

*STELLENBOSCH UNIVERSITY*

*Research Information Management System*

*INFONETICA*



## *Training Manual*

*Compliance/Ethics – New Application*



## *Contents*

- 1. Login*
- 2. Create your Project*
- 3. Complete the questions online*
- 4. Share your application with your supervisor*
- 5. Sign and Submit your application*
- 6. Changes Requested*
- 7. Creating a Sub form (i.e. Progress Report/Amendment)*
- 8. Definitions of Actions in Panel display*
- 9. Definitions of Statuses*

## 1. Login

The URL for the Infonetica site is <https://applyethics.sun.ac.za/>

You will be required to login using your [username@sun.ac.za](mailto:username@sun.ac.za) and network password. Follow the instructions that are applicable to you.



	<p><b>STUDENTS PLEASE NOTE:</b> <i>If you are not a registered student you will not be able to login. Please make sure you are registered before attempting to login.</i></p> <p><i>Students who require applying for ethics clearance before they are registered must do this in consultation with their relevant department as the department will have to add them to the Information Technology SUNID temporary user database so that the student can be issued a username and password by IT. <u>Please note that the SUNID process is not an ethics process, it is a completely separate process and is handled entirely by the relevant department</u></i></p>
--	---

## 2. Create your project

Once logged in, you will see the Infonetica landing page. To create your ethics project online follow the instructions below:

The screenshot shows the 'Research Ethics Applications' landing page. A red callout bubble points to the 'Create Project' button in the 'Actions' menu, with the text '1. Click on 'Create Project''. A red callout bubble points to the 'Work Area' header, with the text 'Your Work Area will open up'. The 'Work Area' section displays a 'General' tab with four sub-tabs: 'Notifications' (1), 'Signatures' (0), 'Transfers' (0), and 'Shared' (0). Below this is a 'Projects' table with the following data:

Project ID	Owner	Date Created	Date Modified	Transfer Status
74	Miss A Applicant	18/05/2017 16:33	18/05/2017 17:46	
65	Miss A Applicant	15/05/2017 13:30		

The table shows 'Showing 1 to 2 of 2 entries'. At the bottom, it says '© Infonetica Ltd 2017 Version 8.7.0.0' and 'Terms and Conditions | Privacy Policy'.

The screenshot shows the 'Create Project' dialog box. A red callout bubble points to the 'Project Title:\*' field, with the text '2. Enter Project Title'. A red callout bubble points to the 'Main Form' dropdown menu, with the text '3. Click on down-arrow and SELECT APPROPRIATE APPLICATION FORM'. The dropdown menu is open, showing the following options:

- Please Select...
- REC Humanities New Application Form
- Animal Care and Use New application Form
- Biosafety-facility Registration Form
- Health Research New Application Form
- HREC Biobank Application Form
- Animal Ethics Notification Form
- HREC Case Report Form
- HREC Exemption Application Form

The 'Close' button is visible at the bottom right of the dialog box.

**Create Project**

Project Title (maximum 200 characters):\*

Enter project title here

Main Form

Health Research New Applica ▼

ONCE YOU SELECT A FORM, THE CREATE BUTTON WILL APPEAR

4. Click on Create

Create Close

**\*\* NB: PLEASE ENSURE THAT YOU SELECT THE CORRECT APPLICATION FORM**

*HUMANITIES APPLICATION FORM:*

**Create Project**

Project Title:\*

Enter Project Title Here

Main Form

Please Select...

REC Humanities New Application Form

Animal Care and Use New Application Form

Biosafety-facility Registration Form

Health Research New Application Form

HREC Biobank Application Form

Animal Ethics Notification Form

HREC Case Report Form

HREC Exemption Application Form

Legacy form - For Administrators

REC: BEE Protocol Application Form

Humanities Eform

Close

Project ID	Owner	Date
119	Mr Xabiso Xesi	02/06
110	Mr Xabiso Xesi	30/05

### ANIMAL APPLICATION FORMS:

**Create Project**

Project Title:\*

Enter Project Title Here

Main Form

Please Select...

- Please Select...
- REC Humanities New Application Form
- Animal Care and Use New application Form**
- Biosafety-facility Registration Form
- Health Research New Application Form
- HREC Biobank Application Form
- Animal Ethics Notification Form
- HREC Case Report Form
- HREC Exemption Application Form
- Legacy form - For Administrators
- REC: BEE Protocol Application Form

Close

**Animal Ethics Eforms**

### BIOSAFETY APPLICATION FORMS:

**Create Project**

Project Title:\*

Enter Project Title Here

Main Form

Please Select...

