

# ERM Human Ethics User Guide For Researchers

Swinburne Research- Research Ethics, Integrity & Biosafety Version 13-8-19

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# 1 Logging in

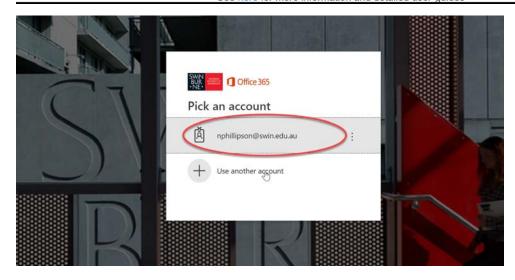
- Go to https://ethicsapps.swin.edu.au/
- Click on Log in on the top right hand corner
- Swinburne (Ethics Review Manager) ERM is fully integrated into the Swinburne Single Sign on. All researchers with an @swin.edu.au or @swin.edu.my will be able to access the application portal
- Use your Swinburne account (Swinburne email address) as the username (or pick your existing account)
- Use your email password for the password- click sign in.
- If you have any issues logging on email <u>resethics@swin.edu.au</u>

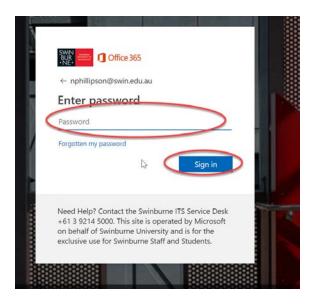
Research Ethics Applications Help -

# Swinburne Ethics Review Manager

#### Applications: Human Ethics, Animal Ethics & Biosafety

To log in click on Log in on the top left hand side. Use your Swinburne account (Swinburne email address) and password to log in If you are already logged in click on Home to take you to your Work Area See here for more information and detailed user-guides





• If you have signed in before your name will appear in the top right hand side indicating you are logged in. Click on home to take you to your work area. If you wish to log in as a different user Log out and you can then log back in again using a different username.



#### 1.1 How to log in as an external applicant (I don't have a Swinburne email address)?

- If you do not have a Swinburne email address contact the Research Ethics team on <u>resethics@swin.edu.au</u> or 03 9214 8145 or 03 9214 3845 and provide the following information
  - o The email address you wish to use to access the ERM
  - Information regarding which Swinburne researchers and project you are collaborating with
  - o A brief summary about your research and Swinburne's involvement.
- We will then create an account for you and email you a username and password.

# 2 Selecting the right ethics application for you

#### 2.1 Different applications available

- There are 3 different types of Human Ethics applications available, details of which are listed below.
- These options are found when you select the 'Create project' icon in the Actions Panel on the left-hand side of the landing page. The drop-down list for Main Form lists these as options
- For more information about what form to use please email: <u>resethics@swin.edu.au</u>

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#### 2.1.1 New Human Research Ethics Application

• This is the standard ethics application for all human research ethics that has not been reviewed or approved by any other Human Research Ethics committee and is not a clinical trial

#### 2.1.2 Human External Approved/Transferred

- Previously called "Expedited review" applications
- If your project has been reviewed and approved by another Australian Human Research Ethics Committee that is registered with the NHMRC your project can undergo expedited review.
- As your project has already undergone ethical review and approval you can complete the substantially shorter Human Ethics Expedited review form which will be reviewed out of session.

#### 2.1.3 HREA (Clinical Trials)

- The NHMRC's Human Research Ethics Application (HREA) should be used for all clinical trials of drugs or devices.
- This application form is specifically designed to answer relevant questions about clinical trials and can be used at other sites (including public hospitals) to apply for ethical approval.
- If you have completed a HREA on hrea.gov.au you can upload the completed HREA into this system. For information on how to do this please contact <u>resethics@swin.edu.au</u>.

#### 2.1.4 Other application types

- The drop-down list contains other application types:
  - Biosafety Clearance Application: For research requiring biosafety clearance as you are using biohazardous materials (e.g. venoms or blood products) and/or genetically modified organisms (e.g. genetically modified cell lines, bacteria, plants or other organisms).
  - SAEC application form: For research requiring animal ethics clearance by the Swinburne Animal Ethics Committee (SAEC), as your research is using animals, animal tissue or observing animals.

# 3 How to complete a standard human ethics application

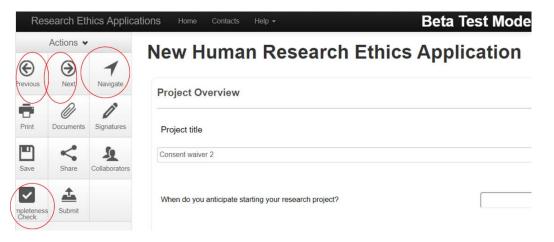
#### 3.1 Drafting your application

Once you have created your application you will be taken to the navigation page displayed below.

