How do I submit a case report/series application?

NAVIGATING THE ONLINE ETHICS APPLICATION SYSTEM

Important links

- The link to log on to your application to submit a progress report: www.applyethics.sun.ac.za
- The link to the Health Research Ethics Office where all the forms, instructions, submission dates, and resource documents can be found: www.sun.ac.za/healthresearchethics
- The link to the Undergraduate Research Ethics Committee (UREC) pages where guidance and information about UREC applications can be found:

http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Undergraduate research/Undergraduate-Research-Ethics-Committee.aspx

Creating the online application form

- Log in to the *Infonetica* ethics application site using your SUN ID and password: www.applyethics.sun.ac.za
- Only SUN ID-registered applicants will be able to access the online ethics application system with their SU username and password
- If you are not yet registered, you will need to request a SUN ID registration from your department/division
- Note that the SUN-ID registration process to obtain an SU username and password is not an ethics process and is not handled by the ethics office

Why is it important to have a SUN-ID?

- When you log in with your SUN-ID (SU username and password) and enter your SU UT number, the *Infonetica* system automatically pulls in your contact information from the HR and Student Affairs electronic systems
- The email address that is pulled in from the HR or Student Affairs system will be the one that is used by the ethics office to communicate all feedback regarding your ethics application. The relevant department that you are registered with must also be correct.
- It is therefore essential that you ensure that your correct department and contact details are loaded on the HR or Student Affairs electronic systems, in order for the correct information to be populated on *Infonetica*

Assistance with SUN-IDs, usernames & passwords

- SUN-ID guidance: http://www.sun.ac.za/itservices/useradm/sunid.htm
- Username guidance: http://www.sun.ac.za/itservices/useradm/usernames.htm
- Password guidance: http://www.sun.ac.za/itservices/useradm/passwords.htm

Getting started

- Make sure you leave enough time to complete the online application before the submission deadline
- Check the submission deadlines online to ensure you submit on time (see HREC/UREC website: Submission dates). Applications must be submitted by 12:00 (midday) on the deadline
- * Make sure you have a **SUN ID and password** so that you can log on to the online application system (www.applyethics.sun.ac.za)
- Ensure you have all the **documents** you need to attach to your online application form (see next slides). NB: The HoD of your/your supervisor's department needs to sign an HoD signature page to be submitted with your application
- Ensure that you have all the information you need to complete the electronic (online) application form (see next slides)

Health Research Ethics

About the Health Research Ethics Office (HREO)

The primary purpose of the Health Research Ethics Office is to support Stellenbosch University researchers towards compliance in the protection of human participant safety, rights and welfare in health research.

Functions of this office include the administration of Stellenbosch University's two Health Research Ethics Committees; providing general guidance on meeting local and international health research ethics requirements; and building institutional health research ethics capacity.

Health Research Ethics Committees (HRECs): Ethics Review

Our office manages the systems, administration and operations of Health Research Ethics review. All health research must, in terms of the Health Act No 61.2003 be approved by an accredited research ethics committee, prior to the start of research activities that anticipate interaction with human participants, the use of potentially identifiable personal records, information or tissue specimens, and human progenitor or

Consult Service

We strive to create a service friendly environment where researchers can access support and guidance for all ethical and regulatory aspects of health research. Contact our office to book a consult where you will be provided with one-on-one guidance on getting your research protocol to meet local and international ethics standards.

Health Research Ethics Capacity

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- · Masters in Clinical Epidemiology;
- · Pre-doctoral short course;
- · One day research overview workshop;
- Postgraduate supervision workshop;
- · Research protocol writing workshop;

▲ IMPORTANT ANNOUNCEMENTS

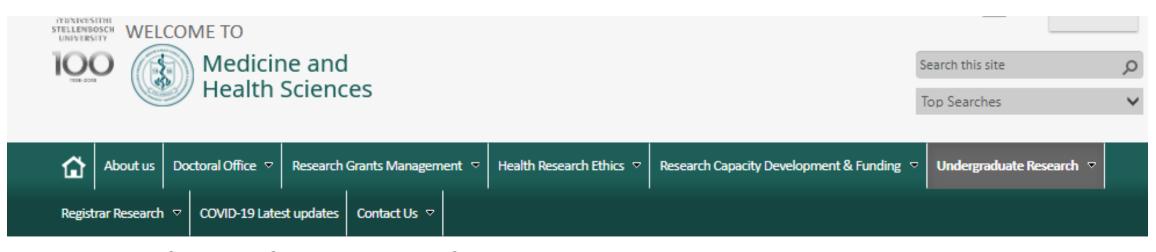
Kindly click here for urgent updates from the Health Research Ethics Office (HREO)

Kindly click here for the LATEST COVID-19 UPDATES

- Health Research Ethics HOME
- Contact Us

■ Electronic Application Process

- ■HREC Review Process
- ■HREC Committee Members
- ■HREC Meetings / Submission Dates
- ■HREC Fees
- ■HREC Forms & Instructions



Research Development and Support

Health Research Ethics

HREC Forms & Instructions

New protocol applications

- » HREC Exemption application guidance for researchers
- » HREC New protocol application guidance for researchers
- » HREC Biobank/Database application guidance for researchers
- » HREC Case Report/Case Series application guidance for researchers
- » HREC New Reciprocal review application guidance for researchers
- » HREC Guidance: Student projects linked to a larger study
- » Insurance for Research

■ Health Research Ethics HOME ■ Contact Us ■ Electronic Application Process ■HREC Review Process ■HREC Committee Members ■HREC Meetings / Submission Dates ■HREC Fees ■HREC Forms & Instructions ■ UDEC SODe & Guidelines

HREC guidance on case report applications

Case reports and series, by definition, tend to be about unique cases and therefore have the potential to reveal very personal information about patients and may even lead to their recognition by readers of the report/paper, particularly if photographs or other visual media are used. In general, informed consent must be obtained from each patient before publishing or presenting a case report or case series.

HREC guidance on case report applications

All case report/series applications should include:

- Completed electronic HREC Case Report and Case Series Application Form submitted via the HREC online application portal, Infonetica© at: http://applyethics.sun.ac.za
- Cover letter
- Signed consent form for each patient (participant/subject of case) or their legally appointed representative, or a clear and adequately motivated justification for a waiver of informed consent for HREC consideration, and
- The case report or draft article/presentation
- Head of Department signature page

Documents needed: Cover letter

The cover letter attached to your case report/series application should include at least the following:

- Name, department/division and contact details of Principal Investigator (main applicant)
- Names and departments/divisions of co-researchers and supervisors where applicable
- Title of case report/series
- Dates when case report/series was conducted/written
- Location at which case report/series was conducted (e.g., Tygerberg Hospital)
- * Rationale for case report (this will be the same was the rationale included on the application form)
- Intentions to disseminate case report/series (e.g., publish in xx journal)
- Any other relevant information that might need to be noted to the ethics committee, particularly around consent, privacy and confidentiality of patient details

Health Research Ethics

HREC Forms & Instructions

" Documentation/Acknowledgement galdance for researchers

» Protocol deviation - guidance for researchers

Continuing review (annual progress reports/final reports)

» Annual progress report: health research/clinical trials/database (registry/repository) - guidance for rese

HREC Consultation Request

» HREC Consultation Request Form

Informed consent and assent forms

» Afrikaans » English » Xhosa Informed consent template - Gene I

» Afrikaans » English » Xhosa Informed assent template - Childre

» Afrikaans » English » Xhosa Informed consent template - Genetic dies

» Afrikaans » English » Xhosa Informed consent template - Case reports

» Afrikaans » English Information leaflet template

» English Informed consent template - Online surveys

CONSENT FORM FOR CASE REPORTS¹

For a patient's consent to publication of information about them in a journal or thesis

