



# ***STELLENBOSCH UNIVERSITY***

## *Research Information Management System*

### ***INFONETICA***



## ***Training Manual***

### *Compliance/Ethics – New Application*

## *Contents*

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## 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.

- Access Ethics RM (Infonetica) using your SU username and password. Upon opening <https://applyethics.sun.ac.za> you will be presented with a login screen. It is here where you enter your SU Username (either username e.g. [pmarais@sun.ac.za](mailto:pmarais@sun.ac.za) or student number [12345678@sun.ac.za](mailto:12345678@sun.ac.za) and network password. If you are an external supervisor, please request a SUNId registration from the Stellenbosch University Division or Department to which you are affiliated. For guidance on SUNId registration, click here: <http://www0.sun.ac.za/itservices/useradm/sunid.htm> Applying for a SUNID supplies you with an SU number. It does not result in an alphabetical username. For this you apply via your affiliated Division or Department. See : <http://www0.sun.ac.za/itservices/useradm/usernames.htm>
- **Login to Infonetica®:** type in your Stellenbosch University username followed by @sun.ac.za (e.g., [username@sun.ac.za](mailto:username@sun.ac.za)) and password. For **username guidance**, click here: <http://www0.sun.ac.za/itservices/useradm/usernames.htm>
- For **password guidance**, click here: <http://www0.sun.ac.za/itservices/useradm/passwords.htm>
- **Clear your browser history:** After multiple logins into the system, you may receive an error message/or similar as displayed below and unable to login to Infonetica again. For guidance on how to clear your browser history, click here: [http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Documents/Ethics/Clear%20bbrowse r.pdf](http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Documents/Ethics/Clear%20bbrowse%20r.pdf)
- If you still experience login issues, contact Ms Jennifer de Beer ([jad@sun.ac.za](mailto:jad@sun.ac.za)) or Ms Elvira Rohland ([elr@sun.ac.za](mailto:elr@sun.ac.za)) for further assistance. Please send a screenshot or cellphone photo of any error message you are receiving. Remember to include your username and SU number in your e-mail.



## Pick an account



elr@sun.ac.za



Use another account



← elr@sun.ac.za

## Enter password

Password

[Forgot my password](#)

Sign in

To Sign-in at Stellenbosch University requires @sun.ac.za username. Passwords can be changed at [www.sun.ac.za/useradm](http://www.sun.ac.za/useradm).

## 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' interface. At the top is a navigation bar with 'Work Area', 'Contacts', and 'Help'. Below this is an 'Actions' panel with icons for 'Create Folder', 'Delete Folder', 'Create Project', 'Delete Project', 'Duplicate Project', and 'Move Project'. A callout points to the 'Create Project' icon, stating 'Click on create project'. To the right is the 'Work Area' section, which includes 'Notifications', 'Signatures', 'Transfers', and 'Shared' tabs. A callout points to the 'Work Area' header, stating 'Your work area will open up'. Below the 'Actions' panel is a form for 'Project Title\* (Max 200 characters)' with a placeholder 'Please enter a title'. A callout points to this field, stating 'Enter project title'. Below the title field is a 'Form\*' dropdown menu. The dropdown is open, showing a list of application forms: 'Please select...', 'Animal Care and Use New application Form', 'Animal Ethics Notification Form', 'Biosafety\_Standard Operating Procedures\_Application Form', 'Biosafety-facility Registration Form', 'HREC Biobank/Database Application Form', 'HREC Case Report-Case series Form', 'HREC Exemption Application Form', 'HREC New Application Form', and 'Legacy form (Administrators only)'. A callout points to this list, stating 'Select the applicable HREC Application Form and click on create'. To the right of the dropdown is a blue 'Create' button.

Research Ethics Applications Work Area Contacts Help ▾

Actions

Create Folder Delete Folder Create Project

Delete Project Duplicate Project Move Project

Work Area

Notifications Signatures Transfers Shared

Click on create project

Your work area will open up

Project Title\* (Max 200 characters)

Please enter a title

Enter project title

Form\*

Please select...

Please select...

