

# Online Forms User Manual

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Version 1.1

May 2014

# I would like to...

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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).

#### Screenshots Steps 1. Go to Online Forms \$ 5 Conline Forms 4 \$ (www.ethicsform.org/nz). IN CHEATE ACCOUNT HELP e to NZ Online For You can use this site to subm Then click "Create Account" in the main menu bar. Health and Ethics Ethics 6 HEALTH Discribul Atom Manage 2. Enter your details, choose a $\diamond$ Online Forms password, and click "Register". Note that the email address you Create Account enter here will be your Title Mailing address 1 the Terrace Mr username in Online Forms. Forename Rohan Surname Murphy Organisation Ministry of Health Suburb/Tow Wellington E-mail Address (User Login) PostCode 6011 rohan\_murphy@moh.govt.nz Country New Zealand Confirm E-mail rohan murphy@moh.govt.nz 04 816 2053 Password ..... Telephone Number Confirm Password ••••• Fax 04 816 2340 Password must be at least 6 characters at least 1 of which must be a number. An email containing a web link 3. Conline Forms \$ and an activation code will be sent to the email address you have entered. Activate Account 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 <u>IT help desk</u> Once you have received the Submit ihodstiwnlfljo55jyqow3uw 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. Your account has been activated. Click here to log in.

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

Ste	ps	Screenshots
1.	Go to Online Forms (www.ethicsform.org/nz). Enter your Online Forms username (i.e., your email address) and password. Click "Submit".	<image/> <complex-block><complex-block><complex-block><complex-block><complex-block><complex-block><complex-block><complex-block></complex-block></complex-block></complex-block></complex-block></complex-block></complex-block></complex-block></complex-block>
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".	Weine Personal       Weine Market V       Vol Contract V       Vol Contract V       Vol Contract V         Vol Contract V       Vol Contract V       Vol Contract V       Vol Contract V       Vol Contract V         Vol Contract V       Vol Contract V       Vol Contract V       Vol Contract V       Vol Contract V         Vol Contract V       Vol Contract V       Vol Contract V       Vol Contract V       Vol Contract V         Vol Contract V       Vol Contract V       Vol Contract V       Vol Contract V       Vol Contract V         Vol Contract V       Vol Contract V       Vol Contract V       Vol Contract V       Vol Contract V         Vol Contract V       Vol Contract V       Vol Contract V       Vol Contract V       Vol Contract V         Vol Contract V       Vol Contract V       Vol Contract V       Vol Contract V       Vol Contract V         Contract Vol Contrat Vol Contract Vol Contract Vol Contract Vol C
4.	To log out of Online Forms at any stage, click "Logout" on the top right of the page.	Version Parameter     Version Parameter

# 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 Online Forms $\diamond$ personal contact database click on "My Contacts" in the main HOME MY PROJECT MY CONTACTS HELP CONT My Projects menu bar and choose option 🖃 🥅 Project Categorie "Add New". New Projects (17) Transfered Projects (0) Projects Requests for Authorisation Transfer Req Approved Projects (0) Old Projects (14) 2. Enter contact details and click My Contacts "Add". Your Contacts Datab Contacts that are cre Contacts New Contact Add

### **Import contacts from Outlook**

### Steps

- 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.

### Screenshots

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	New Zealand for Research       Image: Control of Use Search         HOME       MY CONTACTS       HELP       CONTROL OF Use Search         My Contacts       MY CONTACTS       HELP       CONTROL OF Use Search         My Contacts       My Contacts from Outlook       My Contacts       My Contacts         Your Contacts Database allows you to create and soure your colleagues contact details.       Contacts that are created and saved here can be inserted into any Form wherever you see the "insert contact" icon for Contacts         Contacts       Upload Outlook Contacts       Browse         Select All Deselect All       Browse         Upload File       Cancel
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".	Choose file to upload: ()       Browse         Select All Deselect All       Image: Comparison of the select All Deselect

### <u>Edit a contact</u>

### Steps

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.	HONE       MY PROJECTS       Ave on the provided of the provi					
				Arganization	éction		
			」 ■ Q P Q R S I U Y W X Y Z Position	Organisation	Action View Delete		
			IQPQRSIU⊻₩XYZ Position	Organisation	Action View Delete View Delete		
		All A B C D E E G H I J K L M D Name Ms Sarah Delgado	Administrator	Organisation Ministry of Health	Action View Delete View Delete View Delete		
		All A B C D E E G H I J K L M I Name <u>Ms Sarah Delgado</u> <u>Mr Rohan Murphy</u>	I Q E Q R S I U Y W X Y Z Position Administrator Manager	Organisation Ministry of Health Ministry of Health	Action View Delete View Delete View Delete View Delete		

### Screenshots

 Click "Edit Details".
 Enter details and click "Update" to save changes.

stacts that are created and	saved here can be inserted into any I	form wherever you see the "in	sert contact" icon 💱
Contacts Ms Sarah (	Delgado		
Title	Mo	Address	1 The Terrace
Forename	Sarah		
Sumame:	Delgado		
Position	Administrator		
Organisation:	Ministry of Health	Suburb/Town	Wellington
Department.	HDECs	Postcode	6011
Summary of qualifications	and	Country	New Zealand
Please declare any genera	4	E-mail	sarah_delgado@moh.govt.nz
competing interests		Telephone:	04 8163357
		Fax:	
		Mobile:	
		Phone(AH):	
		Pager	

### **Delete a contact**

### Steps

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.

