

Australian Government

National Health and Medical Research Council

Human Research Ethics Application (HREA) How-to Guide

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Introduction

This guide contains step-by-step instructions on how to carry out all the key stages in using the HREA to prepare, finalise and submit an ethics application to a Human Research Ethics Committee (HREC), from creating your account to revising and re-submitting a previously submitted application.

Before using the HREA, it is recommended that you review the additional HREA guidance available at <u>https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-applications-hrea/human-research-ethics-applications-hrea-resources</u>

If you have any questions or feedback, please contact HREA Help at <u>help@hrea.gov.au</u> or **1800 500 983** (within Australia) or +**61 2 6217 9451** (international callers) between Monday to Friday during 9:00AM to 5:00PM AEST/AEDT, excluding public holidays and ACT public holidays.

How-to Guide

1 Creating and managing your HREA account

1.1 How to create a new account

Navigate to <u>https://www.hrea.gov.au</u> with a web browser.

1. Select 'Register now' from the sign in page.

	Welcome to the NHMRC HREA	
User name		
Password		
-		
	D Log in	
	Can't access your account?	
	Pecet your password	
	Peret your partword Don't have an account?	
	Pecet your password	

2. Complete all the fields on this page. Note that the password must consist of at least 10 characters, comprising at least three of the four types of characters: lower case letter, upper case letter, number and symbol (e.g. @!#). The password box will turn green once the complexity requirements are met.

Please note that your <u>email addr</u>	ress will be used for your <u>username</u> .
Your first name •	
Your last name *	
Choose a password *	
the following four types of chara Alphanumeric.	im of ten characters in length and contain at least three of acters; Uppercase, Lowercase, Numeric and Non
Confirm your password *	
I'm not a robot	reCAPTCHA. Prosty-Terms

- 3. Help on using the **reCAPTCHA** (<u>https://www.google.com/recaptcha/api2/demo;</u> a Google resource to prevent malicious software) is available here: <u>https://support.google.com/recaptcha/?hl=en</u>.
- 4. Select the 'Register' button once you have completed all fields.

Register Please fill out the fields below to create an account.	
Email address	
Please note that your <u>email address</u> will be used for your <u>us</u>	ername.
Your first name	*
Your last name	*
Chilose a password	
Confirm your password	*
I'm not a robot	
* This is to prevent automated submissions.	
« Back	REGISTER

5. You will receive an email confirming your registration with a web link included. Click on this web link to activate your account. If you do not receive an email within 5 minutes, please check your spam/junk email folder. If the activation email is not there, please reset your password following the reset password instructions below.

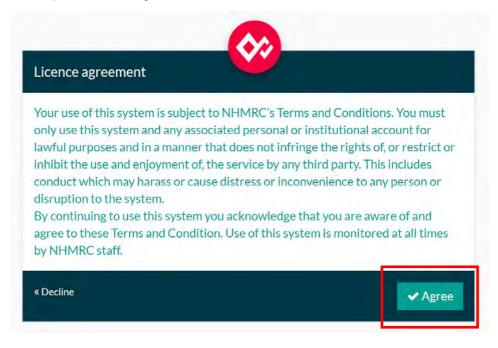
1.2 How to sign in to your HREA account

Navigate to <u>https://www.hrea.gov.au</u> with a web browser.

1. Enter your username (the email address used for registration) and password on the sign in page, then select 'Log in'.

	Welcome to the NHMRC HREA	
	vvelcome to the NHMRC HREA	
User name		
Password		
	+D Log in	
	Can't access your account?	
	Reset your password	
	Don't have an account?	
	Register now	
	Don't want an account?	
	Don't want an account?	

2. Select 'Agree' to accept the licence agreement and enter the HREA.



1.3 How to reset a forgotten password

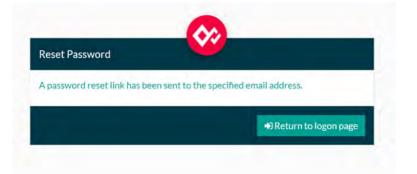
1. Select 'Reset your password' from the sign in page.

	Welcome to the NHMRC HREA	
	Welcome to the NHMIKC HKEA	
User name		
Password		
-		_
	●D Log in	
	€) Log in	
	◆ Log in Can't access your account?	
	Can't access your account? <u>Reset your password</u> Don't have an account?	
	Can't access your account? <u>Reset your password</u>	
	Can't access your account? <u>Reset your password</u> Don't have an account?	

2. Enter your username (the email address used for registration), complete the reCAPTCHA test and select 'Reset password'.

Reset Password you have forgotten your passwo ddress.	rd you can use the form belo	w to send a reset link to your email
nter your user name *		
l'm not a robot	reCAPTCHA Privacy. 1 terms	
This is to prevent automated	submissions.	

3. An email will be sent to the specified email address containing a link to reset the password.



- 4. Open the email and click on the reset password link (or paste the URL into your web browser).
- 5. Type in a new password. Note that the password must consist of at least 10 characters, comprising at least three of the four types of characters: lower case letter, upper case letter, number and symbol. The password box will turn green once the complexity requirements are met.
- 6. Select 'Set password'.

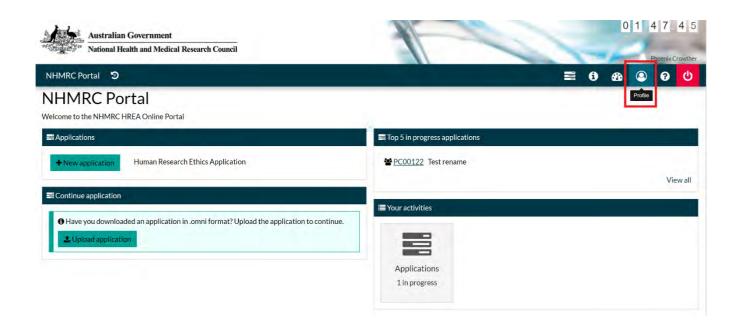
The second such has a wid		
	num of ten characters in leng aracters; Uppercase, Lowerca	th and contain at least three of ase, Numeric and Non
Confirm your password *		

7. If you have successfully reset your password you will see the notification below:

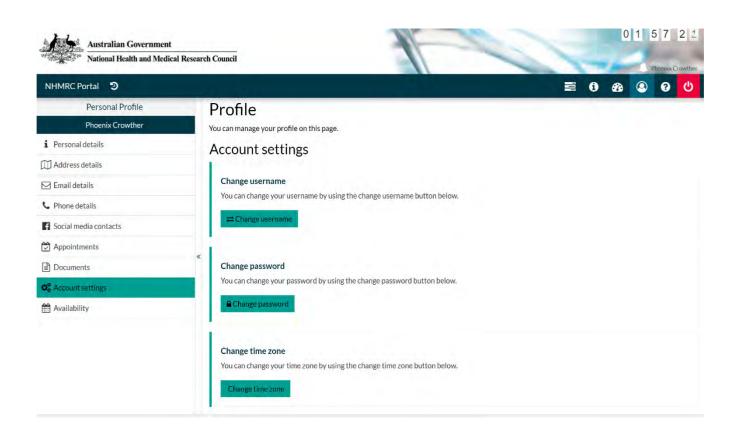


1.4 How to manage your profile

- 1. Sign in to your HREA account.
- 2. Select the 'Profile' button on the HREA Portal page.



3. Select the profile component to modify from the left hand menu.

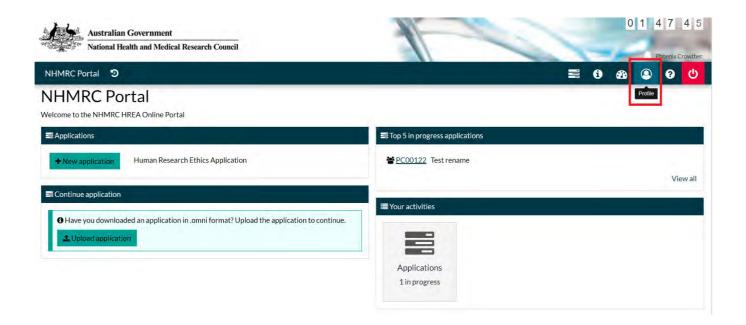


4. Amend details and select 'Save'.

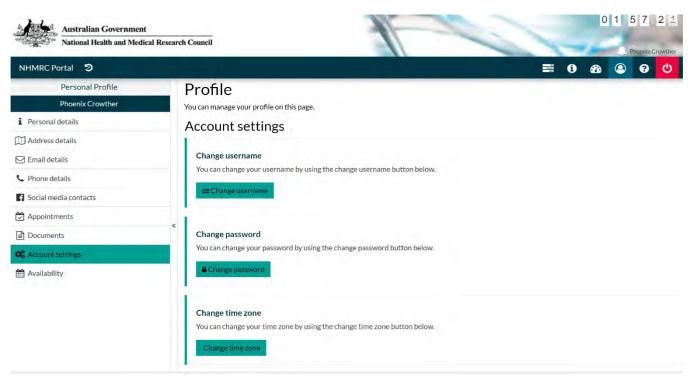
Australian Government	ıl Research Council	1-	0 1 5 4 2 Phoenix Crowther
NHMRC Portal 🥲			
Personal Profile	Profile		
Phoenix Crowther	You can manage your profile and personal setti	ngs on this page.	
i Personal details	Personal details		
Address details	Title *		
🖂 Email details		v	
C Phone details	First name*	Other names	Last name *
Social media contacts	Phoenix		Crowther
Appointments	Preferred name		
Documents	Preferred method of contact		
🗱 Account settings		~	
H Availability	B Save Save		
	Accessibility. Disclaimer Privacy Copyright	Terms and Conditions About User Guide	Feedback

1.5 How to change your username

- 1. Sign in to your HREA account.
- 2. Select the 'Profile' button on HREA Portal page.



3. Select 'Account settings'.



4. Select 'Change username'.

NHMRC Portal	🚍 0 🐵 🔍 9 🕻
Personal Profile	Profile
Phoenix Crowther	You can manage your profile on this page.
i Personal details	Account settings
🖽 Address details	A set of the
🗹 Email details	Change username You can change your username by using the change username button below.
🕻 Phone details	
f Social media contacts	
Appointments	« I
Documents	" Change password
Q^o Account settings	You can change your password by using the change password button below.
🛗 Availability	Change password
	Change time zone
	You can change your time zone by using the change time zone button below.