- Please Select...
- REC Humanities New Application Form
- Animal Care and Use New application Form
- Biosafety-facility Registration Form**
- Health Research New Application Form
- HREC Biobank Application Form
- Animal Ethics Notification Form
- HREC Case Report Form
- HREC Exemption Application Form
- Legacy form - For Administrators
- REC: BEE Protocol Application Form

Close

**Biosafety Eforms**

### 3. Complete the questions online

The system has now created a record for you with a system generated number. The next step is to complete the electronic application form.

Research Ethics Applications Home Contacts Help Beta Test Mode Miss A Applicant

Work Area

Home Notifications

Actions

Project Create Form Create Sub-form

Share Completeness Check Submit

Automatic Submission Refresh Print

Correspond

Enter project title here 0074

Project Tree

Enter project title here

Health Research New Application Form

Form Status Review Reference Date Modified

Not Submitted N/A

Navigation Documents Signatures Collaborators Submissions Correspondence History

Health Research New Application Form

Section Questions

Filter Filter Questions

4. CLICK ON THE BLUE LINK TO OPEN UP YOUR FORM AND BEGIN ANSWERING THE QUESTIONS

You can now complete all the relevant questions in the e-form. Use the NEXT OR PREVIOUS BUTTONS on the left panel to navigate the online form.

Research Ethics Applications Home Contacts Help Beta Test Mode Miss A Applicant

Actions

Previous Next Navigate

Print Documents Signatures

Save Share Collaborators

Completeness Check Submit

Health Research New Application Form 0074 Version: Version 1

Ethics Committees (HRECs)

Research Ethics Committee Application Form. This is an application to the Health Research Ethics Committees

Study for Degree purposes

Is this a study for Degree purposes (including electives and skripsies)?

Yes No

Current level of study:

Masters

1. SHARE YOUR APPLICATION FORM WITH YOUR SUPERVISOR

2. COMPLETE ALL THE QUESTIONS ON EACH PAGE

3. CLICK ON THE NEXT BUTTON TO MOVE TO THE NEXT PAGE OF THE FORM

#### 4. Share your application with your supervisor

**Share** ?

Sharing a form enables others to view/edit the same form. Please select the users you wish to share with.

☒ Read  
☒ Write  
☐ Submit  
☐ Share  
☐ Create all sub forms  
☐ Receive notifications

**1. ENTER YOUR SUPERVISOR'S EMAIL ADDRESS**

**2. TICK THE BOXES TO ALLOW YOUR SUPERVISOR TO READ AND MAKE CHANGES**

**3. CLICK ON SHARE**

A notice will appear that your form has been shared successfully.

Your Supervisor will now be able to login, read and share comments with you while you are working on your form as shown below:

Research Ethics Applications Home Contacts Help ▾ **Beta Test Mode** Ms Nicole Walker ▾

Work Area ▾

Home 24 Notifications

Actions ▾

Create Folder Delete Folder Create Project

Delete Project Duplicate Project Transfer

**Work Area**

General

Notifications 24 Signatures 0 Transfers 0 **Shared 1**


**WHEN YOUR SUPERVISOR LOGS IN IT WILL APPEAR IN THEIR SHARED FOLDER**

Projects

Search Projects

Project Title	Project ID	Owner	Date Created	Date Modified	Transfer Status
Enter project title here	74	Miss A Applicant	18/05/2017 16:33	18/05/2017 16:40	



  
**Tips**

*Tip: If you are working on your e-form and you want to stop and continue at a later stage, you have to Save the e-form information and click on SAVE button icon on the left panel. When you are ready to work on the e-form again, login and click on Filter questions again.*

Research Ethics Applications
Home   Contacts   Help
Beta Test Mode
Miss A Applicant

Actions

Previous

Next

Navigate

Print

Documents

Signatures

Save

Share

Collaborators

Completeness Check

Submit

1  
Comments

## Health Research New Application Form

**Application to the Health Research Ethics Committees (HRECs)**

Application to the Health Research Ethics Committees (HRECs) only  
*Make sure you are completing the correct Research Ethics Committee Application Form. This is an application to the Health Research Ethics Committees (HRECs)*

Please select the type of research you are applying for:

Please click the Information (\*) icon to the right for the definition of Clinical and Health Research.