Animal Care and Use New application Form

Animal Ethics Notification Form

Biosafety\_Standard Operating Procedures\_Application Form

Biosafety-facility Registration Form

HREC Biobank/Database Application Form

HREC Case Report-Case series Form

HREC Exemption Application Form

HREC New Application Form

Legacy form (Administrators only)

Select the applicable HREC Application Form and click on create

Create

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

### 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. Start by clicking on filter questions.

Project Tree ▼

31 May Test

HREC New Application Form

Action Required	Status	Review Reference	Date Modified
No	Approved	HEA-2021-22591	31/05/2021 14:41

Navigation Documents Signatures Collaborators Submissions Centre History

## HREC New Application Form

Section

Filter

General Project Decisions

Contacts

Related Stellenbosch Ethics Applications

Human Subjects Research Protection

Recruitment and Informed consent

Type of Study

Data Collection

Data security and storage

Data sharing and preservation for future use

Responsible party for data management and consent

Questions

Filter Questions

Project Title Project Location Project Funding Project Sponsor

Applicant/Principal Investigator Supervisor(s) Stellenbosch Contacts Non Stellenbosch Contacts Students

Stellenbosch University Ethics Applications

Human Subjects Research Protection

Recruitment and Informed consent

Study Type

Collecting personal information

Data security and storage

Data sharing and preservation for future use

Responsible party for data management and consent

Show Inactive Sections

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 Work Area Contacts Help

## HREC New Application Form

Version: 11.0

Actions

Previous Next Navigate

View as PDF Documents Signatures

Share Collaborators

Click on the next button to move to the next page of the form

Share your application form with your supervisor

### 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 (i) icon to the right for the definition of Clinical and Health Research.

☐ Clinical Trial

☐ Health/Student Research

  
 Tips

*Tip: If you wish to go back to the beginning of your form then click on the **Navigate** button to direct you to the sections page.*

**PLEASE NOTE:**

Always update the form when the system prompts you to do so as a new version of the form has been created. When this happens, a message will appear on top for you to click on the “Update” link.

Note: There is a newer version of the project. [Update](#)

Click on update

**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:

Collaborator email

☒ Read

☒ Write

☐ Submit

☐ Share

☐ Create all sub forms

☐ Receive notifications

+

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.***



Tips

**Tip:** If you are working on your e-form and you want to stop and continue at a later stage, you must **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.

Populate your supervisor's details in the form:

**Supervisor**

Enter your supervisor's surname or email and select

A Fortuin(afortuin@sun.ac.za)

Please search using your supervisors email address

Title	First Name	Surname
Mrs	A	Fortuin
Organisation		
Department	Research Development and Support (Faculty of Medicine and Health Sciences)	
Faculty	Vice-Dean: Research and Internationalisation (FMHS)	
SU #	19247850	
Email	ashleen29@gmail.com	
Address		

Your supervisor's details will automatically populate in the field

Uploading a document and viewing a URL Link:

**Exporting Samples/Data**

Do you anticipate exporting samples/data to other site(s), locally or internationally?

☒ Yes  
☐ No

Please provide a justification for this:

For studies that intend to send/receive data or samples to/from another location, attach a completed **Data/Material Transfer Agreement (DTA/MTA) Term Sheet**

Please see [HREC Forms and Instructions](#)

Upload Document

Any URL links will open up in a new webpage tab



## 5. Sign your application

Complete the declaration/signatures on the application form.

### HREC New Application Form

Version:

Declarations/Signature

0

**NOTE: ONCE YOU HAVE SIGNED/CLICKED ON THE SIGN BUTTON, THE FORM WILL LOCK. HOWEVER, YOU ARE STILL REQUIRED TO "CLICK NEXT" FOR THE FINAL SIGNATURE. ONLY AFTER THE FINAL SIGNATURE, YOUR APPLICATION FORM WILL BE SUBMITTED TO HREC.**

I confirm that I have familiarised myself with the following:

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

Sign

Click on sign to confirm the above

Declarations/Signature

0

I confirm that I have familiarised myself with the following:

- Policy for Responsible Research at Stellenbosch University Conduct
- Stellenbosch (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

Sign

Signed: This form was signed by Miss EL Rohland (elr@sun.ac.za) on 22/06/2021 11:20 AM

After the 1<sup>st</sup> signature, your form will lock, and you will not be able to make any edits. Click next to request your supervisor's signature

## 6. Request Supervisor Signature (STUDENTS ONLY)

If you are a student conducting the study for degree purposes, you must request your supervisor's signature for his/her approval on the signature declaration page. You can request the signature of ONE supervisor ONLY, so if you have more than one supervisor, please contact your supervisors to confirm who will take responsibility for signing your ethics application – preferably the SU supervisor (if you have an external supervisor as well)

Declarations/Signature

0

SUPERVISOR SIGNATURE FOR APPROVAL

**NOTE FOR THE STUDENT:** You confirmed that you are a student conducting this research for degree purposes. To submit this application, you need to request your supervisor's signature first to confirm his/her approval of your ethics application.