HOME MY PROJECTS MY CON	TACTS HELP CONTACT US		
My Contacts			
'our Contacts Database allows you t	to create and store your colleagues conta	ct details.	
contacts that are created and saved	here can be inserted into any Form where	ever you see the "insert contact" icon 🕸	
Comboo to			
Contacts			
Contacts			
Filter by First Name	•		
Filter by First Name	▼ ANQPQRSIUYWXYZ		
Filter by First Name All A B C D E E G H I J K L N Name	▼ ▲NQPQRSIUVWXYZ Position	Organisation	Action
Filter by First Name All A B C D E E G H I J K L N Name	▼ ▲NQPQRSIUVWXYZ Position	Organisation	Action <u>View Delete</u>
Filter by First Name All A B C D E E G H I J K L M Name	▼ ▲NQPQRSIUVWXYZ Position	Organisation	Action View Delete View Delete
Filter by     First Name       All A B Q D E E Q H I J K L M       Name       Ms. Sarah Delgado	▼ M H Q P Q R S I U V W X Y Z Position Administrator	Organisation Ministry of Health	Action View Delete View Delete View Delete
Filter by First Name All & B & Q & E & G & H   J & L & M Massarah Delgado Mr.Rohan Murphy	▼ A N Q P Q R S I U V W X Y Z Position Administrator Manager	Organisation Ministry of Health Ministry of Health	Action View Delete View Delete View Delete View Delete

### Populate contact details into a form

### Steps



# 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.

Ste	55	Screenshots
1.	Under "My Projects" click on "Manage Categories".	Invertige         Invertige         Invertige           Invertige         Invertige         Invertige         Invertige           Invertige
2.	You will see a default folder called "New Projects" where your projects will be stored. To add a new folder, click on "Add Category".	New Zestand         Forms       Forms         Formation       Formation         HOME       MY PROJECTS       MY CONTACTS       HELP       CONTACT US       ADMIN         HOME       MY PROJECTS       MY CONTACTS       HELP       CONTACT US       ADMIN         Image: Manage Categories       Category name       Edit       Delete         Image: Mew Projects       Edit       Delete         Add Category       Move selected forms to category: New Projects       Go
3.	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.	New Zealand Online Forms for Research         HOME       MY PROJECTS       MY CONTACT IS       HELP       CONTACT US       ADMIN         HOME       MY PROJECTS       MY CONTACT IS       HELP       CONTACT US       ADMIN         Image Categories       Image Categories       Image Category       Edit       Delete         Image Mew Projects       Edit       Delete       Image Category         Image Mew Category       Edit       Delete         Add Category       Image Category       Image Category
4.	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".	NOME       MAY PROTECTS       MAY CONTACTS       HERP       CONTACTS       ADMAY         • Remage Categories

# 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

Conline Forms

Conline Forms

 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 <u>permanently</u> transfer a project to another user (refer to section 8).

Ş

Project Filter Transfer Manage Email Notifications

I'd like to submit. (e) a new application to an HDEC ms Wahsha , varsion 1.2 Build 23718

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- 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).

Mr Rohan Hurphy My Account | Logod

Ar Rohan Murphy

Mr Rohan Murphy 07/09/2012 15 58 14

### 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 <u>temporarily</u> 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).

New Zealand Online Forms for Research	\$ \$	 	Ŷ	¢,	$\langle \rangle$	
HOME MY PROJECTS MY CONTACTS H	ELP CONTACT US					
Not named yet						
Form Type: HDEC Reference: None Form Section: N/A Signatures: None						
My Project	Navigate Click <u>here</u> to Navigate by	Documents b begin completing question numbe	Transfer g/reviewing the fe rs v	Authorisation	e-Submission	Post-approval c section
	SCREEN		SECTIO	N		
	RESEARCH	AND STUDY TYP	PE			A B C

- 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).

### Steps

# 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

1.	To fill out the form – open the project and go to the "Navigate" tab. Click <u>here</u> to begin completing/reviewing the form or click on the question number for a specific section.	Provide Version Provide Version V
2.	This will open up the form.	HOME MY PROJECTS MY CONTACTS HELP CONTACT US
	To return to the view above click on the "Navigate" icon.	Form Type: MDEC Reference: None Form Section: RESEARCH AND STUDY TYPE Signatures: None
	To move through the form, click on the previous and next arrows, or on the page numbers in the centre of the screen.	Page: 1 of 88       17 18 20 23 24 29 36 37 48       Seven Undo Previous Net         Health and disability research         These screening questions will help determine whether HDEC review is required for your study. They are based on the rules contained in section three of the Standard Operating Procedures for Health and Disability Ethics Committees.         Don't hesitate to <u>contact us</u> if you'd like help answering these questions, or any others in the HDEC form.
	To print a PDF copy of your form, click "Print Draft".	A. Health and disability research         Will your study aim to improve health and independence outcomes?         ○ Yes         ○ No
	To mark a page as incomplete, click "Incomplete".	Page: 1 of 88 NZ HDEC Form Save Under Previous Net

### **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.

Taripita Driet Droppida	Page: 10 of 68 123455791011	Sava Undo Prévious Test	Terupate Print Docempiles	Page 10 of 88 (Read Only) 122455791011	Previous Net
	HDEC REVIEW			HDEC REVIEW	
HDEC Review Type.			HDEC Review Type.		
0. The question below will determine	te the review pathway appropriate to your study.		O. The question below will determine th	e review pathway appropriate to your study.	
Does your study involve any of the fi	following? (select all that apply)		Does your study involve any of the follo	oing? (select all that apply)	
a new medicine			Da new medicine		
an approved medicine being use	ed for a new indication or through a new mode of administration		an approved medicine being used fi	or a new indication or through a new mode of administration	
a medical device that is or woul Administration (TGA)	Id be classified as a <u>class IIb, class III, or active implantable medical d</u>	evice by the Therapeutic Goods	a medical device that is or would b Administration (TGA)	e classified as a <u>class IIb. class III. or active implantable medical device</u> by	the Therapeutic Goods
a new surgical intervention			a new surgical intervention		
cone or more participants who wi	ill not have given informed consent to participate		one or more participants who will n	ot have given informed consent to participate	
cone or more participants who an	re vulnerable (that is, who have a restricted ability to make independent	decisions about their participation)	one or more participants who are w	Inerable (that is, who have a restricted ability to make independent decision	ns about their participation)
standard treatment being withhe	eld from one or more participants		standard treatment being withheld f	rom one or more participants	
the storage, preservation or use	of human tissue without consent.		the storage, preservation or use of	numan tissue without consent.	
[2] none			none		
Exp. Your study will be reviewed by the Ethics Committees.	expedited review pathway described at section 6 of the <u>Standard Op</u>	erating Procedures for Health and Disability	Full. Your study will be reviewed by the ful Committees.	I review pathway described at section 5 of the <u>Standard Operating Proced</u> .	ures for Health and Disability Ethics
Tavigate avec thrompiete	Page 10 of 88 NZ HDEC Form	Sava Undo Previous Neet	A a fill	Page: 10 of 88 (Read Only) NZ HDEC Form	O O Previous Need

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.