☒ Clinical Trial  
☐ Health Research

i

**Study for Degree purposes**

Is this a study for Degree purposes (including electives and skripsies)?

☐ Yes  
☒ No

0

HOVER OVER THE YELLOW ICON. IT SHOWS THAT YOUR SUPERVISOR IS CURRENTLY ON THIS PAGE AS WELL

Collaborators on this page are: Ms Nicole Walker

ONE COMMENT HAS BEEN ADDED. KEEP TRACK OF COMMENTS BETWEEN YOU AND YOUR SUPERVISOR

Click on the speech bubble icon to view your supervisor comment/s.

Research Ethics Applications
Home   Contacts   Help
Beta Test Mode
Miss A Applicant

Actions

Previous

Next

Navigate

Print

Documents

Signatures

Save

Share

Collaborators

Completeness Check

Submit

1  
Comments

☐ Yes  
☐ No

Will there be students working on this project as part of the research team but NOT for degree purposes?

☐ Yes  
☐ No

**Linked existing/main studies**

Is this a sub-study (new research question) linked to an existing/main study?

OR

Are there any other Stellenbosch University Ethics applications that are related to, or have a bearing on, this new application?

This includes any ethics applications that have already been reviewed or are pending review at any of the 5 Stellenbosch Ethics Committees (HREC1, HREC2, REC: Humanities, REC: AUC or REC:BEE).

☐ Yes  
☐ No

1. CLICK ON THE SPEECH BUBBLE ICON TO VIEW OR ADD COMMENTS

1

You can add comments for your supervisor to view while working through your application form.

The screenshot shows a 'Comments' dialog box with the following elements and instructions:

- 1. CLICK ON ADD COMMENT:** Points to the '+Add Comment' button.
- 2. TYPE COMMENT HERE:** Points to the text input field containing the placeholder text 'You can share comments with your supervisor here'.
- 3. CLICK ON SAVE:** Points to the 'Save' button.
- YOUR SUPERVISORS COMMENTS:** A red box highlights the 'Ensure that you make changes here' text, which is part of the comment being added.

The dialog box also displays a table of existing comments:

Comment	Date Added	Owner
You can share comments with your supervisor here	Now	You
Ensure that you make changes here	Thursday, May 18, 2017 at 5:22 PM	Ms Nicole Walker

At the bottom of the dialog box, there is a 'Close' button and a question: 'Is this a sub-study (new research question) linked to an existing/main study?'.

Keep track of the comments made between you and your supervisor by clicking on the speech bubble or comments button in the action panel.

The screenshot shows the 'Research Ethics Applications' interface in 'Beta Test Mode'. The 'Actions' panel on the left contains several icons, including a 'Comments' button (a speech bubble with the number 2) which is highlighted with a red box and a red arrow pointing to a similar speech bubble icon in the top right corner of the main content area.

A red speech bubble callout points to the 'Comments' button in the 'Actions' panel, containing the text: **YOUR COMMENT HAS BEEN ADDED AND SHARED WITH YOUR SUPERVISOR**.

The main content area shows a form with the following sections:

- Will there be students working on this project as part of the research team but NOT for degree purposes?** (Radio buttons for Yes and No).
- Linked existing/main studies** (Section header).
- Is this a sub-study (new research question) linked to an existing/main study?** (Radio buttons for Yes and No).
- OR**
- Are there any other Stellenbosch University Ethics applications that are related to, or have a bearing on, this new application?** (Radio buttons for Yes and No).

At the bottom of the form, there is a question: 'Does any ethics applications that have already been reviewed or are pending review at any of the 5 Stellenbosch Ethics Committees (HREC1, HREC2, REC: AUC or REC:BEE)?'.

Adding your supervisor's details in the form:

Research Ethics Applications Home Contacts Help **Beta Test Mode** Ms Nicole Walker

0075  
Version: Version 1

### Health Research New Application Form

**Supervisor**

Supervisor's Details

Xabiso Xesi(xabiso@sun.ac.za)

**1. TYPE IN YOUR SUPERVISORS NAME OR EMAIL AND SELECT**

**YOUR SUPERVISORS DETAILS WILL AUTOMATICALLY POPULATE IN THE FIELD**

Title	First Name	Surname
Mr	Xabiso	Xesi

Organisation

Department: Geology

Faculty: Science

Information icon displays at a few questions for further description:

Research Ethics Applications Home Contacts Help **Beta Test Mode** Ms Nicole Walker

Will any radioactive material be administered to the patient during the investigation?

