



# Online Forms User Manual

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Version 1.1

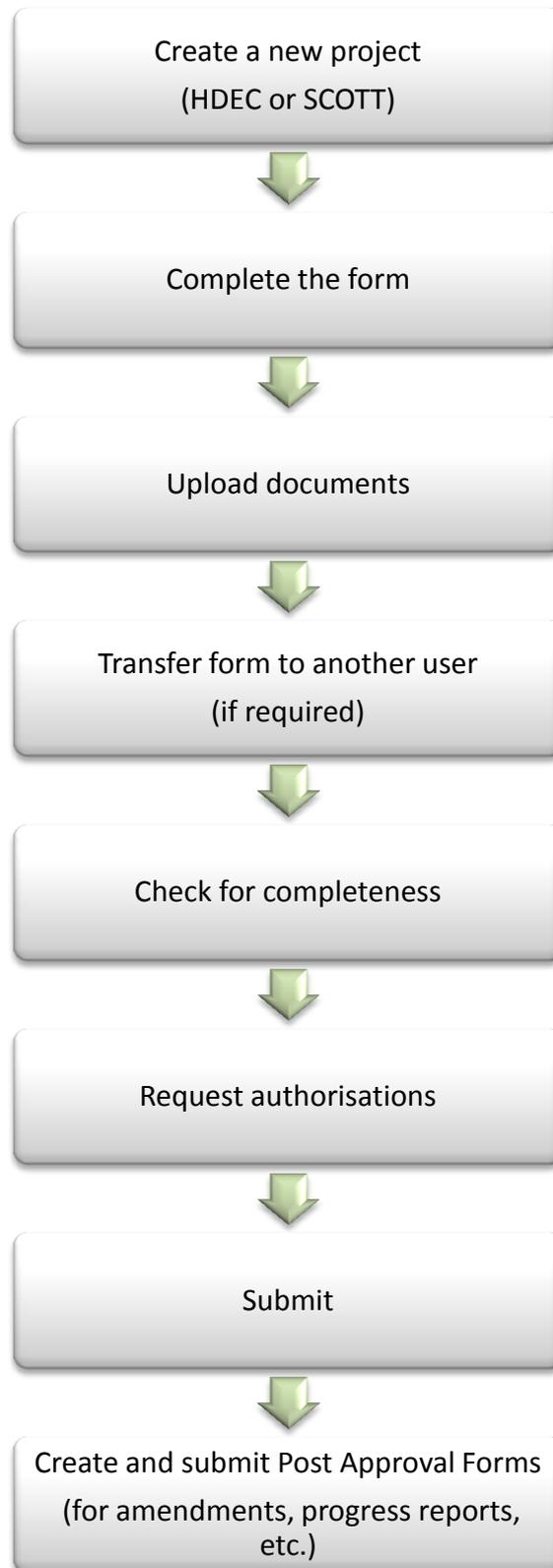
May 2014

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## Overview of Online Forms – HDEC or SCOTT Applications





# 1. Create an account in Online Forms

Online Forms 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).

## Steps

## Screenshots

1. Go to Online Forms ([www.ethicsform.org/nz](http://www.ethicsform.org/nz)).

Then click “Create Account” in the main menu bar.



2. Enter your details, choose a password, and click “Register”.

**Note that the email address you enter here will be your username in Online Forms.**

Title	Mr	Mailing address	1 the Terrace
Forename	Rohan		
Surname	Murphy		
Organisation	Ministry of Health	Suburb/Town	Wellington
E-mail Address (User Login)	rohan_murphy@moh.govt.nz	PostCode	6011
Confirm E-mail	rohan_murphy@moh.govt.nz	Country	New Zealand
Password	*****	Telephone Number	04 816 2053
Confirm Password	*****	Fax	04 816 2340

3. An email containing a web link and an activation code will be sent to the email address you have entered.

Once you have received the activation code, click on the web link, enter the activation code, and click “Submit”. The text below should appear on screen. Click as indicated to log in.

An email containing your activation code has been sent to the account that you registered with. Please enter your account activation code in the box below to activate your account. If you are having problems activating and accessing your account please contact our [IT help desk](#).

Your account has been activated. Click [here](#) to log in.

## 2. Log in to my Online Forms account, and manage my account details

### Steps

### Screenshots

1. Go to Online Forms ([www.ethicsform.org/nz](http://www.ethicsform.org/nz)).

Enter your Online Forms username (i.e., your email address) and password.

Click "Submit".



2. Your screen should look like this.

Your name and email address appear at the top right of the screen.

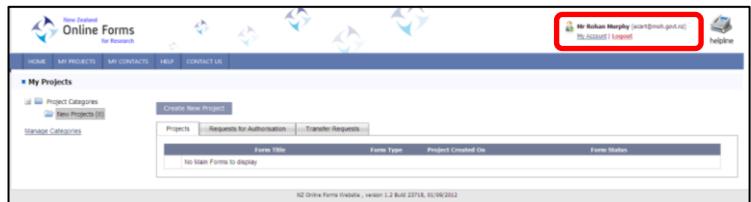
Click on "My Account" to view or change your account details, including your password.



3. If you wish to save any changes you have made to your account details, enter your current password and click "Save".



4. To log out of Online Forms at any stage, click "Logout" on the top right of the page.



## 4. Create, Edit or Delete Contacts

### Create a contact in the database

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

#### Steps

#### Screenshots

1. To add a new contact into your personal contact database click on “My Contacts” in the main menu bar and choose option “Add New”.



2. Enter contact details and click “Add”.

### Import contacts from Outlook

#### Steps

#### Screenshots

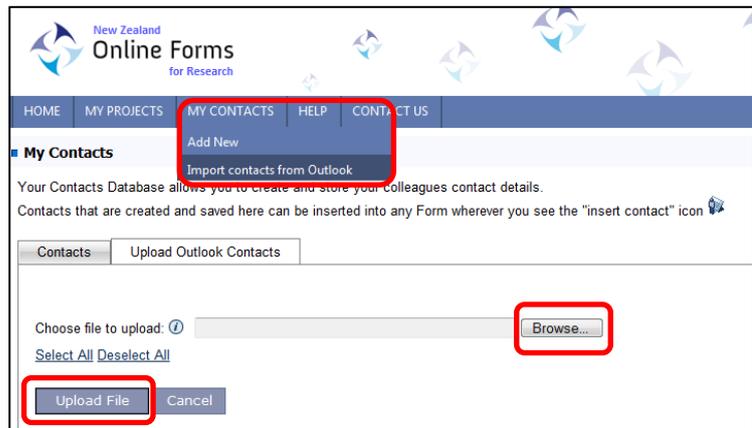
1. To import contacts from Outlook you must generate an Outlook.csv file:
  - Go to Contacts in your MS-Outlook.
  - Select File ->Import and Export from the Main Menu bar. A new window will appear.
  - Select Export to a File from that window. Click Next.
  - Select Comma Separated Values (DOS). Click Next.
  - Select the Contacts folder. Click Next.
  - Select the location where you wish to save the exported file. Click Next, then click Finish.

## Steps

2. Click on “My Contacts” in the main menu bar and choose option “Import Contacts from Outlook”.

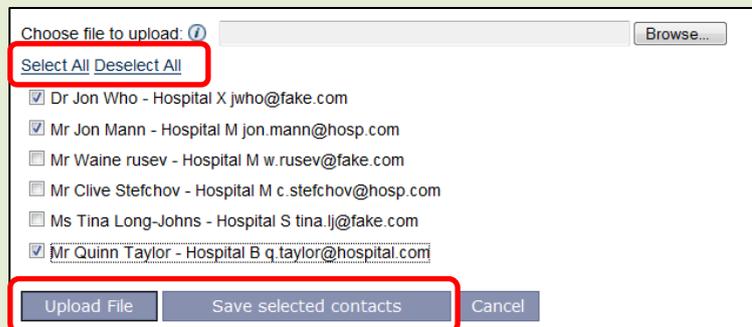
Click the Browse button to find and select the exported file from MS-Outlook with contacts, click Open and then click the Upload File button

## Screenshots



3. To upload the entire list, click on the “Select All” link to ensure that all boxes are checked, and click “Upload File”.

To upload selected contacts, use the “Deselect All” link to uncheck the boxes and check the boxes to mark the contacts to save, then click “Save selected contacts”.

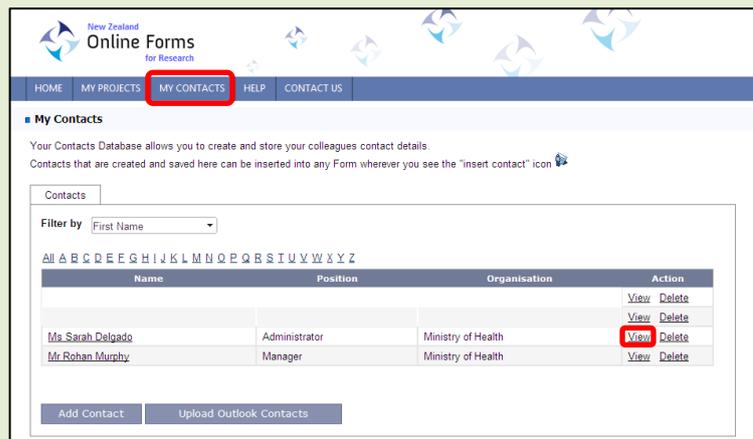


## Edit a contact

### Steps

1. To edit a contact click on “My Contacts” in the main menu bar, then click “View” on the contact you wish to edit.

### Screenshots



## Steps

2. Click "Edit Details".

Enter details and click "Update" to save changes.

## Screenshots

The screenshot shows the 'My Contacts' page with a form for editing details for 'Ms Sarah Delgado'. The form fields include Title, Forename, Surname, Position, Organisation, Department, Address, Suburb/Town, Postcode, Country, E-mail, Telephone, Fax, Mobile, Phone(AH), and Pager. The 'Edit Details' button at the bottom is highlighted with a red box.

## Delete a contact

### Steps

To delete a contact click on "My Contacts" in the main menu bar, then click the "Delete" link by the contact you wish to delete.

You will be asked to confirm the deletion before the contact is actually deleted from the database. Select OK to continue.

### Screenshots

The screenshot shows the 'My Contacts' page with a table of contacts. The table has columns for Name, Position, Organisation, and Action. The 'Delete' link for 'Ms Sarah Delgado' is highlighted with a red box.

Name	Position	Organisation	Action
			<a href="#">View</a> <a href="#">Delete</a>
			<a href="#">View</a> <a href="#">Delete</a>
Ms Sarah Delgado	Administrator	Ministry of Health	<a href="#">View</a> <a href="#">Delete</a>
Mr Rohan Murphy	Manager	Ministry of Health	<a href="#">View</a> <a href="#">Delete</a>

# Populate contact details into a form

## Steps

## Screenshots

- Once a contact is in your contact database you can quickly fill in contact details in a form by clicking on the “Add contact details” icon in the form.

Co-ordinating Investigator (CI)  
The CI has overall responsibility for the conduct of the study, including adherence to established ethical standards.  
In student research, the student him- or herself is the CI.

a.3.1. Are you the CI for this study?  
 Yes  
 No

a.3.1.1. The CI must authorise this application (through the "Authorisations" tab) before it can be submitted to an HDEC for review. You should request authorisation once you have completed all questions in the Online Form, or sign this form as the Co-ordinating Investigator in the Authorisations tab.

Please provide the following information on the study's CI.

**Add Contact** icon highlighted in red.

Title: Forename/Initials Surname

Mailing Address: \_\_\_\_\_

Suburb/Town: \_\_\_\_\_ Phone (BH): \_\_\_\_\_  
 Phone (AH)\*: \_\_\_\_\_  
 Mobile\*: \_\_\_\_\_  
 Postcode: \_\_\_\_\_ Fax: \_\_\_\_\_

Country: \_\_\_\_\_  
 Organisation: \_\_\_\_\_  
 Department\*: \_\_\_\_\_  
 Position: \_\_\_\_\_  
 E-mail: \_\_\_\_\_ (Fields marked with \* are optional)

Page 17 of 88  
NZ HDEC Form

- This will open up your contacts database. Click on the contact you would like to add into the form.

