

STELLENBOSCH UNIVERSITY

Research Information Management System

*Guideline for Issuing a Response to Stipulations and
Modifications*

TRAINING MANUAL

RESEARCH ETHICS COMMITTEE:
ANIMAL CARE AND USE &
BIOLOGICAL AND ENVIRONMENTAL SAFETY



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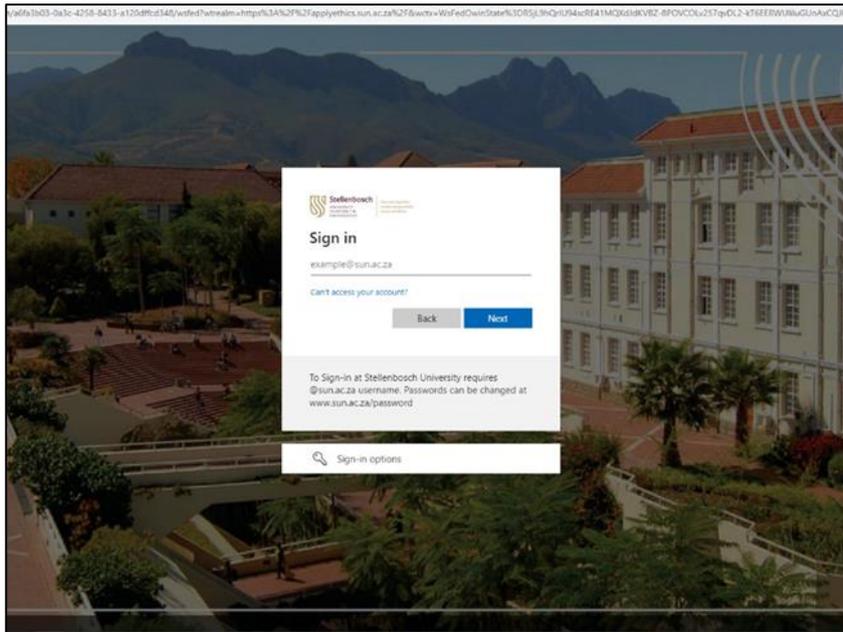
1. Guideline to Response to Stipulations and Modifications as an Applicant:

1.1. Login

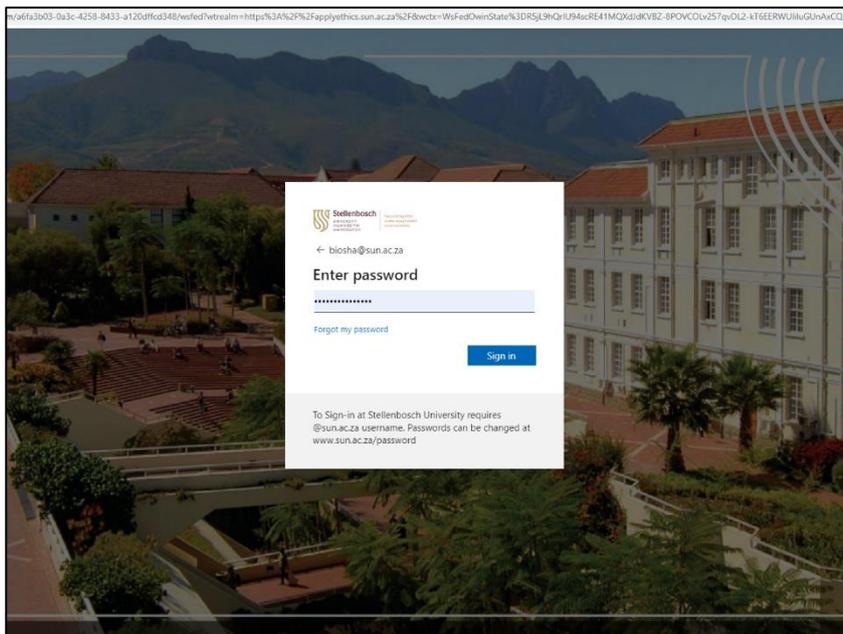
1.1.1. After you, the applicant, receives your Approval with Stipulation or Modifications Required feedback letter, you will be required to submit your response to stipulations or response to modifications within 2 months following the issuing of this letter.

1.1.2. In order to do so, you will need to log in to the Apply Ethics website (<https://applyethics.sun.ac.za>).

1.1.3. You will be required to log in using your username@sun.ac.za and network password.



Enter your login credentials and sign in.



1.1.4. Once you have logged in successfully, you will be directed to your work area. Thereafter, click on your project that requires changes.