☐ Yes  
☒ No

**Biohazardous Materials**

Will any Biohazardous Material be involved in the project?

☐ Yes  
☒ No

**Biohazardous Material** refers to recombinant DNA molecules, viruses, fungi, parasites, bacteria and all other potentially biohazardous material or products that are dangerous to both the experimental patient and the researcher.

**WHEN AN INFORMATION ICON APPEARS YOU CAN CLICK ON IT FOR FURTHER EXPLANATION/DESCRIPTION OF A QUESTION**

**Medical Devices**

Will any Medical Device be tested during this investigation?

☐ Yes  
☒ No

Uploading a document and viewing a URL Link:

Research Ethics Applications

Home

Contacts

Help

Beta Test Mode

Ms Nicole Walker

Actions

Previous

Next

Navigate

Print

Documents

Signatures

Save

Share

Collaborators

Completeness Check

Submit

Participant Insurance

Procedure for acquiring participant insurance through Stellenbosch University:

All **new research applicants** should contact the financial planning and asset management office to **register their new research project with Stellenbosch University insurance brokers.**

Please contact:

Mr Wium van Kerwel, Assistant Account Financial Planning and asset Management tel: 021 - 808 2809 fax: 021 - 808 3663 e-mail: [wwankerwel@sun.ac.za](mailto:wwankerwel@sun.ac.za)

Confirmation of Registration

☒ I confirm that I have registered my research project with with the above

Is the provision of insurance compliant with SAGCP Section 4.11?

See Section 9 "Participant Insurance" of [Health Research Ethics \(HREC\) Standard Operating Procedures \(SOP\)](#)

☒ Yes
☐ No

Please upload document

Upload Document

ANY URL LINKS WILL OPEN UP IN ANOTHER WEBPAGE TAB

CLICK ON UPLOAD DOCUMENT TO SAVE A DOCUMENT IN YOUR FORM

STOP

CRITICAL WARNING

Please note that if you click on any of the links in this form it will open in a separate webpage/tab so remember to check your open webpages to go back to the eform.

Infonetica Training Manual: New Application  
© Stellenbosch University May 2017

11

## 5. Sign and Submit your application

Completing the declaration and signature on application form.

Research Ethics Applications Home Contacts Help Beta Test Mode Ms Nicole Walker 0075 Version: Version 1

### Health Research New Application Form

**Declarations/Signature**

I confirm that I have familiarised myself with the...

- Policy for Responsible Research Conduct at Stellenbosch University
- Stellenbosch University's (SU) procedure for the investigation of allegations of breach or research norms and standards
- National Health Research Ethics Council's Norms and Standards for Health Research
- National Health Act
- Ethics in Health Research Principles, Processes and Structures. Second Edition. Department of Health 2015
- South African Good Clinical Practice Guidelines

Applicant/Principal Investigator's Signature

**Sign**

CLICK ON SIGN TO ACCEPT DECLARATION

### Signatures

Loading...: Checking form is complete...

Close

Stellenbosch University's (SU) procedure for the investigation of allegations of breach or research norms and standards

National Health Research Ethics Council's Norms and Standards for Health Research

If your form isn't complete the system will alert you to this.

### Signatures

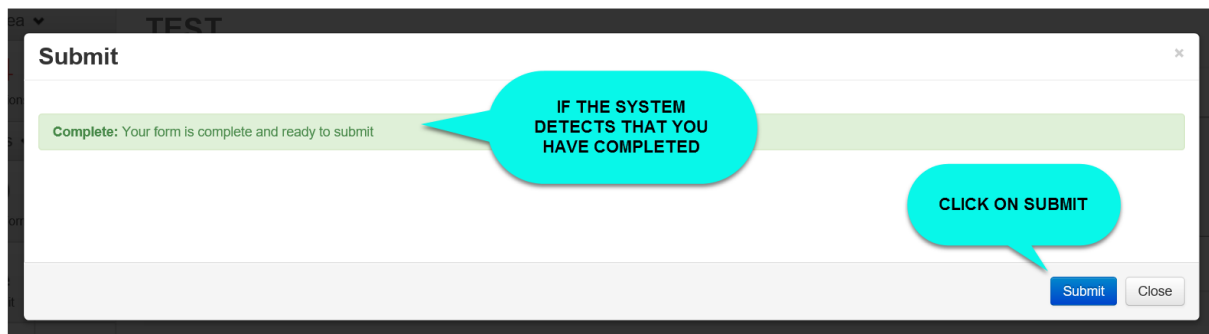
Incomplete: Please complete the following questions:

- Degree/Diploma Name
- Is this a group project for degree purposes?
- Will there be students working on this project as part of the research team but NOT for degree purposes?
- Is this a sub-study (new research question) linked to an existing/main study?
- Has this or any related protocols been submitted or will be submitted for ethics review by any external ethics committee(s)?
- Does your Project have a Sponsor?
- How is this research funded?
- Applicant/Principal Investigator Details
- Are there any other Stellenbosch University Collaborators, Sub-investigators or Co-investigators?
- Are there any other Non Stellenbosch University Collaborators, Sub-investigators or Co-investigators?
- Supervisor's Details
- Please upload document

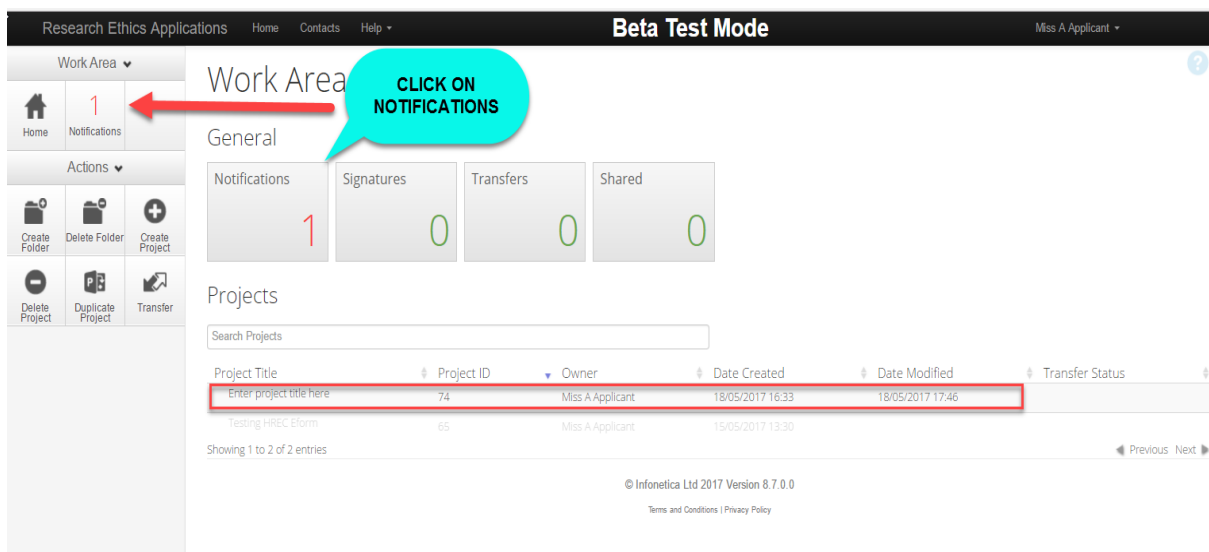
**Sign Anyway** Close

CLICK ON THE LINK AND THE SECTION WILL OPEN UP FOR YOU TO COMPLETE

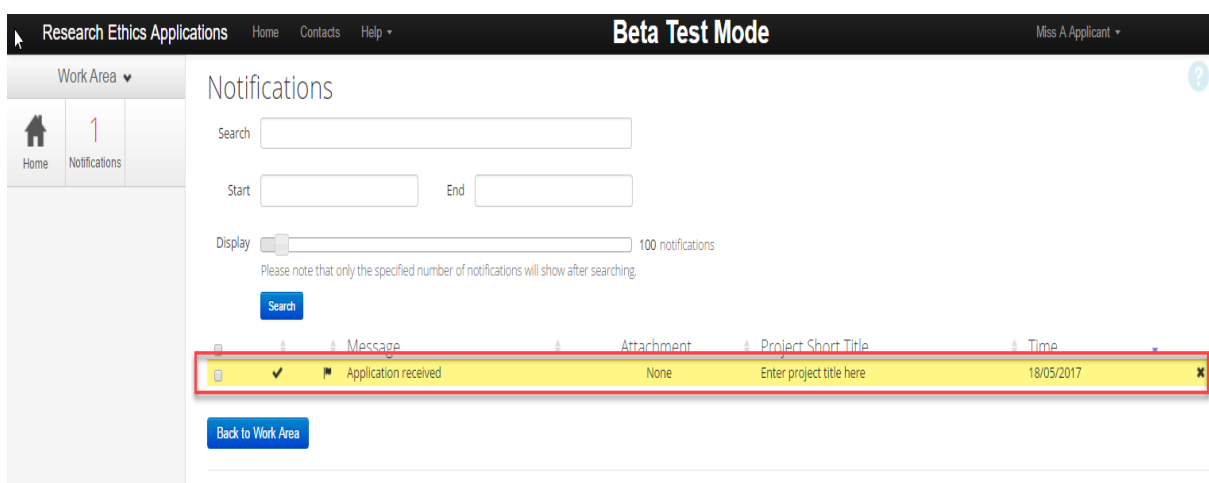
DON'T TRY TO BYPASS THIS SECTION OTHERWISE YOUR APPLICATION WILL BE RETURNED TO YOU



You will receive a successful message once submitting your application. You can track your application once it's been submitted.



Your application has now been submitted for further processing.



## 6. Changes Requested

Login and click on your project list. Make your necessary changes, save and then click on submit to resubmit your application.