Co-ordinating Investigator (CI) [Same as previous screenshot]

Contacts Database Window:

Name	Position	Organisation	Action
Mr Robin Murphy	Administrator	Ministry of Health	View Delete
Mr Robin Murphy	Manager	Ministry of Health	View Delete

Buttons: Add Contact, Upload Outlook Contacts

NZ Online Form Inhibitor - version 1.2 (Build 23716, 6/28/2012)

- This will open up the contact details. Click “Copy contact details into the form”.

Co-ordinating Investigator (CI) [Same as previous screenshot]

Contact Details Window for Mr Robin Murphy:

Forename: Robin Address: 1 The Terrace  
 Surname: Murphy  
 Position: Manager  
 Organisation: Ministry of Health Suburb/Town: Wellington  
 Department: HDECs Postcode: 6011  
 Country: New Zealand  
 Summary of qualifications and relevant expertise: E-mail: robin\_murphy@mh.govt.nz  
 Please declare any general competing interests: Telephone: 04 8142053  
 Fax: \_\_\_\_\_  
 Mobile: \_\_\_\_\_  
 Phone(AH): \_\_\_\_\_  
 Pager: \_\_\_\_\_

Buttons: Add Details, Delete, Cancel

NZ Online Form Inhibitor - version 1.2 (Build 23716, 6/28/2012)

For instructions on how to complete the form please refer to section 6.

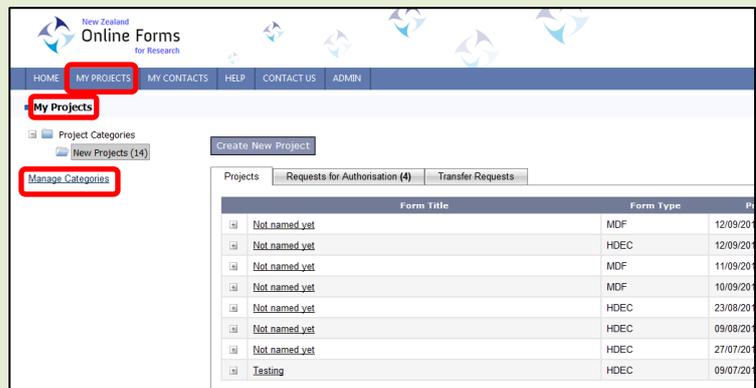
## 5. Manage Project Categories

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

### Steps

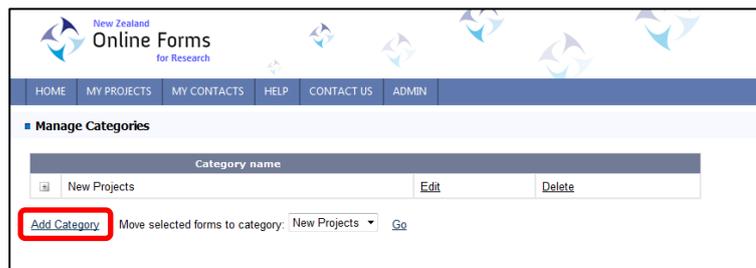
### Screenshots

- Under “My Projects” click on “Manage Categories”.



- You will see a default folder called “New Projects” where your projects will be stored.

To add a new folder, click on “Add Category”.



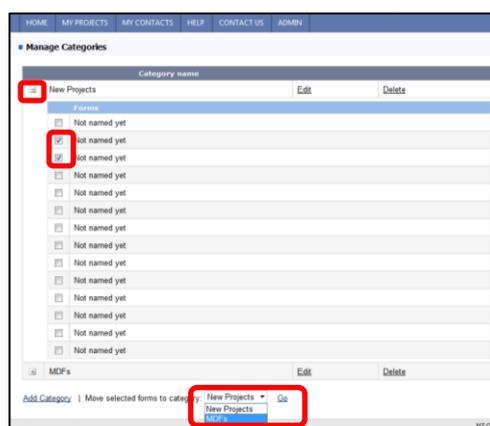
- To name the new folder you have added click “Edit”.

You can delete a folder by clicking “Delete” but only if you do not have any projects stored in it.



- To move a project into a new folder, expand the folder the project is stored in, by clicking “+” and tick the project(s) you would like to move.

Then select the folder you want to move the project into, from the dropdown list at the bottom of the screen, and click “Go”.



## 6. Create a new project

A project consists of:

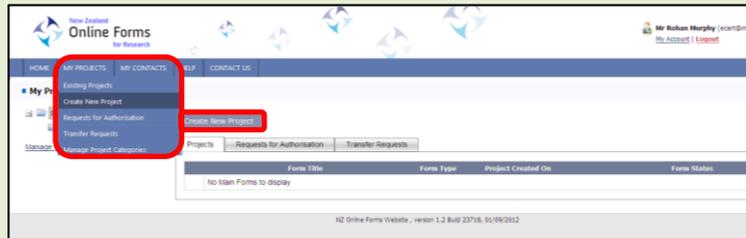
- one main form (which can be an HDEC form, a SCOTT form, or a Minimal Dataset Form), and
- any number of post-approval forms.

### Steps

### Screenshots

1. Go to “My Projects” in the main menu, and select “Create New Project”.

Or, if you are already in the My Projects screen, simply click the “Create New Project” button.

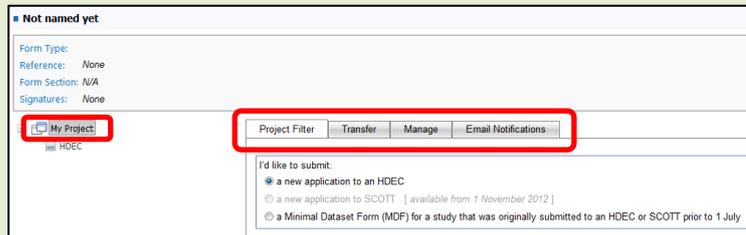


2. A new project titled “Not named yet” will appear.



3. A project has two levels of tabs – the *project-level* tabs and the *form-level* tabs.

The four *project-level* tabs allow you to control the project as a whole and **will only be visible when “My Project” is selected in the project tree at the left of the screen.**



- The “Project Filter” determines the type of form (HDEC, SCOTT or MDF).
- The “Transfer” tab is used to permanently transfer a project to another user (refer to section 8).
- In the “Manage” tab you can duplicate or delete a project (refer to section 15).
- In “Email Notifications” you can nominate who you wish to be included in email notifications from HDECs or SCOTT (refer to section 16).

## Steps

## Screenshots

4. The six *form-level* tabs relate just to the main form, not to the project as a whole and **will only be visible when the form type (i.e. HDEC, SCOTT or MDF) is selected in the project tree at the left of the screen.**

- The “Navigate” tab contains the form (refer to section 6).
- The “Documents” tab allows you to attach relevant documents to your form (refer to section 7).
- The “Transfer” tab is used to temporarily transfer the form to another user (refer to section 8).
- In the “Authorisation” tab you can request electronic signatures from the CI, sponsor etc. (refer to section 10).

The screenshot displays the 'New Zealand Online Forms for Research' interface. At the top, there is a navigation menu with links for HOME, MY PROJECTS, MY CONTACTS, HELP, and CONTACT US. Below this, a project tree on the left shows 'My Project' with a sub-item 'HDEC' highlighted in a red box. The main content area shows a form titled 'Not named yet' with details: Form Type: HDEC, Reference: None, Form Section: N/A, Signatures: None. A horizontal tab bar is visible with tabs: Navigate, Documents, Transfer, Authorisation, e-Submission, Post-approval. The 'e-Submission' tab is highlighted in a red box. Below the tabs, there is a section titled 'SCREENING QUESTIONNAIRE' with a table containing 'RESEARCH AND STUDY TYPE' and 'MAIN CRITERIA'.

- In the “e-submission tab” you can check your application is complete prior to submission (refer to section 9), submit for review (refer to section 11) and monitor the progress of your submission (refer to section 12).
- The “Post-approval” tab allows you to create Post approval forms to submit amendments, progress reports etc. (refer to section 18).

# 7. Complete the form

## How to complete a form

The “Navigate” tab is available on all forms (HDEC, SCOTT, MDF and PAF). It allows you to navigate through the form either by question number or page number. Inactive questions are shaded blue and cannot be clicked on. Active questions have a white background and clicking on them will take you directly to those questions in the form. Certain questions are activated or deactivated depending on your answers to the questions in the form, so not all 88 pages of the form will be active. The form does not need to be completed in one session, as the system will save your progress every time you finish a page.

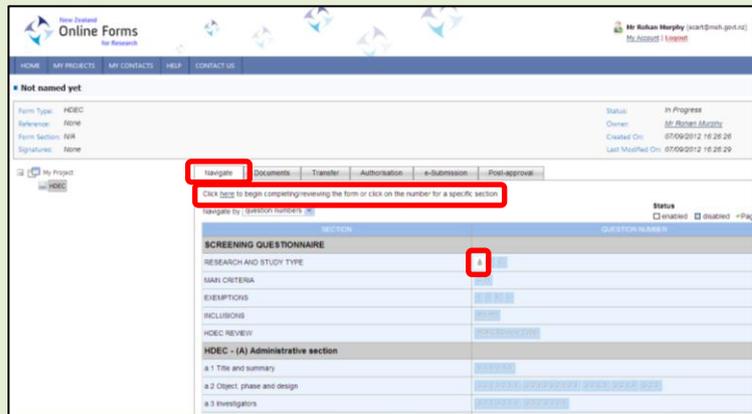
For guidance on the HDEC form screening questions please refer to the Appendix (on page 42).

### Steps

### Screenshots

1. To fill out the form – open the project and go to the “Navigate” tab.

Click [here](#) to begin completing/reviewing the form or click on the question number for a specific section.



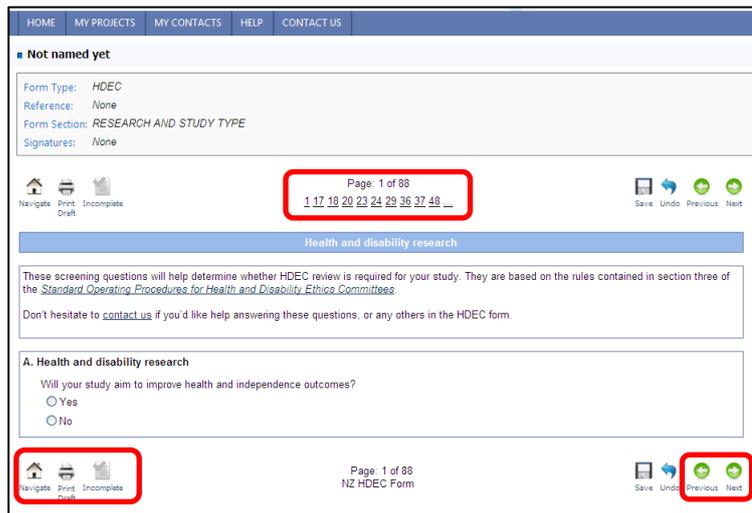
2. This will open up the form.

To return to the view above click on the “Navigate” icon.

To move through the form, click on the previous and next arrows, or on the page numbers in the centre of the screen.

To print a PDF copy of your form, click “Print Draft”.

To mark a page as incomplete, click “Incomplete”.



## Full vs. Expedited 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. Page 10 of the form states the review pathway your application will be assigned to.

The image shows two side-by-side screenshots of the HDEC Form, Page 10 of 88. Both screenshots display the 'HDEC Review Type' section with a list of screening questions. The left screenshot shows the 'Expedited' pathway selected, with a red box around the text: 'Exp. Your study will be reviewed by the expedited review pathway described in section 6 of the Standard Operating Procedures for Health and Disability Ethics Committees'. The right screenshot shows the 'Full' pathway selected, with a red box around the text: 'Full. Your study will be reviewed by the full review pathway described in section 5 of the Standard Operating Procedures for Health and Disability Ethics Committees'. Both screenshots also show a 'Next' button highlighted in red at the bottom right.

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.

