proceed with either of these pathways, click the Proceed option then click Next Page.

My application is out of scope

If, after answering the screening questions, you are confident that your study does not require an HDEC review based on answers input in the screening questionnaire, then please approach the research office at your university or DHB to discuss your study and the internal ethical review process.

If you require formal acknowledgement that, based on your answers, your project is out of scope for HDEC review, please click Proceed then click Next Page. An automated email will be sent to the project owner confirming that the project is out of scope based on the answers of the screening questionnaire.

Please note that if you indicate your project is not health and disability research, you will not be able to receive an acknowledgement as HDEC only reviews health and disability research. The acknowledgement is reserved for projects that may require proof it is out of scope due to uncertainty.

If more than one or no review pathway displays

Please export the application as a PDF (using the 'view as PDF' button on the action menu to the left) and email it to ethicsrm@health.govt.nz. An HDEC advisor will contact you and advise which pathway to proceed with.

We will improve the screening algorithm in a future update.

22. Frequently Asked Questions (FAQ)

General HDEC FAQ

The HDECs have a general FAQ available on their website that is updated periodically.

What web browsers are okay to use with ETHICS RM?
- Chrome and Firefox are supported browsers for ETHICS RM.
- Issues have been reported when using Internet Explorer or Safari with ETHICS RM.

Are there any other extra resources to help me?
- We do have two initial videos available:
  – https://youtu.be/0QdYTCioDUo(external link) - step-by-step guidance on account creation and login, creating, submitting, recalling applications and the main work area screen
  – https://youtu.be/SxxOQVz0HMk(external link) - step-by-step guidance on sharing, transferring form to colleagues and system 'roles', creating post approval items and existing applications from Online Forms.

I accidentally put the wrong version/date on a document. Can I change the version/date of the document after I have submitted it?
- You will need to immediately recall your submission before it is validated to correct your submission.
- If validated, you will need to contact the HDEC's Secretariat immediately (either through hdecs@health.govt.nz or via the ETHICS RM 'Correspondence' tab for the study) and advise us of your mistake. This can only be updated prior to a decision letter being sent.
- We will not be able to update any letter sent before this notification.

The HDEC letter has the wrong version number/date. Can you amend this and resend the letter?
- As the list of documents submitted in the letter has always been automatically generated based on what you have submitted, we are no longer editing these in ETHICS RM. However, if a letter is incorrect because of either an ETHICS RM error or an HDEC error, we are able to amend those.

Can I change the title of my study?
- Unfortunately, a title is unable to be changed once it has been created.

What happened to the old references used before ETHICS RM?
- The format for references used prior to our transition to ETHICS RM is no longer available to us and is currently not something we can change. We apologise for any inconvenience this may cause as some studies may not have clear submission references as previously used.

The 'Submit' button is not showing up for me in my Post Approval Form, how can I submit?
- Check the 'Collaborators' tab and ensure that you have full permission to submit forms. If the project owner has enabled you for limited access only (eg, you can view or edit the form but not submit it) they will need to revise your permissions using the 'Roles' button to grant full access or submit the form themselves.
- If you have permission to submit, you may need to check whether the form needs to be updated first. You will be prompted to do so if this is the case with a red banner stating this.

What does it mean if it says my 'form is obsolete and cannot be submitted'?
- The system will display this message for applications that were migrated from the old Online Forms website. This only refers to the migrated form itself – not the application as a whole.
- Post approval forms can still be created by selecting the 'Create Sub Form' action and will attach to the migrated application.

I have been asked to update the form before I have submitted it, will this remove anything I have put in so far?
- When a new version of the form is published the system will prompt you to update it. All data entered on the form will be preserved unless the question itself has been replaced. The update notes will list any significant changes.
- You can check whether your answers have been removed by clicking 'Check for Completeness'.

I have a study that was submitted before ETHICS RM was introduced and I need to find evidence that the study was authorised. Where can I find this?
- You can find this by checking the metadata of the MDF form by clicking the 'Navigation' tab, then 'Authorisation Report'.

I submitted my response to a provisional approval or had my application invalidated and now I have two versions of my study!
- When a new version of a form is submitted the previous version is archived and kept on record. Previous versions can be found under the 'Submissions' tab for the study.

I have been requested to sign a form but it says it is locked, what does this mean?
- Signing a form should still be possible. Note if you have received a request from a sub form the signature can only be signed on the sub form itself (and is valid for the study it is attached to).

My signature is 'invalidated' what does that mean?
- Any change to the form will invalidate any active signatures. Please note this includes when the HDEC publishes updates. If the signature has been invalidated, it will need to be requested and signed again. Please ensure no changes are made to the form after a request is sent.

Can I upload multiple documents at once?
- This is currently not a supported feature of ERM. The HDEC Secretariat has requested the developer include this feature in future update.

My letter has an error! Can this be corrected?
- If your letter contains an error caused by the HDEC Secretariat it can be reissued. Please use the 'Correspondence' button to send a message through EthicsRM advising of the error and a team member will be in touch.
- If it is a result of researcher error (eg, the wrong version number or date on a document) this cannot be changed as it was the document identifier received by the HDEC at the time of review. Please ensure these are correct before submitting.