**NOTE FOR THE SUPERVISOR/PROMOTOR:**

By responding to this signature request, the supervisor confirms the following:

I, as the supervisor/promotor of this student, declare that I have read and reviewed the full content of this application for scientific soundness, accuracy and completeness, and I am accountable for the ethical conduct of this research.

Supervisors should refer to the supervisor guide for instructions on how to sign the application.

**How to request your supervisor's signature (INSTRUCTIONS FOR STUDENTS)**

**IMPORTANT:** The student requests the signature of the supervisor by following the steps below

- 1) Click on **request signature** below
- 2) You will be asked to enter your supervisor's email address. Please ensure that you type the email address correctly. If you get a message that the user does not exist, please contact the [HREC office](#).
- 3) Once you send the request, the application will be locked until your supervisor responds.
- 4) Once the supervisor responds to the signature request by signing the application, the application will be submitted to proceed to the HREC review process.

Request Signature

Click on the request signature button to request the supervisor's signature

Enter the email address of the supervisor:

Request a signature

Enter the email address of the person you want to sign this form

A Fortuin(afortuin@sun.ac.za) characters)

Request

Close

**Please note:**

Once you request your supervisor's signature, your application is now with your supervisor for sign off before it will be submitted to the HREC Office.

If your application has not been submitted to the HREC office yet, kindly follow up with your supervisor to ensure the supervisor has signed your application.

As soon as the supervisor signs the form, you will receive a notification on Infonetica that the form was submitted.

**Message** ✕

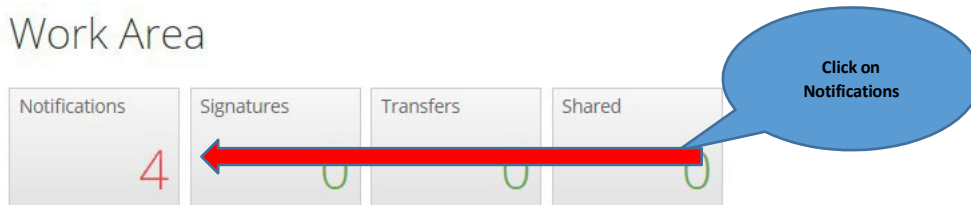
Project Short Title Clubfoot management with the Ponseti regime at a private Johannesburg setting with a specific focus on possible predictors of relapse

Date 16/06/2021 3:00 PM

Your form has been signed by Mrs :

[View Form](#) [Close](#)

Once your application has been submitted; you will receive a notification on Infonetica:



**Keep track of your application by checking the project status:**

HREC New Application Form			
Action Required	Status	Review Reference	Date Modified
Yes	Request Changes		03/05/2021 12:55

If your form requires administrative changes, the status will indicate 'request changes'. If the Action Required is "NO", no further action is required. After your form is submitted, kindly check your email for any HREC correspondence.

Please ensure that you make all corrections and respond to each of the comments in your letter **within 2 working days of the current submission deadline**. This will ensure that your submission will be incorporated in the upcoming HREC review cycle.

## 7. Response to Modifications/Deferral/Stipulations

Login and click on your project list.

- Locate your specific project and click on the project title
- Upload the letter of response and amended documents to your existing **HREC New Application Form**
- If any changes have been requested to the e-application form, please make these changes in the relevant sections in the e-form and indicate in the Response to Modifications/Stipulations cover letter where the changes have been made.
- Under the HREC New Application Form, click on the Additional Documents tab, scroll to the last upload button “Other Documents” to upload your revised documents.

Other Documents (Please name these documents appropriately)

### HREC New Application Form

Section

Filter

General Project Decisions

Contacts

Related Stellenbosch Ethics Applications

Human Subjects Research Protection

Recruitment and Informed consent

Type of Study

Data Collection

Data security and storage

Data sharing and preservation for future use

Responsible party for data management and consent

Research with Children

Additional Documents

Disclosures

Declarations/Signatures

Questions

Filter Questions

Project Title | Project Location | Project Sponsor

Applicant/Principal Investigator | Supervisor(s) | Stellenbosch University Ethics Applications

Human Subjects Research Protection

Recruitment and Informed consent

Study Type

Collecting personal information

Data security and storage

Data sharing and preservation for future use

Responsible party for data management and consent

Research with Children | Non-Therapeutic Research

Additional Documents

Disclosures | Participant Insurance | Export of Data | Diagnostic Tests

Head of Division/Department | Applicant/Principal Investigator

Click on the questions and respond to the modifications/stipulations as requested in the HREC letter