# 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 Online Forms 3 R Hr Rohan "Documents" tab. tot named yet Note that this *form-level* tab will only be visible when the form - HOEC 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 Online Forms 3 4 the document type you wish to upload from the drop-down list. Enter a version number, date and - (C H Navigate Documents Transfer Authorisation e-Subr sion Pest-approval description for the document. - HDEC The details you enter here will Evidence of Cl indemnity Document date: 01/06/2012 10 appear in the letters you receive of indemnity for Dr We (NFS certificate) from HDECs/SCOTT. Browse Click "browse" to find the document on your local drive, Uplo then click "Upload File". 3. This will take you back to the 5 Online Forms 0 4 "List" sub-tab, which will now display the document you have NDE Nore NIA Nore just uploaded. Navigate D Hr Proje List U Return to step 2 to upload another document. View / Manage Click "View / Manage" to view or delete the document, or to inone inone replace it with an updated version.

### Screenshots

4.	Note that if you upload a new	Online Forms	\$ \$	Nº x	X	Ì		â	fr Rohan Hurphy (eart@moh.govt.nz) Iv Account   Legout
	version of the same document,	HOME MY PROBETS MY CONTRA	CTS HEAP CONTACTUS						
	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.	Not named yet     Form Type: HOEC     Raterionical Mone     Form Saction MR     Signifuse: Mone						Datus Conar Cruated On Last Modifi	// Piopiess <u>Mr Robert Months</u> 11/06/2012 18:02 23 ed On: 11/06/2012 17:12:10
		10 C Hy Project	Nesignie Documer	ts Transfer Au	thorisation e-S	ubmission Past-appr	al		
		- 1992	List Upload						
			Document Type Version	(Evidence 23e (11)		Document date (11.96-201			
			Description:	Tviden Strang	elove (392 cert	for De Lficate)			
			Choose file to upload	fields Version and Descri	ption will be visible b	y The assessing organisatio	ice <b>ste</b> ]		
			+ History						
			Uphood Date:	Document Date	Version	System Version	File Size	Upfoaded by Assessing Organisation	Action
			14/09/2012	01/06/2012	13e(i)	z (conerc) 1	352 KB 61 KB		View Upstaded File View Upstaded File Delete

### **Mandatory Documents**

Steps

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	Yes (if "yes" at	-
participants	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.

Open the project and click on the "Transfer Form Temporarily" tab.	medium size study     Form Type: HDEC     Reference: 13/NZTsat/36     Form Section: N/A     Signatures: This form is attached with electronic sign	natures, any changes to the form will invalidate the signatures.
Please make sure the form is selected on the	G C My Project You are here C HDEC	Navigate         Documents         Transfer Form Temporarily         Authorisation         e-Submission         Post-approval           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 transferred a form to a cellowater, this will be a temporary transfer cely.         Post-approval
left of the screen.		Recipient's e-mail: joe .blogs@sessach.co.nz
Enter the recipient's email and click "Transfer		Hi Joe please accept this transfer.
to User".		>> Iransfer to User <<  Transfered From Transfered To Ti
Please note that the		No Transfers to display
recipient of a transferred form must have an		
account with Online	SOW4 UAT 7	
Forms first.	Form Type: Post-approval Reference: 14/NZTest/4/AM02 Form Section: IVA	
Automated emails are generated advising the recipient and owner of the actions taken at various stages of the transfer.	Post-aproval - 395 Post-aproval - 393 Post-aproval - 391 Post-aproval - 392 Post-aproval - 393 Post-aproval - 393 Post-aproval - 395 Post-aproval - 396 Post-aproval - 396 Post-aproval - 396 Post-aproval - 396 Post-aproval - 396 Post-aproval - 396 Post-aproval - 396	Navigate         Documents         Transfer Form Temporarity         e-Submission           Please enter the recipient's e-mail address in the box below         In order to transfer the form on a e-mail address in the recipient must have an account on the online form system.           This option is for transfer the form system         This will be a temporary transfer only.           Recipient's e-mail:         Include personal message:         Include personal message:           >>:         >>:
		Transfered From Transfered To

- 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

1.

### Screenshots

Page 19 of 45

Ste	os	Screenshots		
2.	You will have access to a read-only version of the form while it is in the	Prior Type: ADEC Informa: (4A/27ea/23) Trans Societies: Market and a strander with electronic algorithms, any changes to the form of municipal the scienterize Signature: The form is attached with electronic algorithms, any changes to the form of municipal the scienterize Signature: The science of the science of the form of municipal the scienterize Signature: The science of	Status: Owner: Created On: Last Modified O	Transferrad Out: Submitted (automission code) = PEMUNG << M Gordon Chaming 19/03/2014 13:19:27 = 01/05/2014 13:13:02
	control of another user. You can retrieve the transferred form at any time by clicking on the	This form has been transformed in granther start its notices the form from this sour's account (the user will no longer have accounts the form), click the Starte hickels presend message  This form has been transformed in a second start in the source of	ve Form' button. Transfet 01/05/2014 i	Date. 1/13 PM
	The transfer actions are listed in the transfer history.			

### Transfer a project permanently

You can transfer a <u>project</u> 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

1.	Open the project and click on the "Transfer" tab.	medium size study     Form Type:     Reference: 13/NZTest/26     Form Section: N/A				
	Note that this <i>project-level</i> 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.	Signatures: None		Project Filter Transfer Pro Please enter the recipient's e-mi In order to transfer the form to a The option is for transferme of a Recipient's e-mail: Include personal message: () >> Transfer To User No Transfers to display	yject Ownership Manage all adoress in the tox below ne mail address the recipient n e collaborator.	Email Notifications must have an account on the o Transferred To
2.	Enter the recipient's email and click "Transfer to User".	The part of the pa	Project Filter Transfer Project On Please enter the recipiert's e-mail addre in order to transfer the ferm to an This option is for transfering a form to a Recipiert's e-mail:	membp Managa Email Notifications ess in the lock below address the recipient must have an account on the online collaborator.	form system.	
	Automated emails are generated advising the recipient and owner of the actions taken at various stages of the transfer.		Include personal message: (1)	Transferred To M. Gentor Darley M. Graden Darley M. M. Graden Darley	Transfer Action Persanethy Transferd Frank-Received Requested Transfer	Transfer Date 2103/0214 02 22 PM 2103/0214 02 19 PM 2103/214 03 15 PM
	Please note that the recipient of a transferred form must have an account with Online Forms first.					

