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



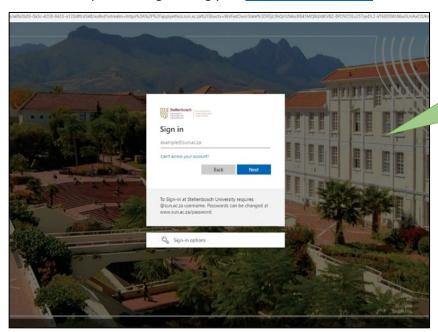
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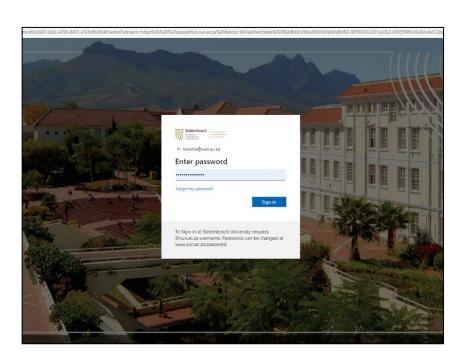
1. Guideline to Response to Stipulations and Modifications as an Applicant:

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 <u>username@sun.ac.za</u> and network password.

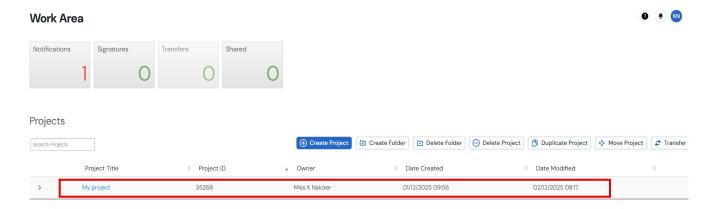


Enter your login credentials and sign in.



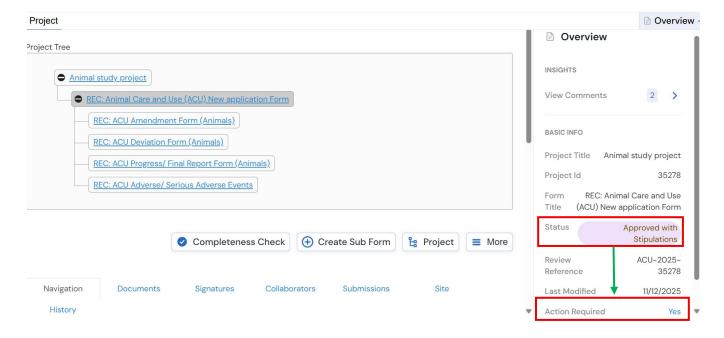
1.1.4.Once you have logged in successfully, you will be directed to your work area.

Thereafter, click on your project that requires changes.

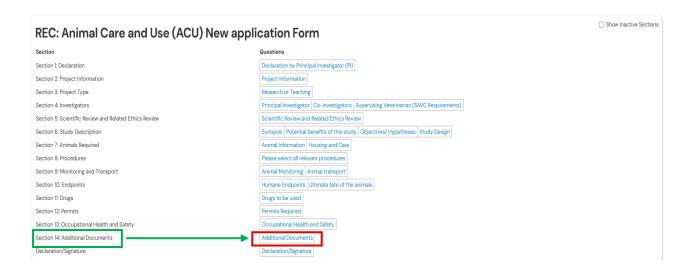


1.2. Response to Stipulations

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.

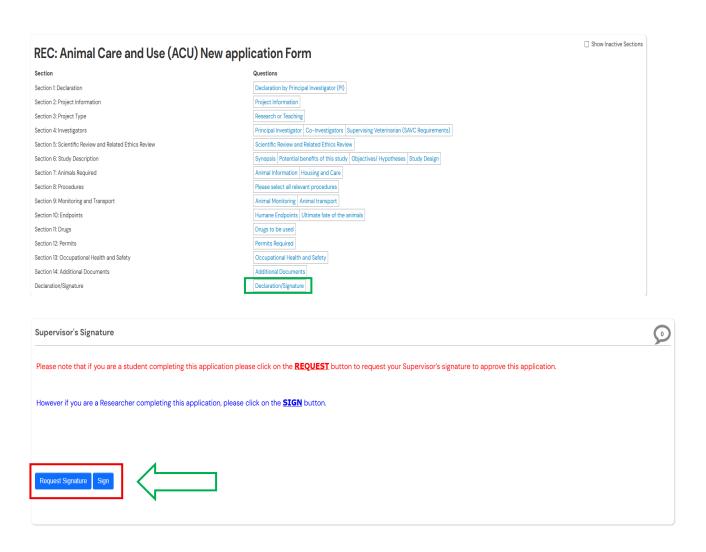


1.2.2.After you have completed all the necessary changes, please upload a response letter under Section 14: Additional Documents. The template for Response Letters has been made available on the REC: ACU and REC: BES websites under the 'Documents' folder.