## My application is out of scope

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

If you are unsure of why your study is out of the scope of HDEC review, or if you require formal acknowledgment of this, then you are welcome to continue completing the questions in the form, by clicking "Next", and then submit your application.

The image shows a screenshot of the HDEC Form, Page 10 of 88. The main content area displays the message: 'Your study does not require HDEC review'. Below this message, there is a paragraph of text: 'However, you are welcome to complete the questions in the Online Form to help you think through the ethical issues involved in your study. You can also use the Form to record authorisations from other parties to your study, such as localities (e.g. DHBs). In addition, your institution may have its own internal ethics review processes. Contact details for some Institutional Ethics Committees are available here.' The 'Next' button at the bottom right is highlighted with a red box.

# 8. Upload study documents

## How to upload study documents

Online Forms allows you to attach study documents (such as protocols, investigator’s brochures, and participant information sheets) to your application for HDEC or SCOTT review. Mandatory documents must be uploaded before you can submit the form to the review body.

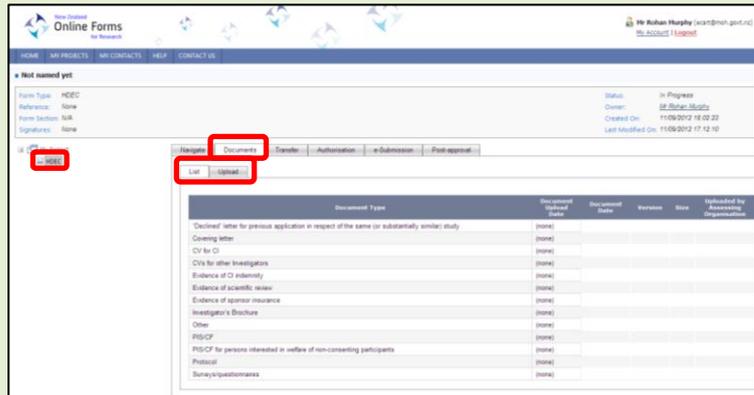
### Steps

### Screenshots

- 1. Open the project and click on the “Documents” tab.

Note that this *form-level* tab will only be visible when the form type (HDEC, SCOTT, or MDF) is selected in the project tree at the left of the screen.

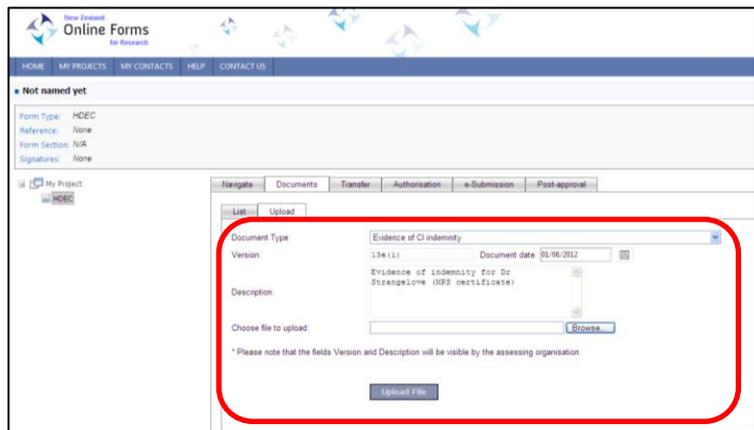
Two sub-tabs – “List” and “Upload” – will be visible.



- 2. In the “Upload” sub-tab, select the document type you wish to upload from the drop-down list.

Enter a version number, date and description for the document. **The details you enter here will appear in the letters you receive from HDECs/SCOTT.**

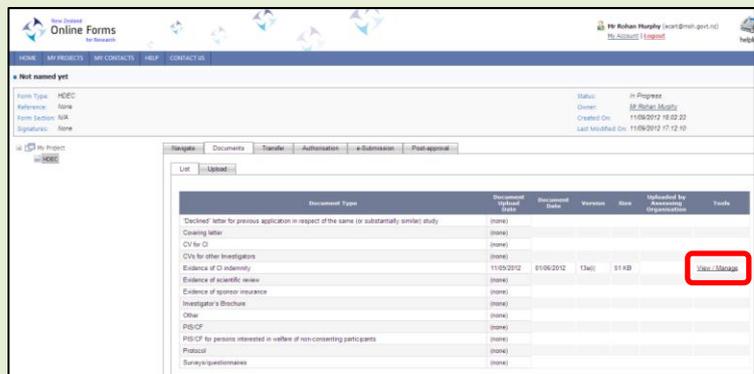
Click “browse” to find the document on your local drive, then click “Upload File”.



- 3. This will take you back to the “List” sub-tab, which will now display the document you have just uploaded.

Return to step 2 to upload another document.

Click “View / Manage” to view or delete the document, or to replace it with an updated version.

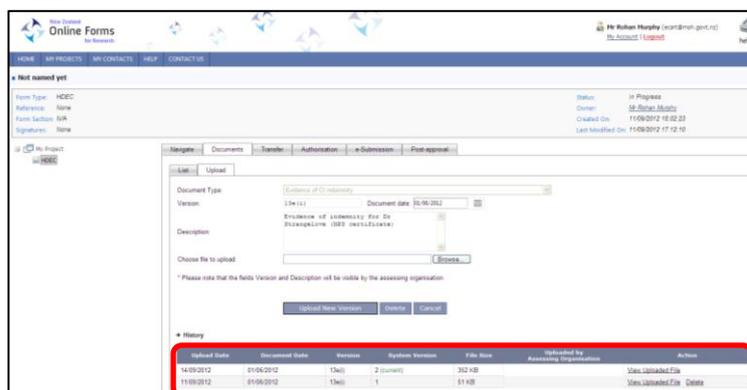


## Steps

- Note that if you upload a new version of the same document, the old version remains in the Online Forms system (unless you delete it yourself).

However, only the most recent version will be submitted with your application.

## Screenshots



## Mandatory Documents

Documents such as the protocol and CV for Co-ordinating Investigator must be uploaded with every application, while other documents become mandatory depending on the answers you give in the form.

Document type	Mandatory for HDEC?	Mandatory for SCOTT?
Protocol	Yes	Yes
CV for Co-ordinating Investigator (CI)	Yes	Yes
CVs for other Investigators	No	Yes
Evidence of favourable peer review	Yes (if "no" at a.8.1)	-
Investigator's Brochure	Yes (if "yes" at a.8.1)	Yes
Participant Information Sheet/Consent Form (PIS/CF)	Yes (if p.3 enabled)	-
PIS/CF for persons interested in welfare of non-consenting participants	Yes (if "yes" at p.1.5)	-
Surveys/questionnaires	Yes (if "yes" at r.2.3.1)	-
Evidence of sponsor insurance	Yes (if "yes" at r.1.7.1.2)	-
Evidence of CI indemnity	Yes (if "yes" at r.1.7.1.2)	-
"Declined" letter for previous application in respect of the same (or substantially similar) study	Yes (if "yes" at a.7.2)	Yes (if "yes" at 1.7.2)
Covering letter	Yes (if "yes" at a.7.2)	Yes (if "yes" at 1.7.2)
GMP certification for manufacturer	-	Yes
GMP certification for packer	-	Yes
Sample labels	-	Yes
Site (re)certification(s)	-	No
Other	No	No

### Are there any restrictions on the type or size of study documents I can upload?

Only files smaller than 32MB can be uploaded.

You can upload any file type you wish into Online Forms – but if we can't open it, we can't review it. For this reason you should only upload common file types such as PDF and MS Office formats.

## 9. Transfer a form to another user

### Transfer a form temporarily

You can transfer a form temporarily if you would like another Online Forms user to review and make changes to your form. Only one person can edit a form at a given time.

- The recipient of a transferred form must have an account with the Online Forms website.
- Do not transfer a form if you are only seeking authorisations, for this please refer to section 10.
- The recipient of a temporarily transferred form is able to edit only the form that has been transferred. For example an application or a post approval form.
- The recipient of a temporarily transferred form cannot submit or create new forms – only edit the existing and transferred form.

#### Steps

1. Open the project and click on the “Transfer Form Temporarily” tab. Please make sure the form is selected on the left of the screen.

Enter the recipient’s email and click “Transfer to User”.

Please note that the recipient of a transferred form must have an account with Online Forms first.

Automated emails are generated advising the recipient and owner of the actions taken at various stages of the transfer.

#### Screenshots

medium size study

Form Type: HDEC  
Reference: 13/NZTest/26  
Form Section: N/A  
Signatures: This form is attached with electronic signatures, any changes to the form will invalidate the signatures.

My Project  
You are here → HDEC

Transfer Form Temporarily

Please enter the recipient's e-mail address in the box below  
In order to transfer the form to an e-mail address the recipient must have an account on the online form system.  
This option is for transferring a Form to a collaborator; this will be a temporary transfer only.  
To transfer the Form permanently, go to [My Project](#)

Recipient's e-mail:  
joe.blog@research.co.nz

Include personal message: ⓘ  
Hi Joe please accept this transfer.

>> Transfer To User <<

Transferred From Transferred To  
No Transfers to display

SOW4 UAT 7

Form Type: Post-approval  
Reference: 14/NZTest/44/AM02  
Form Section: N/A  
Signatures: None

My Project  
HDEC  
Post-approval Forms  
You are here → Post-approval - 392

Post-approval - 391  
Post-approval - 393  
Post-approval - 394  
Post-approval - 395  
Post-approval - 396  
Post-approval - 398  
Post-approval - 415

Transfer Form Temporarily

Please enter the recipient's e-mail address in the box below  
In order to transfer the form to an e-mail address the recipient must have an account on the online form system.  
This option is for transferring a Form to a collaborator; this will be a temporary transfer only.

Recipient's e-mail:

Include personal message: ⓘ

>> Transfer To User <<

Transferred From Transferred To  
No Transfers to display

- **Note:** to Transfer a Post Approval Form you must select the Post Approval Form on the left hand side of the screen and then follow the Temporary Transfer steps.
- **This will only transfer the Post Approval Form.**

## Steps

## Screenshots

2. You will have access to a read-only version of the form while it is in the control of another user.

You can retrieve the transferred form at any time by clicking on the "Retrieve Form" button.

The transfer actions are listed in the transfer history.

Transferred From	Transferred To	Transfer Action	Transfer Date
Mr Gordon Chanley	Commander Nic Aagaard	Requested Transfer	01/05/2014 01:13 PM

## Transfer a project permanently

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

Once the form has been permanently accepted by the recipient you will no longer be the owner of the form and the person to whom the form was transferred will have full access to all management functions, such as being able to transfer the form to other users or to submit the form.

## Steps

## Screenshots

1. Open the project and click on the "Transfer" tab.

Note that this *project-level* tab will only be visible when "My Project" is selected in the project tree at left of the screen.

**Please note that this transfer tab is different to the one shown in the previous page.**

Transferred From	Transferred To	Transfer Action	Transfer Date
Commander Nic Aagaard	Mr Gordon Chanley	Permanently Transferred	21/03/2014 03:22 PM
Commander Nic Aagaard	Mr Gordon Chanley	Form Accepted	21/03/2014 03:18 PM
Commander Nic Aagaard	Mr Gordon Chanley	Requested Transfer	21/03/2014 03:15 PM

2. Enter the recipient's email and click "Transfer to User".

Automated emails are generated advising the recipient and owner of the actions taken at various stages of the transfer.

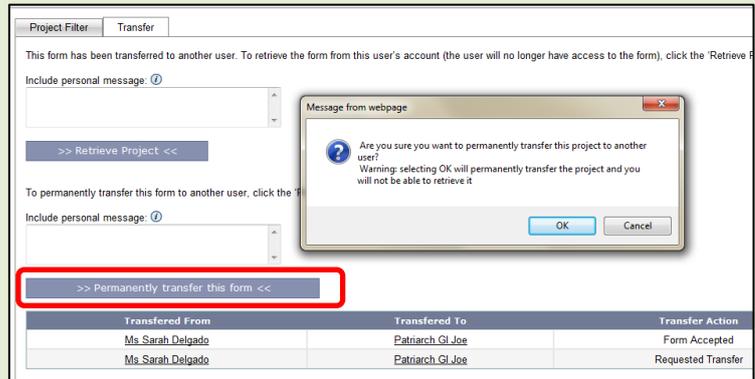
Please note that the recipient of a transferred form must have an account with Online Forms first.