Name of person described in article or shown in photograph:		
Subject matter of photograph or <u>article:</u>		
Title of article:		
Medical practitioner or corresponding <u>author</u>		
name]:	[insert full name] give my consent for nation about MYSELF OR MY CHILD OR WARD/MY RELATIVE [insert full, relating to the subject matter above ("the n") to appear in a journal article, or to be used for the purpose of a thesis or on.	
1. The attention of the second	nd the following: e Information will be published without my name/child's name/relatives name ached and every attempt will be made to ensure anonymity. I understand, wever, that complete anonymity cannot be guaranteed. It is possible that mebody somewhere - perhaps, for example, somebody who looked after me/my ild/relative, if I was in hospital, or a relative - may identify me. e Information may be published in a journal which is read worldwide or an online irnal. Journals are aimed mainly at health care professionals but may be seen by any non-doctors, including journalists. e Information may be placed on a website. an withdraw my consent at any time before online publication, but once the formation has been committed to publication it will not be possible to withdraw the insent.	
Sianed:	Date:	

Documents needed: Consent form (1)

The consent form for your case report/series should include at least the following details:

- Title of case report/series
- Name of patient described or shown in case report/series
- Aims of case report/series
- Description of the text, photo, image, or other material ("information") that will be included about the patient
- ❖ Description of how the information will be used (e.g. its purpose to be presented, published, examination) and who will have access to it
- Description of how confidentiality of the information will be protected and limitations to this (e.g., may be possible to identify due to unique nature of illness / photograph etc.)
- Information about voluntariness of participation / consent with no negative consequences

Documents needed: Consent form (2)

Consent form details continued:

- Whether and how the patient will be remunerated
- Potential risks and benefits of participation
- * How personal information will be managed in terms of POPIA
- ❖ Name and full contact details (including department/division) of Principal Investigator
- Name and full contact details of supervisor/s
- Contact details for HREC/UREC should the patient wish to query/make complaint

NB: The consent form must be translated into the home language of the participant (patient/subject of case report/series)

Health Research Ethics

HREC Forms & Instructions

» English

Informed consent template - Online surveys

Investigator/Supervisor Declaration

- » Investigator / Supervisor Declaration (Pdf format)
- » Investigator / Supervisor Declaration (MS Word format)

Material/Data Transfer Agreement (MTA/DTA) Term Sheet

Material Transfer Agreeement for Human Biological Material and Associated Data (Material). This sample agreement for the transfer of data and specimens has been provided by the National Department of Health and the National Health Research Ethics Council:

» Material transfer agreement South Africa 1.1 Decen er 2020

HREC MTA/DTA requirements, processes and terms et:

- » Material Transfer Agreement (MTA) and Data Tra r Agreement (DTA) HREC requirements and processes
- » HREC Termsheet: Material/Data Transfer Agreem

Head of Division/Department Signature Page

» Head of Division/Department Signature Page



Health Research Ethics Committee (HREC)

HEAD OF DIVISION/DEPARTMENT SIGNATURE PAGE

PROJECT TITLE		
TYPE OF HREC SUBMISSION (Please select only one)		
☐ New case report/series application		
☐ New exemption application		
SIGNATURE		
Head of Division/Department		
Print name		
Signature		
- Statute		
Date		

Information required on the application form (1)

- Project (case report/series) title
- Your contact details you are the Principal Investigator
- If you are a student, degree details
- If you are a student, details of your supervisor
- ❖ If you are registered with a professional body (e.g., HPCSA), your registration number
- Head of Department/Division details

Information required on the application form (2)

- Where the case study/series was conducted
- A rationale for the case report/series
- Steps taken to protect patient confidentiality
- Whether and how informed consent was obtained (if not, detail why not and include motivation for waiver of individual consent)

Health Research Ethics

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- ■HREC Fees
- ■HREC Forms & Instructions

Research Development and Support

Health Research Ethics Committee (HREC)

Electronic Application Process

HOW TO SUBMIT AN HREC APPLICATION

The Stellenbosch University Health Research Ethics Committee (HREC) uses an electronic ethics review management system - Infonetica© - to support the application and review process.

- » To submit an HREC application, click here: HREC APPLICATION
- » To submit a response to modifications/deferral/stipulations required by the HREC, click here for the guidance document.
- » We recommend first time applicants consult the Infonetica© Applicant Manual

- Health Research Ethics HOME
- Contact Us

■ Electronic Application Process

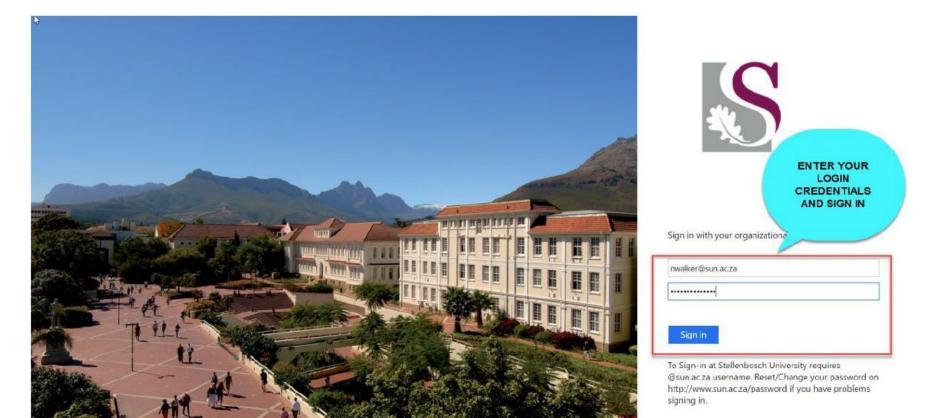
- ■HREC Review Process
- ■HREC Committee Members
- HREC Meetings / Submission Dates
- ■HREC Fees
- ■HREC Forms & Instructions
- ■HRFC SOPe & Guidalinae

Creating the online application form

1. Login

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

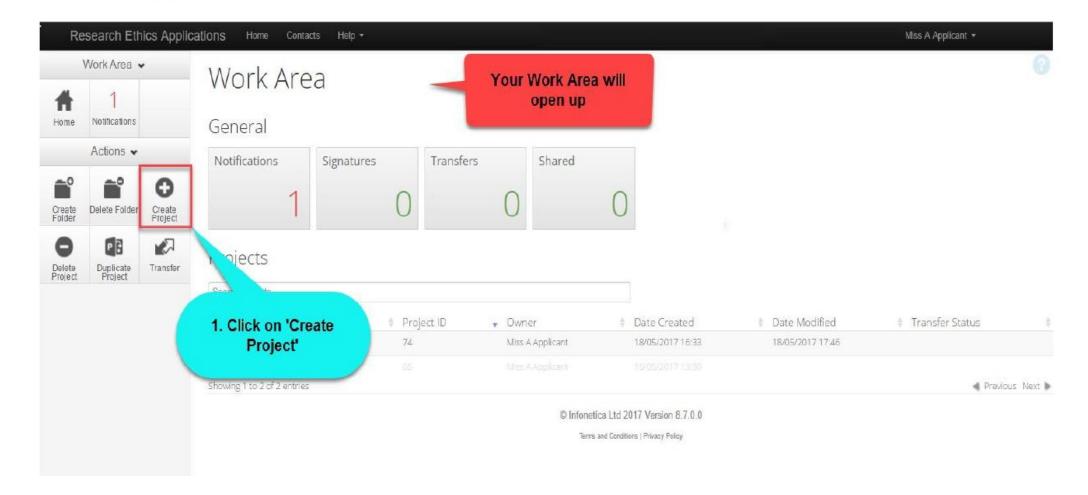
You will be required to login using your <u>username@sun.ac.za</u> and network password. Follow the instructions that are applicable to you.