We strongly recommend you commence at the START section as this will take you through a series of checklists that will create and remove sections depending on how you answer these

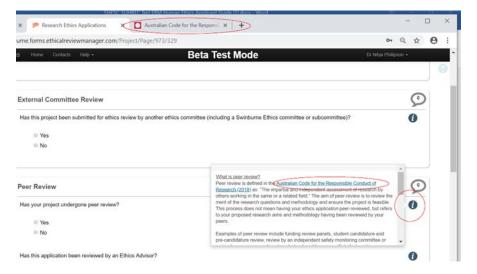
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			Section B - Research Person	nnel	Research Personnel	
			Section C - Research Admin	istration	Research Administration	
			Section D - Project Details		Project Details	
			Section G - Data Manageme	int Plan	Data Management Plan	
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- Navigate through the form by clicking Next or Previous
- You can see the overall structure of the form by clicking on the navigate icon and then click on the relevant sections of the form to take you to that section
- You can conduct a completeness check at any time by selecting the completeness check button in the Actions tab on the LHS and go directly to any incomplete section by clicking on the sections highlighted as incomplete.
- Please Save your application frequently to avoid losing any work. To do this click on the Save button on the LHS actions tab.
- Please note that only the Chief Investigator can submit an ethics application. Please see section 6 of this guide for more information



#### 3.2 Need help with a question

- To see help sections click on the *i* icon next to the question
- A help text will pop up in a window. If you click on a hyperlink they will open in a new tab



#### 3.3 Attaching relevant documents

- You may be prompted at certain points to upload a document. To do this, click upload documents
- Click Browse to select the file on your computer you wish to upload, enter a version date and number to ensure document control

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- You can review all documents uploaded to the application using the Document button on the Actions tab that is located on the left hand side (LHS)
- Documents can be downloaded separately or all together

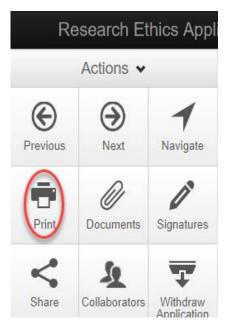
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- 3.4 Using templates for consent information documentation and other associated documents
  - We strongly recommend you use the template documents provided to assist you with your applications. These are all stored within the system.
  - To access the templates go to the 'Help' tab on the top navigation bar and click on Templates.

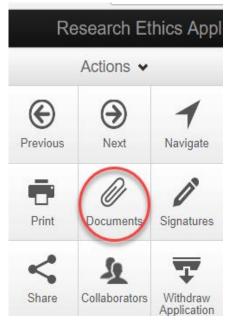
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#### 3.5 Downloading the application and application documents

• In order to download a copy of the application in its entirety as a pdf file, select the print button in the Actions tab on the LHS. This will open the application as a pdf file in a separate browser.



• In order to download individual attachments (e.g. consent instruments), select the documents button in the Actions tab on the LHS.



• This will bring up the following:

Documents

#### Documents

Search Document						
Type	Document Name	File Name	Version Date	+ Version	\$ Size	View
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Explanatory statement	CIS mock document	CIS mock document.docx	17/07/2019	1	11.3 KB	Download
Advertising material	CIS mock document	CIS mock document.docx	17/07/2019	1	11.3 KB	Download
OTHER PROJECT-RELATED DOCUMENTATION	CIS mock document	CIS mock document docx	17/07/2019	1	11 3 KB	Download

• In order to download all documents as a pdf file (i.e. application form and all associated documents/attachments), select Download All as Pdf:

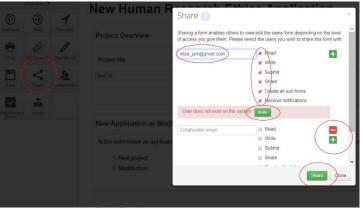
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• In order to download all documents in their original format as a .zip file, select Download All:

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Explanatory statement	CIS mock document	CIS mock document.docx	17/07/2019	1	11.3 KB	Download
Advertising material	CIS mock document	SCIS mock document.docx	17/07/2019	1	11.3 KB	Download
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# 4 How to share and collaborate on a standard human ethics application

- To share your application with other collaborators for their input, click on the Share icon on the LHS action tab
- A pop-up box will appear. Enter the email address of the collaborator.
- Select permission (you can select multiple options)
  - Read person can read the application
  - o Write person can add content to the application
  - Submit person can submit the application (see signature section for more information on submission)
  - Share person can go on to share the application with others and assign these permissions forward
  - Create all sub-forms person can create sub-forms like annual reports and adverse event
  - o Receive notifications person will receive notifications about the application.
- Do this for multiple collaborators by clicking on the addition button and repeat for additional collaborators.
- All persons with an @swin.edu.au or @swin.edu.my email address will immediately be set up with access to Swinburne ERM. If named collaborators do not have an '@swin.edu.au' an invite button will appear, the person will receive an email indicating how to obtain access to the system.
- To remove a collaborator, click on the minus button.
- Click Share to finalise. This can be modified at any time. Please note you cannot click share if you have empty collaborator sections present.



• To review your collaboration or edit permissions click on collaboration icon on LHS Actions tab. You can edit permission by clicking on edit permission button

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# 5 How to make comments on yours or a collaborator's ethics application

- To make a comment for other researchers or collaborators to see click on the comment bubble on the top right-hand side of a question.
- Enter the comment you wish your collaborators to see. These will only be visible to your collaborators and not the ethics committee reviewer

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- You and your collaborators can view a summary of comments, click on the Comments button on the LHS action tab
- A list of all comments will appear, you can click on these comments and it will take you directly to the question the comment refers to.
- You can edit or delete a comment by clicking on the comment and the delete button shows up, or you can amend this comment.

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## 6 How to obtain sign off on a standard human ethics application

- Chief Investigators (CIs) must sign off on ethics applications.
- Students cannot act as CI, the student's primary supervisor should act as CI
- To commence sign off, click on the navigate icon on the LHS actions tab to navigate to the sign off section of the application
- Once an application is submitted, an email will be sent to all ALL investigators and associate investigators listed in the research personnel section of the application notifying them that an application has been submitted with them listed as an investigator. The REO strongly recommends that the application be shared with all listed applicants with at least read permission.