Transferred From	Transferred To	Transfer Action	Transfer Date
Commander Nic Aagaard	Mr Gordon Chanley	Permanently Transferred	21/03/2014 03:22 PM
Commander Nic Aagaard	Mr Gordon Chanley	Form Accepted	21/03/2014 03:18 PM
Commander Nic Aagaard	Mr Gordon Chanley	Requested Transfer	21/03/2014 03:15 PM

## Steps

- Once the recipient has accepted the form, click on “Permanently transfer this form”.

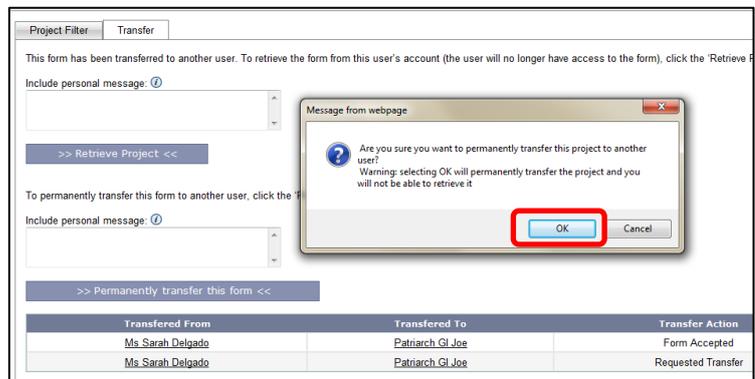
## Screenshots



- Click OK.

Please note that this will permanently transfer the project and you will not be able to retrieve it.

Once transferred the project will disappear from your existing projects.



## Find forms that I have transferred to other users or that others have transferred to me

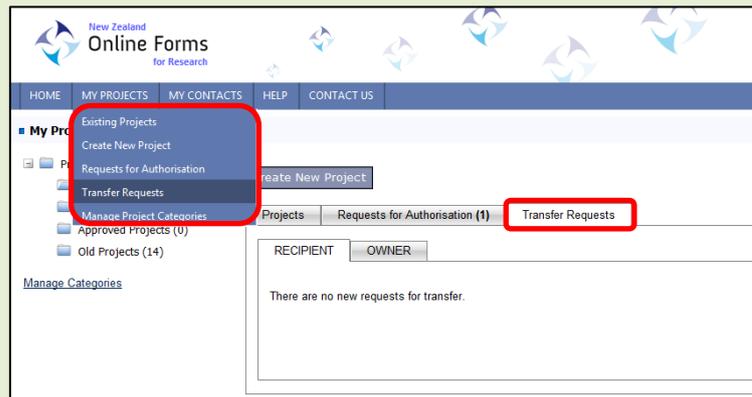
## Steps

- Go to “My Projects” in the main menu, and select “Transfer Requests”.

Or, if you are already in the My Projects screen, simply click the “Transfer Requests” tab.

Two sub-tabs – “Recipient” and “Owner” – will be visible.

## Screenshots



- The “Owner” tab keeps a history of all forms that you have either temporarily or permanently transferred to other users.



## Steps

3. The "Recipient" tab displays forms transferred to you by other users.  
To accept a pending transfer - click on "Accept Application".

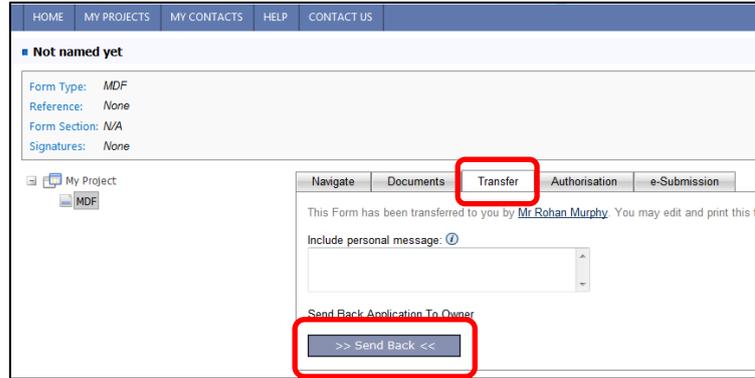
## Screenshots



4. To return a form to its owner go into the form and click the "Transfer" tab.

Then click the "Send back" button.

Once returned the project will disappear from your existing projects.



# 10. Check for Completeness

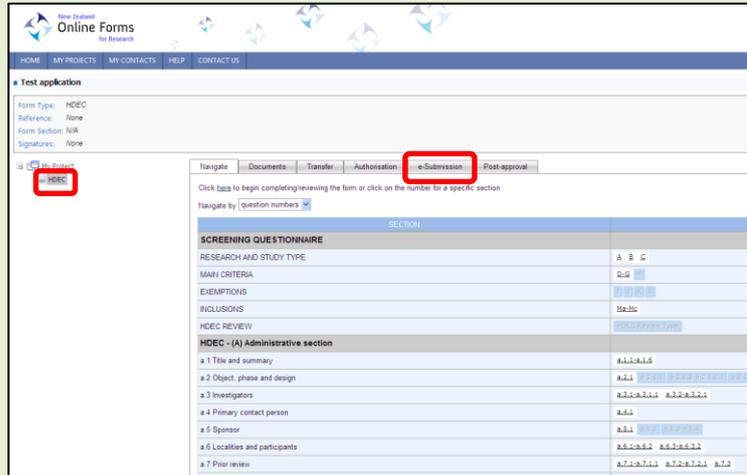
It is important to check for completeness before you request authorisations, to make sure you have answered all the questions in the form.

## Steps

## Screenshots

1. Open the project and click on the “e-Submission” tab.

Note that this *form-level* tab will only be visible when the form type (HDEC, SCOTT, or MDF) is selected in the project tree at the left of the screen.



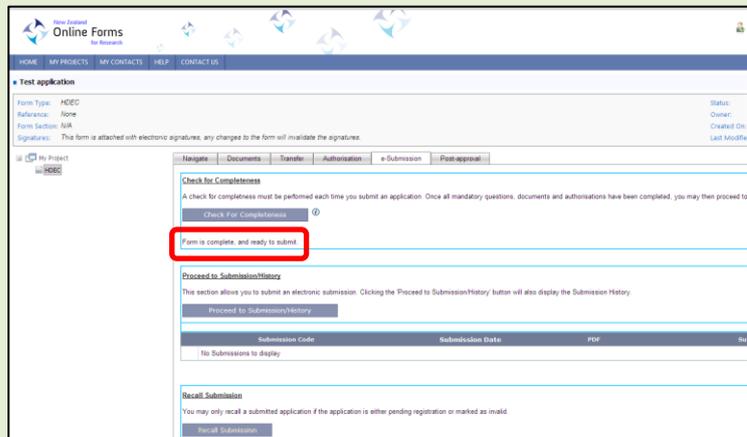
2. Click on “Check for Completeness” to identify missing information from your application. Any outstanding items will be listed.

You must then go back to the relevant tabs to complete all mandatory questions and upload documents before requesting authorisations.



3. Once the application is complete, the check for completeness will say “Form is complete and ready to submit”.

You should now obtain authorisations.



# 11. Request or Grant Authorisations

## What is an authorisation?

Electronic authorisation replaces an 'ink' signature for the Co-ordinating Investigator, Other Investigators, Primary Contact Person, Sponsor, 3rd Party performing sponsor's duties or functions in NZ, Locality and Other on forms generated on the Online Forms system. This avoids the need to take or post paper copies of forms to the various individuals who need to authorise the application forms. More than one electronic authorisation may be requested at the one time, though the persons authorising the form must have an Online Forms account.

You should obtain authorisations only once you are confident the form is complete (see section 9).

**Please note that any changes made to the form will invalidate the authorisations that are in place, but uploading extra documents will not invalidate these.**

## Mandatory authorisations

Mandatory authorisations must be obtained before you can submit the form for HDEC review; however you can request non-mandatory authorisations (e.g. locality authorisations) at any time.

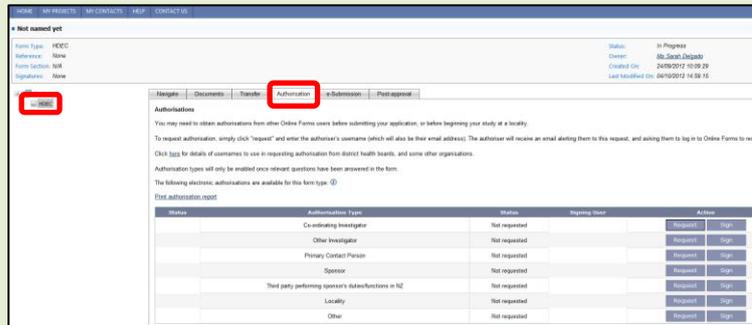
Authorisation type	Mandatory prior to submission?
Co-ordinating Investigator (CI)	Yes
Other Investigator	No
Primary contact person	Yes
Sponsor	Yes (unless "no sponsor" at a.5.1)
Third party performing sponsor's duties or functions in NZ	Yes (if "yes" at a.5.3)
Localities	No
Other	No

# How to request authorisations

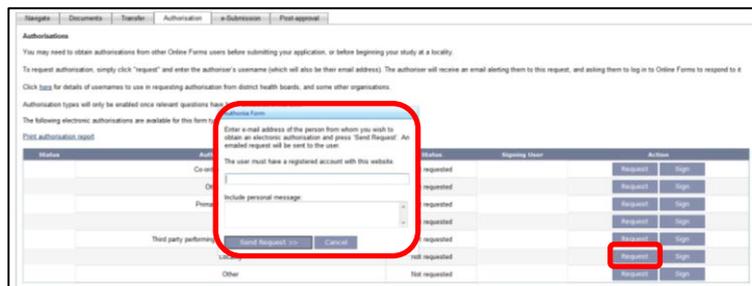
## Steps

## Screenshots

- Open the project and click on the "Authorisation" tab. Note that this *form-level* tab will only be visible when the form type (HDEC, SCOTT, or MDF) is selected in the project tree at the left of the screen. This tab will list all the electronic authorisations that are available for that particular form.

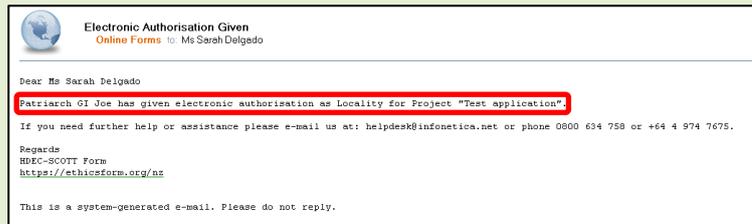
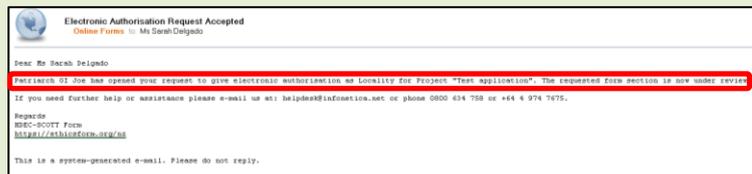


- Select the relevant type of authoriser and click "Request". Enter the email address of the authoriser and include a personal message if necessary. Click the "Send Request" button.

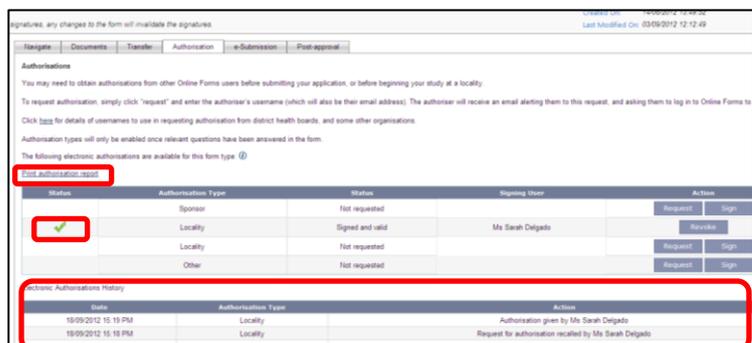


**Please note that the authoriser must have an account with Online Forms.**

- As the author of the form you will receive automated emails advising you of the progress of your authorisation request.