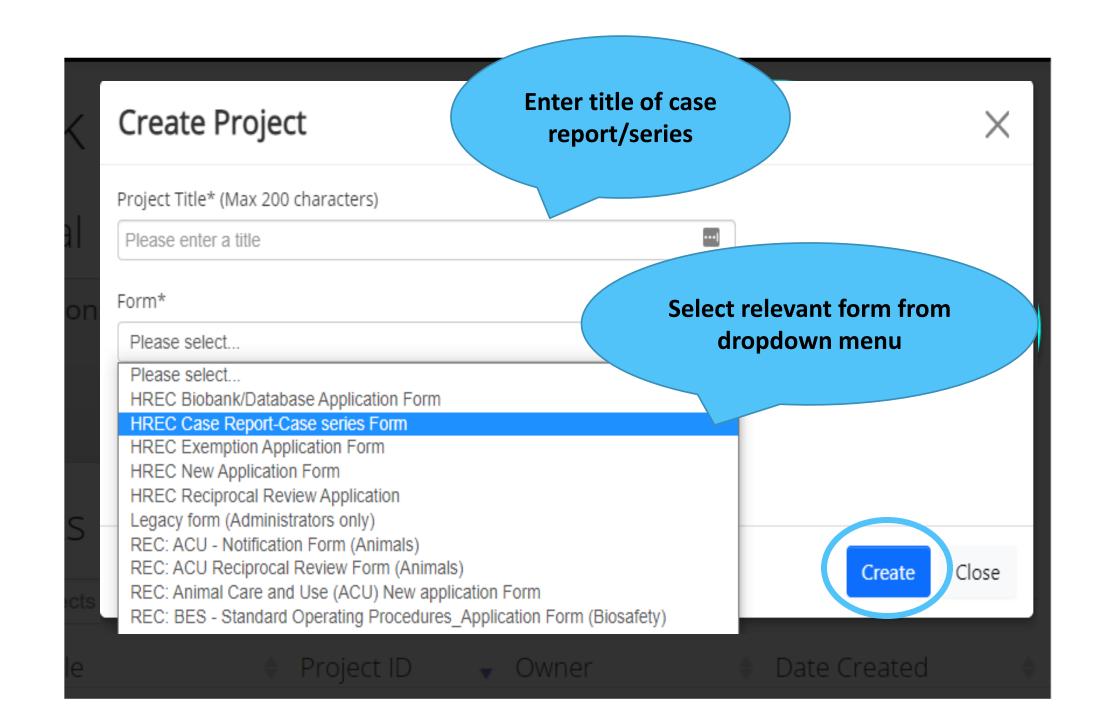


Once you have logged on, you need create a new application

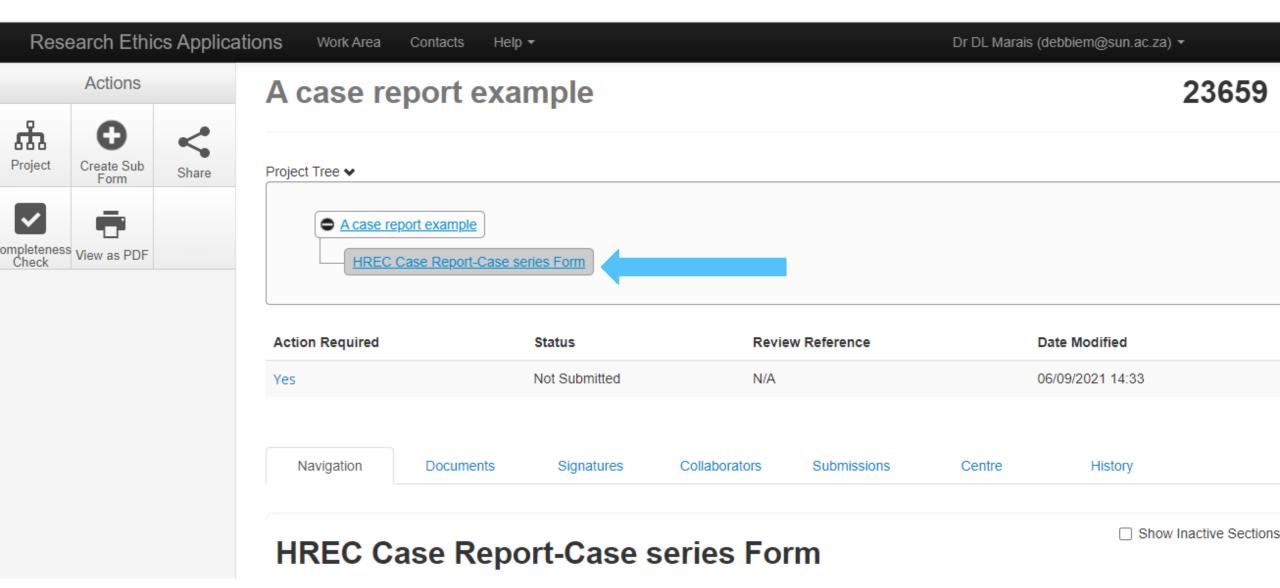
2. Create your project

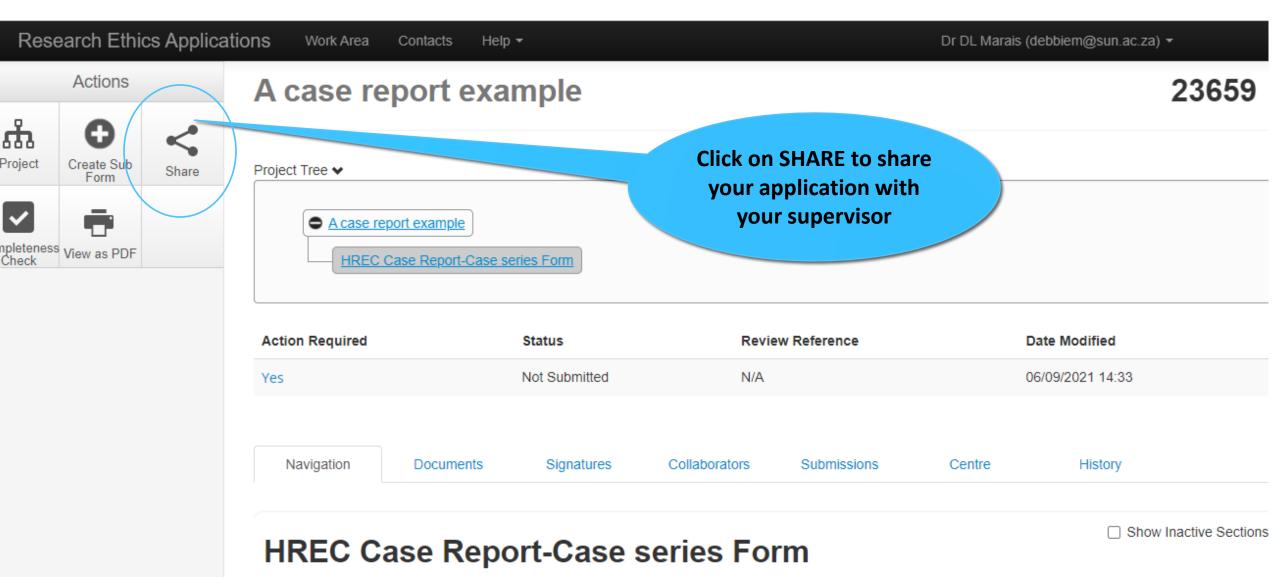
Once logged in, you will see the Infonetica landing page. To create your ethics project online follow the instructions below:

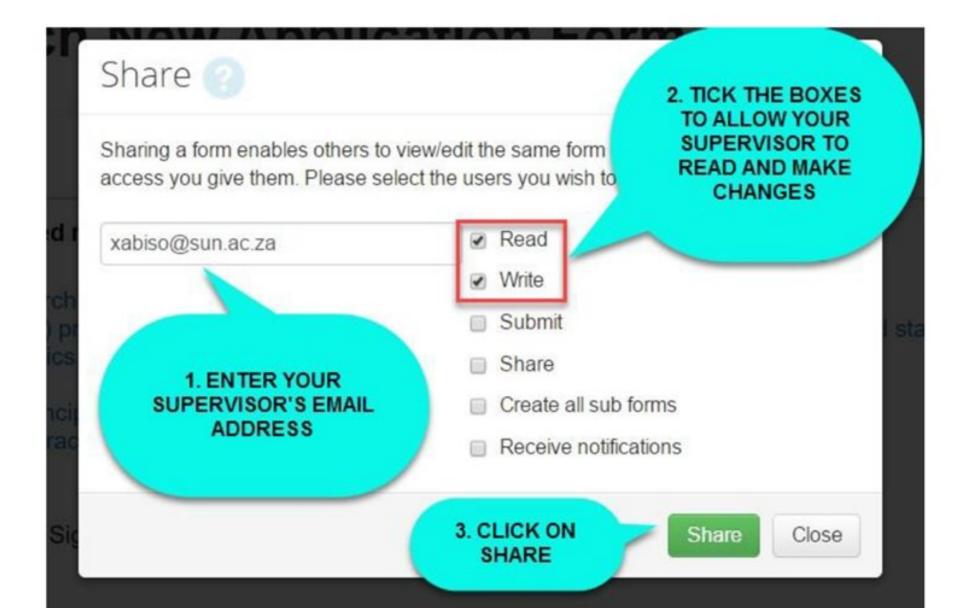




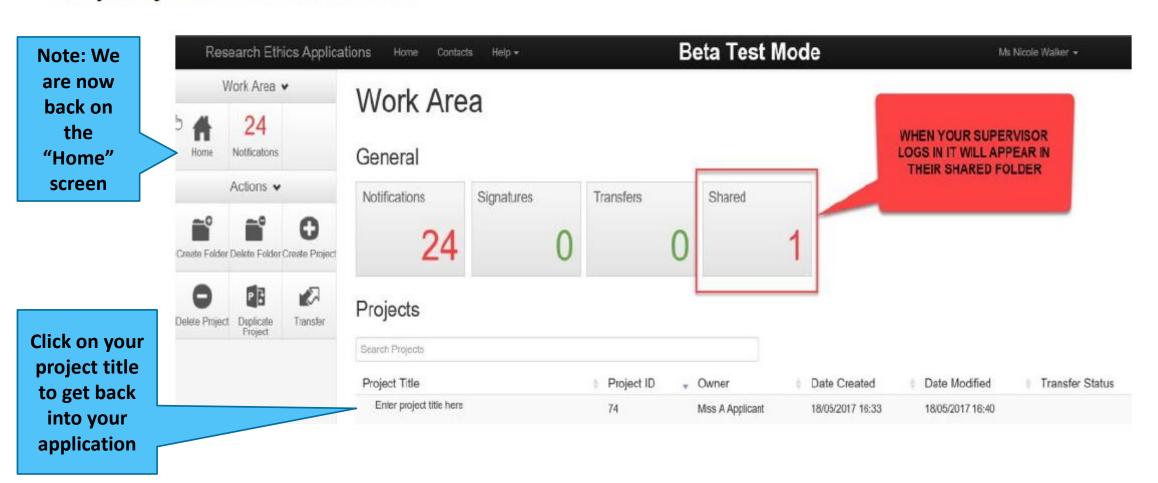
Application form has been created

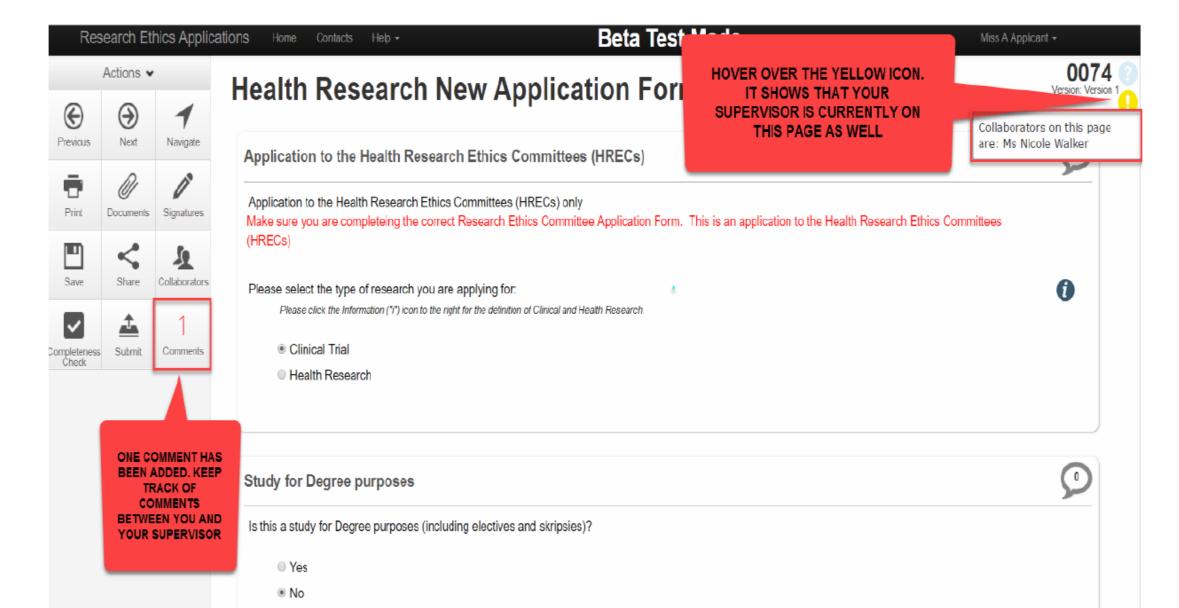




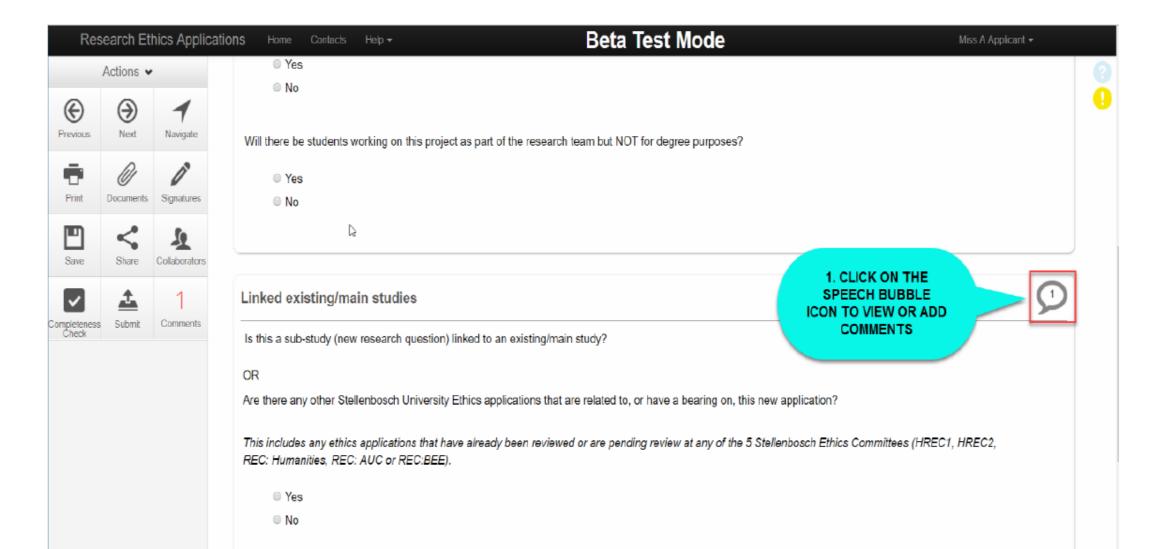


Your Supervisor will now be able to login, read and share comments with you while you are working on your form as shown below:

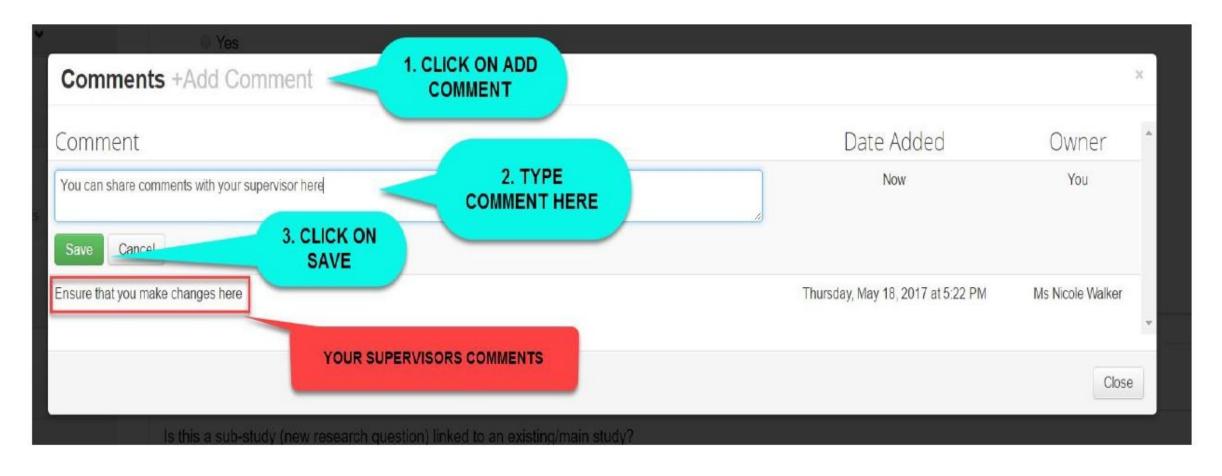




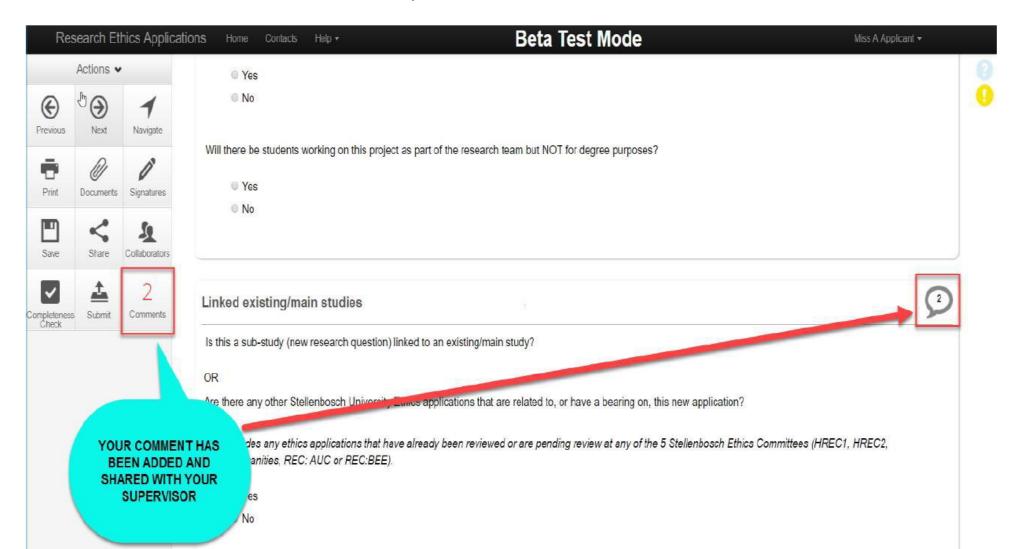
Click on the speech bubble icon to view your supervisor comment/s.

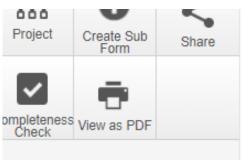


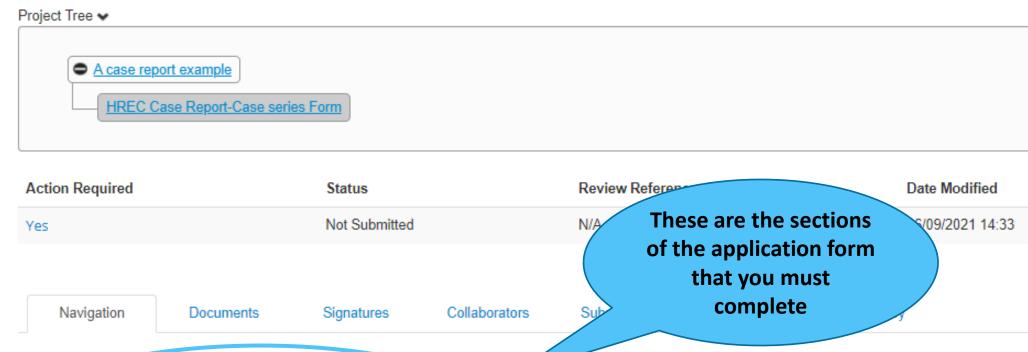
You can add comments for your supervisor to view while working through your application form.



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







Questions

Page 1

Page 2

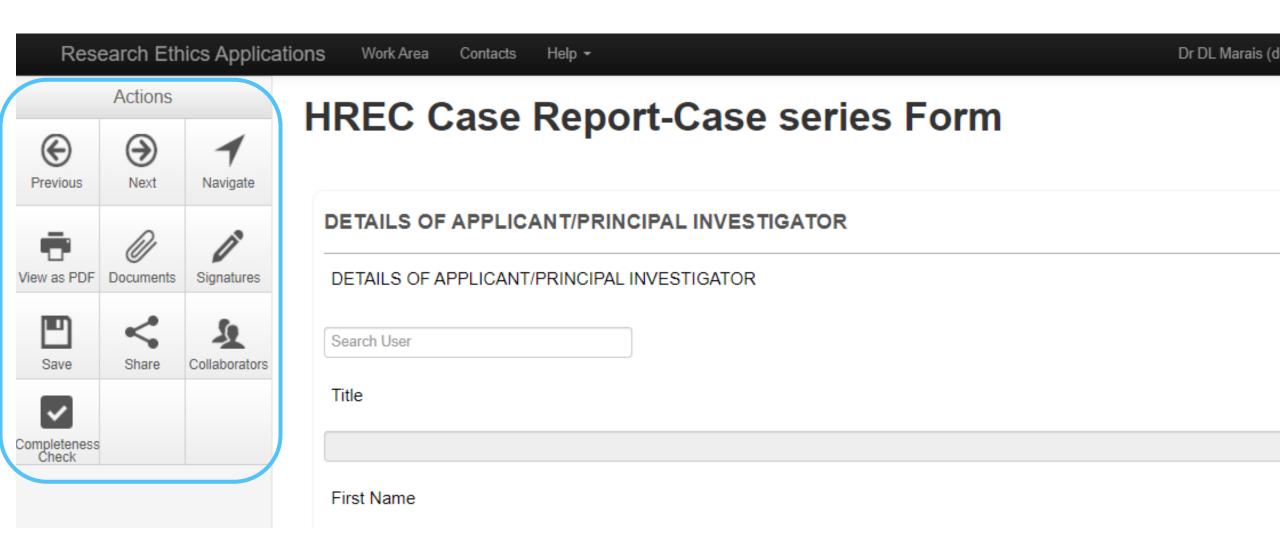
Page 3

Page 4

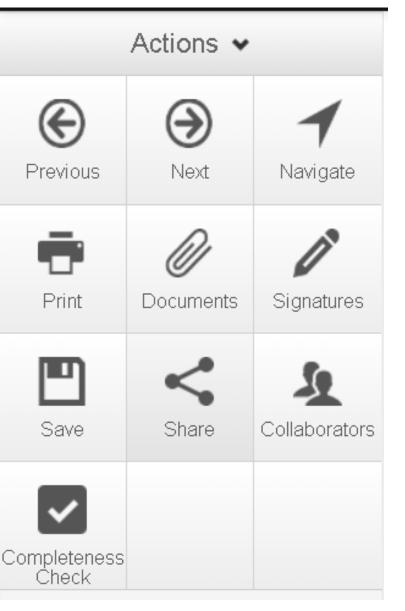
Page 5

HREC Case Report-Case series Form





Action buttons



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 abl 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.