5. Enter your password and the new username, then select 'Save'. Note that the username must be an active email address.

Australian Government National Health and Medical Research	A Change username
NHMRC Portal	Enter your password for verification*
Personal Profile	Pro Password must be specified.
Phoenix Crowther	You can Enter your desired username *
i Personal details	Accc
🖽 Address details	Please note that you will be logged out and an email containing further instructions will
🖂 Email details	Cha be sent to your email address.
C Phone details	You
Social media contacts	Cancer A Cancer
🔁 Appointments	
Documents	Change password
Q ^e Account settings	You can change your password by using the change password button below.
Availability	Change password
	Change time zone You can change your time zone by using the change time zone button below.

You will be informed if the new email address has an existing account associated with it.

Australian Government National Health and Medical F	tesearch Council	Change username	0 0 2 9 5 4
NHMRC		Enter your password for verification	information Applications Profile Help
Personal Profile Rob Rigby	Profile	Enter your desired username clinicaltrialsready@nhmrc.gov.au A user with that username aready exists.	
Personal detail: Adorett, details Phone details Ernail details		E Soc X Cancel	
Account settings	Change p You can ch		

You will also be informed if the new username is not in the correct email address format.

Australian Government National Health and Medical Research Coun	d Change username				0		4 Idenis C	2 6
NHMRC Portal	Enter your password for verification*		-	0	6 3	۲	0	Ċ
Personal Profile Pro	Enter your desired username •							
i Personal details Acco	The username must be a valid email address							
🖽 Address details	Please note that you will be logged out and an email containing further instructions will be sent to your email address.	_						
Email details Ch								
C Phone details	B Save Cancel							
Social media contacts								
Appointments								
	nange password							
O ₆ Account services Yo	u can change your password by using the change password button below.							
Availability	Change pussword							
	ange time zone							
Yo	u can change your time zone by using the change time zone button below.							
	Diange time zone							

6. You will be logged out from the HREA Portal and an email will be sent to the original email address with a web link for you to verify the change to the username. You must access this email and click on the link to confirm the change of username.

7. Clicking on the link in the email will display the HREA home page with confirmation at the bottom of screen that the username has been changed. Enter the new username and password to confirm the change has occurred.

User name		
Password		į
	+) Log in	
	Can't access your account? <u>Reset your password</u>	
	Don't have an account? <u>Register now</u>	
	Don't want an account? Guest access	

8. To make sure that emails are now sent to your new username, select the 'Profile' button on the HREA Portal page.

Australian Government National Health and Medical Research Council	0 1 4 7 4 5 Eboenix Crowther
NHMRC Portal	😆 🛛 🕰 🖉 🖉
NHMRC Portal Welcome to the NHMRC HREA Online Portal	Profie
■ Applications	■ Top 5 in progress applications
+ New application Human Research Ethics Application	★ PC00122 Test rename View all
Continue application Have you downloaded an application in .omni format? Upload the application to continue. Upload application	E Your activities

9. Select 'Email details'.

Australian Government National Health and Medica	al Research Council	1		_	U		hoenix C	Crowther
NHMRC Portal				0	-	(0	Q
Personal Profile	Profile							
Phoenix Crowther	You can manage your profile on	this page.						
i Personal details	Email details							
Address details	• To add a new email address	s click the button below						
🖂 Email details	+ Add new email address	science and below.						
C Phone details	* Add new email additess							
Social media contacts	Show 10 ~ entries			Searc	ch:			
Appointments	- Preferred	Email address						
_								

10. Select 'Add new email address'.

Australian Government		Al-C			0	1	57	0 3
National Health and Medica	l Research Council				1	-	hoenix C	rowther
NHMRC Portal 🤊			a Ba Ta	0	20	9	0	Ċ
Personal Profile	Profile							
Phoenix Crowther	You can manage your profile on th	is page.						
i Personal details	Email details							
Address details	• To add a new email address	lick the button below.						
🖂 Email details	+ Add new email address							
C Phone details	«							
Social media contacts	Show 10 v entries			Sear	:h:			
🖾 Appointments	- Preferred	Email address						
Documents	•	phoenix.crowther@nhmrc.gov.au						
Count settings	Showing 1 to 1 of 1 entries				< Previ	ious	1 Ne	ext >
Availability								

11. Enter the new email address (your new username), tick 'Preferred' and select 'Save'.

Australian Government		-					01554						
National Health and Medic	al Research Council			-	2	2,	Phoenix C	rowther					
NHMRC Portal 🤊			-	0	-	٩	0	Ċ					
Personal Profile	Profile												
Phoenix Crowther	You can manage your profile on this page.												
i Personal details	Email details												
Address details	Email •												
🖂 Email details	help@hrea.gov.au							*					
C Phone details	Preferred												
Social media contacts	« Save * Cancel												
🛱 Appointments	Save Cancel												
Documents	Show 10 ~ entries			Searc	:h:								
O [®] Account settings													

1.6 How to change your password

- 1. Sign in to your HREA account.
- 2. Select the 'Profile' button on HREA Portal page.



3. Select 'Account settings'.

NHMRC Portal 🤊						0 🙆	9 (9 U
Personal Profile	Profile							
Phoenix Crowther	You can manage	your profile and personal settings on t	nis page.					
Personal details	Personal	details						
🗍 Address details		Title *						
Email details			~					
C Phone details		First name *	Othe	r names	Last nar			
f Social media contacts		Phoenix			Crow	ther		
Appointments		Preferred name						
Documents		Preferred method of contact *						
😋 Account settings			Ŷ					
Availability		Save D Reset						
	Accessibility Discl	aimer Privacy Copyright Term	and Conditions	About User Guide Feed	back			

4. Select 'Change password'.

Australian Government National Health and Medica	I Research Council
NHMRC Portal 🤊	≅ 6 AB (2) O (4)
Personal Profile	Profile
Phoenix Crowther	You can manage your profile on this page.
i Personal details	Account settings
🗍 Address details	
Email details	Change username
Phone details	You can change your username by using the change username button below.
Social media contacts	≓Change username
Appointments	
Documents	« Change password
38 Account settings	You can change your password by using the change password button below.
Availability	Change password
	Change time zone You can change your time zone by using the change time zone button below.
	Change time zone

5. Enter the current password and the new password and select 'save'. Note that the password must consist of at least 10 characters, comprising at least three of the four types of characters: lower case letter, upper case letter, number and symbol. The password box will turn green once the complexity requirements are met.

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National Health and Medical	Research Counci	Change	bassword												
NHMRC Portal 🧐		Current passv	vord *							-	 0	6 36	۲	0	Ċ
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i Personal details	Acco		d must be a mii												
Address details	1	of the follow Alphanumeri	ng four types o c.:	of characters;	; Uppercase	e, Lowercasi	e, Numeric an	d Non							
🖂 Email details	Cha	Confirm new j	bassword*												
C Phone details	You								- 11						
Social media contacts															
Appointments	i i						E Save	* Cancel							
Documents	« Cha	ange passwoi	d												
OS Account settings	You	can change yo	ur password I	by using the	change pa	assword bu	utton below.								
Availability		Change passwo	frie												
	Cha	ange time zor	ie												
	You	can change yo	ur time zone l	by using the	change tir	ime zone b	utton below.								
		Hange Hine wa													

6. The change to the password will be confirmed on-screen.

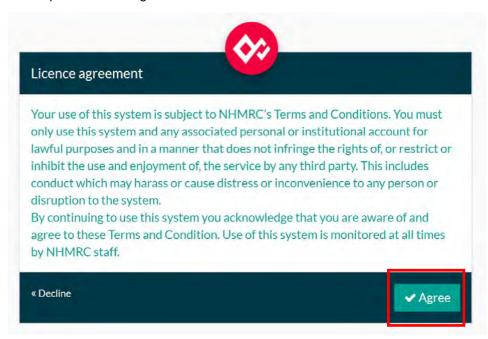
1.7 How to access the HREA as a Guest

Navigate to <u>https://www.hrea.gov.au</u> with a web browser. Note that an application created using guest access cannot be saved in HREA; you will need to download the .omni file in order to save and re-upload your application at a later time. See **3.1 How to finalise and submit your application** for information on how to save your .omni file.

1. Select 'Guest Access'.

	Welcome to the NHMRC HREA	
User name		
Password		
_		_
	D Log in	
	Can't access your account?	
	Reset your password	
	Don't have an account? <u>Register now</u>	
	Don't want an account?	

2. Select 'Agree' to accept the licence agreement and enter the HREA.



2 Creating your ethics application

2.1 How to start a new application

- 1. Sign in to your HREA account or as a guest.
- 2. Select the 'New application' button.

Australian Government National Health and Medical Research Council	
NHMRC Portal 🤊	I 0 8
NHMRC Portal Welcome to the NHMRC HREA Online Portal	
看 Applications	■ Top 5 in progress applications
+ New application Human Research Ethics Application	PC00122 Test rename
In the second sec	March March
Have you downloaded an application in .omni format? Upload the application to continue. Lipload application	I≣ Your activities
	Applications 1 in progress

3. Enter an Application title, any comments you want to include and select 'Done'.

+ the second sec	Die Co			0	1 4	8	5 2
Australian Government National Health and Medical Research Count						hoenix G	
NHMRC Portal 🕲	Please provide a name for the new application below (this will be used as a part of the submission process).	100	0	686	۲	0	Ċ
NHMRC Portal Welcome to the NHMRC HREA Online Portal	Application title Application comments						
New application Human Research Ethics App Entropy of the second se	✓ Done X Cancel					View	all
Have you downloaded an application in .omni format? Upload application							

4. This will take you to the first page of the HREA. You must select 'Acknowledge and Continue' at the bottom of the Introduction page to access the questions. From here, you can answer HREA questions and complete your application.