Steps		Screenshots	
3.	Once the recipient has accepted the form, click on "Permanently transfer this form".	Project Filter       Transfer         This form has been transferred to another user. To retrieve the include personal message: (?)         >> Retrieve Project <<         To permanently transfer this form to another user, click the 'finclude personal message: (?)         >> Permanently transfer this form <         Include personal message: (?)         >> Permanently transfer this form <         Include personal message: (?)         >> Permanently transfer this form <         Mis Sarah Delgado         Mis Sarah Delgado	form from this user's account (the user will no longer have access to the form), click the Retrieve F          Message from webpage         Image: Accept and the permanently transfer this project to another of the project and you will not be able to retrieve it.         Image: Accept and the permanently transfer the project and you will not be able to retrieve it.         Image: Accept and the permanently transfer the project and you will not be able to retrieve it.         Image: Accept and the permanently transfer the project and you will not be able to retrieve it.         Image: Accept and the permanently transfer the project and you will not be able to retrieve it.         Image: Accept and the permanently transfer the project and you will not be able to retrieve it.         Image: Accept and the permanently transfer the project and you will not be able to retrieve it.         Image: Accept and the permanently transfer the project and you will not be able to retrieve it.         Image: Accept and the permanently transfer the project and you will not be able to retrieve it.         Image: Accept and the permanently transfer the project and you will not be able to retrieve it.         Image: Accept and the permanently transfer the project and you will not be able to retrieve it.         Image: Accept and the permanently transfer the project and you will not be able to retrieve it.         Image: Accept and the permanently transfer the project and you will not be able to retrieve it.         Image: Accept and the permanently transfer the permanently transfer the permanently transfer the permanently transfer the permanently transfe
4.	Click OK.	Project Filter Transfer This form has been transferred to another user. To retrieve the	form from this user's account (the user will no longer have access to the form), click the 'Retrieve F
	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	Include personal message: ①  >> Retrieve Project <<  To permanently transfer this form to another user, click the T Include personal message: ①  >> Permanently transfere this form <<  Transfered From	Message from webpage Or and the permanently transfer this project to another Or ming: estecting OK will permanently transfer the project and you Or Cancel
	projects.	Ms Sarah Delgado Ms Sarah Delgado	Patriarch GI Joe Form Accepted Patriarch GI Joe Requested Transfer

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

### Steps

1.	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.	New Zesland           Online Forms           During Projects           My Projects           My Projects           Create New Project           P           Requests for Authorisation           Transfer Requests           Manage Projects (14)           Manage Categories	HELP CONTACT US  CONTACT CONTA	(1) Transfer Requests	
2.	The "Owner" tab keeps a history of all forms that you have either temporarily or permanently transferred to other users.	HE CORRECTOR  CORRECTOR  Properts for Addression (1) = Toronfor Reports)  Properts for Addression (1) = Toronfor Reports)  Properts Toronfor Toronfor  Properts Toronfor Toronfor  Properts Toronfor  Prope	Transforment to Detacats.Cl.Am M. Thotas Manatay M. Thatas.Manatay Transforment & Transforment &	Frankrewstein Perneuelty Tasteleet Pern Russel Frank Russel Pern Russel Pern Russel	7946017 192 2560017 192 4477017 198 1956017 1946 1956017 1946 1956017 1946 4560217 1947

Steps		Screenshots
3.	The "Recipient" tab displays forms transferred to you by other users. To accept a pending transfer - click on "Accept Application".	HE         CORACTOR           Physics         Resets for Addinance (E)           Physics         Resets for Addinance (E)           Vector Physics         Resets for Addinance (E)
4.	To return a form to its owner go	HOME MY PROJECTS MY CONTACTS HELP CONTACT US
	into the form and click the "Transfer" tab.	Not named yet
		Form Type: MDF Reference: None Form Section: N/A
	Then click the "Send back"	Signatures: None
	button.	Image: Second seco
	Once returned the project will	Include personal message: 🕖 🔺
	disappear from your existing	×
	projects.	Send Back Application To Owner >> Send Back <<

#### **Check for Completeness** 10.

to submit".

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 Open the project and click on the 1. $\mathbf{i}$ Ý Online Forms $\langle \! \! \rangle$ "e-Submission" tab. IOME MY PROJECTS Note that this *form-level* tab will only be visible when the form Navigate Documents Transfer Author HDEC type (HDEC, SCOTT, or MDF) is Click here to begin Click here to begin completing/revie Navigate by question numbers 🛩 selected in the project tree at the SCREENING QUESTIONNAIRE left of the screen. RESEARCH AND STUDY TYPE A B C D-G H MAIN CRITERIA EXEMPTIONS INCLUSIONS <u>На-Нс</u> HDEC REVIE HDEC - (A) Administrative section a.1 Title and summ a.1.1-a.1.6 a.2 Object, phase and desig a.2.1 0.2 a.3 Investigators a.4 Primary conta a.3.1-a.3.1.1 a.3.2-a.3.2.1 a.4.1 a.5 Sponsor a.5.1 0/ a.6 Localities and part a.6.1-a.6.2 a.6.3-a.6.3.2 Click on "Check for 2. Navigate Documents Transfer Authorisation e-Submission Post-approval Completeness" to identify Check for Com missing information from your 055 application. Any outstanding items will be listed. You must then go back to the relevant tabs to complete all mandatory questions and upload Proceed to Submise n/History documents before requesting his section allows you to submit an electronic sub too/ buttoo will also display the Sul Proceed to Submission/History authorisations. 3. Once the application is complete, **\$**2 V 2

Online Forms the check for completeness will OME MY PR say "Form is complete and ready Test application Navigate Documents Transfer Authorisation e-Submission Post Check for Completeness You should now obtain Check For Completeness authorisations. Proceed to Submission/History his section allows you to submit an elec Recall Submis You may only recall a submitted ap ication if the application is either per fing registration or marked as invalid sian