Click on Additional Documents tab

Show Inactive Sections

**Go to the last upload button to upload the response to modifications or response to stipulations**  
**Remember to sign the form and request your supervisor's signature (If applicable)**

### Documents - Default

Please attach your Default here:

Document Name	Version Date	Version
<input type="button" value="Browse"/>	<input type="text"/>	<input type="text"/>
		<input type="button" value="Upload"/>

**PS: Remember to sign as the applicant and request your supervisor's signature to submit the response to modifications/stipulations.**

## 8. Create a Sub form (i.e., Progress/Final Report, Amendment, HREC Documentation)

### Work Area

Notifications	Signatures	Transfers	Shared
41	0	0	2

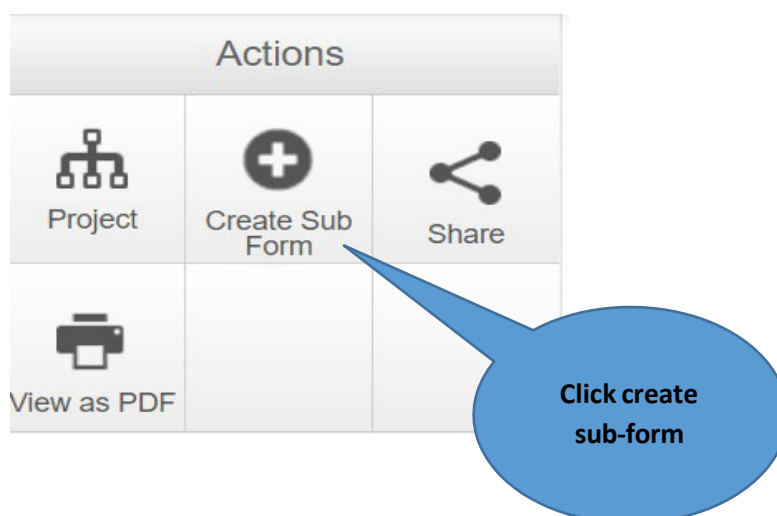
### Projects

Search Projects

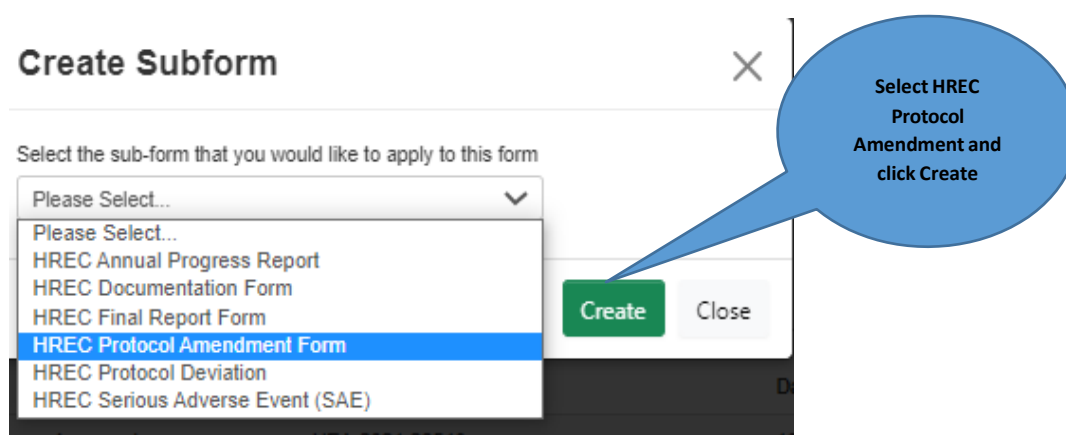
Project Title	Project ID	Owner	Date Created	Date Modified	Transfer Status
21 June TEST	22849	Miss EL Rohland	21/06/2021 16:21	21/06/2021 16:22	
TEST RECIP 20210618	22831	Miss EL Rohland	18/06/2021 13:40	18/06/2021 15:39	
10 June 2021	22745	Miss EL Rohland	10/06/2021 12:45	14/06/2021 16:00	
test 1234567	22724	Miss EL Rohland	08/06/2021 15:01	08/06/2021 15:01	
Test 01 June 2021_RECIP	22639	Miss EL Rohland	01/06/2021 15:58	21/06/2021 16:27	
31 May Test	22591	Miss EL Rohland	31/05/2021 14:41	31/05/2021 14:41	
27 May 2021 Test	22543	Miss EL Rohland	27/05/2021 17:20	31/05/2021 14:39	
20210525 TEST	22519	Miss EL Rohland	25/05/2021 15:49	14/06/2021 15:58	
Elvira Test	22348	Miss EL Rohland	12/05/2021 20:34	22/06/2021 12:27	
Test RECIP	22270	Miss EL Rohland	06/05/2021 14:36	06/05/2021 14:36	
Test 16 March 2021	21861	Miss EL Rohland	16/03/2021 13:55	16/03/2021 14:00	
TEST 22 Feb	21717	Miss EL Rohland	22/02/2021 15:19	12/03/2021 08:02	
Alert Testing 28 Jan	21543	Miss EL Rohland	28/01/2021 15:05	28/01/2021 15:06	
Test (5)		Miss EL Rohland	24/04/2020 09:47	24/04/2020 09:47	
TEST 28 Jun 2019 (ER)			28/06/2019 14:30	28/06/2019 14:35	
ER Test 29 May 2019			29/05/2019 09:59	29/05/2019 10:06	