NHMRC Portal 🧐		Applications	Information	Dashboards	Profile	Help	🕑 Sign out
CC01205 - In	troduction screen						
Introduction	Introduction					Previes	w 🖺 Save
HREC Directory							Next 🔶
	Before completing this application, acknowledge that:						
	1) The HREA has been designed for ethics review of human research, as defined	ned in the National	Statement.*				
	The <u>National Statement</u> states that research is: "widely understood to include at least investigation undertaken to gain knowledge and their data or tissue".			nan research is rese	earch conduct	ed with or ab	out people, or
	 The <u>Australian Code for the Responsible Conduct of Research (the Code</u>) states that research "the creation of new knowledge and/or the use of existing knowledge in a new and creat 		e new concepts, me	thodologies invent	ions and unde	erstandings."	
	 Research excludes activities that are carried out exclusively for quality improvement, quality Audit-type activities may be considered research if investigating a potential research question Non-research projects that will be published and some student internships may need ethics n Contact your institution's ethics or research office for guidance on whether your project requ 	n. eview, but not necessaril					
	2) Adequate resources must be available to conduct this research project.*						
	 <u>National Statement 1.1.(!</u>) states that research that has merit is: "conducted using facilities and resources appropriate for the research". 						
	 It is expected that adequate resources will be available for this research project. Resources m Consult with your institution's ethics or research office for further advice. 	ay include: financial reso	ources, human resou	irces, equipment, f	acilities and in	-kind support	t.
	3) All relevant institutional polices pertaining to the conduct of this research	project should be o	onsidered and	adhered to. *			
	Institutions may have policies in place that relate to the conduct of research. These policies sh research. Consult with your institution's ethics or research office for further advice. Ensure all investigators are familiar with their institutional policies and note that if you are co					ghout the con	duct of the
	4) Research activities must not commence until ethics approval (and site aut	horisation, if appro	priate) has been	provided.*			
	You must not start your research project until you have received written ethics approval and This includes screening of participants and/or data collection activities.						
	5) The HREA requires the attachment of a Project Description/Protocol.						
	 It is strongly recommended that you prepare the <u>Project Description/Protocol</u> before comme <u>Description/Protocol</u>. 	ncing this HREA. Advice	on what to include	in this document is	available on t	the <u>Project</u>	
	Note: You cannot complete the HREA unless you acknowledge the above statements.						
	Acknowledge and Continue						

2.2 How to share your application

The HREA allows you to share your HREA online while it is being prepared. This feature can be used to invite anyone to review and amend your application. If you invite someone without a HREA account, they will be prompted to create an account.

1. Navigate to the 'Applications' page

NHMRC Porta	<u>د</u> ا								9 29 29 0
Applica	tions								
nis page shows a	II applications you o	can access.							
+ New applie	ation ± Upload	application							
	ation 2 Upload	l application						S	Search:
		€ Title	Version	≑ Status	\$ Owner	Organisation	\$tage	S Status	Search:
	🛓 Export CSV			\$ StatusIn Progress	Owner Phoenix Crowther	Organisation	 \$ Stage Stage 1 		
+ New applie	 Export CSV Identifier 	≑ Title	<u>1.01</u>	and a state of the		Organisation		Status	Created date

2. Identify the application you wish to share and select the 'Options' button (three dots on the left side of the Identifier).

NHMRC Porta	9							= (6 6 2 6
Applicat	ions								
	l applications you o	can access.							
Bolow are ve	ur applications Cli	sk the link to open an existing apr	lication use th	o 'Now application'	button bolow to start a	now one or click the '	Unload applic	ation' button to	o rocumo a downloadod
application.	ur applications. Cli	ck the link to open an existing app	nication, use th	e new application	button below to start a	new one, of click the	opioad applica	ation button to	o resume a downloaded
and the second se									
A Mary months	• Union	I annullizzabilitza							
+ New applic	ation 🕹 Upload	application							
		l application						s	Search:
	Export CSV	f application						S	Search:
		f application	Version	≑ Status	\$ Owner	Organisation	≑ Stage	Status	Search:
	🛓 Export CSV]	* Version <u>1.01</u>	\$tatusIn Progress	Owner Phoenix Crowther	Organisation			
+ New applic	Lexport CSV	¢ Titie				+ Organisation		Status	Created date

3. Select the 'Invite user to register or share application' button.

NHMRC Por	tal D							0 28 2 0	Ċ
Applica	ations								
	all applications you can access.								
Below are	your applications. Click the link to open an ex	isting application, use th	e 'New application	' button below to start a	new one, or click the '	Jpload applic	ation' button to	o resume a downloaded	
application.			and the second second						
+ New app	lication 🔹 Upload application								
L Download	L Export CSV						S	šearch:	
L Download	 ▲ Export CSV ⇒ Identifier ⇒ Title 	+ Version	≎ Status	≑ Owner	Organisation	‡ Stage	Status	earch:	
Download		* Version <u>1.01</u>	≑ Status ● In Progress	Owner Phoenix Crowther	Organisation	‡ Stage Stage 1	-		Ń
	≎ Identifier	1.01	1. Postov	12 Contractor	Organisation	Stage 1	≑ Status		
	Identifier Title Application information Copy application Drymland data file		In Progress	Phoenix Crowther	≑ Organisation		≑ Status ● Open	Created date 23/06/2021 12:22:05 P 09/06/2021 02:02:42 P	м
	Identifier Title Application information Copy application Drymland data file	<u>1.01</u> 1.00	In Progress	Phoenix Crowther	Organisation	Stage 1	≑ Status ● Open	Created date 23/06/2021 12:22:05 P 09/06/2021 02:02:42 P	
	Identifier Title Application information Copy application Drawnload data file	<u>1.01</u> 1.00	In Progress Completed	Phoenix Crowther Phoenix Crowther	Crganisation About User Guide	Stage 1	≑ Status ● Open	Created date 23/06/2021 12:22:05 P 09/06/2021 02:02:42 P	м

4. Enter the username (i.e. the email address) of the person with whom you wish to share the application. They will be added to the list of assigned users. Select from either the 'View' or 'Edit' access option. 'View' will allow the user to open the application but not make any edits to it. 'Edit' will allow the user to open and edit the application.

	Send		Name	Jsernam	9			Access statu	IS	Modify access		
+ N	9 9 Add	another user	L ti	lser help@	ddress and t		fication will be sent to able to access this	No current a	access	Share with v Share with v Share with e	ew access	i O
Down	IIGen	+ Identifier	‡ Title	÷N	ersion	≑ Status	= Owner	÷ (Organisation	= Stage	⇒ Status	Created date
	:	* PC00122	Test rename	<u>1.0</u>	1	In Prog	ress Phoenix Cro	wther		Stage 1	Open	23/06/2021 12:22:05 Pt
	1	PC00121	Test Application Phoenix C	<u>1.0</u>	0	Comple	eted Phoenix Cro	wther		Stage 1	Open	09/06/2021 02:02:42 Pt

5. Select the 'Save and send' button.

	* Inv	ite user to regisi	ter & manage access			-	-			01327	Ō
NHMF	The list	t of users currentl	y assigned to this application are	listed below							wither C
	Send		Name U:	sername			Access status	Modify access			0
App This page Bel applic	C Add	another user	Us		u is found. A notificatio: the user will be able to		No current access	Share with v	iew acc → ✓ Save a	₽ P	
2 00.		÷ Identifier	= Title	= Version	= Status	= Owner	+ Organisation	\$ Stage	÷ Status	= Created date	
+	ł	* PC00122	Test rename	1.01	In Progress	Phoenix Crowth	ier	Stage 1	Open	23/06/2021 12:22:05 PM	
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			<u>Accessibility</u> D	isclaimer Priva	<u>kcy Convright</u>	Terms and Conditions	<u>About</u> <u>User Guide</u>	Feedback			

6. The person with whom you have shared the application will receive an email. If the person does not have a HREA account, they will be prompted to create one.

From:	🗌 no-reply@hrea.gov.au	Sent: Wed 12/10/2016 11:49 AM
To:	- HREA Help	
Cc: Subject:	[SEC=UNCLASSIFIED]HREA Portal application share (< <applicationid>>)</applicationid>	
Dear H	REA,	e33 ^
Robert	Rigby has shared a Human Research Ethics Application with you that is entitled "Test 6". The Application ID is RR02766.	
To acce	ess this application, please log in to the HREA and click on the Applications Tab.	
Regard	ls,	
The HR	REA team	

7. The 'Share' icon (on the left side of the Identifier) indicates that an application is being shared. Note that only one person can edit a shared application at a time.

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is page s	hows a	II applications you c	can access.									
Below	v are vo	ur applications. Cli	ck the link to open an existing app	plication, use th	ne 'New application'	button below to start a	new one, or click the	Upload applic	ation' button t	o resume a c	lownloaded	1
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			application									
+ Nev	v applic	ation 🛛 🚨 Upload	application									
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		🛓 Export CSV							_			
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8. To 'unshare' an application, identify the application you wish to 'unshare' and select the 'Options' button on the left side of the Identifier. Note that only the application owner can 'unshare' an application.

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+ New applie		application	¢ Version	Status	* Owner	Organisation	Stage	⇒ Status		ated date	
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9. Select the 'Invite user to register or share application' button.

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	Il applications you can access.								
	n ar en la nacionalista				P. 1. 11				
Below are years application.	our applications. Click the link to open an exis	ting application, use th	e new application	button below to start a	new one, or click the	Upload applic	ation button t	o resume a downloa	adea
+ New appli	tation								
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10. Identify the user/s you wish to remove, select the tick box on the left side of their name, and then select the 'Delete' button on the right side of the access menu.

invite user to	o register & manage access			0 1 2 6
The list of users cu	urrently assigned to this appli	ication are listed below		
Send	Name	Username	Access status	Modify access
	Help, HREA	help@hrea.gov.au	Shared with view access	Share with view acr 👻
Add another use	er			
lic				Save and send K Cancel

11. Deleted users will no longer appear in the 'Assigned users' list. Select 'Save and send' to complete and return to the 'Applications' list screen.

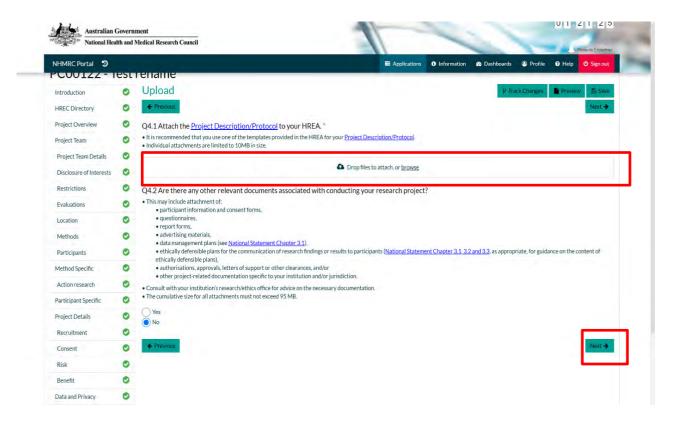
	e are currently	no users assigned to this application	on.						
is pag	other user								
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applic	an d Ualo	ad application		_	_	_			
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owing 1 to 2 of 2 er	ntries								Previous Next

- 12. Note: If you share an application with another user and provide them with 'edit' access, they will be able to complete the application on your behalf.
- 13. Note: When an application is completed and generated, it will no longer be shared with other users and will automatically disappear from the list of applications visible to those users. Only the original owner of the application will be able to access it.