Research Ethics Applications Work Area Contacts Help Beta Test Mode Ms B Thompson

Work Area

Notifications 14 Signatures 0 Transfers 0 Shared 0

Projects

Project Title	Project ID	Owner	Date Created	Date Modified	Transfer Status
ACU proj	27937	Ms B Thompson	04/05/2023 09:44	08/06/2023 12:20	
BES - Tygerberg Doctoral Office - 2	27792	Ms B Thompson	24/04/2023 09:52	24/04/2023 11:06	
Doctoral Office testing	27764	Ms B Thompson	21/04/2023 07:34	24/04/2023 11:08	
Biosha NF	27628	Ms B Thompson	04/04/2023 13:37	14/04/2023 14:29	
Animal Tissue	27594	Ms B Thompson	30/03/2023 14:11	30/03/2023 14:17	
ACU project Biosha	27398	Ms B Thompson	08/03/2023 08:30	24/05/2023 10:13	
BES application Micro	27182	Ms B Thompson	08/02/2023 11:49	08/02/2023 11:50	
gosp lab	27152	Ms B Thompson	02/02/2023 12:39	02/02/2023 12:39	

Showing 1 to 8 of 8 entries

1.2. Response to Stipulations

1.2.1. Once you have clicked on your project, please consult with your feedback letter to make the necessary changes in your application form.

Research Ethics Applications Work Area Contacts Help Beta Test Mode Ms B Thompson

ACU proj 27937

Project Tree

- ACU proj
 - REC: Animal Care and Use (ACU) New application Form
 - REC: ACU Deviation Form (Animals)
 - REC: ACU Adverse/ Serious Adverse Events

Action Required on Form	Status	Review Reference	Date Modified
Yes	Approved with Stipulations	ACU-2023-27937	09/06/2023 11:31

Navigation Documents Signatures Collaborators Submissions Centre History

REC: Animal Care and Use (ACU) New application Form

Section

- Section 1: Declaration
- Section 2: Project Information
- Section 3: Project Type
- Section 4: Investigators
- Section 5: Scientific Review and Related Ethics Review
- Section 6: Study Description
- Section 7: Animals Required
- Section 8: Procedures
- Section 9: Monitoring and Transport

Questions

- Declaration by Principle Investigator (PI)
- Project Information
- Research or Teaching
- Primary Investigator | Co-Investigators | Supervising Veterinarian (SAVC Requirements)
- Scientific Review and Related Ethics Review
- Synopsis | Potential benefits of this study | Objectives/ Hypotheses | Study Design
- Animal Information | Housing and Care
- Please select all relevant procedures
- Animal Monitoring | Animal transport

1.2.2. After you have completed all the necessary changes, please upload a response letter under Section 15: Additional Documents.

Research Ethics Applications | Work Area | Contacts | Help | Beta Test Mode | My B Thompson

27937

Action Required on Form: Yes | Status: Approved with Stipulations | Review Reference: ACU-2023-27937 | Date Modified: 09/06/2023 11:31

Navigation | Documents | Signatures | Collaborators | Submissions | Centre | History

REC: Animal Care and Use (ACU) New application Form

Section 15: Additional Documents (highlighted in green)

Declaration/Signature

Questions: Additional Documents (highlighted in red)

Declaration/Signature

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Research Ethics Applications | Work Area | Contacts | Help | Beta Test Mode | My B Thompson

27937

REC: Animal Care and Use (ACU) New application Form

Project Title: ACU proj

Version: Beta

Compare with Previous Submission

Additional Documents

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Default	BES General Biosafety SOP	BES General Biosafety SOP.docx	06/06/2023	1	11.8 KB	Download	Delete

Upload Document (highlighted in red)

Previous page | Next page

1.2.3. After uploading the response letter, please ensure that your form is signed, before submitting it. **If you are the RESEARCHER, please “Sign” the form. If you are the STUDENT, please select “Request Signature”.**

Research Ethics Applications Work Area Contacts Help + Beta Test Mode Me B Thompson

27937

Action Required on Form	Status	Review Reference	Date Modified
Yes	Approved with Stipulations	ACU-2023-27937	09/06/2023 11:31

Navigation Documents Signatures Collaborators Submissions Centre History

REC: Animal Care and Use (ACU) New application Form

Section 1: Declaration
 Section 2: Project Information
 Section 3: Project Type
 Section 4: Investigators
 Section 5: Scientific Review and Related Ethics Review
 Section 6: Study Description
 Section 7: Animals Required
 Section 8: Procedures
 Section 9: Monitoring and Transport
 Section 10: Endpoints
 Section 11: Drugs
 Section 12: Permits
 Section 14: Occupational Health and Safety
 Section 15: Additional Documents
 Declaration/Signature

Questions
 Declaration by Principle Investigator (PI)
 Project Information
 Research or Teaching
 Primary Investigator Co-Investigators Supervising Veterinarian (SAVC Requirements)
 Scientific Review and Related Ethics Review
 Synopsis Potential benefits of this study Objectives/ Hypotheses Study Design
 Animal Information Housing and Care
 Please select all relevant procedures
 Animal Monitoring Animal transport
 Humane Endpoints Ultimate fate of the animals
 Drugs to be used
 Permits Required
 Occupational Health and Safety
 Additional Documents
 Declaration/Signature

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Research Ethics Applications Work Area Contacts Help + Beta Test Mode Me B Thompson

REC: Animal Care and Use (ACU) New application Form

Project Title: ACU pr03

Version: Beta

Compare with Previous Submission

Supervisor's Signature

Please note that if you are a student completing this application please click on the **REQUEST** button to request your Supervisor's signature to approve this application.