- Once the authorisation is given, a green tick will appear next to it. An authorisation history at the bottom of the page keeps a record of all authorisation requests. You can also print an authorisation report for your records.



## Steps

5. You can **recall** an authorisation request by clicking the “Recall” button.

## Screenshots

The screenshot shows the 'Authorisation' page with a table of requests. The 'Recall' button for the first row is highlighted in red.

Status	Authorisation Type	Status	Signing User	Request	Sign
	Sponsor	Requested	Ms Emma Phelan	Request	Sign
	Sponsor	Not requested		Request	Sign
	Locality	Not requested		Request	Sign
	Other	Not requested		Request	Sign

6. You can also **revoke** an authorisation that has already been granted by clicking the “Revoke” button.

The screenshot shows the 'Authorisation' page with a table of requests. The 'Revoke' button for the second row is highlighted in red.

Status	Authorisation Type	Status	Signing User	Request	Sign
✓	Sponsor	Not requested		Request	Sign
	Locality	Signed and valid	Ms Sarah Delgado	Request	Sign
	Locality	Not requested		Request	Sign
	Other	Not requested		Request	Sign

## How do I authorise my own study?

If you are the CI or primary contact person you may need to authorise your own study.

## Steps

1. If you need to authorise your own study you can do so by clicking the “Sign” button.

## Screenshots

The screenshot shows the 'Authorisation' page with a table of requests. The 'Sign' button for the first row is highlighted in red.

Status	Authorisation Type	Status	Signing User	Request	Sign
	Coordinating Investigator	Not requested		Request	Sign
	Other Investigator	Not requested		Request	Sign
	Primary Contact Person	Not requested		Request	Sign
	Sponsor	Not requested		Request	Sign
	Third party performing sponsor's duties/functions in NZ	Not requested		Request	Sign
	Locality	Not requested		Request	Sign
	Other	Not requested		Request	Sign

2. Enter your username and password and click “Sign”.

The screenshot shows the 'Authorisation' page with a form for signing. The 'Sign' button is highlighted in red.

Please enter your username and password and the details relevant to your study at a locality.

Username (Your full e-mail address)

Password

Authoriser (Organisation Name or Individual's Name)

Lead Investigator(s) at Locality (this field is for Locality Authorisation only)

Locality

Other

Status	Signing User	Request	Sign
Not requested		Request	Sign
Not requested		Request	Sign
Not requested		Request	Sign
Not requested		Request	Sign
Not requested		Request	Sign
Not requested		Request	Sign
Not requested		Request	Sign

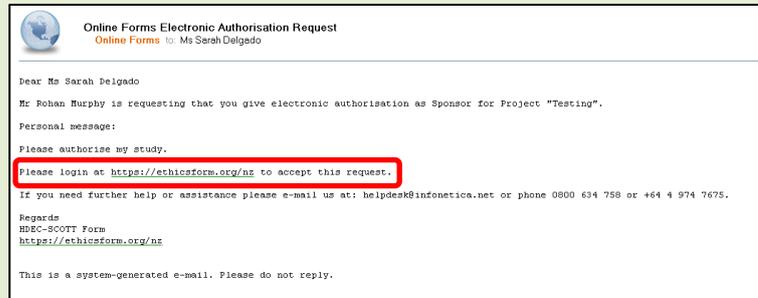
## I've been asked to authorise a study – what do I do?

If you receive a request for electronic authorisation with an incorrect research personnel title (authorisation type), reject the form and immediately notify the owner of the request.

### Steps

### Screenshots

1. If you have been asked to authorise a study, you will receive an email with a link to log in to Online Forms.



2. Once you log into Online Forms, in the main "My Projects" page click into the "Requests for Authorisation" tab. Any outstanding requests for authorisation will be displayed under the "Requests" tab. Click "Open Request" to review and sign the form.



3. Click the "Review Requested Form" button to check the information in the form in a read-only format.



4. Navigate through the form by clicking the Next and Previous arrow buttons.

After reviewing the form, click the "Navigate" icon and then click into the "Authorisation" tab again.



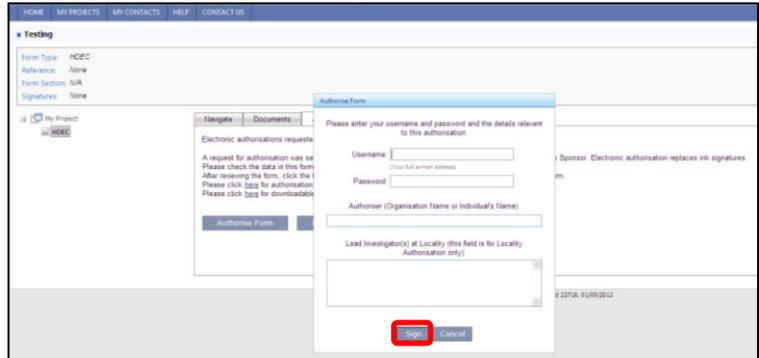
## Steps

- In the "Authorisation" tab - Click the "Authorise Form" button to generate an electronic signature. (Alternatively, click the "Reject Request" button if for some reason you cannot sign the form).

## Screenshots



- Enter your username and password. Also enter the Authoriser (this may be the Organisation Name or Individual's Name) and the names of the Lead Investigator(s) at the Locality (this field is for Locality Authorisation only) - this information appears when you generate an authorisation report.



Then click the "Sign" button.

- A history of all electronic authorisations you have previously granted/not granted will appear under the "Signed" tab.



## 12. Submit a form

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

### Steps

### Screenshots

1. Open the project and click on the “e-Submission” tab.

Note that this *form-level* tab will only be visible when the form type (HDEC, SCOTT, or MDF) is selected in the project tree at the left of the screen.

The screenshot shows the 'New Zealand Online Forms for Research' interface. The navigation menu at the top includes 'HOME', 'MY PROJECTS', 'MY CONTACTS', 'HELP', and 'CONTACT US'. Below this, the 'Test application' section is visible, showing 'Form Type: HDEC', 'Reference: None', 'Form Section: N/A', and 'Signatures: None'. The 'e-Submission' tab is highlighted in the navigation bar. A table titled 'SCREENING QUESTIONNAIRE' is displayed, listing various sections like 'RESEARCH AND STUDY TYPE', 'MAIN CRITERIA', 'EXEMPTIONS', 'INCLUSIONS', and 'HDEC REVIEW'. The 'HDEC - (A) Administrative section' is expanded, showing sub-sections a.1 through a.7.

2. Click “Check for Completeness”.

Once the application is complete, the check for completeness will say “Form is complete and ready to submit”.

The screenshot shows the 'Check for Completeness' section of the interface. The 'Check for Completeness' button is highlighted. Below it, the message 'Form is complete, and ready to submit' is displayed. The 'Proceed to Submission/History' button is also visible. The 'Recall Submission' section is also present, with a 'Recall Submission' button.

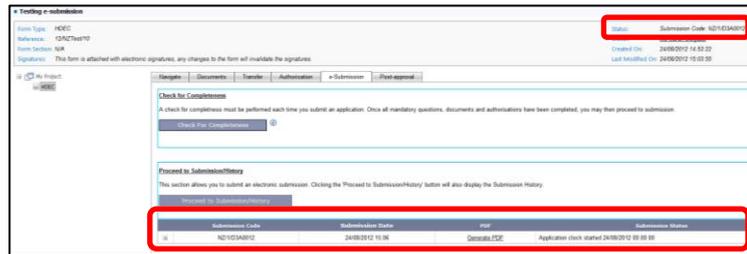
3. Click “Proceed to Submission/History”, and then click on the “Submit to HDEC” button that appears below.

The screenshot shows the 'Proceed to Submission/History' section of the interface. The 'Proceed to Submission/History' button is highlighted. Below it, the 'Submit to HDEC' button is visible. The 'Recall Submission' section is also present, with a 'Recall Submission' button.

## Steps

## Screenshots

- Once submitted a submission code will be generated and you will be able to track the progress of your application (refer to section 12).



The screenshot displays the HDEC submission interface. At the top right, a red box highlights the 'Submit' button and the 'Submission Code: NS16034810'. Below this, there are tabs for 'Changes', 'Documents', 'Forms', 'Authorisation', 'Submission', and 'Post approval'. The main content area includes a 'Check for Completion' button and a 'Proceed to Submission/History' button. At the bottom, a table shows the submission history with columns for 'Submission Code', 'Submission Name', 'Type', and 'Submission Status'. A red box highlights the first row of the table.

Submission Code	Submission Name	Type	Submission Status
NS16034810	Submission NS16	Generate PDF	Application check started 24/06/2016 09:58:59

### 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 (see section 13).

### To what committee has my application been submitted to?

For HDEC applications submitted for full review you will have the option to have your application reviewed 'as soon as possible' or 'as near as possible'.

As soon as possible - will be assigned to the next available HDEC meeting regardless of location.

As near as possible - will be assigned by the secretariat to the HDEC that meets nearest to the CI.

HDEC applications submitted for expedited review will be assigned by the secretariat to the HDEC nearest to the CI.

# 13. Follow the progress of my submission and view correspondence from HDECs/SCOTT

In the e-submission tab you can monitor the progress of your application through the key stages in the review process and view correspondence from HDECs and SCOTT.

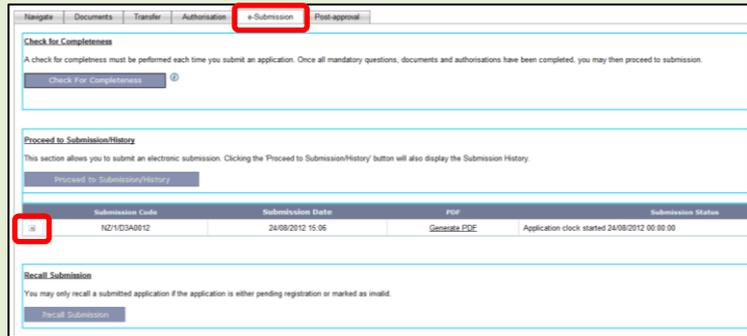
## Steps

## Screenshots

1. Open the project and click on the “e-Submission” tab.

Under the section titled “Proceed to Submission/History” - Click on the “+” to expand the history.

To view correspondence for a Post Approval Form you must go into the e-submission tab of the Post Approval Form itself (not in the HDEC, SCOTT or MDF parent form).



2. The submission history table will allow you to monitor the progress of your application.



3. Letters from the HDECs can be downloaded from the documents table.



## 14. 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 (i.e. the submission is awaiting the committee secretariat to upload the application). If your application has been successfully recalled you may amend the form, upload/amend your supporting documents and request authorisations prior to re-submitting the application.

If you are not able to recall your application and would like to withdraw your application at any time, please contact the secretariat at [hdecs@moh.govt.nz](mailto:hdecs@moh.govt.nz) or on 0800 4 ETHICS.

### Steps

### Screenshots

1. Open the project and click on the “e-Submission” tab.

Note that this *form-level* tab will only be visible when the form type (HDEC, SCOTT, or MDF) is selected in the project tree at the left of the screen.