2.3 How to attach the Project Description/Protocol

Attachment of a Project Description/Protocol to the HREA is mandatory and it is attached separately to any other relevant (optional) documents.

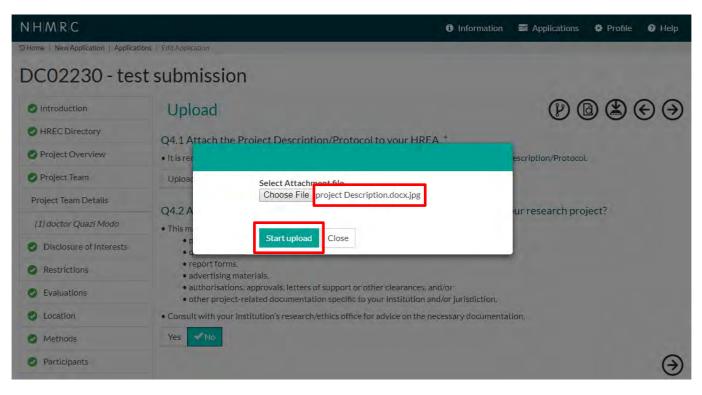
1. Navigate to Q4.1 on the 'Upload' page. Select 'Browse' and the HREA will open the file explorer on your computer.



2. Select the file for attachment and select 'Open'.

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	Project Overview	Q4.1 Attach the Pro	jj <u>ect Description/Protocol</u> to your HREA.*
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er		(i + 💷	Drop files to attach, or browse
Copy HREA New Cover Cove	cation PC00122_v1_00.zip of Institution Position.vks How to Guide v3.1 Feb 2021-sen User response tormatics Frag. vr_outmant him liestin discut Access him liestin di discut A	4/06/2021 1:24 PM 23/06/2021 1:22 PM 18/06/2021 2:12 PM	s (see <u>National Statement Chapter 3.1).</u> ans for the communication of research findings or results to participants (<u>National Statement Chapter 3.1, 3.2 and 3.3</u> , as appropriate, for guidance on the content of k), jubis, letters of support or other clearances, and/or
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3. Ensure the correct filename is displayed and select 'Start upload'.



4. Confirm the correct document has been uploaded. Selecting 'Open' will download and open the attached document. The attached document is a copy of the original document. The original document will remain on your computer.

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Introduction HREC Directory	 ✓ Upload ✓ Previous 	P Track Changes Preview 🖺 S.
Project Overview Project Team	 Q4.1 Attach the <u>Project Description/Protocol</u> to your HREA.* It is recommended that you use one of the templates provided in the HREA for your <u>Project Description/Protocol</u>. Individual attachments are limited to 10MB in size. 	
Project Team Details	S File Name	Size
Disclosure of Interests	New User Request Form.docx	174.05 kB
Restrictions	©	
Evaluations	 Q4.2 Are there any other relevant documents associated with conducting your research project? This may include attachment of: 	
Location	 participant information and consent forms, questionnaires, 	
Location Methods Participants Method Specific	 participant information and consent forms, questionnaires, (peport forms, export forms, advertising materials, data management plans (see <u>National Statement Chapter 3.1</u>), data management plans for the communication of research findings or results to participants (<u>National Statement Chapter</u> 4thically defensible plans), 	rr <u>3.1.3.2 and 3.3</u> , as appropriate, for guidance on the content of
Methods Participants	 participant information and consent forms, questionnaires, eport forms, eport forms, advertising materials, advertising materials, data management plans (see <u>National Statement Chapter 3.1</u>), data management plans for the communication of research findings or results to participants (<u>National Statement Chapter</u>) 	17 3.1 3.2 and 3.3, as appropriate, for guidance on the content of
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5. To remove the attached Project Description/Protocol, select the X button on the left side of the file name.

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Project Overview	☑ Q4.1,	ttach the Project Description/Protocol to yo	ur HREA.*				
Project Team		commended that you use one of the templates provided lual attachments are limited to 10MB in size.	in the HREA for your Project Description/Prot	tocol.			
Project Team Details	0	File Name				Size	
Disclosure of Interests	⊘ ×	New User Request Form.docx				174.05 kB	
Restrictions	0						
Evaluations	042	re there any other relevant documents asso	ciated with conducting your research	project?			
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6. **Note:** Please avoid uploading large files (e.g. uncompressed photos) to the HREA. Your application may not open if you have attached files with a cumulative size of 100MB or more.

2.4 How to attach other relevant documentation

Attaching other documents is not mandatory, but other documents may be needed for a particular project. The process for attaching other relevant documents is slightly different to the process for attaching the mandatory Project Description/Protocol.

1. Navigate to Q4.2 on the 'Upload' page.

		🔤 Applications 🚯 Information 🆓 Dashboards 🕥 Profile 🚱 I	Help O Sign out
Introduction	•	Upload 🛛 Track Changes 🐚 🖡	Preview 🛛 🖺 Save
HREC Directory	0	+ Previous	Next 🔿
Project Overview	0	Q4.1 Attach the <u>Project Description/Protocol</u> to your HREA.*	
Project Team		It is recommended that you use one of the templates provided in the HREA for your <u>Project Description/Protocol</u> Individual attachments are limited to 10MB in size.	
Project Team Details	0	File Name Size	
Disclosure of Interests	0	× New User Request Form.docx 174.05 kE	В
Restrictions	0		
Evaluations	S	Q4.2 Are there any other relevant documents associated with conducting your research project? This may include attachment of:	
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Methods	0	• questionnaires, • report forms, • advertising materials,	
Participants	0	data management plans (see National Statement Chapter 3.1).	
Participants Method Specific	0	 data management plans (see <u>National Statement Chapter 3.1</u>). ethically defensible plans for the communication of research findings or results to participants (<u>National Statement Chapter 3.1, 3.2 and 3.3</u>, as appropriate, for guidance of ethically defensible plans). 	on the content of
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2. Select 'Yes' at Q4.2 to show the 'Upload attachment' and 'Description of attachment' fields.

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		× New User Request Form.docx			174.05 kB
Restrictions	0				
Evaluations	0	Q4.2 Are there any other relevant documents associated w • This may include attachment of:	ith conducting your research project	?	
Location	0	 participant information and consent forms, 			
Methods	0	 questionnaires, report forms, advertising materials, 			
Participants	0	 data management plans (see <u>National Statement Chapter 3.1</u>). 			
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Participant Specific	۲	Consult with your institution's research/ethics office for advice on the n The cumulative size for all attachments must not exceed 95 MB.	ecessary documentation.		
Project Details	2	Yes			
Recruitment	9	No			
Consent	0	Attach any other relevant documents associated with cond	ucting your research project.		
Risk	0	 Ensure that you give meaningful and unique names to your files before u Provide a meaningful description for each file at Q4.2.2. 	ploading them.		
Benefit	0	 Individual attachments are limited to 10MB in size. 			
Data and Privacy	0		A AN AN TOTAL STATES		and the second
Generate HREA docume	-	Q4.2.1 Upload attachment*	Q4.2.2 Description of attachment		Completion
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	nent	Press the '+' button to add another row for additional documents to atta Press the delete button to remove an attached document.	ch.		

3. To add more attachments, select the 'Add Another' button. In this example, three rows have been added in order to add three separate attachments.

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		Drop files to attach, or browse					

4. To add an attachment, select 'Browse' and the HREA will open the file explorer on your computer.

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Methods	0	report forms,						
Participants	0	 advertising materials, data management plans (see National Statement Chapter 3.1).					
1.1.10.10		ethically defensible plans for the communication of research	findings or results to participants (National Stateme	ent Chapter 3.1, 3.2	2 and 3.3, as approp	riate, for guida	nce on the o	ontent of
Method Specific	0	 ethically defensible plans), authorisations, approvals, letters of support or other clearan 	ces and/or					
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Participant Specific		nsult with your institution's research/ethics office for advice on e cumulative size for all attachments must not exceed 95 MB.	the necessary documentation.					
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		Drop files to attach, or <u>browse</u>						
		Drop files to attach, or <u>browse</u>						

5. Select the file for attachment and select 'Open'.

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6. Ensure the correct filename is listed and select 'Start upload'.

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Project Team	Clear content selection (project Description.docx.jpg) [0	ect Attachment me	
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Ø Disclosure of Interests	participant information a ouestionnaires.	Close Close	
Restrictions	report forms, advertising materials,		
Evaluations	authorisations, approvals, letters of support or other project-related documentation specific t		
 Location 	Consult with your institution's research/ethics office		
Methods	Yes No		
Participants	Attach any other relevant documents assoc	iated with conducting your research project.	
Method Specific	• Ensure that you give meaningful and unique names t	o your files before uploading them. Also provide a meaningful descri	ption for each file at Q4.2.2.
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7. Confirm the correct document has been uploaded. The attached document is a copy of the original document. The original document will remain on your computer.

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Project Team Details	File Name			Size
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Evaluations	 Q4.2 Are there any other relevant documents associat This may include attachment of: 	ed with conducting your research project?		
Location	 participant information and consent forms, 			
Methods	equestionnaires, ereport forms,			
Participants	advertising materials, data management plans (see <u>National Statement Chapter 3</u> ;			
Method Specific	 ethically defensible plans for the communication of research ethically defensible plans), 		nt Chapter 3.1, 3.2 and 3.3, as a	ppropriate, for guidance on the content of
Action research	 authorisations, approvals, letters of support or other clearan other project-related documentation specific to your institution 			
Participant Specific	 Consult with your institution's research/ethics office for advice on The cumulative size for all attachments must not exceed 95 MB. 	the necessary documentation.		
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Recruitment Consent Risk	 Attach any other relevant documents associated with. ensure that you give meaningful and unique names to your files be envious a meaningful description for each file at Q4.2.2. Individual attachments are limited to 10MB in size. The cumulative size for all attachments must not exceed 95 MB. 	fore uploading them.		Completion
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8. Add the description of the attachment. When a document has been successfully uploaded and the description added, the 'Completion' field changes from a cross to a tick.