# 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.



lathorisations			
fou may need to obtain authorizations from other Online Forma users before submitting your application, or before beginning your st	udy at a locality.		
fo request authorisation, simply click "request" and enter the authoriser's usemame (which will also be their email address). The aut	horiser will receive an en	mail alerting them to this request, and	asking them to log in to Online Forms to respond to
Sets have for details of occurrances to occur in resourcion authorization from district health bearts, and some other emerications			
and the second			
utromation types will only be enabled once relevant questions have suburnation types			
he following electronic authorisations are available for this form ty Enter e-mail address of the person from whom you wish to			
Vet authorisation report obtain an electronic authorisation and press 'Send Request'. A amailed report will be send to the user	6		
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The second secon	betreupent requested requested requested		Report Sign Report Sign Report Sign Report Sign
Prov	requested betreupers requested requested betreupers ther		Report Sign Report Sign Report Sign Report Sign Report Sign

you will	Electronic Authorisation Request Accepted Okline Forms to Mit Sterk Dogedo				
	Dear Hs Sarah Delgado				
	Patriarch 01 Joe has opened your request to give electronic authorisation as Locality for Project "Test application". The requested form section is now under review				
5 01	If you meed further help or assistance please e-mail us at: helpdesk@infometica.met or phone 0000 634 759 or +64 4 974 7675.				
	Regards BBC-BCUT Form BC-gar//athiesform.org/an				
	This is a system-generated e-wall. Flease do not reply.				
	Electronic Authorisation Given Online Forms to: Ms Sarah Delgado				
	Dear Hs Sarah Delgado				
	Patriarch GI Joe has given electronic authorisation as Locality for Project "Test application".				
	If you need further help or assistance please e-mail us at: helpdesk@infonetica.net or phone 0800 634 758 or +64 4 974 7675.				
	Pagnit HDr2-Scott Form https://ethicsform.org/nz				
	This is a system-generated e-mail. Please do not reply.				
	Chazed on: 1400/2012 13 ket b2				
given, a	signatures, any charges to the form will invalidate the signatures. Last Modified On: 03/09/2012 12:12:49				
	Naxigate Documents Transfer Authorisation e-Submission Post-approval				

 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.

ignatures, any changes to the form will inva	ildate the signatures.		Last Mod	dified On: 03/09/2012 12:12:49
Navigate Documents Transfe	er Authorisation e-Submission	Post-approval		
Authorisations				
You may need to obtain authorisations fr	iom other Online Forms users before submitting	your application, or before beginning your stu	dy at a locality.	
To request authorisation, simply click "re	equest" and enter the authoriser's username (w	hich will also be their email address). The auth	oriser will receive an email alerting them to this request,	and asking them to log in to Online Forms to
Click here for details of usernames to us	e 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 ar	re available for this form type: 🕖			
Print authorisation report				
Status	Authorisation Type	Status	Signing User	Action
	Sponsor	Not requested		Request Sign
Image: A start of the start	Locality	Signed and valid	Ms Sarah Delgado	Revoke
	Locality	Not requested		Request Sign
	Other	Not requested		Request Sign
ectronic Authorisations History				
Date	Authorisation Type		Action	
18/09/2012 15:19 PM	Locality		Authorisation given by Ms Sarah De	igado
18/09/2012 15:18 PM	Locality		Request for authorisation recalled by Ms S	arah Delgado

Steps		Screenshots				
5.	You can <b>recall</b> an authorisation request by clicking the "Recall" button.	Integrate         Decomment         Transfer         Adversation         Rest appoint           Adversations         Participation         Adversation         Section adversations from other Online Forms users before submitting your application, or before beginning your study at is locality.           The sequent adversations from other Online Forms users before submitting your application, or before beginning your study at is locality.         The sequent adversations from the Online Form Submit of the Section adversations are used adversations are used adversations.           Chick happed wheat of exercises to a requestion thate been research in the form.         The following doors: adversations are available for the time type:           The following doors: adversations are available for the time type:         If adversation type:         If adversations           Details adversation to adversation table form:         If adversation type:         If adversations         If adversation type:				
		Electronic Authorisations History	Sponsor Sponsor Locality Other Authorisation Type	Requested Not requested Not requested Not requested	Ma Emma Pitelan	Recal Request Sign Request Sign
6.	You can also <b>revoke</b> an authorisation that has already been granted by clicking the "Revoke" button.	2010/2012 13 42 PM	Sponsor late the signatures.		Request for authorisation sent by Ms Sarah Delgado	to Ma Emma Phelan I um reconstruit 7 talen ag diffied On: 03/09/2012 12:12:49
		Paragen Decements Transfer Authoritatione Yau may need to datan authorisations flo To sequent authorisation, simply click "reg Click <u>http:</u> for details of usernames to use Authorisation types will wrigh be analised or The Minimige electronic authorisations are <u>Plot authorisation mood</u>	Autorisation e-Submission in other Online Forms users before submittin vest" and enter the authoriser's username ( in requesting authorisation from district heat on existent questions have been answered inabilities for this form type: (2)	Part appresat in your application, or before beginning your stu- inhich will also be their email address). The auth th boards, and some other organisations. in the flow.	by at a locality,	, and asking them to log in to Online Forms to
		Status	Authorisation Type	Status	Signing User	Action
			Sponsor	Not requested		Reguest Sign
		A	Locality	Signed and valid	Ms Sarah Delgado	Revoke
			Locality	Not requested		Request Sign
			Other	Not requested		Request Sign
		Electronic Authorisations History				
		Date	Authorisation Type		Action	
		18/09/2012 15:19 PM	Locality		Authorisation given by Ms Sarah D	Delgado
		18/09/2012 15:18 PM	Locality		Request for authorisation recalled by Ms	Sarah Delgado