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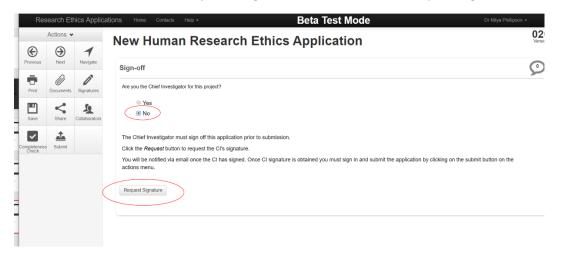
#### 6.1 If the applicant is the Cl

- Using the navigate icon on the LHS actions tab to navigate to the sign off section of the application
- The sign off question asks: Are you the chief investigator of this project?
- If the applicant is the CI then then click Yes.
- A completeness check will be undertaken. Sections that are incomplete will be highlighted. Click on the relevant section of the application which will indicate the incomplete section. The application cannot be submitted until all mandatory sections have been completed.
- A CI declaration will appear. This must be carefully read and if agreed to, click on the Submit button.
- Your application has now been submitted and will be locked. The REO will automatically receive this information and an automated email will be sent confirming submission.

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Completeness	Submt	permit this form	By submitting this application, I, the Chief investigator, agree that: • All information is truthful and as complete as possible: - Vell conduct the project in accordance with our responsibilities under the National Statement on Ether Information and the Australian Code for the Responsible Conduct of Research: • Vell conduct the project in accordance with Swithburne requirements and the standard or special at • Vell conduct the project in accordance with Swithburne requirements and the standard or special at • Vell conduct the project in accordance with Swithburne requirements and the standard or special at • Vell conduct the project in accordance with Swithburne requirements and the standard or ethical manner; and • Vell immediately report in writing to the HREC of any modifications to this application, and any adve	vith these; hiss clearance conditions including provision of reports as required; to be conducted according to good research practice and in an
			Submit the application by clicking on the submit button in the actions menu. The investigators listed in the molecular with them listed as an immediators.	this application will automatically notified that you have submitted an

#### 6.2 If the applicant is NOT the CI

- Use the navigate icon on the LHS actions tab to navigate to the sign off section of the application
- The sign off question asks: Are you the Chief Investigator of this project?
- If the applicant is NOT the CI then then click No. Please note students cannot act as CIs this should be the student's primary supervisor or project lead.
- You will be asked to request a signature of the CI, click on Request Signature



- Enter the CI's email address, a message for the CI (optional) and click on Request
- The CI must also be listed an applicant on the application otherwise an error message will appear.
- When you click on Request, a completeness check will be undertaken. Sections that are incomplete will be highlighted. Click on the relevant section of the application which will indicate the incomplete section. The application cannot be submitted until all mandatory sections have been completed.

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• The CI will receive an email requesting sign off. The link in the email will take the CI to the project (sign in required using Swinburne single sign on user ID (<u>name@swin.edu.au</u>) and password).



#### Dear Ms Tester

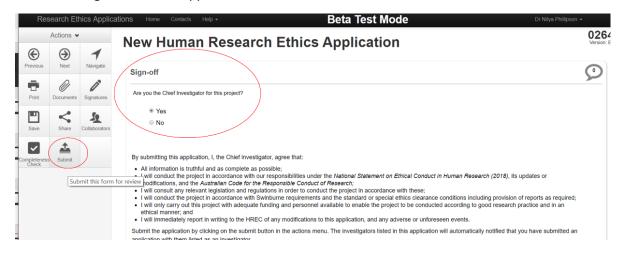
You have received a signature request from Current User Full Name with a message.

#### Hey sign my app

To view your outstanding signature requests, click on the following link:

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

• When the CI signs off on the application you will receive notification via email. You must then go back to the application and select submit in the LHS action tab.



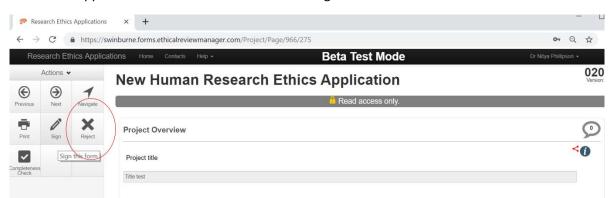
#### 6.3 Signing an ethics application as CI

- You will receive an email asking you to sign in to ERM and sign off on an application
- Click on the Signatures tile in the Work Area
- Here you can see all applications waiting on signatures, as well as those previously signed
- Click on view application- you will have read only access to the application.
- If you are happy with the application, click on the Sign icon on the LHS action tab
- You will be prompted to re-enter your email address and password.
- An email will now be sent to the applicant indicating sign off.

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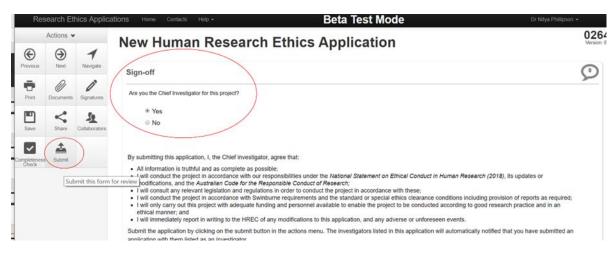
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- If you do not wish to sign off on the ethics application, click on the Reject icon on the LHS actions tab.
- You will be prompted to provide feedback to the applicant. This will be sent in an email to the applicant and the form unlocked for changes.