Click on the project title  
to open the project

## CREATE A HREC PROTOCOL AMENDMENT FORM



**PLEASE NOTE:** All Health forms are prefixed with HREC, so kindly ensure that you select the correct form before completing.



**Complete all the Sections as shown below.**

### HREC Protocol Amendment Form

☐ Show Inactive Sections

Section

APPLICATION FOR A MINOR/MAJOR STUDY AMENDMENT: GUIDELINES

SECTION 1: Minor or Major Amendment

SECTION 2: Details of Principal Investigator

SECTION 3: Project Details

SECTION 4: How is this research funded?

SECTION 5: Type of Amendment

SECTION 6: Summary of changes

SECTION 7: Additional document uploads

SECTION 8: Declaration

Questions

Page 1

Page 1

Page 1

Page 1

Page 2

Page 2

Page 3

Page 3

Page 3

When making changes to the protocol, please ensure you submit the revised protocol with a new version number and date, highlighting text with TRACKED CHANGES

## HREC Protocol Amendment Form -

Version: 1

TYPE OF AMENDMENT

Amendment to the protocol (i.e. changes in study aims, objectives or design)

☒ Yes  
☐ No

If yes, please submit the revised protocol with a new version number and date, highlighting text with TRACKED CHANGES.

Once all the questions are completed and documents uploaded, please remember to sign your form, and request your supervisor's signature (if applicable)

## HREC Protocol Amendment Form -

Version: 12.0

DECLARATION

NOTE: ONCE YOU HAVE SIGNED/CLICKED ON THE SIGN BUTTON, THE FORM WILL LOCK. HOWEVER, YOU ARE STILL REQUIRED TO "CLICK NEXT" FOR THE FINAL SIGNATURE. ONLY AFTER THE FINAL SIGNATURE YOUR APPLICATION FORM WILL BE SUBMITTED TO HREC.

I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility of it. I consider that it would be reasonable for the proposed amendment to be implemented.

Sign

Applicant/Principal Investigator's Signature

Please note that if you are a study coordinator completing this application on behalf of the Applicant/Principal Investigator, then please click on the **REQUEST** button to request the PI's signature to approve this application. However if you are the Applicant/Principal Investigator completing this application then you need to click on the **SIGN** button.

Request Signature

Sign

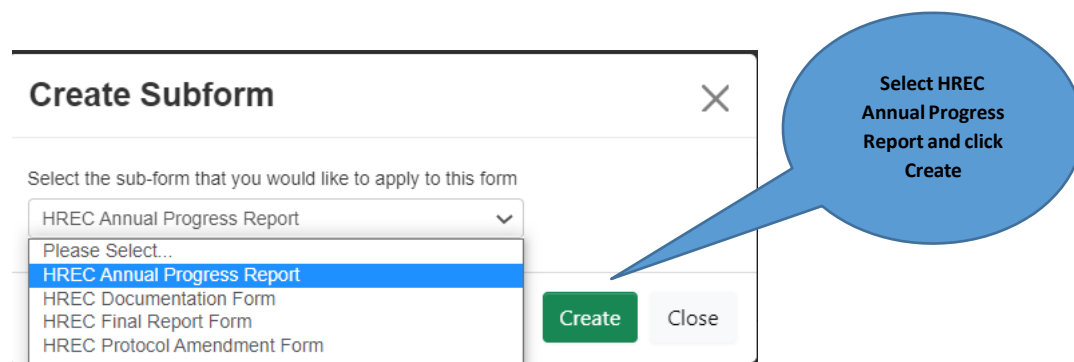
Previous page

Next page



## CREATE A HREC PROGRESS REPORT

Click on the project title to open the project.