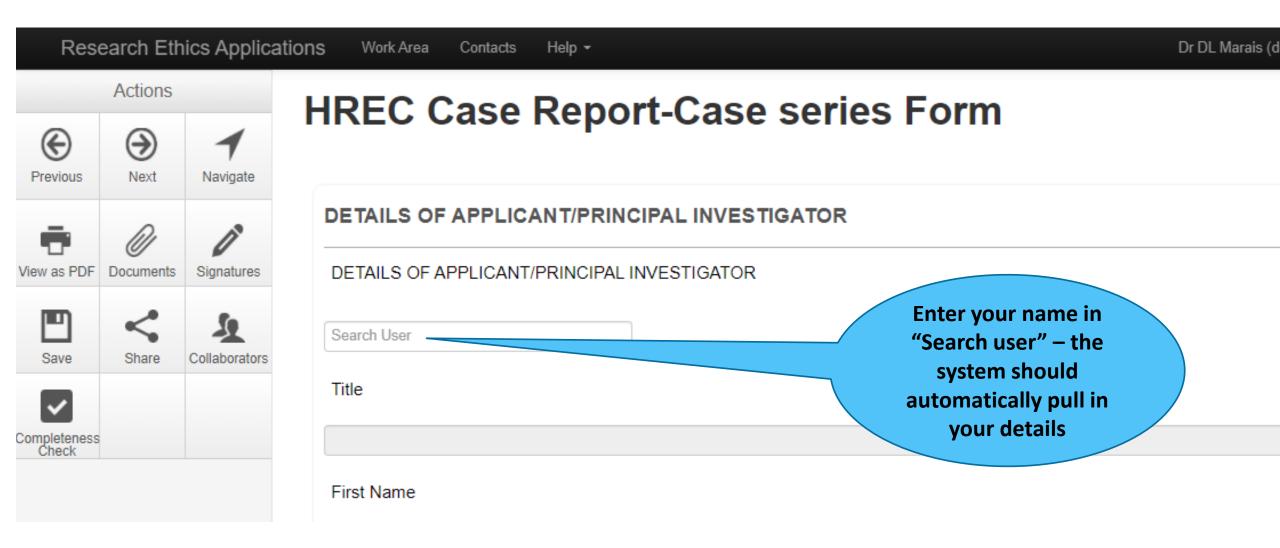
Signatures: This button you can view any signatures that may have been requested.

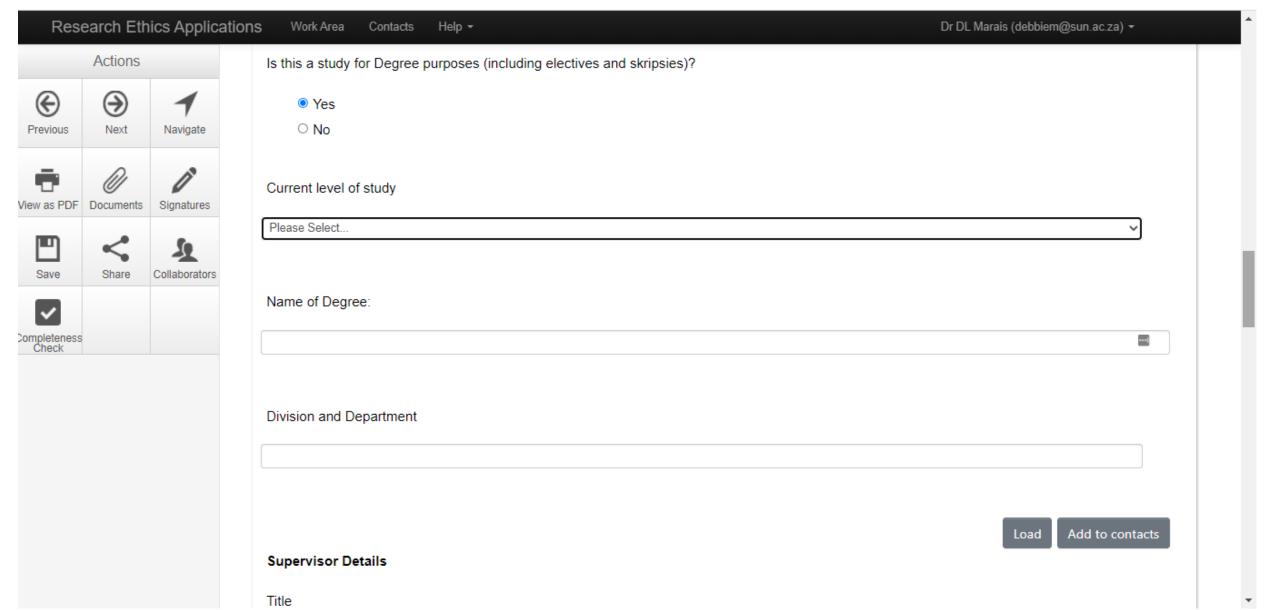
Save: This button can be used before moving to the next page after completing a section or page or if you can't complete your form but wish you come back to continue with it at a later stage then save before logging out.

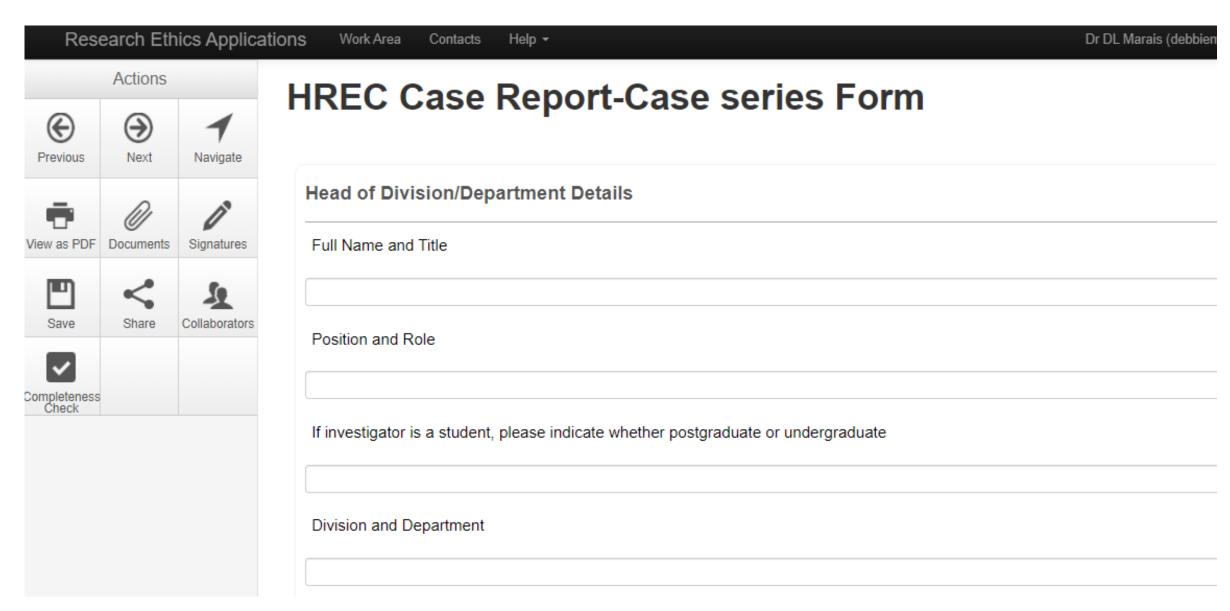
Share: This button allows you to share your project with your supervisor. Allowing him read and write access.