#### 6.4 Submitting an ethics application

- Once the CI has signed the application (or you are the CI) you may submit the form.
- Click on the Submit button the LHS actions tab



# 7 How to organise your projects

- You can create custom folders to store your ethics applications
- In the work area click on create folder, and name as you choose
- You can then drag and drop applications out of the list of all applications into relevant folders, the folder will turn yellow when you are about to drop something into it
- Please note that when you search for projects in this list of all applications any projects placed in sub folders will not show up.
- To move a project, click into the folder and select move folder button on LHS action tab. This will then allow you to move the project into other existing folders or the work area.

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Home Notifications Actions Create Folder Create Froject	General Folder Title (maximum 40 characters):* ARC COEI Create Create	Close
Research Ethics Applications Homo Com Work Area • Notifications	Antacob Help + Beta Test Mode Dr. Netra Philippon + Signatures Transfers Shared	1 *
Actions • Folders	0 3 2	
Project     P	UoM         DEMO         Monash         ARC CoE           Consent waiver3         262         Dr Nitya Philipzon         09/05/2019 12:32         09/05/2019 12:32	
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# 8 How to duplicate an existing application

- Click on Duplicate project in the LHS actions tab of the work area
- Select the application you wish to duplicate out of the drop-down list. All applications within the work area will be listed. If the application you wish to duplicate is in a folder, enter that folder and then select duplicate. The applications listed in the drop down available to be duplicated will now only be for those in the folder you are accessing this button from.
- Enter a new title for the duplicate application
- You can now amend the duplicated application as appropriate

Work Area 💌	Signatures	Transfers	hared
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		How to review an application testing collaborators	
		HREA test fhad Test2	e Crea (5/2019
		Test45	5/2019

## 9 How to search for a project

To search for projects that you have not allocated to projects follow the steps below:

- The work area has all your ethics applications that are not in folders in a searchable list. To search for an ethics application, type in the title or key word. The list of projects will start narrowing down as you type.
- Please note that projects in folders cannot be found using this search bar. For that you must enter the project folder and search within that folder.

Work Area 👻	Work Are	a						
tomi Notifications	General							
Actions 🛩	Notifications	Signatures	Transfers	Shared				
Polder Delete Folder Create Project	28	1	2	2				
Project Duplicate Transfer	Folders							
	RMIT	UoM	DEMO	Monash	ARC COE	test		
	0	1	2	1	0		0	
	Projects							
	Search Projects					>		
	Project Title		I Project ID	• Owner		ate Created	‡ Date Modified	I Transfer Status
	Test 89		269	Dr Nitya Phili		05/2019 10:49	10/05/2019 10:50	
	Test 18		268	Dr Nitya Phili		05/2019 09:43	10/05/2019 09:49	
	Track changes demo		266	Dr Nitya Phili		05/2019 08:35	10/05/2019 08:42	
	Test 15		264	Dr Nitya Phili		105/2019-14-52	09/05/2019 15:47	
	Consent waiver3		262	Or Nitya Phili		K05/2019 12:32	09/05/2019 12:32	
	phd students		261	Dr Nitya Phili	pson 09	105/2019 12:23	09/05/2019 12:23	
	demo		260	Dr Nitya Phili	pson 09	05/2019 12:05	09/05/2019 12:19	
	go		257	Dr Nitya Phili	pson 07	/05/2019 15:24	07/05/2019 15 53	
	Consent waiver 2		256	Dr Nitva Phili		/05/2019 12 59	07/05/2019 12:59	

# 10 How to transfer an application

If you are no longer CI on a project or you are leaving Swinburne, you will need to transfer your project to a new CI. To do this:

- Click on the Transfer icon on the LHS of the actions tab in the work area
- Enter the email address of the new CI and a message regarding the transfer, then select the applications you wish to transfer.
- The new CI will receive an email indicating the transfer. The Research Ethics Office will also be notified about the transfer so they can support the old and new CI in any changes to documentation required.
- Research Ennoc Applications
   tow
   oracle
   tow
   tow
- You will no longer have access to a transferred application.

#### 10.1 How to accept or reject a transferred application

- You will receive an email indicating a project has been transferred to you.
- Log into ERM and go to the transfer icon on the work area
- This will show you all transfers, transfers requiring your action will be highlighted in yellow. To accept a transfer, click on view project
- You can accept or reject the transfer using accept transfer and reject transfer icon on the LHS actions tab.

V	Vork Area	•	Work Area	
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Home	Notifications		General	
	Actions 🛩		Notifications Signatures Transfers Shared	
reate Folder	Delete Folder	Create Project	20 0 2 2	
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Search Trar	nsfers						
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13		You	Dr Ann Gaeth	hi pls accept my projects	09/05/2019 12:24	Request	ed View Project
12	test NP 3-1-19	You	Dr Ann Gaeth	hi pls accept my projects	09/05/2019 12:24	Request	ed View Project
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# 11 Committee feedback

#### 11.1 Receiving feedback

- You will be notified via email when you have received feedback from the ethics office or ethics committee.
- This email will contain a link to the ethics application in ERM and attachment that includes a list of the comments made in the application