Complete all the Sections as shown below.

### HREC Annual Progress Report

#### Section

SECTION A: REPORT AND STUDY TYPE  
SECTION B: INVESTIGATOR DETAILS  
SECTION C: RESEARCH PROJECT DETAILS  
SECTION D: PROJECT FUNDING  
SECTION F: SUMMARY OF PROGRESS  
SECTION G: SERIOUS ADVERSE EVENTS  
SECTION H: PROTOCOL NON-COMPLIANCE  
SECTION I: ATTACHMENTS  
SECTION J: DECLARATION

#### Questions

Report and Study Type  
Investigator details  
Research Project details  
Project funding  
Summary of progress  
Serious Adverse Events  
Protocol non-compliance (Please attach details)  
Attachments  
Declaration



Please remember to sign your form

## HREC Annual Progress Report -

### DECLARATION

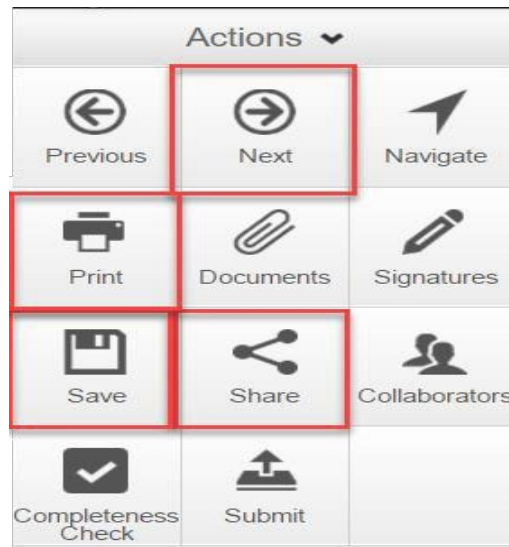
NOTE: ONCE YOU HAVE SIGNED/CLICKED ON THE SIGN BUTTON, THE FORM WILL LOCK. HOWEVER, YOU ARE STILL REQUIRED TO "CLICK NEXT" FOR THE FINAL SIGNATURE. ONLY AFTER THE FINAL SIGNATURE YOUR APPLICATION FORM WILL BE SUBMITTED TO HREC.

I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.

Sign



## 9. 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:** View signatures and request for signatures

**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 and want to come back to continue at a later stage, then save before you log out.

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

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

**Completeness Check:** This button will run a check on your application to see whether it's complete or whether any mandatory questions are incomplete.

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

## **10. Withdrawal of projects**

Applicants must provide written communication requesting withdrawal of a project. Upon receipt of this request, the applicant will receive an email confirming the withdrawal of the project. A formal letter can be requested.

## **11. HREC Consults – Post HREC Submission**

Consultation involves meeting either in-person or via telephone or MS Teams with Staff of the Health Research Ethics Office and or the Health Research Ethics Committee Chairperson or members depending on the nature of the request. *N.B. In line with the current SU work-from-home guidelines, consultations are offered via MS Teams or telephonically only at this time.*

To clarify specific concerns or recommendations by HREC as per the HREC letter, the Principal Investigator can apply for a HREC consult by clicking on the link below. This will allow for clarification and will obviate further delays in granting ethics approval.

[http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Documents/Ethics/20210621\\_HREC%20Consultation%20Request%20Form\\_fillable%20pdf.pdf](http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Documents/Ethics/20210621_HREC%20Consultation%20Request%20Form_fillable%20pdf.pdf)

## 12. Definitions of statuses

**Scheduled for Meeting 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 plausible to review via expedited review procedures.

**Acknowledged:** This status is used for submissions other than new applications, i.e., Serious Adverse events (SAEs), HREC Documentation, and Protocol Deviations. These submissions are acknowledged by the committee/expedited review. This status is also used by the coordinator to acknowledge receipt of a submission.

**Approved:** The proposal and all attachments are 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).

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**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.

**Deferred:** The proposal is referred 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 HREC, 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 was 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 be reviewed by the REC: Humanities committee or vice versa.

**Withdrawn:** The study was withdrawn by HREC as requested by the PI

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