SECTION	
<b>SCREENING QUESTIONNAIRE</b>	
RESEARCH AND STUDY TYPE	A B C
MAIN CRITERIA	DIG
EXEMPTIONS	F G H I J
INCLUSIONS	K L M N
HDEC REVIEW	O P Q R S T U V W X Y Z
<b>HDEC - (A) Administrative section</b>	
a 1 Title and summary	A.1.1.a.1.d
a 2 Object, phase and design	A.1.1
a 3 Investigators	A.1.1.a.1.1 a.1.1.a.1.2
a 4 Primary contact person	A.1.1
a 5 Sponsor	A.1.1
a 6 Localities and participants	A.1.1.a.1.1 a.1.1.a.1.2
a 7 Prior review	A.1.1.a.1.1 a.1.1.a.1.2

2. Once in the e-submission tab click the “Recall Submission” button at the bottom of the page.

Submission Code	Submission Date	PDF	Submission Status
NZ1034012	24/08/2012 15:06	Generate PDF	Application clock started 24/08/2012 05:00:00

Status	Date
Application clock started 24/08/2012 05:00:00	24/08/2012
Application marked as valid	24/08/2012
Application registered by review body - awaiting validation Northern A Health and Disability Ethics Committee and 12/NTA/05	24/08/2012
Application submitted to Northern A Health and Disability Ethics Committee for review on 12/08/2012 01:00:00 pending registration by review body	24/08/2012

File Name	Document Type	Received Date
NZ1034012	Form Submission	23/08/2012
Members.xlsx		
HDEC claim form.xls		15/08/2012

**Recall Submission**  
You may only recall a submitted application if the application is either pending registration or marked as invalid.

**Recall Submission**

## 15. Duplicate or Delete a Project

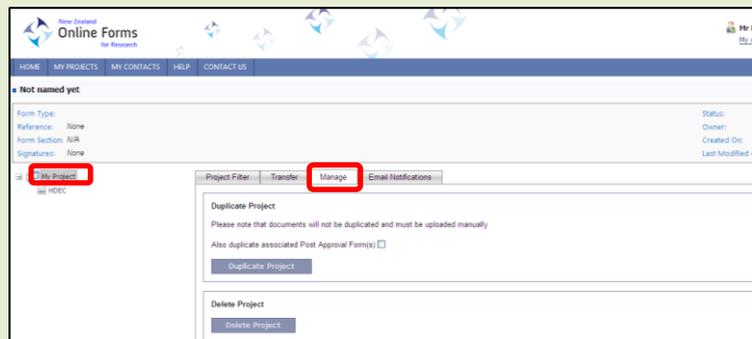
The Manage tab allows you to duplicate the information in an application into a new project or to delete an entire project.

### Steps

### Screenshots

1. Open the project and click on the “Manage” tab.

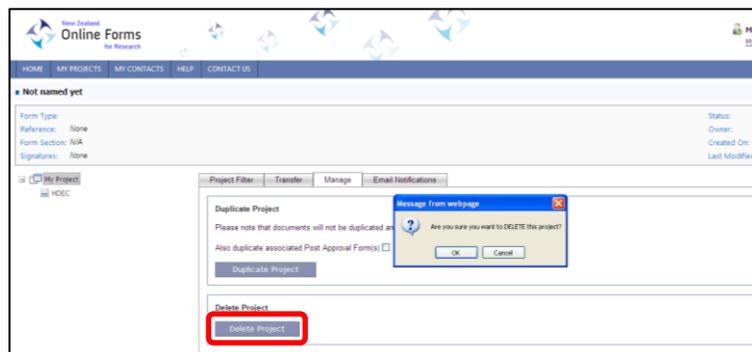
Note that this *project-level* tab will only be visible when “My Project” is selected in the project tree at the left of the screen.



2. To **delete** the project, click “Delete Project”.

A pop-up window will appear. Click “OK” to delete the project permanently.

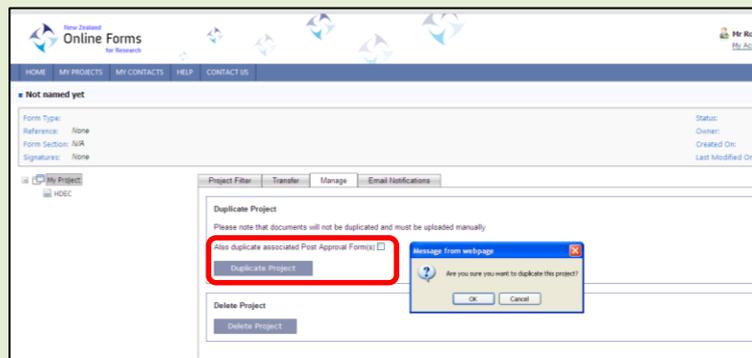
Once the project has been deleted you will not be able to retrieve it.



3. To **duplicate** the project, click “Duplicate Project”.

If the project includes post-approval forms, and you’d like to duplicate these too, make sure that the check box is ticked beforehand. Otherwise, leave it unchecked.

A pop-up window will appear. Click “OK” to duplicate the project.



4. Click on “Existing Projects” in the “My Projects” menu. A duplicate project will appear in your list of projects. Note that documents and authorisations associated with the original project are not duplicated, and will need to be added in the normal way.



### Why can't I delete a project?

Once a project has been submitted for review, it can't be deleted unless you recall it first. For instructions on how to recall a project please refer to section 13.

## 16. Set up email notifications for a project

Online Forms will notify you – the “form owner” – by email when a letter from the HDECs or SCOTT is available about your project.

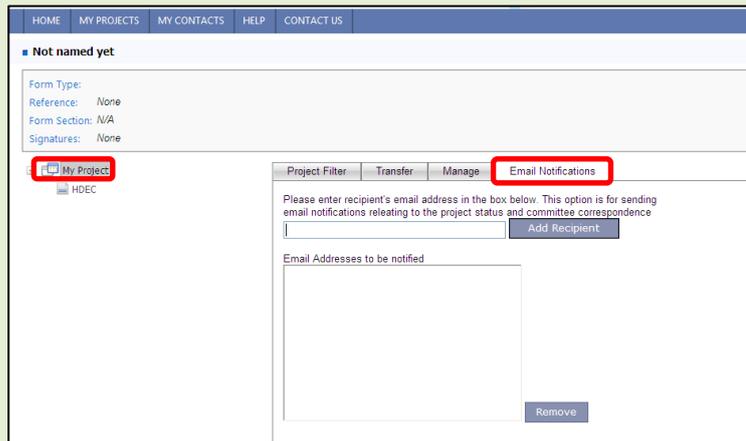
You can decide who else will be copied into email notifications by following the steps below.

### Steps

### Screenshots

1. Open the project and click on the “Email Notifications” tab.

Note that this *project-level* tab will only be visible when “My Project” is selected in the project tree at the left of the screen.



The screenshot shows a web interface with a navigation menu at the top containing 'HOME', 'MY PROJECTS', 'MY CONTACTS', 'HELP', and 'CONTACT US'. Below the menu, there is a project summary section for 'Not named yet' with fields for 'Form Type', 'Reference: None', 'Form Section: N/A', and 'Signatures: None'. A sidebar on the left shows a tree view with 'My Project' and 'HDEC' under it; 'My Project' is highlighted with a red box. The main content area has tabs for 'Project Filter', 'Transfer', 'Manage', and 'Email Notifications', with 'Email Notifications' selected and highlighted with a red box. Below the tabs, there is a text input field for an email address, a 'Please enter recipient's email address in the box below. This option is for sending email notifications relating to the project status and committee correspondence' instruction, and an 'Add Recipient' button. Below that is a larger text area labeled 'Email Addresses to be notified' with a 'Remove' button at the bottom right.

2. Enter the email address of the person who you wish to receive email notifications.

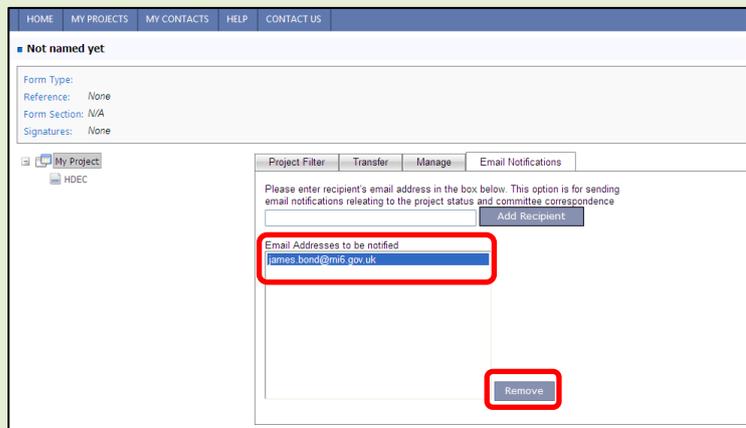
Click “Add recipient”.



This screenshot is similar to the first one, but the text input field for the email address is now filled with a red box, indicating that an email address has been entered. The 'Add Recipient' button is still visible.

3. You can add as many recipients as you like by repeating step 2 above.

You can remove a recipient by selecting their email address and clicking “Remove”.



This screenshot shows the 'Email Addresses to be notified' list with one entry: 'James.bond@shis.gov.uk'. This entry is highlighted with a red box. The 'Remove' button at the bottom right is also highlighted with a red box.

### **Can recipients of email notifications access the project in Online Forms?**

Not necessarily. For others to have read-only access to the project in Online Forms you must request authorisation from them.

### **Do users who have authorised the main form automatically receive email notifications?**

No. Apart from the form owner, only email addresses entered in the “Email notifications” tab will receive email notifications.

### **I've not received email notifications, but should have. What has gone wrong?**

Check your spam folder for emails from [admin@ethics.health.govt.nz](mailto:admin@ethics.health.govt.nz).

## Overview of Online Forms – MDF and PAFs



# 17. Create and submit a Minimal Dataset Form for a study approved before 1 July 2012

If your study was approved before 1 July 2012 you need to register your study in the new system by creating a Minimal Dataset Form or MDF. To submit post approval items (amendments, progress reports, etc.) you must create a Post Approval Form – you will be unable to do so unless you have first created and submitted an MDF. You only need to submit an MDF once per study.

If your study has been approved by an HDEC and by SCOTT you will need to submit two MDFs – one for HDEC and one for SCOTT.

## Steps

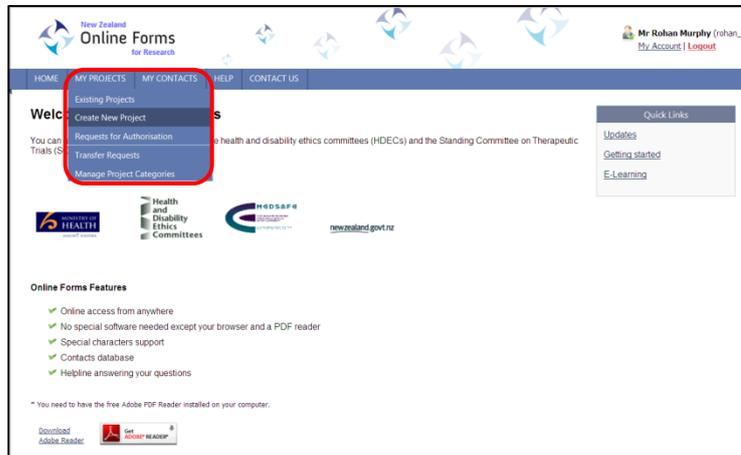
## Screenshots

1. Log in to your Online Forms account at [www.ethicsform.org/nz](http://www.ethicsform.org/nz).

If you haven't already created an account, you will need to do this before you can log in (see section 1).



2. Once you have logged in, go to "My Projects" in the main menu, and click "Create New Project".



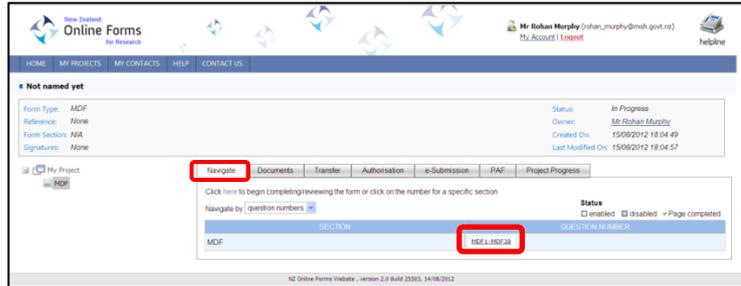
3. Select "Minimal Dataset Form" in the Project Filter tab.

Then click on the "MDF" icon to the left of the page to open the form.