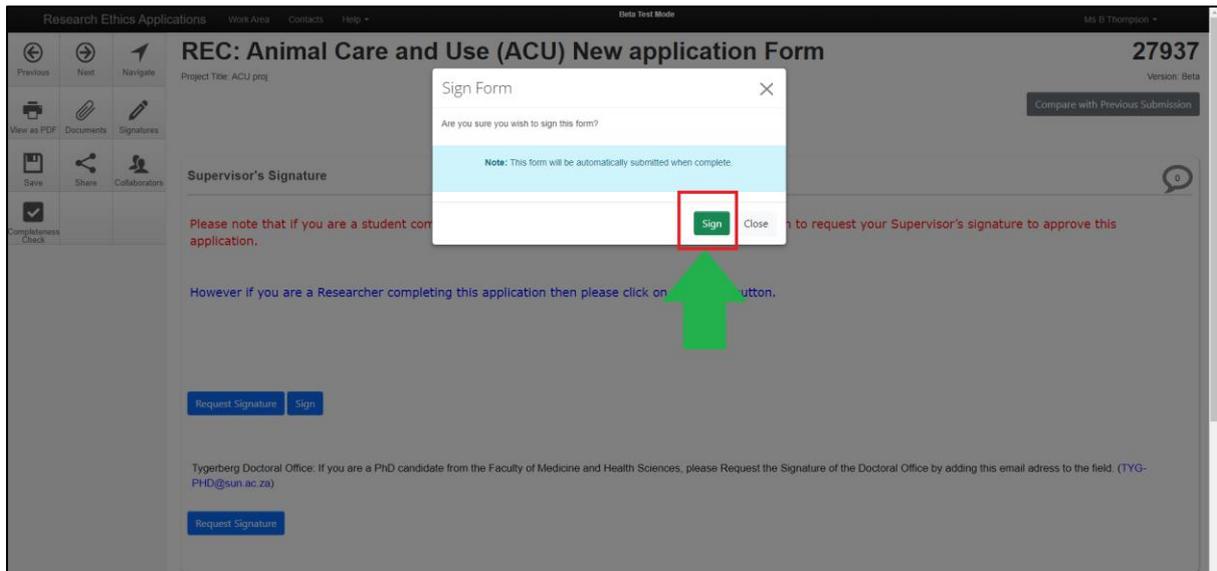
However if you are a Researcher completing this application then please click on the **SIGN** button.

Request Signature Sign

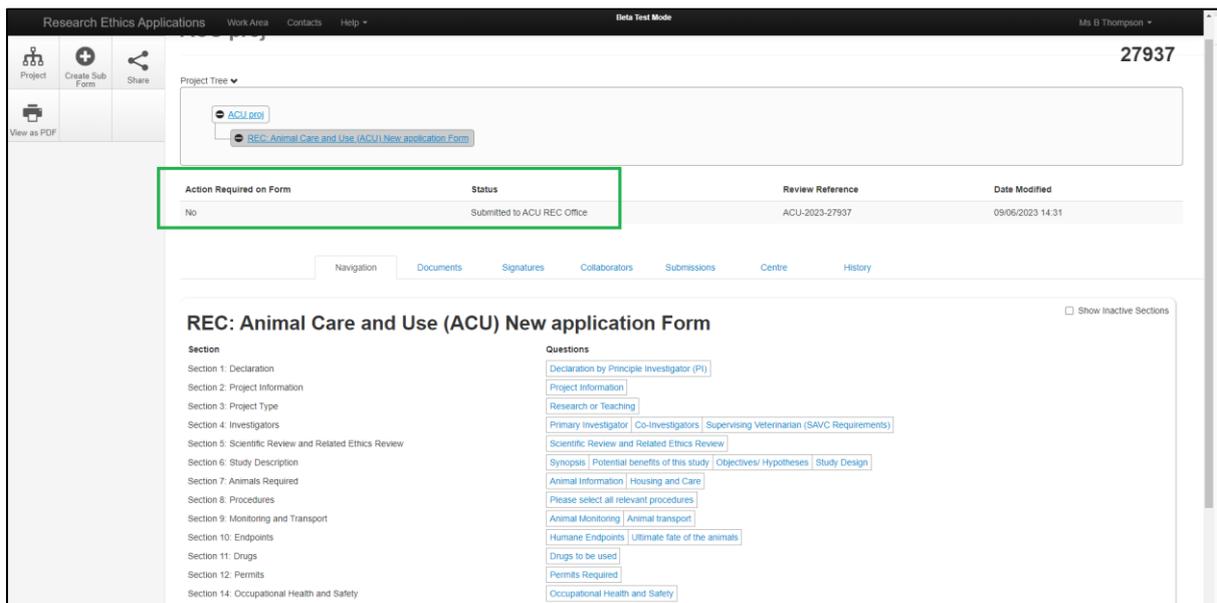
Tygerberg Doctoral Office: If you are a PhD candidate from the Faculty of Medicine and Health Sciences, please Request the Signature of the Doctoral Office by adding this email address to the field. (TYG-PHD@sun.ac.za)