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Restrictions	0								
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Method Specific	0	 ethically defensible plans for the communic ethically defensible plans). 	cation of research findings or	results to participants (National	Statement Chapter 3.1.	3.2 and 3.3, as appro	priate, for guidar	ince on the c	ontent
Action research	0	 authorisations, approvals, letters of suppor other project-related documentation speci 		jurisdiction.					
Participant Specific	۲	 Consult with your institution's research/ethics of The cumulative size for all attachments must not 		ary documentation.					
Project Details	0	Yes							
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9. To remove an incorrect attachment, select the X on the left side of the file name.

To remove a row in the attachments table altogether (whether a document is attached or not), select the Delete button (rubbish bin) on the right side of the Completion field. The attachment will be removed from your application, but the original will remain on your computer.

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Location	0	participant information and consent forms, questionnaires,					
Methods	۲	report forms, advertising materials,					
Participants	0	 data management plans (see <u>National Statement Chapter 3.1</u>). ethically defensible plans for the communication of research find 	ings or secults to participants (Mational Stateme	nt Chapter 21 22	and 2.2 or appropr	iste for quidance on the sc	intent of
Method Specific	0	 ethically defensible plans), authorisations, approvals, letters of support or other clearances, 		ne chapter 0.1, 0.2	and o.o. as appropr	late, for guidance of the ce	intent of
Action research	0	 other project-related documentation specific to your institution 					
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10. **Note:** Please avoid uploading large files (e.g. uncompressed photos) to the HREA. Your application may not open if you have attached files with a cumulative size of 100MB or more.

2.5 How to attach an investigator's declaration

The HREA will automatically generate a declaration for each person listed in the 'Project Team' section. These can be signed by either attaching a digital signature, signing on screen or printing a blank space for a 'wet ink' signature.

1. Navigate to the 'Declarations' page and select 'Upload other evidence'. Then select 'Browse' to upload your file.

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Introduction	0	Declaration
HREC Directory	0	← Previous
Project Overview	0	This declaration must be completed by each of the researchers/investigators or, where applicable, one member on behalf of the research team.
Project Team	0	 Consult your institution's policy for guidance on whether all members must sign this application or whether one member can sign on behalf of the research team. You can use the share feature to have other researchers/investigators complete their declaration within this application - see the HREA How to Guide for details.
Project Team Details	0	Vou can upload evidence of the other researchers/investigators' agreement to this declaration (e.g. a PDF of an email). Vou can have researchers/investigators sign this application after it is completed and printed (i.e. a 'wet ink' signature).
Disclosure of Interests	۲	Ensure you answer Q1.9.11 for each team member before completing this section.
Restrictions	0	I. Phoenix Crowther, certify that:
Evaluations	0	All information in this application and supporting documentation is correct and as complete as possible;
Location	0	 I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines; I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
Methods	0	 All relevant financial and non-financial interests of the project team have been disclosed; and In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this
Participants	0	application and those associated with the student's educational program.
Method Specific	0	Q4.7 How will Phoenix Crowther agree to these terms?* • You can use the HREA 'sign on screen' function to electronically sign this application.
Action research	0	Select Upload other evidence' to upload and attach other evidence, such as an email. Select Upload other evidence' to upload and attach other evidence, such as an email. Select Sign after printing if you intend to sign the HREA after it is printed (i.e. / we link' signature).
Participant Specific	0	• Seece Sign aree printing in you meetid osign the risk-A aree it is printed (ce: wet link signature).
Project Details	0	Upload other evidence
Recruitment	۲	Wet ink sign after printing
Consent	0	Opload Signature
Risk	0	

2. The HREA will open the file explorer on your computer. Select the file for attachment and select 'Open'.

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Project Description.docx	20/01/2016 9:20 AM	Microsoft Word D	1		
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O Project Overview	team.	inpleted by each of the researchers/investigato	is or, where applicable, one member on behall of the research
O Project Team			tion or whether one member can sign on behalf of the research team. ration within this application – see the HREA How to Guide for details.
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Location	 In the capacity of a superviso 	r, as applicable, I have reviewed this application and I will p application and those associated with the student's educat	rovide appropriate supervision to the student(s) in accordance with the ional program.
Methods		azi Modo agree to these terms?*	
Participants		n screen function to electronically sign this application.	
Method Specific		e' to upload and attach other evidence, such as an email. ou intend to sign the HREA after it is printed (i.e. 'wet ink' s	ignature).
Biospecimen analysis research	Sign on screen Vpload	other evidence Wet ink sign after printing	
O Participant Specific	Upload Signature*		
People in other countries	Upload New		
Project Details			
Recruitment			9

4. Confirm the correct file has been uploaded. Selecting 'Open' will download and open the attached document. The attached document is a copy of the original document. The original document will remain on your computer.

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Introduction	 Declaration 		P Track Changes	Preview 🖺 Save
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Project Overview	This declaration must be completed by each of the research.	archers/investigators or, where applicabl	e, one member on behalf of the research t	eam.
Project Team	 Consult your institution's policy for guidance on whether all membe You can use the share feature to have other researchers/investigate 			
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Disclosure of Interests	 Ensure you answer Q1.9.11 for each team member before completing 			
Restrictions	I. Phoenix Crowther, certify that:			
Evaluations	 All information in this application and supporting documentation is 			
Location	 I have read and addressed in this application the requirements of t I have familiarised myself with, considered and addressed in this application. 			
Methods	 All relevant financial and non-financial interests of the project tear In the capacity of a supervisor, as applicable, I have reviewed this a 		n to the student(s) in accordance with the arrangem	ents specified in this
Participants	 application and those associated with the student's educational prog 			
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Action research	 Select 'Upload other evidence' to upload and attach other evidence' Select 'Sign after printing' if you intend to sign the HREA after it is 	e, such as an email.		
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Project Details	C Upload other evidence			
Recruitment	Wet ink sign after printing			
Consent	Upload Signature*			
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Data and Privacy	0			
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5. To remove the attached file, select the X on the left side of the file name.

2.6 How to sign on screen

1. Navigate to the 'Declarations' page and select 'Sign on screen'.

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	O This declaration must be completed by each of the researchers/investigators or where applicable one member on behalf of the research team
Project Team	• You can use the share feature to have other researchers/investigators complete their declaration within this application – see the <u>HREA How to Guide</u> for details.
Project Team Details	 You can upload evidence of the other researchers/investigators' agreement to this declaration (e.g. a PDF of an email). You can have researchers/investigators sign this application after it is completed and printed (i.e. a' wet ink' signature).
Disclosure of Interests	• Ensure you answer Q1.9.11 for each team member before completing this section.
Restrictions	I. Phoenix Crowther, certify that:
Evaluations	 All information in this application and supporting documentation is correct and as complete as possible;
Location	 I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines; I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
Methods	 Interchancial and non-financial interests of the project team have been disclosed; and In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this
Participants	 application and those associated with the student's educational program.
Method Specific	Q4.7 How will Phoenix Crowther agree to these terms?"
and the state of t	 You can use the HREA' sign on screen' function to electronically sign this application. Select' Upload other evidence' to upload and attach other evidence, such as an email.
	 Select 'Sign after printing' if you intend to sign the HREA after it is printed (i.e. 'wet ink' signature).
Participant Specific	Sign on screen
Project Details	Q Upload other evidence
Recruitment	Wet ink sign after printing.
Consent	Signature *
Risk	o 3 *
Benefit	0
Data and Privacy	0
Generate HREA document	Sign above
Upload	0
HREC	

2. Sign in the box using the mouse or finger/stylus if using a touchscreen or tablet. Use the 'Clear' button (two arrows in the shape of a circle) to clear the signature box and start again.

1.00

IKEC Directory		
Project Overview	0	This declaration must be completed by each of the researchers/investigators or, where applicable, one member on behalf of the research team.
Project Team	0	 Consult your institution's policy for guidance on whether all members must sign this application or whether one member can sign on behalf of the research team. You can use the share feature to have other researchers/investigators complete their declaration within this application - see the <u>HREA How to Guide</u> for details.
Project Team Details	0	 You can upload evidence of the other researchers/investigators' agreement to this declaration (e.g., a PDF of an email). You can have researchers/investigators sign this application after it is completed and printed (i.e. a' wet ink' signature).
Disclosure of Interests	0	Ensure you answer Q1.9.11 for each team members <u>before</u> completing this section.
Restrictions	0	I, Phoenix Crowther, certify that:
Evaluations	0	All information in this application and supporting documentation is correct and as complete as possible;
Location	0	 I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines; I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
Methods	0	 All relevant financial and non-financial interests of the project team have been disclosed; and In the capacity of a supervisor, as applicable. I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this
Participants	0	application and those associated with the student's educational program.
Method Specific	0	Q4.7 How will Phoenix Crowther agree to these terms?"
Action research	0	You can use the HREA' sign on screen' function to electronically sign this application. Select' Upload other evidence' to upload and attach other evidence, such as an email.
Participant Specific	0	Select 'Sign after printing' if you intend to sign the HREA after it is printed (i.e. 'wet ink' signature).
Project Details	0	Sign on screen Upload other evidence
Recruitment	0	Wet ink sign after printing
Consent	0	Signature *
Risk	0	
Benefit	0	
Data and Privacy	0	JOC
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Upload	0	
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2.7 How to wet ink sign

1. Navigate to the 'Declarations' page and select 'Wet ink sign after printing'.

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Introduction	0	Declaration	Preview	🖺 Save
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Project Overview	0	This declaration must be completed by each of the researchers/investigators or, where applicable, one member on behalf of the research te	am.	
Project Team	0	 Consult your institution's policy for guidance on whether all members must sign this application or whether one member can sign on behalf of the research team. You can use the share feature to have other researchers/investigators complete their declaration within this application - see the HREA How to Guide for details. 		
Project Team Details	0	 You can have researchers/investigators sign this application after it is completed and printed (i.e. a 'wet ink' signature). 		
Disclosure of Interests	0	Ensure you answer Q1.9.11 for each team member <u>before</u> completing this section.		
Restrictions	0	I. Dr x x. certify that:		
Evaluations	0	All information in this application and supporting documentation is correct and as complete as possible;		
Location	0	 I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines; I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies; 		
Methods	0	 All relevant financial and non-financial interests of the project team have been disclosed; and In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangement 	nts snarifie	d in this
Participants	0	application and those associated with the student's educational program.	ine specific	un un
Method Specific	0	Q4.7 How will Dr x x agree to these terms?"		
Participant Specific	0	You can use the HREA'sign on screen' function to electronically sign this application. Select 'Upload other evidence' to upload and attach other evidence, such as an email.		
Project Details	0	Select 'Sign after printing' if you intend to sign the HREA after it is printed (i.e. 'wet ink' signature).		
Recruitment	0	Sign on screen		
Consent	0	Wet ink sign after printing		
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- 2. Complete the rest of the HREA, generate the HREA document and print the form.
- 3. Sign the HREA form on the 'Investigator Team Declarations' section on the printed form.