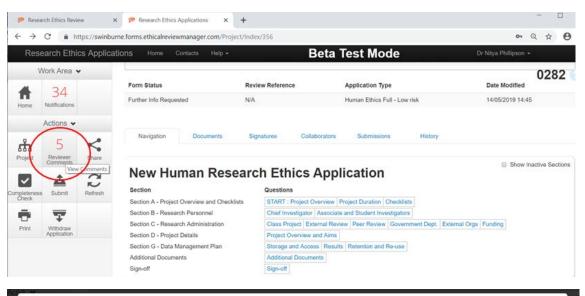
Tue 14/05/2019 2:53 PM donotreply@infonetica.net
Request for further information - Research Ethics application 20190282-256
S Nitya Phillipson
Letter.pdf 57 KB
Dear All,
We refer to your Human Research Ethics application 20190282-256 : Reviewer Comments 2 submitted in May 2019
We require clarification on some aspects of your application. For detailed instructions please see the applicant User guide:
1. See the attached document outlining the comments about the application
2. Provide a response to each of these comments in a new document
3. Log into ERM and upload the response to comments document in the Additional Documents section of the application
4. Go to the relevant sections of the form relating to the comments and amend the ethics application accordingly.
If you have any issues reviewing the comments please contact the Research Ethics Office.
Regards,
Dr Nitya Phillipson
Research Ethics Office
Swinburne University of Technology
P: 03 9214 8069   E: resethics@swin.edu.au

#### 11.2 How to respond to feedback

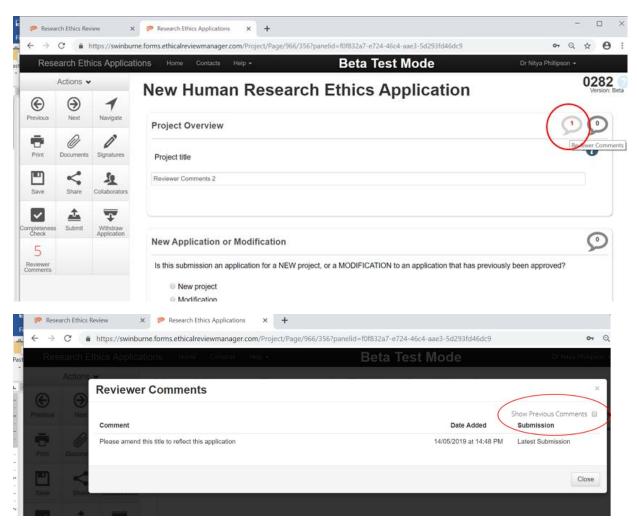
- Create a word document and copy and paste all the comments in the attachment into this word document.
- Provide a response to each of the queries in this document

<b>5</b> •0 •							Respo		ents 1.docx - \	Vord				
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- Log into ERM and make any relevant changes to the sections required
- To see all the comments made, click on the Reviewer comments button on the LHS actions tab
- A list of all the comments made about specific questions will pop up
- Clicking on the comment will take you to the page of the application form the comment relates to. You may need to scroll down to find the question that the comment pertains to
- Click on the comment bubble on the top RHS of the question to view the question.
- Amend the response in the application accordingly.
- To see previous comments related to previous submission click on show previous comments.



Overall Reviewer Panel Comments		
Comment	Date Added	Show Previous Comments Submission
Please amend this title to reflect this application	14/05/2019 at 14:48 PM	Latest Submission
Is this start date feasible? Please comment	14/05/2019 at 14:48 PM	Latest Submission
Are you obtaining data from the medical record? If so please amend this questions	14/05/2019 at 14:49 PM	Latest Submission
Please outline the researchers relevant expertise in this area	14/05/2019 at 14:49 PM	Latest Submission
Did the grant undergo peer review? If so amend this section.	14/05/2019 at 14:50 PM	Latest Submission
		Close
Section G - Project Locality - Project Control - Project Control and Section Section and Access - Sections and Access - Sections and Access - Sections and Access - Sections - S	Results - Reservers and Revolution	



#### 11.3 Upload your responses

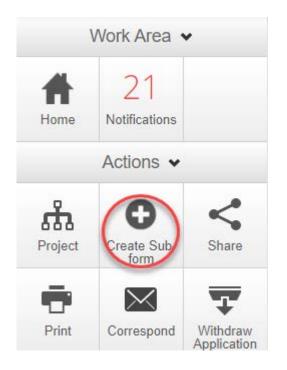
- If changes are required to the consent information statement or other documentation use track changes in Word to make any relevant changes to these document
- Upload the "response to queries" document and any amended documents in the upload documents section of the applications
- Ensure these documents are carefully named and the version date and version number are accurate. This will allow you and the committee to ensure the correct documents are reviewed.
- **Resubmit the application**. Note if you are not the CI you will be required to obtain sign off from the CI on this resubmission. To do this see section 6 of this guide.