Request Signature

1.2.4. After signing, your form should be submitted.



1.2.5. Your application will reflect this on your application work area.



1.3. Response to Modifications

1.3.1. Once you have clicked on your project, please consult with your feedback letter to make the necessary changes in your application form.

Research Ethics Applications Work Area Contacts Help + Beta Test Mode Ms B Thompson

ACU proj 27937

Project Tree

- ACU proj
 - REC: Animal Care and Use (ACU) New application Form

Action Required on Form	Status	Review Reference	Date Modified
Yes	Modifications required	ACU-2023-27937	08/06/2023 12:20

Navigation Documents Signatures Collaborators Submissions Centre History

REC: Animal Care and Use (ACU) New application Form

Section

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- Section 9: Monitoring and Transport
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Questions

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- Animal Information Housing and Care
- Please select all relevant procedures
- Animal Monitoring Animal transport
- Humane Endpoints Ultimate fate of the animals

1.3.2. After you have completed all the necessary changes, please upload a response letter under Section 15: Additional Documents.

Research Ethics Applications Work Area Contacts Help + Beta Test Mode Ms B Thompson

27937

Action Required on Form	Status	Review Reference	Date Modified
Yes	Modifications required	ACU-2023-27937	09/06/2023 11:15

Navigation Documents Signatures Collaborators Submissions Centre History

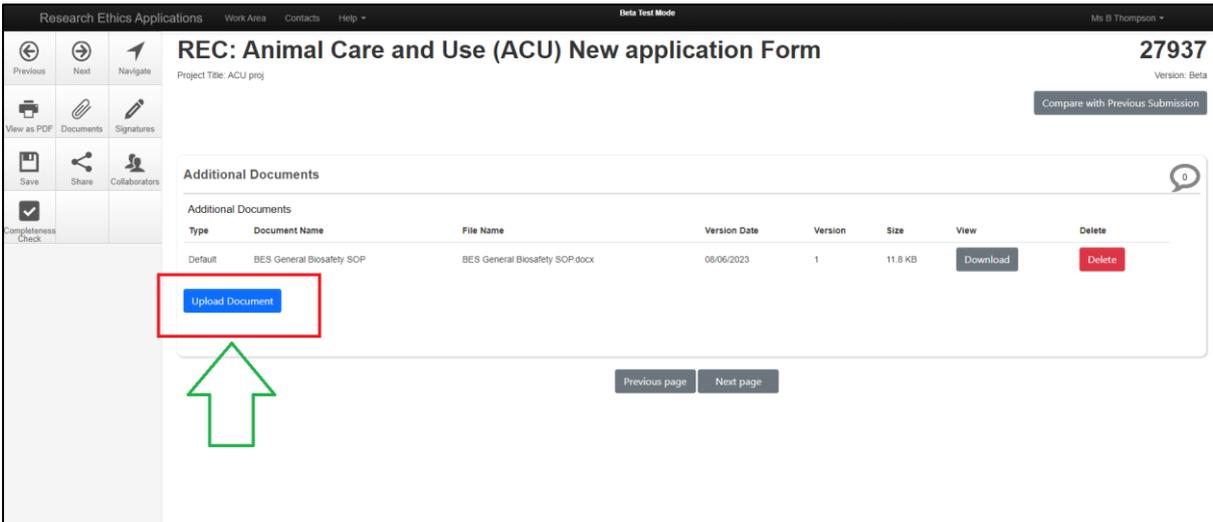
REC: Animal Care and Use (ACU) New application Form