Investigator Team Declarations

The research team has certified that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

Ms Jane Doe	
Sign here:	

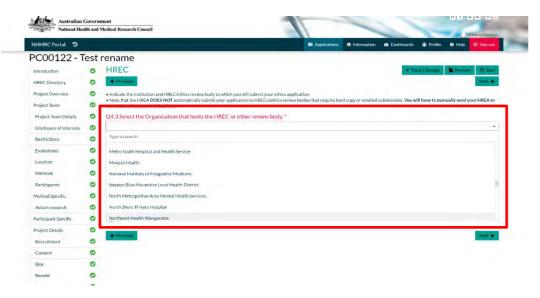
3 Submitting and revising your ethics application

3.1 How to finalise and submit your application

1. Once you have completed all other application questions, navigate to Q4.3 on the 'HREC' page.

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Project Team Details	Q4.3 Select the Organisation that hosts the HREC or other review body.*
Disclosure of Interests	0
Restrictions	This field is required
Evaluations	Q4.5 Under which review pathway are you intending to submit this application?
Location	Before answering this question, consider the guidance provided by the institution to which you are applying and contact the ethics or research office for advice.
Methods	This field is required
Participants	Note: The institution to which you are applying will review your application and determine the level of risk of the research project. Your answer to this question will only inform them of the
	intended review pathway.
Action research	Q4.6 Will this application be reviewed under the National Mutual Acceptance scheme?*
Participant Specific	Ves
Project Details	♦ Previous
Recruitment	
Consent	0
Risk	0
Benefit	0
Data and Privacy	
Generate HREA document	0
Upload	
HREC	
Declaration	
Generate HREA document	

2. Use the drop-down menu to select the Organisation that hosts the HREC (or other ethics review body) to which you wish to submit your application. If you are unsure which Organisation to choose, contact your institution's ethics/research office for advice.



3. Selecting an Organisation will generate a list of HRECs (and/or other ethics review bodies) hosted by that Organisation. At Q4.4, select the HREC (or other ethics review body) to which you wish to submit your application. If you are unsure which HREC or Organisation to choose, contact your institution's ethics/research office for advice.

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Introduction	HREC Proview ED Save
HREC Directory	♦ Previous
Project Overview	
Project Team	• Note that the HREA DOES NOT automatically submit your application to HRECs/ethics review bodies that require hard copy or emailed submissions. You will have to manually send your HREA to the ethics office once it is finalised.
Project Team Details	Q4.3 Select the Organisation that hosts the HREC or other review body.*
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Restrictions	
Evaluations	• The HRECs and other review bodies available in the list below are filtered by the Organisation you have selected above.
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Participants	
Method Specific	This field is required
Action research	Note: The institution to which you are applying will review your application and determine the level of risk of the research project. Your answer to this question will only inform them of the intended review pathway.
Participant Specific	Q4.6 Will this application be reviewed under the National Mutual Acceptance scheme?"
Project Details	
Recruitment	No No
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4. Contact information for Organisations and HRECs (or other ethics review body) can be found in the HREC Directory.

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HREC Directory		← Previous			Next 🗦
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Project Team	0	You may wish to seek advice from a HREC while con	npleting your application. Each HREC's contact informatio	n is provided below.	
Project Team Details	0	Organisation	HREC	Contact Phone	Contact Email
Disclosure of Interests	0	Aboriginal Health & Medical Council of NSW	Aboriginal Health & Medical Research Council Ethics Committee	(02) 9212 4777	ethics@ahmrc.org.au
Restrictions	0	Organisation	HREC	Contact Phone	Contact Email
Evaluations	0	Aboriginal Health Council of WA	Western Australian Aboriginal Health Ethics Committee	(08) 9227 1631	ethics@ahcwa.org
Location	0	Organisation	HREC	Contact Phone	Contact Email
Methods	0	ACT Health Directorate	ACT Health Human Research Ethics Committee	(02) 6174 7968	Ethics@act.gov.au
Participants	0	Organisation	HREC	Contact Phone	Contact Email
Method Specific	0	Adventist Health Care Limited	Adventist Health Care Human Research Ethics Committee	(02) 9480 9609	research@sah.org.au
Participant Specific	0	Organisation	HREC	Contact Phone	Contact Email
Project Details	0	Albury Wodonga Health	Albury Wodonga Health Human Research Ethics Committee	(02) 6064 1572	ethics@awh.org.au
Recruitment	0		Committee		
Consent	0	Organisation	HREC	Contact Phone	Contact Email

5. Select the review pathway under which you intend your application to be considered. Note that not all Organisations have separate review pathways, and that the institution to which you applying will review your application and determine the level of risk of the research project. Your answer to Q4.5 will only inform them of the intended review pathway.

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6. Navigate to the 'Generate HREA document' page.

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Risk	0
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Data and Privacy	0
Generate HREA document	0
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 7. Verify that the application is complete and the Project Description/Protocol and any other documents have been attached. Completed sections are marked with a tick symbol.

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Recruitment	0

8. If the form is incomplete, you will not be able to submit it until all the mandatory questions have been completed. Incomplete questions will show a validation error at the top of screen and incomplete sections are marked with a cross symbol.

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9. Once the form is complete, select 'Generate HREA document'.

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10. The 'Application submission' dialogue box will open, where you can download your HREA files. Download <u>all</u> the files by clicking on each link.

The .zip file contains .pdf and .rtf versions of your application, along with any documents you have attached. Note that the .pdf and .rtf files **<u>cannot</u>** be uploaded into the HREA if they need to be amended.

The .omni file is a file type unique to the HREA. It allows the completed application to be re-uploaded to make any amendments required by the HREC or to use the completed application as the basis of a new application in the future.

Note: the 'tracked changes' .docx file will only appear if you have created a 'tracked changes' version. See **3.4 How to view a revised application with changes highlighted.**

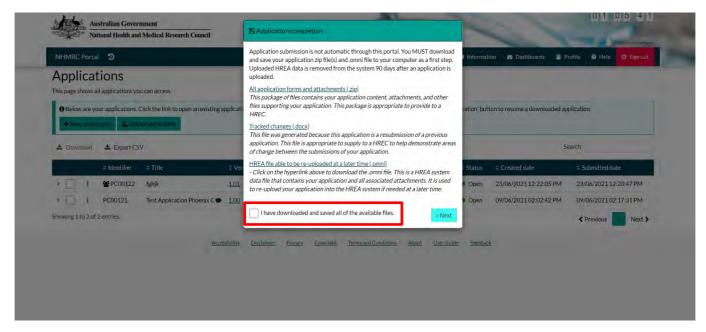
NHMRC Portal 🧐	Application submission is not automatic through this portal. You MUST download and save your application zip file(s) and .omni file to your computer as a first step.	Information	🚯 Dashboards 🕘 Pi	rofile 🛛 Help 😃 Signout
Applications	Uploaded HREA data is removed from the system 90 days after an application is uploaded.			
This page shows all applications you can access.	All application forms and attachments (_zip)			
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📩 Download 🎿 Export CSV	application. This file is appropriate to supply to a HREC to help demonstrate areas of change between the submissions of your andication		Se	earch:
= Identifier = Title = Ve	HREA file able to be re-uploaded at a later time (.omni) Crick on the typer link above to download the .omni me. This is a HREA system	Status	Created date	= Submitted date
1 i PC00122 fghjk 101	date first the second structure condition and all every state data shows at this could	Open 3	23/06/2021 12:22:05 PM	23/06/2021 12:20:47 PM
F PC00121 Test Application Phoenix C 1.00		Open (09/06/202102:02:42 PM	09/06/2021 02:17;31 PM
Showing 1 to 2 of 2 entries	I have downloaded and saved all of the available files.			< Previous Next >
Accessibility	Disclaimer: Privacy Copyright Terms and Conditions About User Guide	Eedback		

You must download <u>both</u> the .omni file and the .zip file/s and save them in a safe place.

You must ensure you have saved all the files you need before closing this dialogue box.

Completed applications and data is removed from the HREA system after 90 days.

11. Once you have downloaded all the files you require and have confirmed they have been saved, tick the confirmation box and select 'Next'.



12. A dialogue box will be displayed that shows how your chosen HREC wishes to receive the application. Follow the instructions provided to submit your application. You will also receive an email at your preferred contact email address with these instructions.

The HREC/institution to which you are applying determines their preferred method of submission.

Note: If you have any questions about the HREC/other ethics review body submission process, you should contact the HREC using the contact details provided or the institution's ethics/research office.

 Application completion 	
Congratulations. Your application is now ready to be sent to the HREC.	
To submit your application:	
 save the application zip file(s) and '.omni' file(s) to your computer with your other application documents, and then consult and follow your institution's policies to submit your HREA. 	
Contact your institution's ethics/research office if you have any questions abo how to submit your application after downloading your files.	ut
Note: Research activities must not commence until ethics approval has beer provided.	Î.
	se

13. If you need to re-download the .zip and/or .omni files, select 'Back' and download the files. To finish your session, select 'Close'.

Note: It is strongly recommended that you confirm all the files you require have been downloaded and saved before closing the session.