V	Vork Area	cs Applicati	ONS Home Contacts Hel	• Beta lest N	IOCE Dr Nitya Phill
			Form Status	Review Reference Applicatio	n Type Date Mod
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Check	Submit	N	Section Section A - Project Overview and C Section B - Research Personnel Section C - Research Administratic Section D - Project Details	Questions           mecklists         START : Project Overview         Project Durat           Chief Investigator         Associate and Studen           Class Project         External Review         Peer Re           Project Overview and Aims         Project Overview and Aims         Peer Re	Dn ion Checklists t Investigators view Government Dept. External Orgs Funding

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# 12 Modifications

- All modifications to approved ethics applications must be submitted and approved prior to implementation
- Select the project you wish to modify
- In the top left-hand corner under 'Actions', click on 'Create Sub-form'



• This will bring up the following

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

• Select 'Human Ethics Modification Request' from the drop-down list

1

Create Sub-form		×
Select the sub-form that you would like to apply to this form		
Human Ethics Modification Request		
	Create	Close
<ul> <li>Then click on 'Create'</li> </ul>		
Create Sub-form		×
Select the sub-form that you would like to apply to this form		
Human Ethics Modification Request		
	Create	Close

• This will bring up the following

Human Ethics Modification Request								
Form Status		Review Reference			Application Typ	e	Date Modified	
Not Submitted		N/A			N/A		13/08/2019 11:25	
				\$				
	Navigation	Documents	Signatures	Collaborators	Submissions	History		

Human Ethics Modification Request					
Section	Questions				
Section B - Modifications/Additions Requested	Modifications/Additions Requested				
Section C - Attachment Checklist	Attachment Checklist				
Section D - Declaration	Declaration				

Show Inactive Sections

## Click on 'Modifications/Additions Requested'

Form Status		Review Reference			Application Ty	be .	Date Modified	
Not Submitted		N/A			N/A		13/08/2019 11:25	
					b			
	Navigation	Documents	Signatures	Collaborators	Submissions	History		

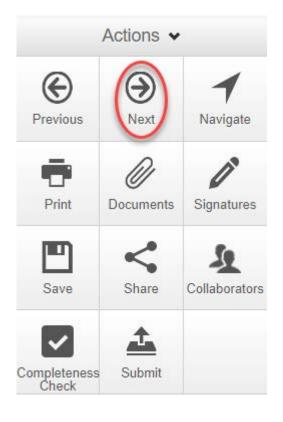
Indinan Ethics modification Request	
Section	Questions
Section B - Modifications/Additions Requested	Modifications/Additions Requested
Section C - Attachment Checklist	Attachment Checklist
Section D - Declaration	Declaration

• This will bring up the following

#### **Human Ethics Modification Request**

Change	Change of Personnel				
Indicate an	ty changes to the following:				
Indicate an	ty changes to the following:				
	Change in chief investigator/supervisor of the project Addition of Co-investigators (including student researchers or other personnel accessing identifiable data) other than students Removal of Co-investigators Other None of the above				
	k				
Other C	hanges				
Indicate ch	anges or additions required to the following:				
Tick all tha	t apply				
	Project Title(s), particularly on consent documents Project aims as given on current ethics clearance documentation Project methods/procedures/instruments Project participant cohort(s) or number(s) Other None of the above				
Have there	any been any changes/additions or developments to the following:				
	Financial or other resourcing for the project Researcher interests (see Help)				

• Scroll down and answer the questions and then click on 'Next' in the top left-hand corner under 'Actions' in order to navigate to the next page



• This will bring up the following

# Human Ethics Modification Request

Attachment Checklist
Are any of the following attached? Tick all that apply I NB. Revised procedures/instruments should preferably be submitted using tracked changes. In addition, a 'clean' version using version control should be submitted. Cross reference attachments to information supplied on this form with clearly delineated/paginated/headed attachments.
<ul> <li>Additional/revised research instruments (questionnaires, interview schedule, etc.)</li> <li>Additional/revised consent instruments (info statement, consent form, etc.)</li> <li>Additional/revised recruitment or publicity instruments (flyer, advert, etc.)</li> <li>Additional/revised debneting instrument</li> <li>Additional/revised external permissions/authonty</li> <li>Other</li> <li>None of these</li> </ul>

W

• If relevant, click on the relevant documents to be updated and upload them by selecting the 'Upload Document' button

# Attachment Checklist Are any of the following attached? Tick all that apply NB. Revised procedures/instruments should preferably be submitted using tracked changes. In addition, a 'clean' version using version control should be submitted. Cross reference attachments to information supplied on this form with clearly delineated/paginated/headed attachments. Additional/revised research instruments (questionnaires, interview schedule, etc.) Additional/revised consent instruments (info statement, consent form, etc.) Additional/revised debriefing instrument Additional/revised debriefing instrument Additional/revised external permissions/authority Other None of these

• This will bring up the following

Documents - Modi	fication supporting do	DCS	X
Please attach your Modification su	pporting docs here: Version Date	Version	
Browse			Upload
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• Click on 'Browse'

Documents - Moo	dification supporting docs		x
Please attach your Modification	supporting docs here:		
Document Name	Version Date	Version	
Browse			Upload
			Close

• Select the 'Version Date' from the calendar

13										
ease attach your Modification supporting docs here:				_	_	_				
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		11	12	13	14	15	16	17		
	Nauth	18	19	20	21	22	23	24		
	1	25	26	27	28	29	30	31		

• Enter the 'Version' number

Documents - Modification support	ng docs		×
Please attach your Modification supporting docs here:			
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guide-informed-consent-instrum	13/08/2019		Upload
guide-informed-consent-instruments (7).docx		$\bigcirc$	
			Close

• Click on 'Upload'

Documents - Modification support	ing docs		X
Please attach your Modification supporting docs here:			
Document Name	Version Date	Version	
guide-informed-consent-instrun	13/08/2019	1	Upload
guide-informed-consent-instruments (7).docx			
			Close
			Close