Section

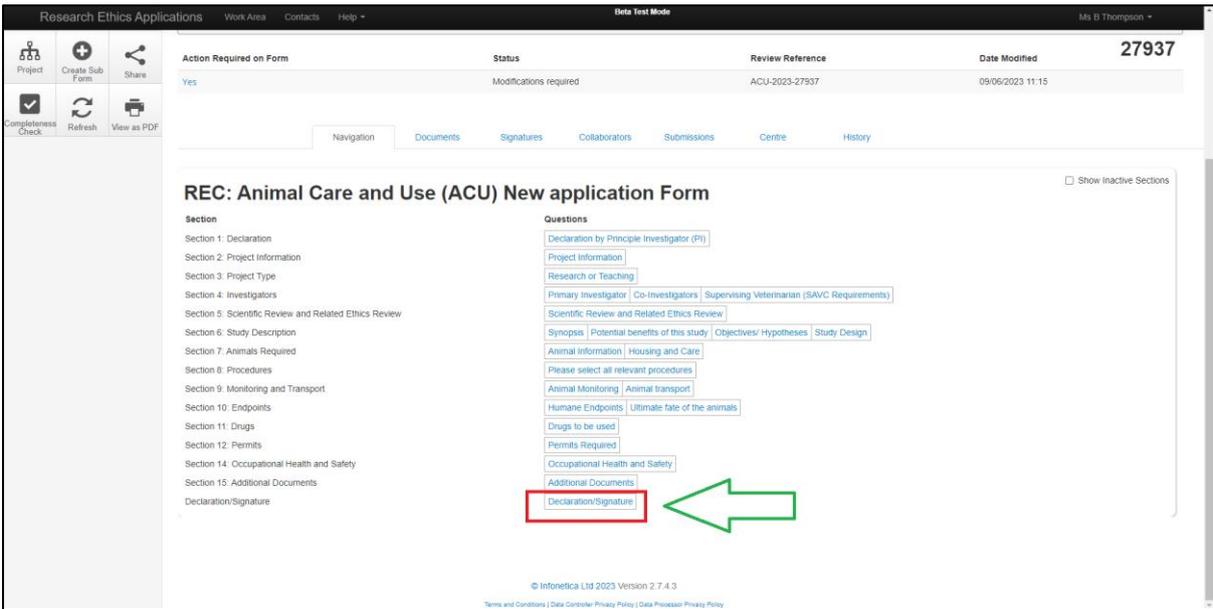
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- Section 14: Occupational Health and Safety
- Section 15: Additional Documents**
- Declaration/Signature

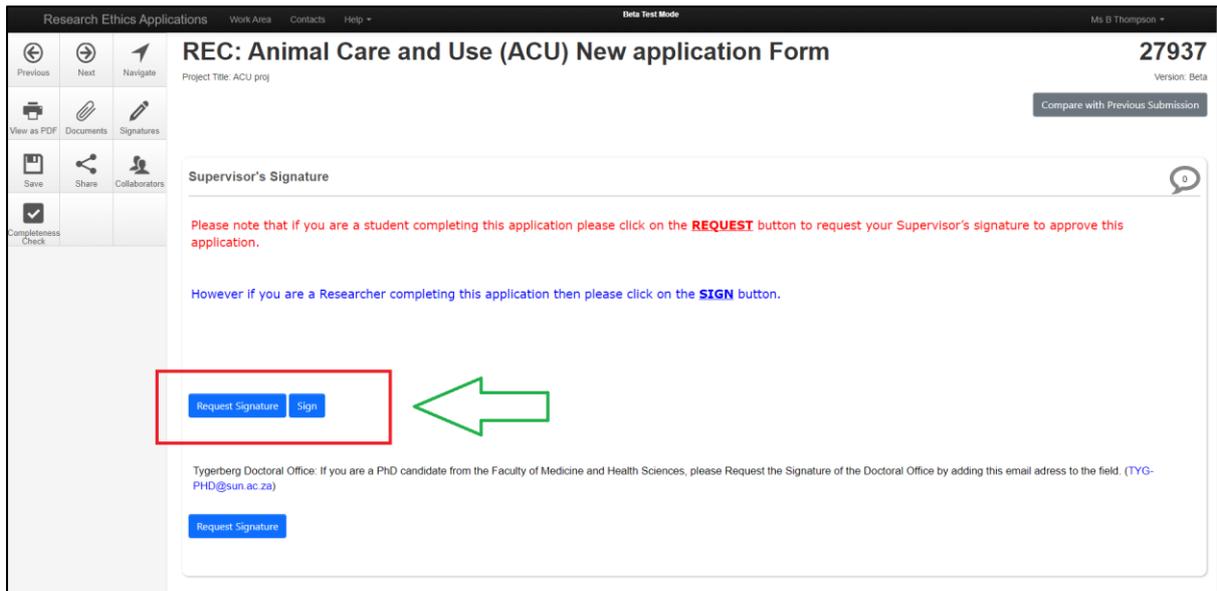
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- Additional Documents**
- Declaration/Signature