### How do I authorise my own study?

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

1	If you need to putherice your	HOME MY PRONCTS MY CONTACTS H	R# CONTACT VS				
⊥.	If you need to authorise your	Not named yet					
	own study you can do so by	Norm Type: MOEC Indexence: None Form Section: NON Signature: None				Status Daner Created On Last Modifie	In Plagress Ms.Soch.Delgads x 2409/2012 10:09:29 wd Circ. 04/10/2012 14:59:15
	clicking the "Sign" button.	in State	Import         Descent         Automation         Mathematic           Marchandbar         Marchandbar <td>asan Pasa agenosi subrithey your exploration, or before legatesing or amounts photch will also be three rend address; Th and chadth Seath, and some other arganizations, researed in the form.</td> <td>ur stely at a locality. e activitar will receive an email a Shakes</td> <td>lefting them to this request, an</td> <td>d aving them to bg in to Obline Forms to no</td>	asan Pasa agenosi subrithey your exploration, or before legatesing or amounts photch will also be three rend address; Th and chadth Seath, and some other arganizations, researed in the form.	ur stely at a locality. e activitar will receive an email a Shakes	lefting them to this request, an	d aving them to bg in to Obline Forms to no
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			Other Investig	ptor	Not requested		Request Sign
			Primary Contact	Person	Not requested		Request Figs
			Sporeor		Not requested		Request Sign
			Third party performing sponsor's	duties/functions in N2	Not requested		Requist Sign
			Locality		Not requested		Requiret Sign
			Other		Not requested		Request Sign
2.	Enter your username and password and click "Sign".	Advantational Advantations Advantation of Advantations Vour may need to Oddam authorisad To request authorisation, singly of Click base for details of seremene Authorisation types will anyly be en The following electronic authorisation Post authorisation, seport	Autorise (Organization Rame or Individual Vision)	where beginning your study at a locality email address). The authoriser will rece ber organisations.	r. ive an email alerting them to	this request, and asking	(Nem to log in to Oxfore Forms to rea
		Status	Authorisation only):	Status	Signing U	ser	Action
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			Locasty	rvot requested			Nequeat Sign
			Other	Not requested	1		Request Sign

### <u>I've been asked to authorise a study – what do I do?</u>

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

1.	If you have been asked to authorise a study, you will receive an email with a link to log in to Online Forms.	Online Forms Electronic Authorisation Request           Online Forms to Ms Sereh Delgado           Pear Hs Sarah Delgado           Hr Rohan Burphy is requesting that you give electronic authorisation as Sponsor for Project "Testing".           Personal message:           Please authorise my study.           Please login at https://thiosform.org/nt to accept this request.           If you need further help or assistance please e-mail us ati helpdask@infonetica.net or phone 0800 634 758 or +64 4 974 7675.           Regards           MbC-BOOT Form           https://thiosform.org/nr           This is a system-generated e-mail. Please do not reply.
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.	Control Forms         Contro Forms         Control Forms         Control F
3.	Click the "Review Requested Form" button to check the information in the form in a read-only format.	Institute       Mit Construction       NEW       Contract in 5         Institute       Institute       Institute       Institute         Institute       Institute       Institute       Institute <t< td=""></t<>
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.	HOME       MY PROJECTS       MY CONTACTS       HELP       CONTACT US         I TESTING         Form Type:       HECC         Reference:       None         Form Section:       RESEARCH AND STUDY TYPE         Signatures:       None         Iterings       Image:       1 of 88 (Read Only)         Iterings       Image:       1 of 88 (Read Only)         Itering and the complete       Image:       1 of 88 (Read Only)         Itering and the complete       Image:       Image:       1 of 88 (Read Only)         Itering and the complete       Image:       Image: <td< td=""></td<>

### Screenshots

5.	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).	Incl         United Total         United Total <thunited th="" total<="">         United Total</thunited>	2         CONTACTUE           Integrate         Documents         Autom           Electricic automatices representatives         Autom           Anapestative Automatices representatives         Automatices           Anapestative Automatices representatives         Automatices           Averagetative Automatices representatives         Automatices           Averagetative Automatices representatives         Automatices           Automatices from         Report	Advances Pestagenet A Color Ma A Color Ma Marcol Marcol Marcol Marcol Marcol Marcol Marcol Song the Taxas Reputed Form Tubes col and free on Marcolant submerst to Advance the fee or and free on Marcolant submerst to Advance the fee systep instructions on electronic adformations. Request	Biofus One Crea Line Electrons autorisation replaces els signatures
6.	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.	eeder Unrinders Unricontilicts ■ Testing Horm Type / ACEC Retrieve None Trans Sates, AA Spatness, None Si @ In Freed III @ In Freed	CONTACT US     CONTACT US     Image      Contract Us     Contract     Contract Us     Contract Us     Contract     Contract Us     Contract     Contrac	Autorian fram Please enter you reservance and passoord and the details relevant to the autoritation. Uservance Passoord Passoord Authoriser (Organization Name or Individual's Flaney) Lead Investigation() at Locality (Net Reld is for Locality Autoriser or you for the conterport of the Conterport Lead Investigation() at Locality (Net Reld is for Locality Autoriser or you for Locality	1 Sponsor Dectoric autorization replaces int signatures. m.
	Then click the "Sign" button.				

Steps

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

HOME MY PROJECTS MY CONT	IACTS HELP CONTACT US	
My Projects		
Project Categories     Mexe Projects (17)     Transferred Projects (1)     Approved Projects (1)     Oid Projects (14)	Costo fee Privat     Poperation     Appendix     Appendix     Costo fee Private     Costo     Costo	
lanage Categories	Short Title	Form Type Request
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	· Testing	HOEC Mr. Rahan Murphy
	iii Bab	HOEC Mr. Rahan Murphy
	Bit named yet	HOEC Ms. Sarah Delgad
	Extension perityping	HOEC Patriach GLIce
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# 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 Open the project and click on the 1. $\mathbf{i}$ Ý Online Forms $\langle \! \! \rangle$ "e-Submission" tab. IOME MY PROJECTS M None N/A None Note that this *form-level* tab will only be visible when the form Navigate Documents Transfer Authorisation e-Si HDEC Click here to begin completing/revie Navigate by question numbers 🛩 type (HDEC, SCOTT, or MDF) is selected in the project tree at the SCREENING QUESTIONNAIRE left of the screen. RESEARCH AND STUDY TYPE A B C D-G H MAIN CRITERIA EXEMPTIONS INCLUSIONS На-Нс HDEC REVIE HDEC - (A) Administrative section a.1 Title and summary a.1.1-a.1.6 a.2 Object, phase and desig a.2.1 0.2 a.3 Investigators a.4 Primary conta a.3.1-a.3.1.1 a.3.2-a.3.2.1 a.4.1 a.5 Sponsor a.5.1 0.5 a.6 Localities and participant a.6.1-a.6.2 a.6.3-a.6.3.2 Click "Check for Completeness". 2. Ś Online Forms \$ 4 Once the application is complete, HDEC None n: N/A the check for completeness will a 🛃 My Project say "Form is complete and ready Navigate Documents Transfer Author ion e-Su ion Post-a Check for Com pleteness pletness must be perfor to submit". eck for c Check For Completeness rm is complete, and ready to submit. Proceed to Submission/History Recall Submi Pacal Submission Click "Proceed to 3. Online Forms ×? Ŷ V 2 Submission/History", and then click on the "Submit to HDEC" None NA button that appears below. My Projec Navigate Documents Transfer Authorisation e-Submission Post-app Check for C r Completeness and ready to submit d to Submission/History