• The uploaded document will then as per the below

Attachm	ent Checklist							
Tick all that NB. Revise	d procedures/instrum		tracked changes. In addition, a 'clean' version usi attachments.	ng version control sho	uld be subm	itted. Cross	reference attach	iments to
800000	Additional/revised Additional/revised Additional/revised	I research instruments (questionnaires, i I consent instruments (info statement, co I recruitment or publicity instruments (flye I debriefing instrument I external permissions/authority	nsent form, etc.)					
Type Nodification Upload Doo	supporting docs	Document Name guide-informed-consent-instruments (7)	File Name guide-informed-consent-instruments (7).docx	Version Date 13/08/2019	Version 1	Size 45.5 KB	View Download	Delete

• If you wish to view the document, click on 'Download.' If you wish to delete the document, click on 'Delete'

Are any of the	he following attached?								
Tick all that	apply								
		ents should preferably be submitted us n with clearly delineated/paginated/head	ing tracked changes. In addition, a 'clean' v ded attachments.	ersion using v	ersion control sho	uld be subm	itted. Cross	s reference attach	ments to
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Modification Upload Doc	supporting docs	guide-informed-consent-instruments (7)	guide-informed-consent-instruments (7	').docx	13/08/2019	1	45.5 KB	Download	Delete

• Click on 'Next' in order to bring up the next page. If you are the Chief Investigator, select 'Yes' and then click on 'Sign'

Declaration
Are you the Chief Investigator of this project?
• Yes • No
Please sign this modification request and then submit the request using the submit button on the left hand side action button:
<ul> <li>By submitting this modification request, I declare that the above report accurately reflects the outcome or progress of the project to date.</li> <li>I acknowledge that an internal Swinburne or external audit may be conducted on the conduct of the project and as regards secure data retention/disposal.</li> </ul>
Sign

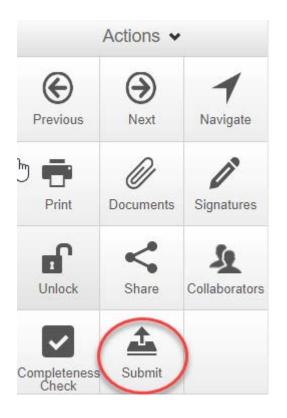
• This will bring up the following. Enter your e-mail address as your Username and enter your password and then click on 'Sign'

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

• This will bring up the following

	🔒 This form has been locked through signatures/requests
Declaration	
Are you the Chief Investigator of this p	roject?
Yes	Ν
No	la de la companya de
Please sign this modification request and th	en submit the request using the submit button on the left hand side action button:
	clare that the above report accurately reflects the outcome or progress of the project to date. r external audit may be conducted on the conduct of the project and as regards secure data retention/disposal.
r dechowiedge that an internal owniburie of	externar deals may be considered on the considered in the project and the regards secure data reconsidiopodal.
Sign	
Signed: This form was signed by Ms Ethics	Officer (resethics@swin.edu.au) on 13/08/2019 13:29

• In order to submit the modification request to the Ethics Office, you then need to click on 'Submit' under 'Actions' in the top left-hand corner



• This will bring up the following. You then need to click on 'Submit'

ubmit	
Complete: Youl <sup>2</sup> form is complete and ready to submit	
	Sutanit Close

• This will bring up the following

# Form Submitted

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

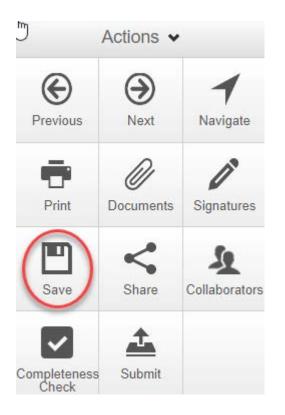
Your form will now be checked by the Research Ethics Office who will contact you if any clarification is required. If the form needs to be reviewed by an Ethics Committee or Sub-committee it will be assigned to the next meeting. Check meeting dates here. Contact the Research Ethics Office if you have any questions.

Home

• If some questions haven't been answered, the following will appear upon sign-off

Signatures	>
Incomplete: Please complete the following questions:	
Required mods     Has this project been approved by another Australia HREC?     Attachments	
	Close

• You will then need to go back and answer these questions, ensuring that you click on 'Save' in the top left-hand corner under 'Actions' after answering each question



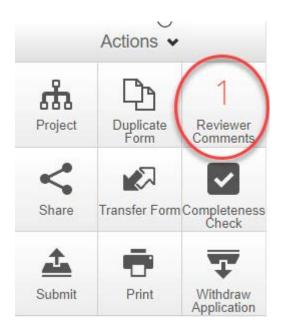
- Once you have answered all of the necessary questions, repeat the sign-off process as per above
- If you are not the Chief Investigator on the project, you need to indicate this at sign-off and then click on the 'Request Signature' button in order to request the Chief Investigator's sign-off on the request

Declaration	
Are you the Chief Investigator of this pro	ject?
Yes	
No	
Please request a signature from the Chief Inv	estigator of this project.
Once signed, you will need to log back i	n and submit this modification request form using the submit button on the left hand side action tab.
Request Signature	

• This will bring up the following. You then need to enter their e-mail address and, if necessary, a short message. They will then receive a notification from within ERM requesting them to sign off on the request

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

- Once they have signed off on it, you need to log back in and submit the request to the Ethics Office as per the above
- If the committee member reviewing the modification request has queries, the request will be returned to you within ERM and you will receive a notification from within ERM detailing the query/ies. You will then need to log into ERM and view the request in question. In order to view the member's query/ies, click on 'Reviewer Comments' under 'Actions' in the top left-hand corner