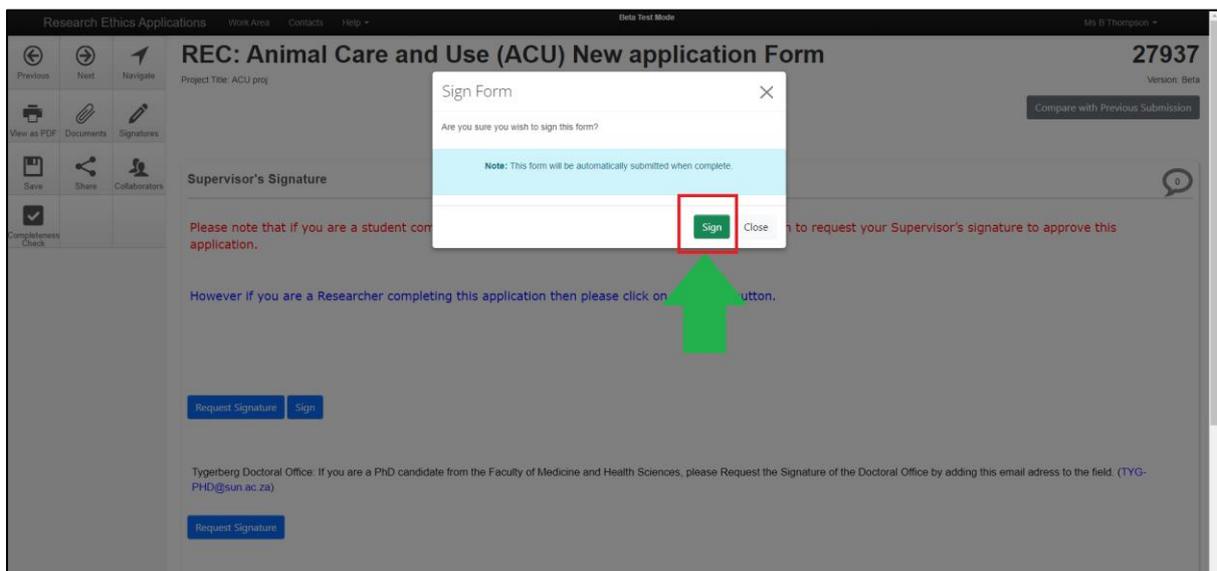


1.3.3. After uploading the response letter, please ensure that your form is signed, before submitting it. **If you are the RESEARCHER, please “Sign” the form. If you are the STUDENT, please select “Request Signature”.**

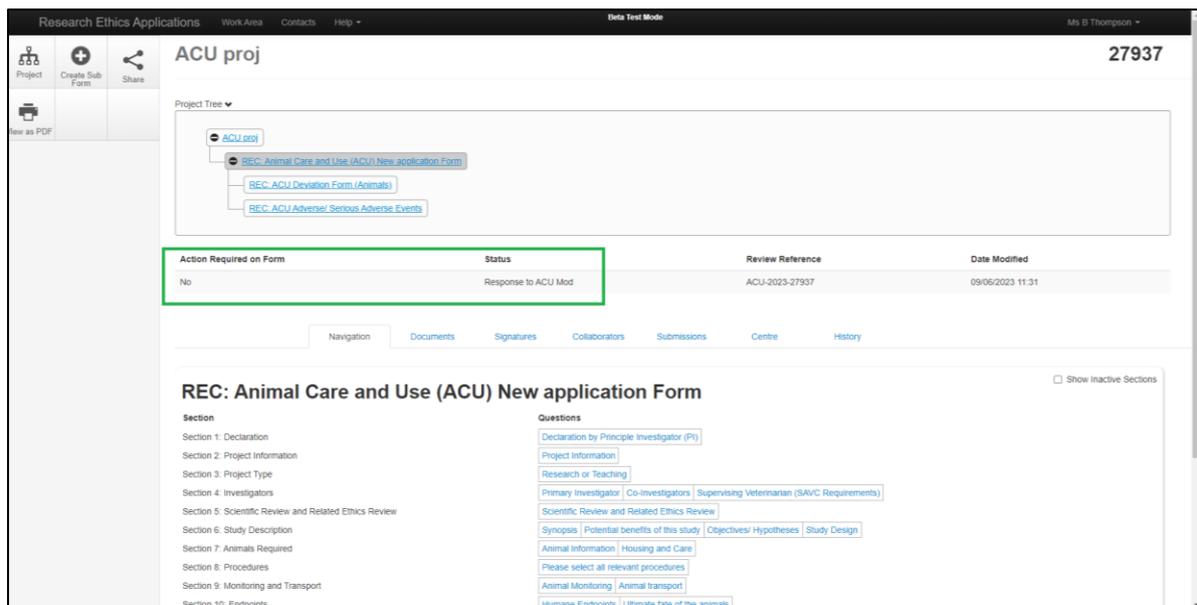




1.3.4. After signing, your form should be submitted.



1.3.5. Your application will reflect this on your application work area.



1.4. Turnaround times

1.4.1. If you had submitted a response to stipulations, you will be provided with feedback within 7 – 10 business days. Please take note, that as you have received approval with stipulations, you are able to conduct and or continue your experiments whilst awaiting feedback on your response to stipulations.