### **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).

Form Type: HDEC					38	shir	Subriasion Code: N2/1/034
Raference: 12/NZTRet/10 Form Section: N/A Signatures: This form is attached	vith electronic agredures, any i	charges to the form will invalidate the signals			0	eated Chi. at Modified Chi	24/06/2012 14:53 22 24/06/2012 15:03:55
in C My Project	Nergete	Descreets Transfer Adheses	ation e-Submission Past-approal				
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### 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.

### Page 30 of 45

### Steps

# **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

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).	Integer         Oncentors         Automatic         Oncentor           Code AC Completeness         Code activation of the performed each time you submit as application. Once all mandatory questions, documents and automations have been completed, you may then proceed to submission.           Code af or Completeness         Image: Code activation of the performed each time you submit as application. Once all mandatory questions, documents and automations have been completed, you may then proceed to submission.           Code of the Completeness         Image: Code activation of the Code activation of Code activatio Code activation of Code activation of Code activati
2.	The submission history table will allow you to monitor the progress of your application.	Research Schembelweitherup           Backenseiner Gebenseinen, Olicologi für Prüssent für Budmissen-Nelaziry habten und das digslig für Budmissen Heinry.           Backenseiner Gebenseinen, Olicologi für Prüssent für Budmissen-Nelaziry habten und das digslig für Budmissen Heinry.           Backenseiner Gebenseinen, Olicologi für Prüssent für Budmissen-Nelaziry habten und das digslig für Budmissen Heinry.           Backenseiner Gebenseinen, Olicologi für Prüssent für Budmissen-Nelaziry Heinry.           Backenseiner Gebenseinen, Steffent           Backenseiner Gebensteinen Backenseinen Gebensteinen Gebensteinen Gebensteinen Backenseinen Gebensteinen Gebenstei
3.	Letters from the HDECs can be downloaded from the documents table.	Stream Allows you to advect and advectories advectories to Budinesses Malerary holds will allow digitity the Budinesses Malerary A

#### **Recall an application submitted for HDEC review** 14.

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 or on 0800 4 ETHICS.

### **Steps**

### **Screenshots**

- Open the project and click on the 1. Online Forms  $\langle \rangle$ "e-Submission" tab. Note that this *form-level* tab will Test application HDE only be visible when the form None N/A None type (HDEC, SCOTT, or MDF) is Navigate Documents Transfer Authorise HDEC selected in the project tree at the Click here to begin completing/reviewing igate by question numbers 💌 left of the screen. SCREENING QUESTIONNAIRE MAIN CRITERIA EXEMPTIONS INCLUSIONS HDEC REA HDEC - (A) Administra a.1 Title and s a.2 Object, phase and
   a.3 Investigators a.4 Primary contact a.5 Sponsor
- Once in the e-submission tab 2. click the "Recall Submission" button at the bottom of the page.

	allows you to submit an electronic submission	<ol> <li>Clicking the 'Proceed to Submission'History' button</li> </ol>	vill also display the Submission	n History.	
Pro	ocead to Submission/History				
	Submission Code	Submission Date	POF	Submission Statu	8
	NZ/1/D3A0012	24/08/2012 15:06	Generate PDF	Application clock started 24/08/2012 00:00:00	
			History		
		Ste	tus		
Αρρ	lication clock started 24/08/2012 00:00:00				24/08
Арр	fication marked as valid				24/08
Αρρ	Reation registered by review body - awaiting va	Idation: Northern A Health and Disability Ethics Comm	ittee and 12/NTA/25		24/08
Арр	lication submitted to Northern A Health and Dr	sability Ethics Committee for review on 12/09/2012 01:	0.00 pending registration by re	mew body	24/08
	Nama	Description	Documents	Document Date	
NZ/1	1/D3A0012	Form Submis	sion	DOLEMMENT DATE	
Man	nbers xisx			23/08/2012	
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a.1.1-a.1.6

<u>a.2.1</u> a.3.1-a.3.1.1 a.3.2-a.3.2.1

8.4.1

a.5.1 0.5.2 0.5.8-0.5. a.6.1-a.6.2

# 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 Open the project and click on the 1. \$° \_> Ý A Hr Online Forms $\langle \rangle$ "Manage" tab. ed vet Note that this *project-level* tab will only be visible when "My Project Filter Transfer Project" is selected in the project tree at the left of the screen. Please note that docu nts will not be dunlicate cate associated Post Approval Form(s) Duplicate Project Delete Project To **delete** the project, click 2. Online Forms Ŷ S) 0 2 "Delete Project". lot named yet A pop-up window will appear. tion: N/A Click "OK" to delete the project 🗉 💭 My Project Project Filter Transfer Manage Email Notifications permanently. 2) lion dunlinate apponiated Post An OK Cano Once the project has been ect deleted you will not be able to retrieve it. To **duplicate** the project, click 3. Online Forms 🔒 Hri \$ "Duplicate Project". IOME MY PRO If the project includes post-Not named yet approval forms, and you'd like to duplicate these too, make sure My Project ect Filter Transfer Manage Email Notifications that the check box is ticked beforehand. Otherwise, leave it unchecked. A pop-up window will appear. Click "OK" to duplicate the project. Click on "Existing Projects" in the 4. Online Forms 4 "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 Not named yet In Progress In Progress Not named yet HDEC 11/09/2012 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.