 Application completion 	
Congratulations. Your application is now ready to be sent to the HREC.	
To submit your application:	
1) save the application zip file(s) and ' omni' file(s) to your computer with you other application documents, and then 2) consult and follow your institution's policies to submit your HREA.	ir
Contact your institution's ethics/research office if you have any questions at how to submit your application after downloading your files.	out
Note: Research activities must not commence until ethics approval has bee provided.	en



3.2 How to revise and resubmit a previously submitted application

HRECs or other ethics review bodies will often require an application to be revised and resubmitted following an initial review. A previously submitted application can be opened and amended within the HREA for resubmission.

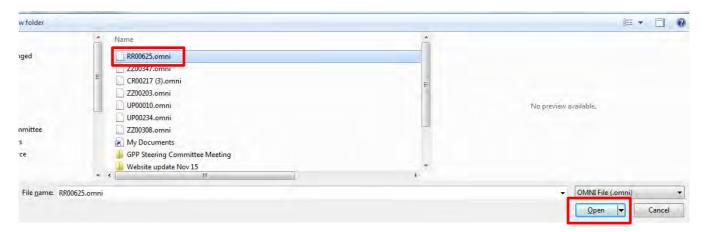
For HREA users, completed applications are stored in the HREA for 90 days. If more than 90 days have passed, the completed application .omni file will have to be uploaded to the HREA.

If you need to upload a previously downloaded .omni file:

1. Navigate to the 'Applications' page and select 'Upload application'.

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NHMRC Porta	al 🤊								0 🚳	9 8	e 6
Applica	tions										
is page shows a	all applications you o	can access.									
application.		ck the link to open an existing app									
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application. New applic Download iiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiii	cation ▲ Upload ★ Export CSV ♦ Identifier	application ¢ Title		* Status	and the second se	Organisation		≑ Status	Creat 23/06/2		

2. Navigate to the .omni file you saved on your computer for the application you wish to upload and select 'Open'. Once the file opens, it should then appear in your Applications list.

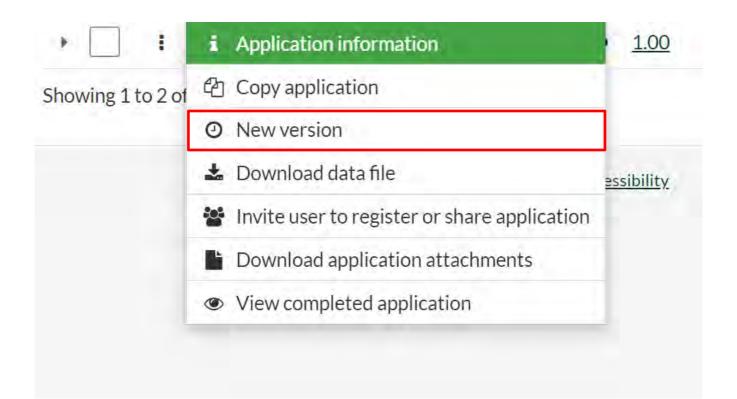


If the completed form is still listed in the HREA Applications list:

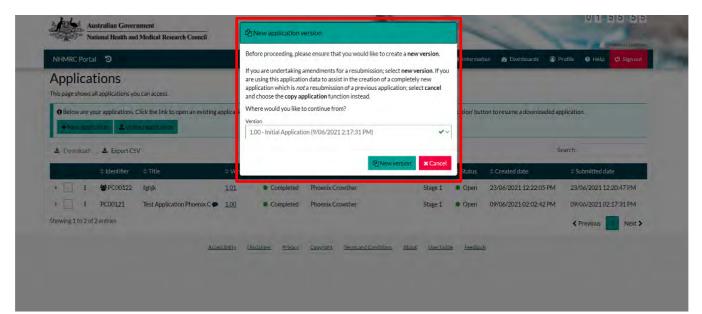
1. Navigate to the 'Applications' page and expand the menu by selecting the 'Options' button (three dots on the left side of the Identifier) next to the completed application you want to revise.

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NHMRC Porta	al D								8 28 2 9
pplica	tions								
is page shows a	all applications you o	can access.							
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Application. Answer application. Download	★ Export CSV ♦ Identifier	≑ Title	1/11			Organisation		≑ Status	Created date

2. In the 'Options' menu, select the 'New version' button.



3. Once you have selected 'New version', a dialogue box will ask you if you want to create a new version of an existing application or to copy an application instead.



3. Select 'New Version' to create a new version of your application. If you want to copy your application, see **3.3 How to use an existing application as a template for a new application.**

Australian Government National Health and Medical Research Council	2 New application version	0/1 5/5 5/5
NHMRC Portal Applications This page shows all applications you can access.	Before proceeding, please ensure that you would like to create a new version . If you are undertaking amendments for a resubmission, select new version . If you are using this application data to assist in the creation of a completely new application which is <i>not</i> a resubmission of a previous application; select cancel and choose the coay application function instead.) Information 📾 Dashboards 🕲 Profile 🛛 Help 😃 Sign out
Below are your applications. Click the link to open an existing applicat How upplication Alsocial application	And Choose the Copy application interaction instead. Where would you like to continue from? Version 1.00 - Initial Application (9/06/2021 2:17:31 PM)	cation' button to resume a downloaded application.
	②New version × Cancel	Search:
	Completed Phoenix Crowther Stage 1 Completed Phoenix Crowther Stage 1	Open 23/06/2021 12:22:05 PM 23/06/2021 12:20:47 PM Open 09/06/2021 02:02:42 PM 09/06/2021 02:17:31 PM Previous 1 Next >
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4. Enter the title of the new version of the application, enter any application comments and then select 'New Version'.

Australian Government National Health and Medical Research Council	图 New application version	
NHMRC Portal 3	You are about to create a new version of the selected application. If you would I to continue, click the 'new version' button below. If you would like to rename th	ike
Applications	application, please provide the new name below.	
This page shows all applications you can access.	Application title	
	Test Application	the second se
O Below are your applications. Click the link to open an existing application	Application comments	ation' button to resume a downloaded application.
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I PC00121 Test Application Phoenix C 9 1.00	Completed Phoenix Crowther Stage 1	Open 09/06/2021 02:02:42 PM 09/06/2021 02:17:31 PM
Showing 1 to 2 of 2 entries		< Previous U Next >
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- 5. The new version will be added to your Applications list.
- 6. The new version can now be opened, reviewed and edited. Note that when a new version of an existing application is created (whether that existing application has been submitted or not) a copy with changes highlighted can be downloaded. Selecting the 'Track Changes' button will generate a version of your application with changes between the previous version and the new version highlighted in coloured font.

See **3.4 How to view a revised application with changes highlighted** for further information on generating and viewing tracked changes versions of applications.

NHMRC Portal 🤊	Explications
PC00121 - Test	Application
Introduction	Introduction
HREC Directory	Next
Project Overview	Before completing this application, acknowledge that:
Project Team	1) The HREA has been designed for ethics review of human research, as defined in the <u>National Statement</u> .*
Project Team Details	Interinca has been easilied to each as revew of numerices and, as defined in the <u>reactional datement</u> . The National Statement states that research is:
Disclosure of Interests	"widely understood to include at least investigation undertaken to gain knowledge and understanding or to train researchers Human research is research conducted with or about people, their data or tissue".
Restrictions	The <u>Australian Code for the Responsible Conduct of Research (the Code</u>) states that research includes: "the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies inventions and understandings."
Evaluations	Research excludes activities that are carried out exclusively for quality improvement, quality assurance or evaluation.
Location	 Audit-type activities may be considered research if investigating a potential research question. Non-research projects that will be published and some student internships may need ethics review, but not necessarily by an HREC.
Methods	 Contact your institution's ethics or research office for guidance on whether your project requires ethics review.
	2) Adequate resources must be available to conduct this research project. *
Participants	National Statement 1.1 (f) states that research that has merit is:
Method Specific	"conducted using facilities and resources appropriate for the research".
Participant Specific	It is expected that adequate resources will be available for this research project. Resources may include: financial resources, human resources, equipment, facilities and in-kind support. Consult with your institution's ethics or research office for further advice.
Aboriginal and Torres Strait	3) All relevant institutional polices pertaining to the conduct of this research project should be considered and adhered to. *
Islander Peoples	• Institutions may have policies in place that relate to the conduct of research. These policies should be consulted prior to completing this application and adhered to throughout the conduct of the
Project Details	research. • Consult with your institution's ethics or research office for further advice.
Recruitment	• Ensure all investigators are familiar with their institutional policies and note that if you are conducting research at multiple sites that institutional policies may differ.
Consent	4) Research activities must not commence until ethics approval (and site authorisation, if appropriate) has been provided. st
Consent	 You must not start your research project until you have received written ethics approval and site authorisation (if appropriate).

Note: The new version/amend/submit process can occur as many times as necessary.

3.3 How to use an existing application as a template for a new application

The 'Copy application' function can also be used to generate a template for a new application from a completed application or another in-progress application. For example, if you regularly make applications with the same investigator team you could create a template that contains all their information, avoiding the need to enter it every time you create an application. There are two options available:

- a) If required, upload the .omni file of a completed application from your computer.
- b) Create a copy within the HREA if it is less than 90 days since your application was completed. To copy within HREA, perform the following steps.
- 1. Navigate to the 'Applications' page, identify the application you wish to share and select the 'Options' button (three dots on the left side of the Identifier) next to it.