1.4.2. If you had submitted a response to modifications, you will be provided with feedback within 7 – 14 business days.

1.4.2.1. Please note, that as you have not received an approval on your application, you are unable to conduct any experimentation whilst you await REC: ACU or REC: BES approval.

1.4.2.2. If you receive an approval with stipulations on your response to modifications, you will be able to begin conducting your experiments. However, you will still need to submit a response to stipulations thereafter.

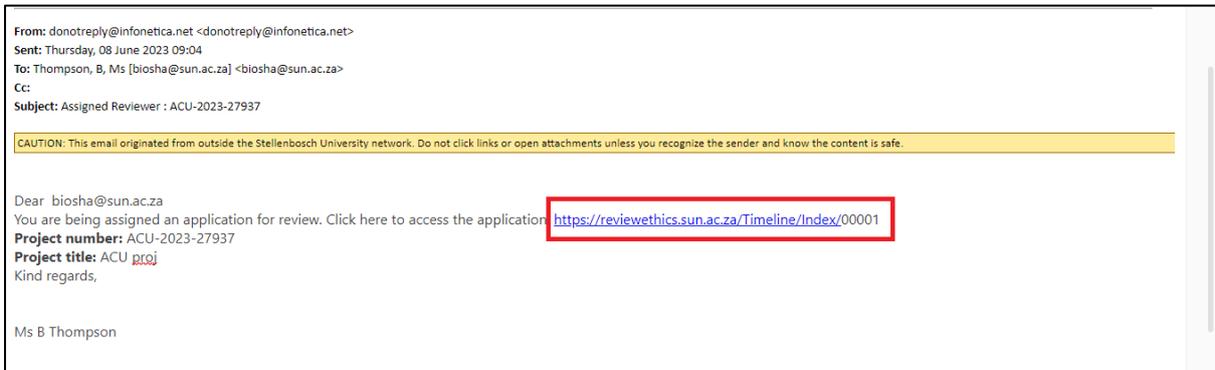
1.4.3. Once your response to stipulations or response to modifications has been approved, you will be required to submit a progress report to the committee on an annual basis. Once you have completed your project, you will be required to submit your final progress report to the committee.

2. Guide to Response to Stipulations and Modifications as the Reviewer:

2.1. Notification

2.1.1. After the Research Ethics Office is notified of the submission of a Response to Stipulations and Response to Modifications, the submission is screened by the REC: Coordinator and Administrative Officer to ensure it has been sufficiently amended.

2.1.2. Thereafter, it is assigned to the Reviewers and an email notification is sent from the Infonetica system to the Reviewer notifying them of the Response to Stipulations or Modifications. Please see below:

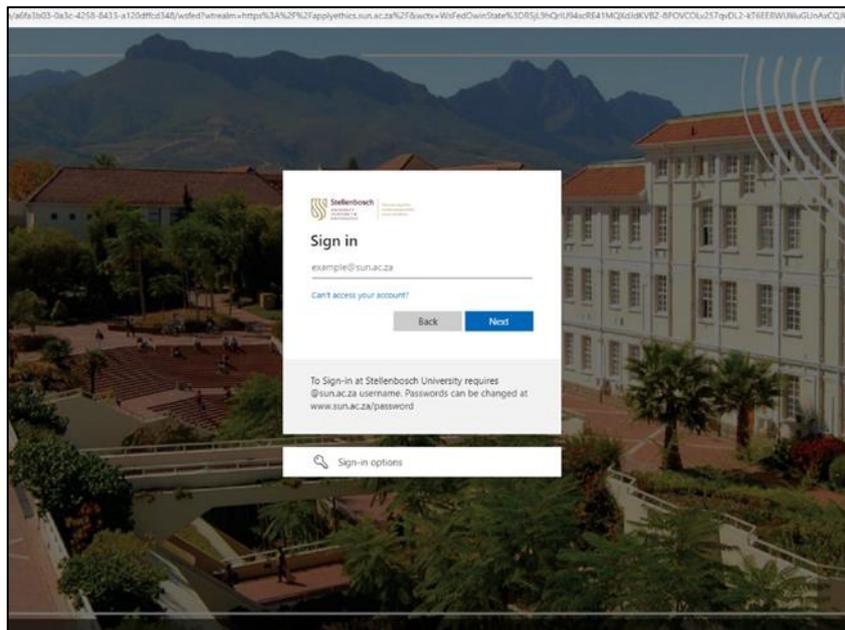


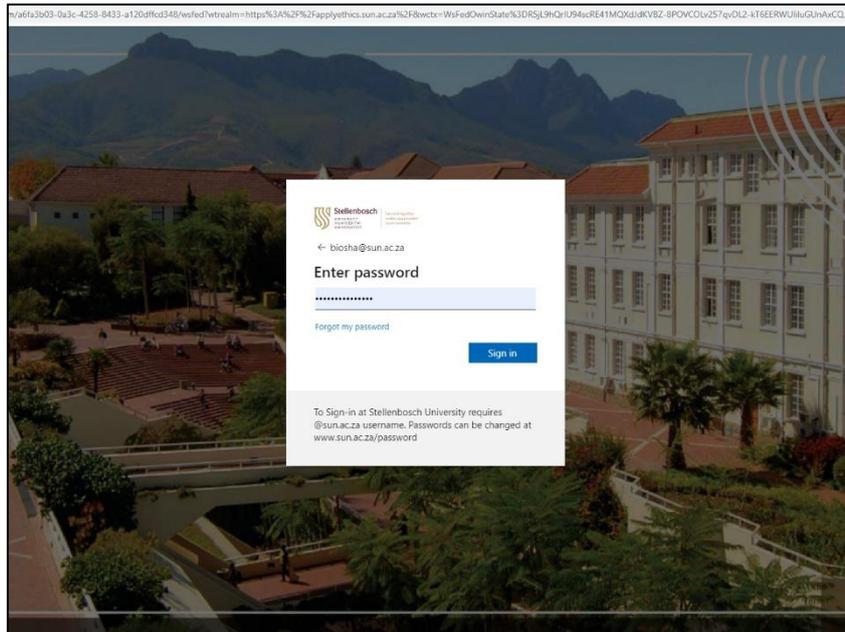
2.1.3. By clicking on the link, you will be directed to the Review Ethics site.

2.2. Login

2.2.1. As the Reviewer, you will need to log in to Review Ethics

(<https://reviewethics.sun.ac.za>) using your SU username (e.g., username@sun.ac.za) and password.



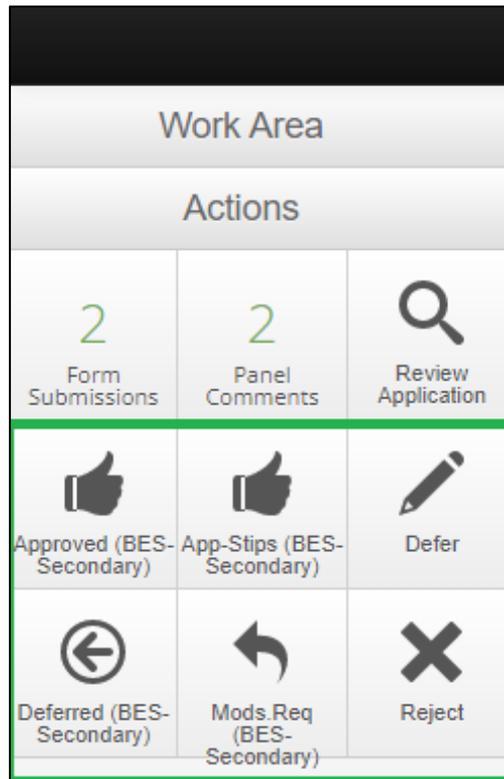


2.2.2. You will be directed to the Response to Stipulations or Modifications submission.

2.3. Response to Stipulations and Modifications

2.3.1. Please make use of the previous feedback letter and the response letter submitted by the applicant to determine whether the applicant had sufficiently responded to all the necessary points. Additionally, please screen and review the application to ensure that the applicant has made all the changes in the form and not just in the response letter.

2.3.2. After you have thoroughly reviewed the application, please provide feedback on the response to stipulations or modifications by selecting one of the tiles as seen below:



2.3.3. Please provide feedback on the application within 7 – 10 working days for responses to stipulations and 7 – 14 working days for responses to modifications.

3. Guideline to Response to Stipulations and Modifications as the Coordinator:

3.1. Administrative Review

3.1.1. Once the Response to Stipulations or Response to Modifications has been received, the REC: Coordinator or REC: Administrative Officer will perform an administrative review, to ensure that you, the applicant, has addressed all the issues raised in the original feedback letter, that all supporting documents have been attached, that you have submitted a response letter in question and answer format (Q & A format) addressing all the stipulations or modifications in great detail.

3.2. Turnaround time

3.2.1. Following the administrative review, if the stipulations listed in the original feedback letter are considered to be of minor importance, the Response to Stipulations may be approved immediately by the REC: Coordinator or REC: Administrative Officer.

3.2.2. However, if the stipulations requested by the committee are considered to be of major importance, the application may be sent for a secondary review.

3.2.3. The turnaround time for the review of Responses to Stipulations are 7 – 10 working days.

3.2.4. For all Response to Modifications, the application form will be sent for secondary review immediately after the REC: Coordinator or REC: Administrative Officer performs the administrative review.

3.2.5. The turnaround time for the review of Responses to Modifications are 7 – 14 working days.