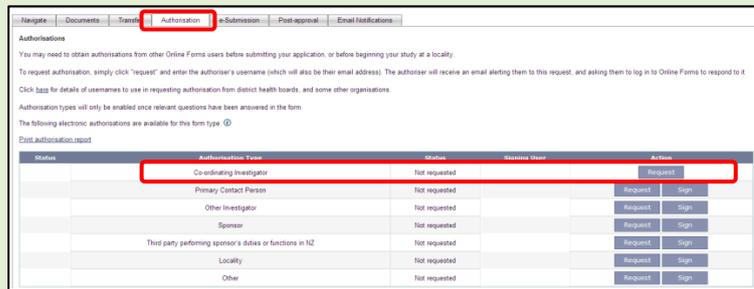
- Complete the MDF by answering the questions in the “Navigate” tab. Click on MDF1-MDF8 to answer.

Please note that if the information you enter in the form is different to what we have on file you may be asked to recall your MDF, correct the information and re-submit. The format of the reference number must be identical to what we have on file (e.g. MEC/01/01/01).



- If you are not the Co-ordinating Investigator (CI) for the study, the CI will need to authorise the MDF before it can be submitted.

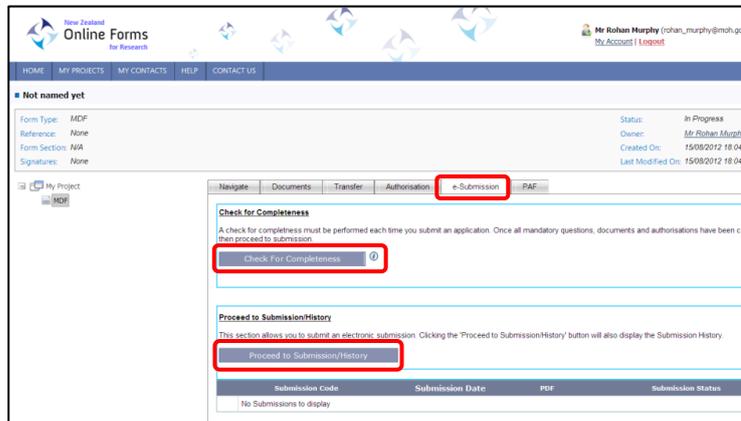
You can request authorisation from the CI through the “Authorisation” tab (refer to section 10). Please note the CI must have an account in Online Forms to do this.



- In the “e-Submission” tab, click “Check For Completeness”.

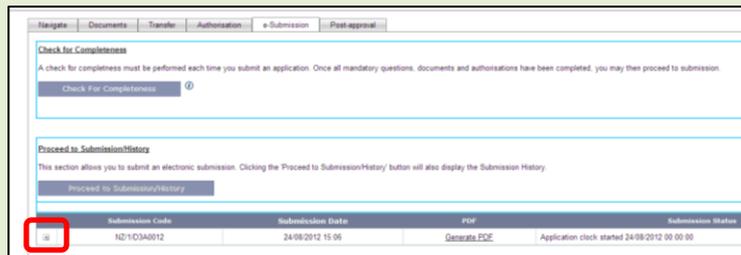
If your form is complete, you can submit it by clicking “Proceed to Submission/History”, and then click the “Submit” button that appears below.

A message confirming submission of your MDF should appear.



- You will receive an automatic email once your MDF has been registered in the system. You can view correspondence from HDECs and SCOTT in the MDF’s e-submission tab by clicking on the “+” icon in the submission history (see section 12).

As soon as the MDF is submitted, you can submit post-approval items, such as annual progress reports and amendments.



## 18. 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.

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 [Standard Operating Procedures](#), 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
<p>Significant amendments are required to be submitted for HDEC review. Examples of these include:</p> <ul style="list-style-type: none"><li>- Significant changes to the design/methodology of the study.</li><li>- Significant changes to the type and/or number of procedures undertaken by participants.</li><li>- Changes relating to the safety of physical or mental integrity of participants, or to the risk/benefit assessment for the study.</li><li>- Significant changes to study documentation (such as participant information sheets).</li><li>- The appointment of a new CI.</li><li>- Any significant change to the study protocol or the information provided in the application for approval.</li><li>- Notification of urgent safety measures taken to protect participants from a significant, immediate hazard to their health and safety.</li><li>- Temporary halts to the study due to safety concerns.</li><li>- Substantial protocol deviations.</li><li>- Early termination of a study.</li></ul>	<p>Minor amendments are not required to be submitted for HDEC review. Examples of these include:</p> <ul style="list-style-type: none"><li>- Minor or administrative changes to study documentation.</li><li>- Updated versions of the Investigator’s Brochure (where the study involves a new medicine).</li><li>- Changes to the research team (including lead/principal investigators at particular localities) other than the appointment of a new Co-ordinating Investigator.</li><li>- Changes in funding arrangements, except where these may alter the ability of participants to access publicly-funded compensation in the event of injury.</li><li>- Changes in arrangements for recording or analysing study data, or for storing or transporting samples.</li><li>- 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.</li><li>- Routine closure of a site.</li><li>- Addition of a new site.</li></ul>

# How to create and submit a Post Approval Form?

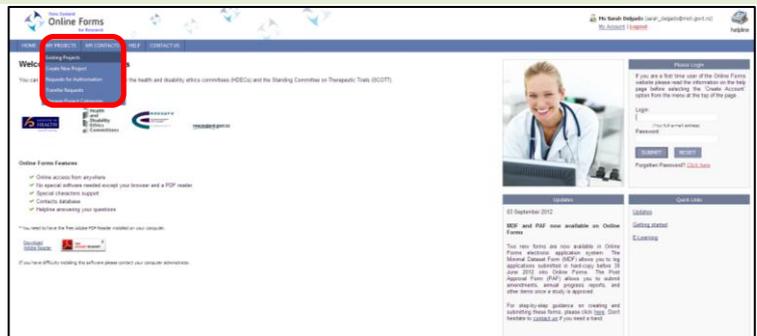
## Steps

## Screenshots

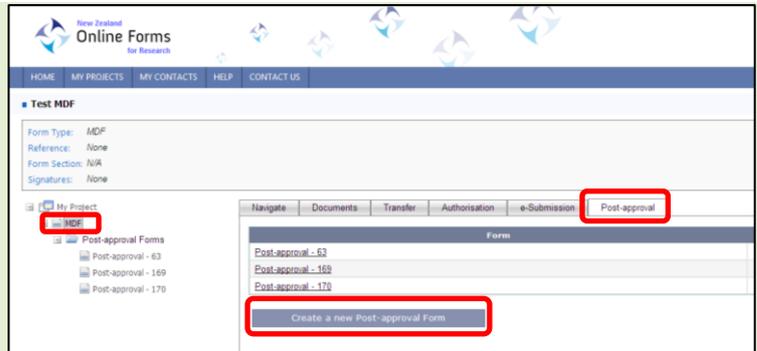
1. Log in to your Online Forms account at [www.ethicsform.org/nz](http://www.ethicsform.org/nz).



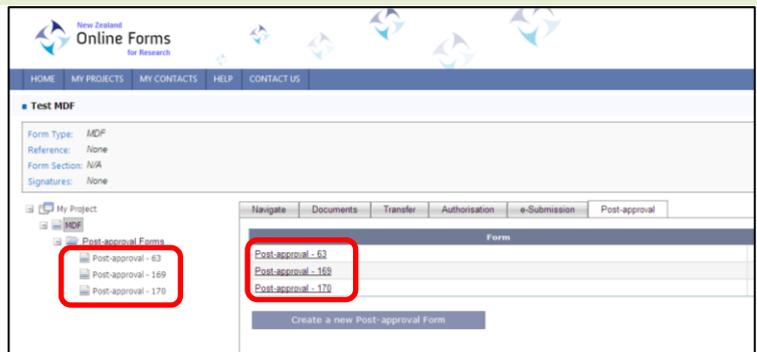
2. Once logged in, go to “My Projects” in the main menu, then click “Existing Projects” and choose the appropriate study.



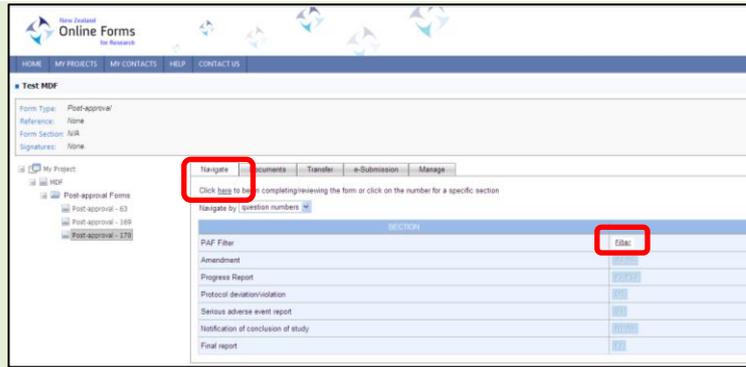
3. Six *project-level* tabs will be visible. Note that the form type (HDEC, SCOTT, or MDF) must be selected in the project tree at the left of the screen. Go to the “Post Approval” tab and click “Create a new Post Approval Form”. You can create as many post approval forms as needed.



4. Click on the title of the Post Approval Form to open it – You can do this in either of the two ways indicated on the screenshot.



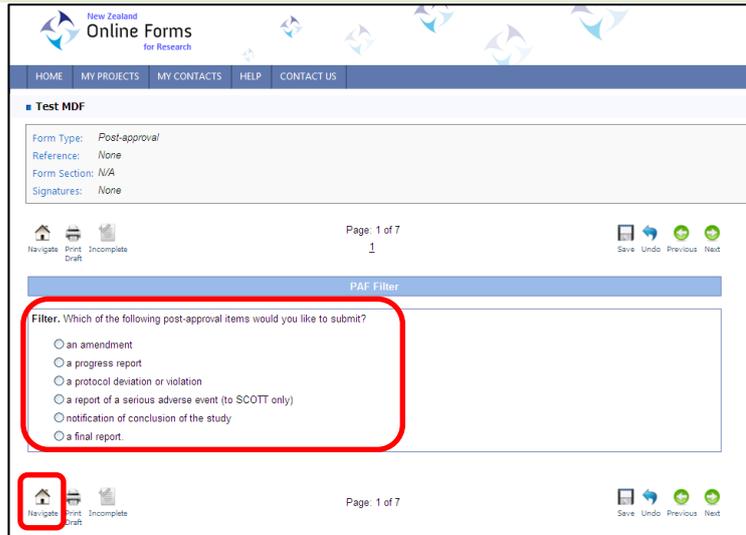
- In the “Navigate” tab click on “Filter” to begin completing the Post Approval Form.



- Indicate which type of post-approval item you wish to submit (e.g. progress report), then answer the remaining questions in the form.

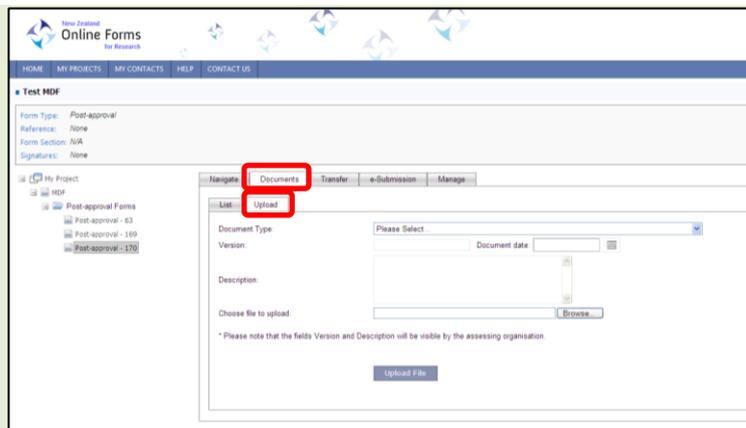
**Please note that all 7 pages won't be active, only those relevant to the post-approval item you have chosen.**

Once you have completed all questions, click the “Navigate” icon to go back to the form tabs (as shown above).