#### • This will bring up the following

Overall Reviewer Panel Comments		×
Comment	Date Added	Show Previous Comments
Please supply tracked changes versions as well	13/08/2019 at 13:52 PM	Latest Submission
		Close

• If you click on the comment/s in question, it will take you to the section being referred to as per the below with the section in question highlighted in red

Attachme	ent Checklist							90
Tick all that	d procedures/instrum	ients should preferably be submitted using n with clearly delineated/paginated/headed	tracked changes. In addition, a 'clean' version usin attachments.	g version control shou	uld be submi	tted. Cross	reference attachn	nents to
	<ul> <li>Additional/revised consent instruments (info statement, consent form, etc.)</li> <li>Additional/revised recruitment or publicity instruments (flyer, advert, etc.)</li> <li>Additional/revised debriefing instrument</li> <li>Additional/revised external permissions/authority</li> <li>Other</li> </ul>							
Туре		Document Name	File Name	Version Date	Version	Size	View	Delete
Modification Upload Doc	supporting docs	guide-informed-consent-instruments (7)	guide-informed-consent-instruments (7).docx	13/08/2019	1	45.5 KB	Download	Delete

• If you wish to read the comment/s again, click on the speech bubble in the top right-hand corner



• This will bring up the comment

Reviewer Comments	
Ç₂ Comment	Show Previous Comments   Date Added Submission
Please supply tracked changes versions as well.	13/08/2019 at 13:52 PM Latest Submission
	Close

- After you have amended the request as per the member's comment/s, you need to submit the modification request to the Ethics Office as per the process by which it was originally submitted. If the member is satisfied with the revised request, then the request will be approved. If they have further queries, the process will be repeated until they are satisfied and able to approve the request
- If the request is approved as submitted, you will receive notification of its approval from within ERM. The status of the request will also indicate this in the ERM record for the modification request, as per the below

Form Status		Review R	eference		Application	Type		Date Modified
Modification Approved	20191243-1177							13/08/2019 14:16
	Navigation	Documents	Signatures	Collaborators	Submissions	Correspondence	History	

#### **Human Ethics Modification Request**

Section	Questions
Section B - Modifications/Additions Requested	Modifications/Additions Requested
Section C - Attachment Checklist	Attachment Checklist
Section D - Declaration	Declaration

# 13 Annual/Final Reports

- You will receive an email from the system 30 days before a report is due and the day before a report is due. You will also receive reminder emails after the report is due if you fail to submit one.
- Sign in to ERM and go the project requiring a report (email will indicate project number and title)
- Click on the Create sub form button in the LHS action tab
- Select the Sub form: Human Ethics Report- Standard for projects originally reviewed by Swinburne and Human Ethics Report - Ext. Approved for expedited review projects and click on Create

Re	search Ethics	Applicati	ions Home Co	ontacts Help -		Beta	Test Mode	
	Work Area 👻		Annual re	eport tes	ŧ			
Home	37 Notifications		Project Tree 🛩					
Project	Actions ~	Share sub-form	Annual re     New	port test	Ethics Application			
-	$\times$	T	Form Status		Review Reference		Application Type	
Print	Correspond A	Withdraw pplication	Application Approved	1	20190296-260		Human Ethics Full - Lo	w risk
			Navigation	Documents	Signatures	Collaborators	Submissions	Correspo
r	Creat	e Su	b-form				×	
	Select the	sub-forn	n that you woul	d like to app	ly to this form			
	Please S	elect			•			
ual re	Please S					_		
Nev			eport - Standard dverse Events -				Close	

- For standard expedited review projects, select 'No' under A3 and upload the report that was submitted to the original ethics committee and evidence of this committee's approval of it under A4.
- For expedited review projects that were transferred into Swinburne, select 'Yes' under A3 and work through the rest of the report
- For all other projects, work through the report starting at Section A. Some of this data is auto-generated from the associated ethics application.
- Navigate through the form by clicking the Next or Previous button or Navigate button on the LHS of the Action tab.
- To share the annual report form with investigators click on the Share button on the LHS Action tab. See section 4 on more information on using the Share functionality.
- To submit click on the submit button on the LHS action tab.
- If you have any questions please contact resethics@swin.edu.au

Actions 👻	Form Status	Rev	iew Reference		Application Type	
<b>м О (</b> •	Not Submitted	N/A			N/A	
	Navigation	Documents	Signatures	Collaborators	Submissions	Histor
Completeness Submit Re Check	Human	Ethics Re	eport - St	andard	Questions	ı
	Section A - Project	Details			Project De	etails
	Section B - Progres	ss Summary			Progress	Summary
	Section C - Condu	ct of Project			Conduct of	of Project
	Section D - Declara	ation			Declaratio	n

# 14 Reporting an adverse event

- Sign in to ERM and go to the project requiring an adverse event report
- Click on the Create sub form button in the LHS action tab
- Select the Sub form: Human Ethics- Adverse Events and click on Create
- Work through the report starting at Section A. Some of this data is auto-generated from the associated ethics application
- Navigate through the form by clicking the Next or Previous button or Navigate button on the LHS of the Action tab.
- To share the annual report form with investigators click on the Share button on the LHS Action tab. See section 4 of this user guide for more information on using the Share functionality.
- To submit click on the submit button on the LHS action tab.
- If you have any questions please contact <u>resethics@swin.edu.au</u>



New Human Research Ethics Application