## 7. Creating a Subform (i.e. Progress Report, Amendment)

The screenshot displays the 'Research Ethics Applications' interface in 'Beta Test Mode'. The top navigation bar includes 'Home', 'Contacts', and 'Help'. The user is logged in as 'Miss Nicole Walker'.

**Work Area Overview:**

- Home: 35
- Notifications: 35
- Signatures: 1
- Transfers: 0
- Shared: 3

**Projects Table:**

Project Title	Date Created	Date Modified	Transfer Status
Friday	02/06/2017 09:02	02/06/2017 09:42	
Feedback	30/05/2017 07:30	30/05/2017 07:43	
Testing Animal Ethics application 25/05/2017	25/05/2017 08:43	25/05/2017 08:44	
Testing to see whether only Lauren can view this in UREC Admin	24/05/2017 14:49	24/05/2017 14:50	
NW Testing	19/05/2017 13:13	19/05/2017 13:13	
Checking that Clinical Trial form works - form to delete	19/05/2017 10:05	19/05/2017 10:06	

**1. CLICK ON YOUR PROJECT TITLE**

The project 'Testing Animal Ethics application 25/05/2017' is selected, showing its details:

- Project ID: 0097
- Project Tree: Testing Animal Ethics application 25/05/2017, Animal Care and Use New application Form
- Form Status: Submitted by Applicant
- Review Reference: ACU-2017-0097-62
- Date Modified: 25/05/2017 08:44

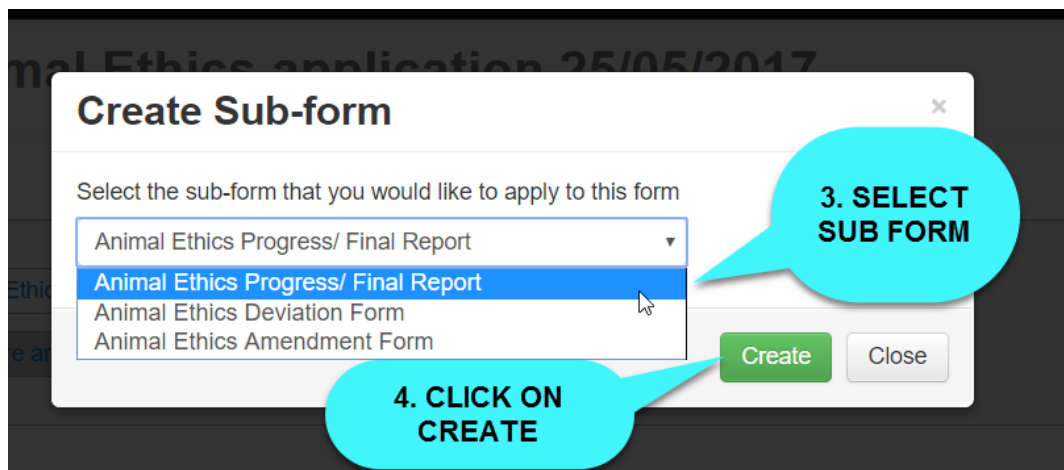
**2. CLICK ON CREATE SUBFORM**

The 'Create Sub-form' button in the left sidebar is highlighted. The 'Animal Care and Use New application Form' is selected, showing its sections:

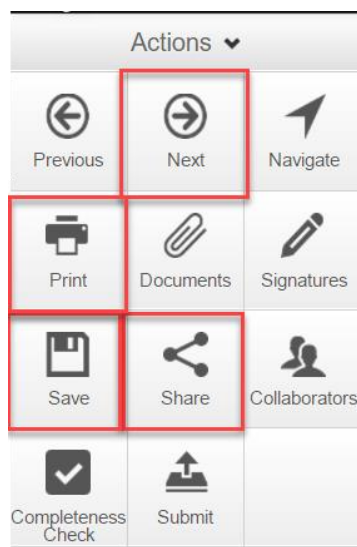
- Section 1: Declaration
- Section 2: Project Information
- Section 3: Project Type

The 'Questions' section includes:

- Declaration by Principle Investigator (PI)
- Project Information
- Research or Teaching



## 8. Definitions of ACTIONS in Panel:



**Previous:** This button will take you to the previous page in your application.

**Next:** This button will take you to the next page in your application

**Navigate:** This button will always take you to the beginning of your project where you will be able to view all sections/pages.

**Print:** This button allows you to print your application or save it in a PDF version.

**Documents:** This button will display all the documents saved in your application which you have uploaded.



**Signatures:** This button you can view any signatures that may have been requested.

**Save:** This button can be used before moving to the next page after completing a section or page or if you can't complete your form but wish you come back to continue with it at a later stage then save before logging out.

**Share:** This button allows you to share your project with your supervisor. Allowing him read and write access.

**Collaborators:** This button will allow you to view the collaborators.

**Completeness Check:** This button will run a check on you application.

**Submit:** This button is used once you have completed your application and your supervisor is happy to approve it.

## 9. Definitions of statuses:

**Scheduled Full Review:** To be used by ethics admin staff only. The application needs to be reviewed by the full ethics committee and cannot be reviewed via expedited procedures.

**Scheduled Expedited Review:** To be used by ethics admin staff only. The applicant has requested an expedited review and no major risks are involved in the study, making it possible to review it via expedited procedures.

**Acknowledged:** This status is used for submissions other than new applications, i.e. serious adverse events, etc. These submissions are acknowledged by the committee/expedited review. This status is also used by the coordinator to acknowledge receipt of an application.

**Approved:** The proposal and all attachments can be approved and no changes are required.

**Approved with stipulations:** The proposal can be approved and the study can start, but the approval has stipulations attached to it, either in the form of very minor changes that do not need to come back to the committee or the project cannot commence until additional approvals have been obtained (e.g. WCED or PGWC).

**Modifications required:** Significant changes need to be made to the research proposal prior to approval. The approval can either be finalised by the primary reviewer and Chairperson and need not go back to the full committee or in more serious cases, the proposal must be reviewed at the next committee meeting. This status can also be used for expedited review.

**Rejected/Disapproved:** The application for ethics approval is rejected completely due to noncompliance with minimum ethics considerations.

**Suspended:** The study has been suspended, for whatever reason, either by the committee or by the researcher. It could continue if circumstances change, with the approval of the ethics committee.

**Deferred:** The proposal is referred back to the primary investigator (PI) to rewrite and resubmit. This status is mostly used for proposals reviewed by full committee review.

**Terminated:** The study has been terminated permanently either by the REC, but more often by the sponsor or researcher.

**No Quorum:** To be used by ethics admin staff only. Not enough voting members were present at the meeting to reach a quorum; the proposal will have to be reviewed and ratified at a next meeting.

**Referred to convened REC:** A submission was reviewed via expedited procedures but after careful review, it is decided that it should rather be scheduled for a full committee review.

**Referred to other ethics committee:** To be used by ethics admin staff only. The application was submitted to the Health ethics office and should actually be reviewed by the REC: Humanities committee or vice versa.

**Expired:** To be used by ethics admin staff only. The approval or request for modifications has expired.