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NHMRC Porta	al ' D								0 23	~	ک (
Applica	tions all applications you c										
	our applications. Cli	ck the link to open an existing app	incation, use ti	ie new application	button below to start a	new one, of click the	opioad applica	ation buttont	o resultie a u	ownoaded	
application. + New appli	cation LUpload	l application						5	Search:		
application. + New appli		application ⇒ Title	♦ Version	≑ Status	≑ Owner	Organisation		¢ Status	Search:	d date	
application.	Ł Export CSV]	Version 1.01	StatusIn Progress	Owner Phoenix Crowther	Organisation	Stage 1		≑ Create	d date)21 12:22:0	15 PM
application.	▲ Export CSV ↓ Identifier	¢ Title		of contracts		¢ Organisation		Status	Creater 23/06/20	a particular	

2. Select the 'Copy application' button.

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Showing 1 to 2 o	街 Copy application	
	 New version 	
	🛓 Download data file	<u>essibility</u>
	Invite user to register or share application	
	Download application attachments	
	 View completed application 	

3. Select 'New application'.

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National Health and Medici	al Research Council	đ) Copy applicati	ion		i.	-			Contraction Construction
NHMRC Portal 🤊			reate a New version of this applica on's data into a New application?	ition or would you	like to	Information	🕸 Dashboards	Profile	Help O Sign out
Applications This page shows all applications you can ac	cess.		n from the options menu next to the npleted application for re-submissi						
Below are your applications. Click the Holew application Lipication		pplicatii application that is <u>r</u> Where would you I	ition below if you are copying an ap not a re-submission of a previously ike to continue from?			ation' button to r	resume a download	led applicati	on.
🛓 Download 🔺 Export CSV		Version 1,00 - Initial Appli	ication (9/06/2021 2:17:31 PM)		*~			Search:	
¢ Identifier 🔶 Title	Version	a Sta	line of			date	= Submitted date	1	 Modified date
• I <u>PC00121</u> Test App	olication 9 <u>1.01</u>	• In	↑ Nev	vapplication	K Cancel	21 10:21:07 AM			06/08/2021 10:21:05 AM
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ihowing 1 to 2 of 2 entries								<	Previous I Next >
	árr.	sibility Disclaimer Priva	cv Copyright Terms and Cond	itions About	UserGuide	Feedback			

4. Enter the title of the new application and select 'New application'.

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NHMRC Porta	al D	_	_			the selected application w application' button be		e for the new	application	and click	Information	🙆 Dashboards 🏾 🗴 Profi	
Applica	tions	-			Applicati	ion title							
This page shows a	all applications	you can access.			Test A	pplication - Copy of app	lication			~			
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🛓 Download	📥 Export (csv					< Back	+ New appl	lication	× Cancel		Searc	ifi:
	= Identifier	‡ Title	# Versi	on 😄 Sta	itus	≑ Owner	Organisation	- Stage	© Status	© Created	date	C Submitted date	+ Modified date
× 1	PC00121	Test Application 🗩	1.01	• In	Progress	Phoenix Crowther		Stage 1	Open	06/08/202	21 10:21:07 AM		06/08/2021 10:21:05 AM
• 🔲 👔	*PC00122	fghjk	<u>1.01</u>	• C	ompleted	Phoenix Crowther		Stage 1	Open	23/06/202	21 12:22:05 PM	23/06/2021 12:20:47 PM	06/08/2021 10:06:59 AM
Showing 1 to 2 of	2 entries												< Previous 🔽 Next >
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5. The new application will be added to your Applications list. Open the new application and remove all the 'non-template' information.

Note: It is strongly recommended that any templates you create are saved locally on your computer as .omni files, as inactive incomplete applications will be removed from the HREA after a period of 365 days.

Alternatively, you can start a new application, partially compete it as appropriate and use this as a template for future applications. As above, it is recommended that any templates are saved on your computer as .omni files, as inactive incomplete applications will be removed from the HREA after 365 days.

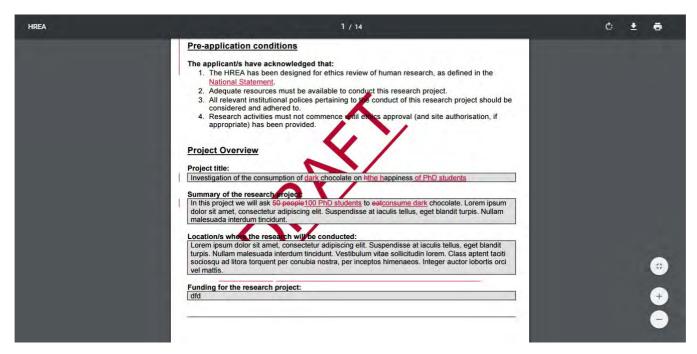
3.4 How to view a revised application with changes highlighted

The HREA includes a feature to generate a 'tracked changes' version of a revised ethics application. This can be used to review any changes at any time when a revised application is in progress, and may also be requested by the HREC or other ethics review body when submitting a revised application.

- 1. Create a 'New version' of an application. See **3.2** 'How to revise and resubmit a previously submitted application' for details on how to do this. Ensure you name the new version appropriately in order to keep track of multiple versions of an application.
- 2. Revise the new version as appropriate. You can generate a .docx version of the draft application highlighting any changes at any time by selecting the 'Track Changes' button.

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NHMRC Portal 🤊	Applications 🛛 Information 🏤 Dashboards 🏵 Profile 🖌 Heip 💙 Sign out
200121 - Test	Application
Introduction	Introduction ProckChanges
HREC Directory	Next)
Project Overview	Before completing this application, acknowledge that:
Project Team	1) The HREA has been designed for ethics review of human research, as defined in the National Statement. *
Project Team Details	The National Statement states that research is:
Disclosure of Interests	"widely understood to include at least investigation undertaken to gain knowledge and understanding or to train researchers Human research is research conducted with or about people, or their data or tissue",
Restrictions	The <u>Australian Code for the Responsible Conduct of Research (the Code</u>) states that research includes: "the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies inventions and understandings."
Evaluations	Research excludes activities that are carried out exclusively for quality improvement, quality assurance or evaluation.
Location	 Audit-type activities may be considered research if investigating a potential research question. Non-research projects that will be published and some student internships may need ethics review, but not necessarily by an HREC.
Methods	Contact your institution's ethics or research office for guidance on whether your project requires ethics review.
Participants	 2) Adequate resources must be available to conduct this research project. National Statement 11 (f) states that research that has merit is:
Method Specific	<u>National statement</u>
Participant Specific	It is expected that adequate resources will be available for this research project. Resources may include: financial resources, human resources, equipment, facilities and in-kind support. Consult with your institution's ethics or research office for further advice.
Aboriginal and Torres Strait	3) All relevant institutional polices pertaining to the conduct of this research project should be considered and adhered to. *
Islander Peoples	Institutions may have policies in place that relate to the conduct of research. These policies should be consulted prior to completing this application and adhered to throughout the conduct of the research.
Project Details	Consult with your institution's ethics or research office for further advice.
Recruitment	Ensure all investigators are familiar with their institutional policies and note that if you are conducting research at multiple sites that institutional policies may differ.
Consent	 4) Research activities must not commence until ethics approval (and site authorisation, if appropriate) has been provided. You must not start your research project until you have received written ethics approval and site authorisation (if appropriate).
Risk	rou must not start your research project until you have received written ethics approval and site authorisation (if appropriate). This includes screening of participants and/or data collection activities.
Benefit	5) The HREA requires the attachment of a <u>Project Description/Protocol</u> .

2. The .docx document shows the changes made to the draft application in coloured text.



3.5 How to submit a revised version of an application to an HREC

The process for submitting a revised version of an application is the same as the initial submission. However, you will also have the opportunity to download a 'tracked changes' version of the revised application.

1. Follow the instructions at **2.3.1 How to finalise and submit your application** to submit your HREA to the HREC (or other review body) and download your application for your records up to the point where the 'Application submission' dialogue box opens. The dialogue box will include the option to download a 'tracked changes' version of the application:

Application submission Application submission is not automatic through this portal. You MUST download and save your application zip file(s) and .omni file to your computer as a first step. Uploaded HREA data is removed from the system 90 days after an application is uploaded. All application forms and attachments (.zip) This package of files contains your application content, attachments, and other files supporting your application. This package is appropriate to provide to a HREC. Tracked changes (.docx) This file was generated because this application is a resubmission of a previous application. This file is appropriate to supply to a HREC to help demonstrate areas of change between the submissions of your application. HREA file able to be re-uploaded at a later time (.omni) - Click on the hyperlink above to download the .omni file. This is a HREA system data file that contains your application and all associated attachments. It is used to re-upload your application into the HREA system if needed at a later time. I have downloaded and saved all of the available files. Next

2. Once the documents you require have been downloaded, continue to submit your revised application as per the requirements of the HREC. Note: the 'tracked changes' version downloaded here will not be watermarked as 'Draft'.

Note: You must download the .omni file, the .zip file and the tracked changes .docx file and save them in a safe place on your computer.

Ensure you have saved all the files before moving from this page.

3.6 How to access your files after submission

As outlined above, you should download all the files you need and save them in a safe place on your computer. However, if you need to access your files after submission, they are available on the Applications page for 90 days.

You must not rely on the HREA to store your submitted or completed applications – always download and save your applications on your computer as you would for any important document.

1. Navigate to the 'Applications' page.

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2. Identify the application you want to download. Select the 'Options' button next to that application to expand the menu (three dots on the left side of the Identifier).

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Belov	w are yo	our applications. Clic	ck the link to open an existing app	plication, use t	ne 'New application'	button below to start a	new one, or click the '	Upload application	ation' button	to resume	a downlo	baded
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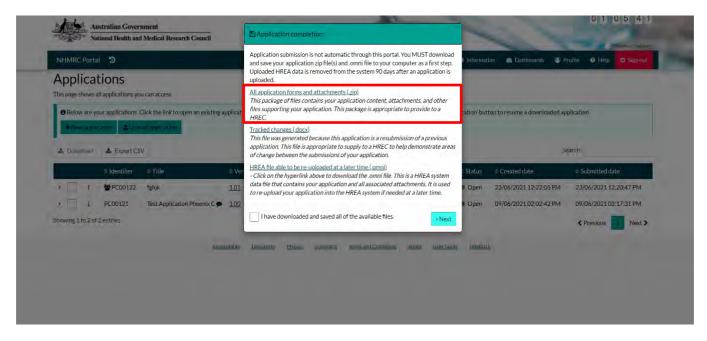
3. To download the .omni file (which can be re-uploaded into the HREA to create a new version or a template for a new application), select 'Download data file'. The .omni file will be downloaded to your computer's default downloads folder.

·	i Application information	<u>1.00</u>
Showing 1 to 2 of	Copy application	
	 New version 	
	🛓 Download data file	ssibility
	Invite user to register or share application	
	Download application attachments	
	 View completed application 	

4. To download the .zip file (which contains the .pdf and .rtf version of your application along with any attachments you included in your HREA) select the 'Download application attachments' button.

•	i	Application information	1.00
Showing 1 to 2 of	ළු	Copy application	
	0	New version	
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5. From the dialogue box that opens, select the .zip file labelled 'All application forms and attachments'. If this is an amended application, you will also see an option to download a 'tracked changes' document.



6. The .zip file will be downloaded to your default downloads folder and appear at the bottom of screen.