Ste	ps	Screenshots
1.	Open the project and click on the "Email Notifications" tab. Note that this <i>project-level</i> tab will only be visible when "My Project" is selected in the project tree at the left of the screen.	HOME       MY PROJECTS       MY CONTACTS       HELP       CONTACT US <ul> <li>Not named yet</li> <li>Form Section: WA</li> <li>Signatures:</li> <li>Nore</li> <li>Project Filter</li> <li>Transfer</li> <li>Manage</li> <li>Email Notifications</li> <li>Please enter recipient's email address in the box bolow. This option is for sending email notifications releasing to the project status and committee correspondence</li> <li>I Add Recipient</li> <li>Email Addresses to be notified</li> <li>Ramove</li> </ul>
2.	Enter the email address of the person who you wish to receive email notifications. Click "Add recipient".	HOME       MY PROJECTS       MY CONTACTS       HELP       CONTACT US         • Not named yet       -
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".	HOME       MY PROJECTS       MY CONTACTS       HELP       CONTACT US         • Not named yet       Form Type:       Reference:       None         Form Stores       None       Signatures:       None         Form Stores       None       Project Filter       Transfer       Manage       Email Notifications         Image: The store of the project store of the project state and committee correspondence       Add Nacpoint       Email Addresses to be notified         Image: The store of the project store of the project state and committee correspondence       Add Nacpoint       Email Addresses to be notified         Image: Data       Image: Bood@mile gov.uk       Image: Bood@mile gov.uk       Remove

### 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 <u>admin@ethics.health.govt.nz</u>.

# **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.



 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 <u>identical</u> to what we have on file (e.g. MEC/01/01/01).

5. 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.

6. 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.



Navigate Documents Trans	fe Authorisation e-Submission	Post-approval	Email Notifications							
Authorisations										
Yeu 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 authorise's usemame (which will also be their email address). The authoriser will receive an email aleting them to this request, and asking them to log in to Orline Forms to respond to it.										
Click here for details of usemames to a	Click have for details of usemames to use in requesting authorisation from district health boards, and some other organisations.									
Authorisation types will only be enabled	I once relevant questions have been answ	red in the form.								
The following electronic authorisations	ere available for this form type: 🕢									
Print authorisation report										
Status	Authorisation Typ			Status	Signing User	Action				
	Co-ordinating Investig	itor		Not requested		Request				
	Primary Contact Per	on		Not requested		Request Sign				
	Other Investigator			Not requested		Request Sign				
	Spansor			Not requested		Request Sign				
	Third party performing sponsor's dutie	s or functions in NZ		Not requested		Request Sign				
	Locality			Not requested		Request Sign				
	Other			Not requested		Request Sign				



Navigate	Documents Transfer Authori	ation e-Submission Post-approval		
Check for Co	empleteness			
A check for c	ompletness must be performed each time	you submit an application. Once all mandatory ques	tions, documents and authorisations	have been completed, you may then proceed to submission.
Check	k For Completeness			
Proceed to S	Submission/History			
This section a	ellows you to submit an electronic submis	ion. Clicking the 'Proceed to Submission'History' bu	tton will also display the Submission	History.
Proc	ceed to Submission/History			
	Submission Code	Submission Date	POF	Submission Status
	NZ/1/D3A0012	24/08/2012 15:06	Generate PDF	Application clock started 24/08/2012 00:00:00

# 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 <u>Standard Operating Procedures</u>, 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
<ul> <li>Significant amendments are required to be submitted for HDEC review.</li> <li>Examples of these include: <ul> <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> </ul> </li> </ul>	<ul> <li>MINOR AMENDMENTS</li> <li>Minor amendments are not required to be submitted for HDEC review.</li> <li>Examples of these include: <ul> <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</li> </ul> </li> </ul>
<ul> <li>the application for approval.</li> <li>Notification of urgent safety measures taken to protect participants from a significant, immediate hazard to their hoalth and safety.</li> </ul>	<ul> <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> </ul>
<ul> <li>Temporary halts to the study due to safety concerns.</li> <li>Substantial protocol deviations.</li> </ul>	- Addition of a new site.

- Early termination of a study.

### How to create and submit a Post Approval Form?









# 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 the authorisation is given a 4. aution e-Submission Post-approval sfer Autho green tick will appear next to it. ur study at a locali An authorisation history at the bottom of the page keeps a record of all authorisation requests. Request Si Not requester Signed and valid 1 Locality Ma Sar Revoke You can also print an authorisation report for your records. Locale

Go to <u>http://ethics.health.govt.nz/applying-review/research-contacts</u> 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

Form Type: HDEC

🖃 🤠 My Project

Reference: 13/NTA/147 Form Section: N/A

Signatures: This form is attached with electron

- 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.



res, any changes to the form will invalidate the signature

Navigate

ts Transfer Authorisation e-Submission Post-approval

- 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.





- 4. For New documents, go to the upload tab.
- For example you can upload a word document responding to questions raised by the Committee.

List	Upload	ITAIISIEI	Planutisation	8-300 III Salut	Postapproval							
			Document Type			Document Upload Date	Description	Document Date	Version	Size	Uploaded by Assessing Organisation	Tools
"Decline	ed" letter for previo	us application	in respect of the sar	me (or substantially	similar) study	(none)						
Coverin	g letter					(none)						
CV for 0	CI					(none)						
CVs for	other Investigator	s				(none)						
Evidenc	e of CI indemnity					(none)						
Evidenc	e of scientific revi	ew				(none)						
Evidenc	e of sponsor insu	ance				(none)						
Investig	ator's Brochure					(none)						
Other						(none)						
PISICF						29/04/2014	Test	23/04/2014	1	12 KB		View / Manag
PISICF	for persons intere	sted in welfare	of non-consenting p	articipants		(none)						
Protoco	al .					(none)						
0	aniestionnaires					(none)						

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.

I	Vavigate	Documents	Transfer	Authorisation	e-Submission	Post-approval	
	List	Upload				· · · ·	
	Document Type:		Ot	Other			
	Version:		1		Document d	ate: 30/04/2014	I
	Description:		Re	Response to Committee			
	Choose file to upload:			H:\General\Temporary\Ethics cover lette Browse			
* Please note that the fields Ver			s Version and D	rrsion and Description will be visible by the assessing organisation.			

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.



Navigate Documents Transfer Au

ion e-S

n Pos

- 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.