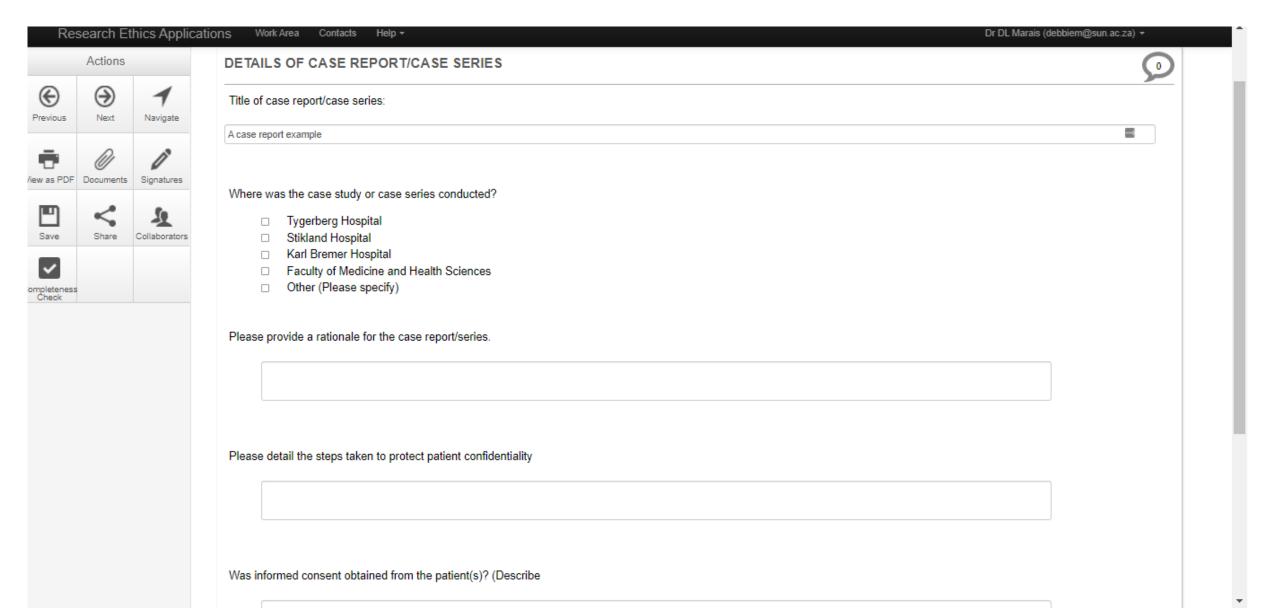
Collaborators: This button will allow you to view the collaborators.

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

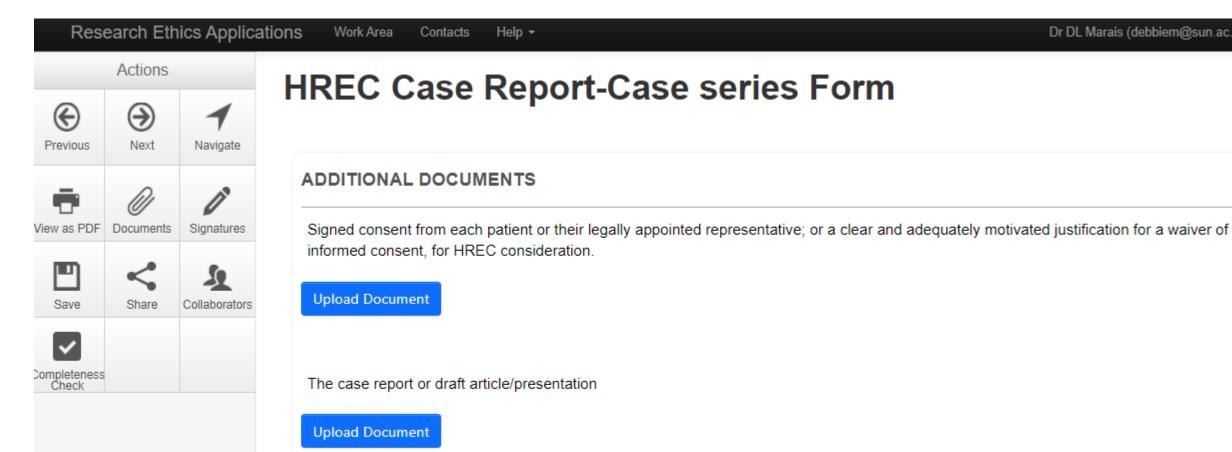








Dr DL Marais (debbiem@sun.ac.za



Cover Letter

Upload Document

Research Ethics Applications

Actions

H

Navigate

Next Navigate

New as PDF Documents Signatures

Save Share Collaborators

Completeness Check

HREC Case Report-Case series Form

Head of Division/Department Upload Signature Page

Help ▼

Your Divisional/Departmental Head must sign this signature page to indicate that they are aware of, and approve the conduct of this case report/case series in their environment. Please see Forms and Instructions on our HREC webpage to access the template signature page.

Dr DL Marais (debbiem@sun.ac.za)

Upload Document

Work Area

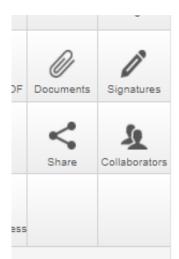
Contacts

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.

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.



FOR THE FINAL SIGNATURE, ONLY AFTER THE FINAL SIGNATURE YOUR APPLICATION FORM WILL BE SUBMITTED TO HREC.