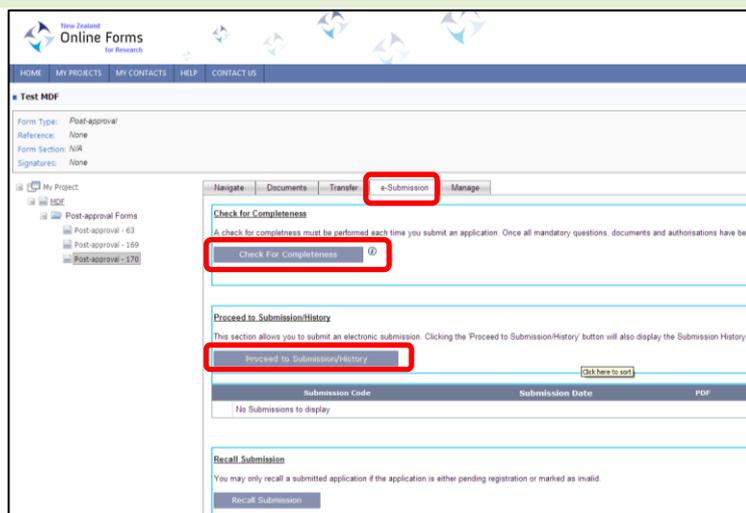
- Upload any documents associated with your post-approval item in the “Documents” tab.

For instructions on how to upload documents please refer to section 7.



- In the “e-Submission” tab, click “Check For Completeness”. If your form is complete, you can submit it by clicking “Proceed to Submission/History”, and then click “Submit”.

You will receive an automatic email once your PAF has been registered in the system. You can view correspondence from the HDEC in the PAF's e-submission tab by clicking on the “+” icon in the submission history (see section 12).



# 19. Add a new locality

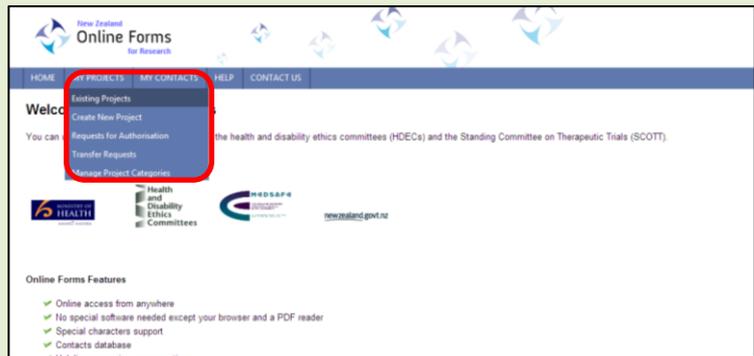
Before a study commences at a given locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

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 advising HDECs of the addition of a new locality.

## Steps

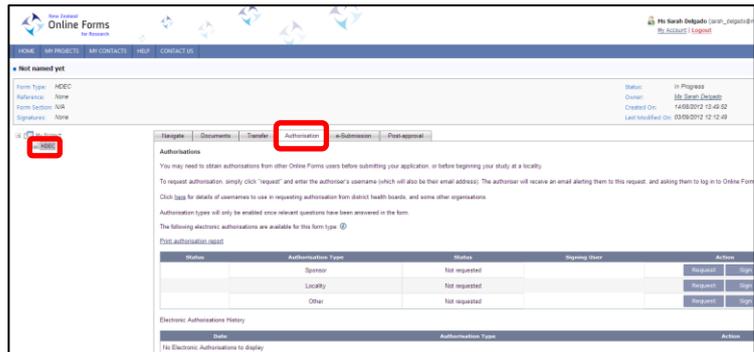
## Screenshots

- Once logged in to Online Forms, go to "My Projects" in the main menu, then click "Existing Projects" and choose the appropriate study.

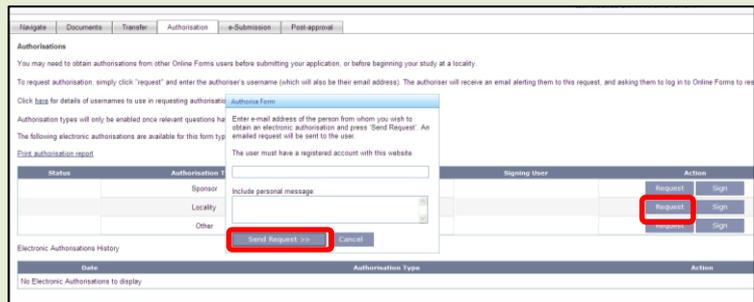


- Once in the project - go to the "Authorisation" tab.

Note that this *form-level* tab will only be visible when the form type (HDEC, SCOTT, or MDF) is selected in the project tree at the left of the screen.



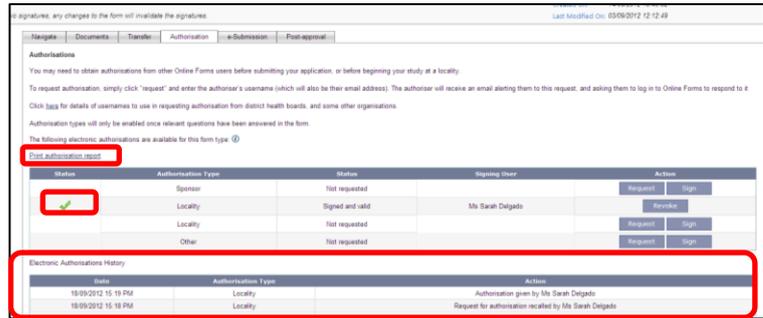
- Select Locality and click "Request". Enter the email address of the authoriser and include a personal message if necessary. Click the "Send Request" button. Please note that the authoriser must have an account with Online Forms. You can request authorisation from as many localities as necessary.



## Steps

## Screenshots

- Once the authorisation is given a green tick will appear next to it. An authorisation history at the bottom of the page keeps a record of all authorisation requests. You can also print an authorisation report for your records.



if signatures, any changes to the form will invalidate the signatures

Navigation: Documents Transfer Authorisation **e-Submission** Post-approval

### Authorisations

You may need to obtain authorisations from other Online Forms users before submitting your application, or before beginning your study at a locality.

To request authorisation, simply click "request" and enter the authoriser's username (which will also be their email address). The authoriser will receive an email alerting them to this request, and asking them to log in to Online Forms to respond to it.

Click [here](#) for details of usernames to use in requesting authorisation from district health boards, and some other organisations.

Authorisation types will only be enabled once relevant questions have been answered in the form.

The following electronic authorisations are available for this form type: @

Status	Authorisation Type	Status	Requesting User	Action
	Sponsor	Not requested		Request Sign
✔	Locality	Signed and valid	Ms Sarah Delgado	Request Sign
	Locality	Not requested		Request Sign
	Other	Not requested		Request Sign

### Electronic Authorisations History

Date	Authorisation Type	Action
18/09/2012 15:18 PM	Locality	Authorisation given by Ms Sarah Delgado
18/09/2012 15:18 PM	Locality	Request for authorisation received by Ms Sarah Delgado

Go to <http://ethics.health.govt.nz/applying-review/research-contacts> to find contact details for district health boards, and some other organisations.

## 20. Submit a Response for Requests for Further Information

- The Provisional Approval Response section is only enabled if the application has been provisionally approved by HDEC.
- This section allows you to submit your response to a request for further information via the documents tab. The application itself will be READ ONLY.

### Steps

### Screenshots

1. Go to the Documents Tab to upload the revised documentation requested by the secretariat

2. To update versions of documents, go to the List tab. Select View/Manage to upload a newer version of the document.

- For example you can upload new versions of the PIS/CF
- Remember to track changes.

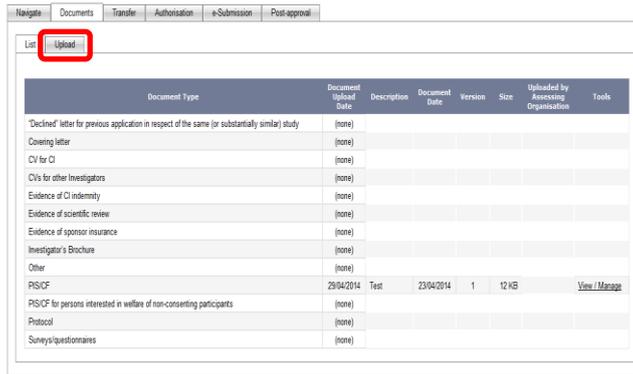
Document Type	Document Upload Date	Description	Document Date	Version	Size	Uploaded by Assessing Organisation	Tools
"Declined" letter for previous application in respect of the same (or substantially similar) study	(none)	(none)					
Covering letter	(none)	(none)					
CI/ for CI	(none)	(none)					
CI's for other Investigators	(none)	(none)					
Evidence of CI indemnity	(none)	(none)					
Evidence of scientific review	(none)	(none)					
Evidence of sponsor insurance	(none)	(none)					
Investigator's Brochure	(none)	(none)					
Other	(none)	(none)					
PIS/CF	29/04/2014	Test	23/04/2014	1	12 KB		<a href="#">View / Manage</a>
PIS/CF for persons interested in welfare of non-consenting participants	(none)	(none)					
Protocol	(none)	(none)					
Surveys/questionnaires	(none)	(none)					

3. When you click View/Manage for a particular document it will take you to the upload tab for that document.

- Update the version number and document date.
- Browse to find the new version of the file.
- Click 'Upload New Version'
- Once the upload is complete the history will populate with the new version.

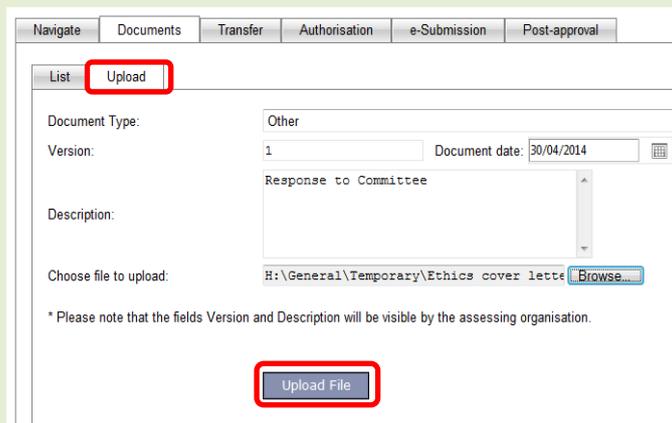
Upload Date	Document Date	Version	System Version	File Size	Uploaded by Assessing Organisation	Action
29/04/2014	24/04/2014	2	2 (current)	12 KB		<a href="#">View Uploaded File</a>
29/04/2014	23/04/2014	1	1	12 KB		<a href="#">View Uploaded File</a> <a href="#">Delete</a>

4. For New documents, go to the upload tab.



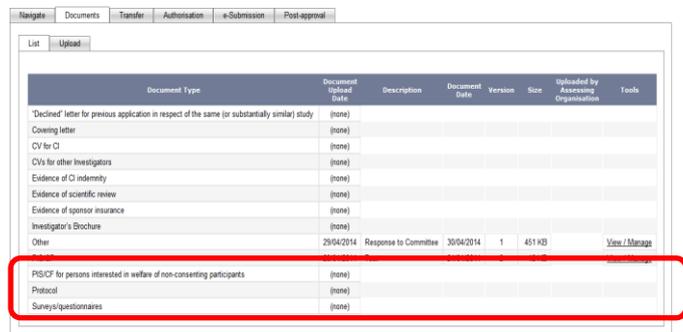
5. Select the document type. Add a version number, document date and add a description if required.

Browse your computer to find the new file and select Upload File.

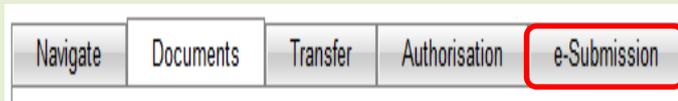


6. The new document will now be uploaded and visible on the List Tab.

**Before submitting check to see all your documents are on the List tab and are displaying the correct version and document date.**



7. Once you have uploaded all new documents or updated all existing documents click the E-Submissions tab.



8. Scroll down until you see 'Provisional Approval Response'.

This button will only be able to be used when you have received a 'Provisional Approval' letter.

**Please note:** only click submit once.