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Request Signature

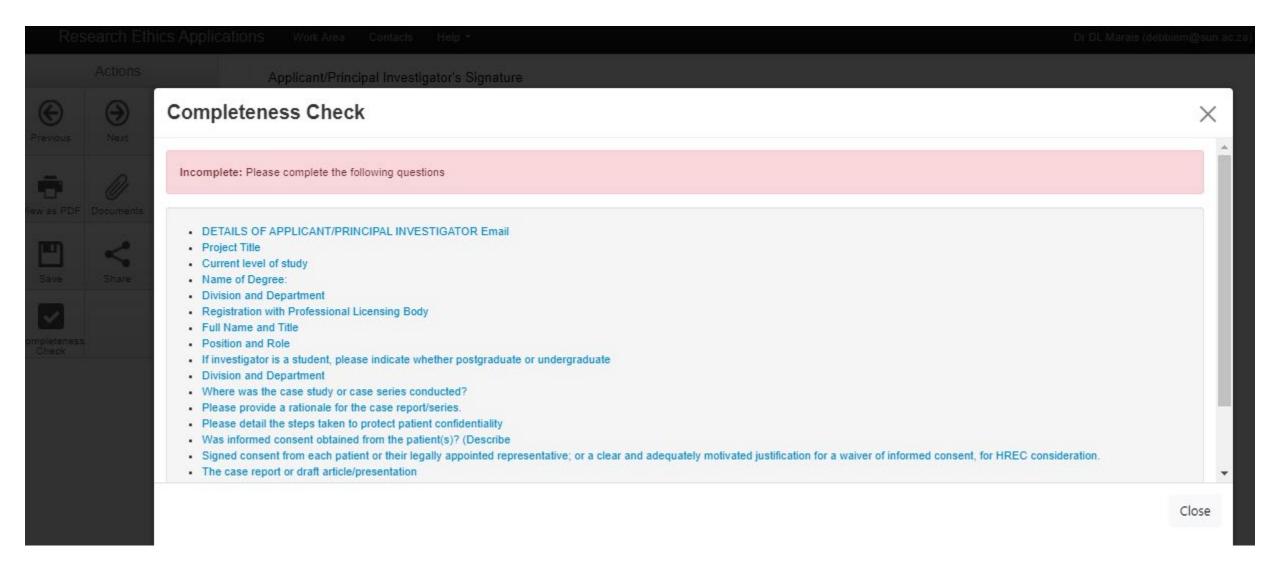
Sign

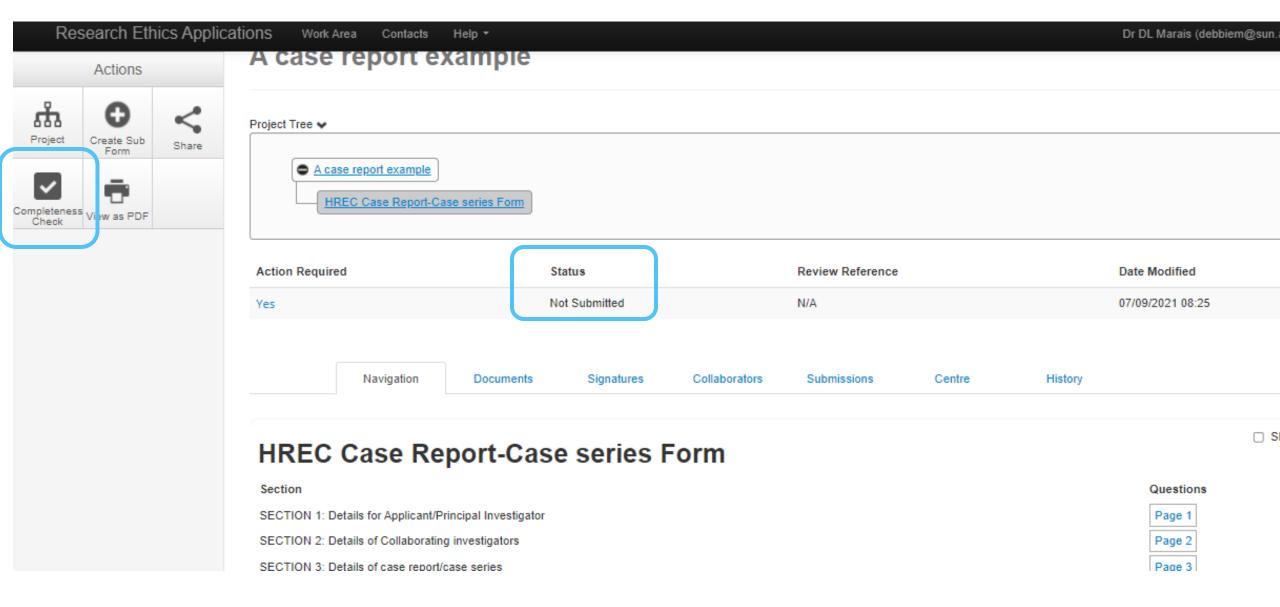
How to request your supervisor's signature (INSTRUCTIONS FOR STUDENTS)

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

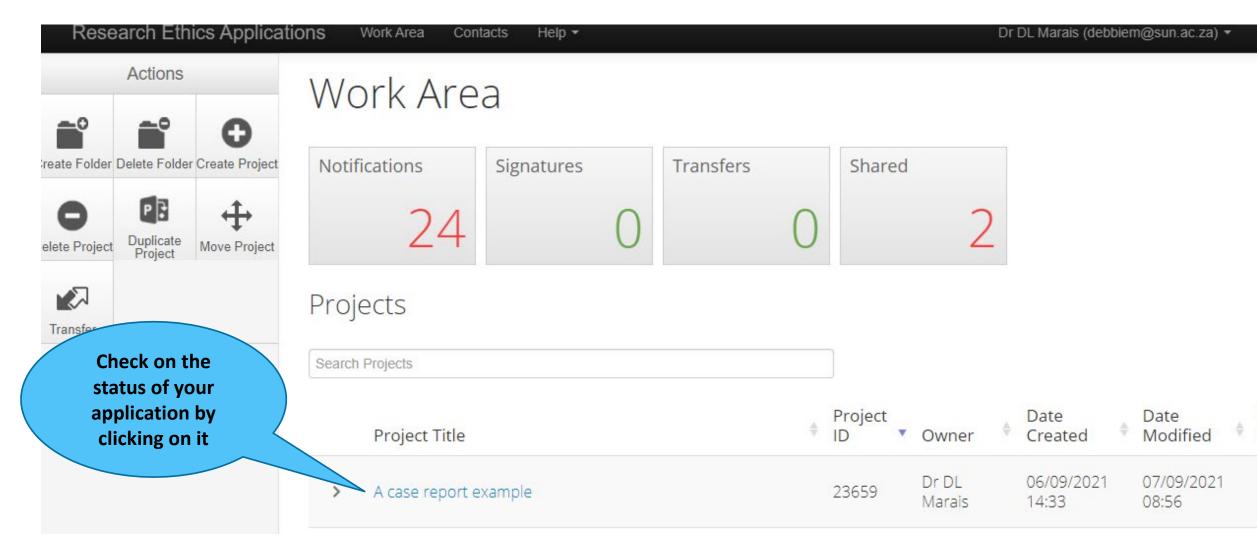
- 1) Click on request signature below
- 2) You will be asked to enter your supervisor's email address. Please ensure that you type the email address correctly. If you get a message that the user does not exist, please contact the HREC office.
- Once you send the request, the application will be locked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

Request Signature

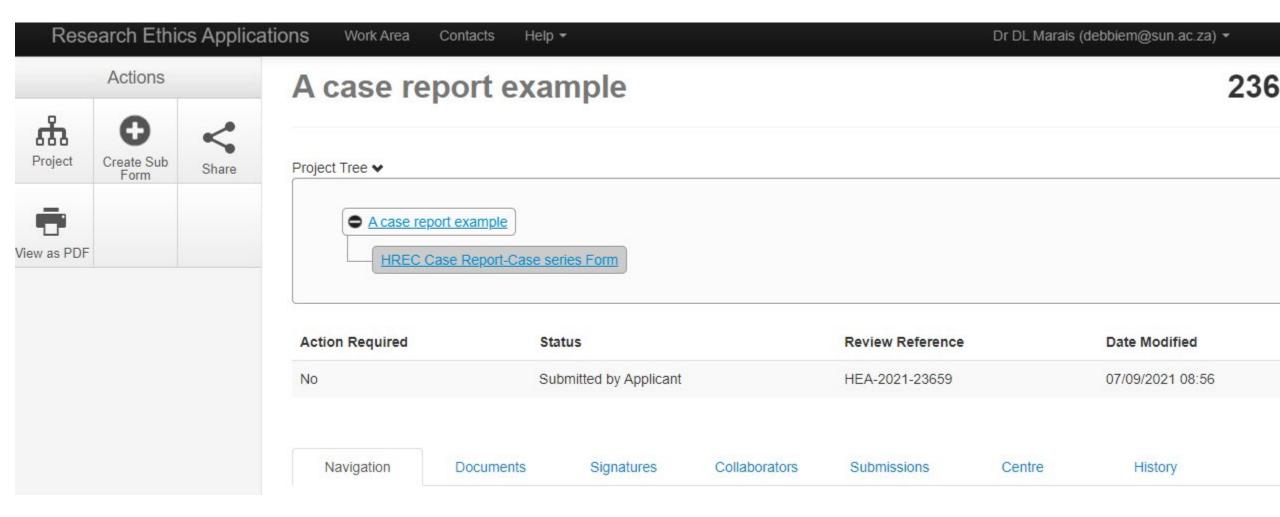




Checking the status of your application



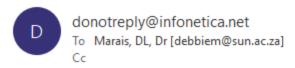
Checking the status of your application



Checking the status of your application



Application submitted - HEA-2021-23659: A case report example



Tue 07

≪ Reply All

← Reply

(i) You forwarded this message on 07 Sep 2021 9:01 AM.

If there are problems with how this message is displayed, click here to view it in a web browser.

CAUTION: This email originated from outside the Stellenbosch University network. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr DL Marais

Your application for project "A case report example" has been submitted for ethics review. (23659)

Please refer to your Project ID in ALL correspondence relating to your ethics application.

Your application is now locked for editing and is currently being screened for completeness by our HREC administrator. This is not a formal HREC review of your project but rather an administrator of your submission for accuracy and completeness. You will receive correspondence from our HREC office within the next few days if any corrections/changes are required.

To check the progress of your application, please access your project here: https://applyethics.sun.ac.za/Project/Index/40218

Please retain this email as proof of your submission.

HREC office contact details: 021 938 9677; 021 938 9819

Kind regards,

Support available

Infonetica guidance manual on submitting online applications:

http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics application package.aspx

- Enquiries about the HREC/UREC application and review process:
 - Ms Elvira Rohland (021 938 9677) elr@sun.a.ca (HREC)
 - Mrs Ashleen Fortuin (021 938 9819) afortuin@sun.ac.za (HREC)
 - Mrs Lauren Hendricks (021 938 9820) <u>laurenv@sun.ac.za</u> (UREC)
- **Enquiries about technical difficulties with the online application system:**
 - Ms Jennifer de Beer (021 808 9444) jad@sun.ac.za