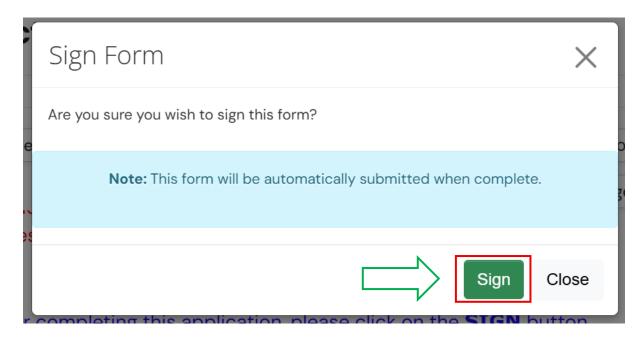




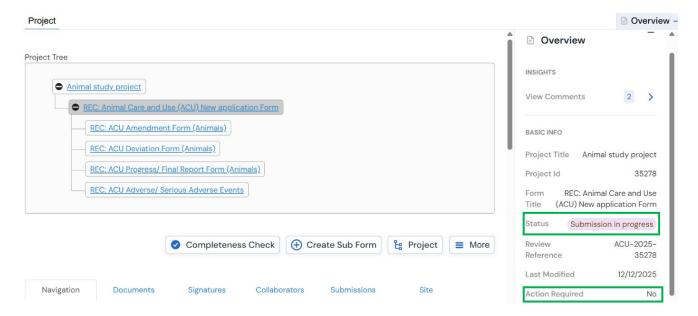
1.2.3. After uploading the response letter, please ensure that your form is signed, before submitting it. If you are the RESEARCHER, please "Sign" the form. If you are the STUDENT, please select "Request Signature".



1.2.4. After signing, your form should be submitted.

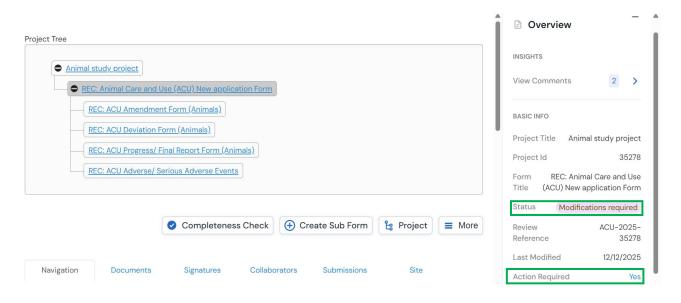


1.2.5. Your application will reflect this on your application overview panel.

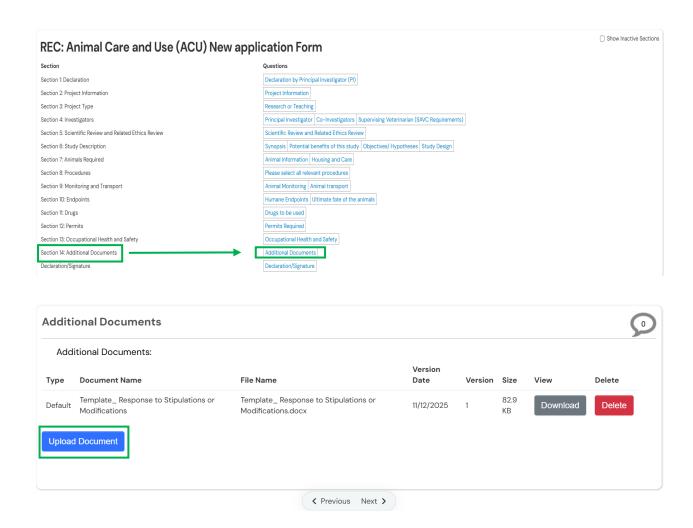


1.3. Response to Modifications

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.

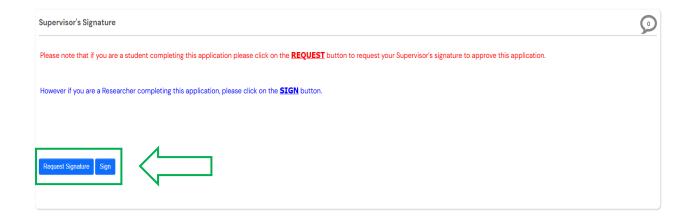


1.3.2. After you have completed all the necessary changes, please upload a response letter under Section 14: Additional Documents.

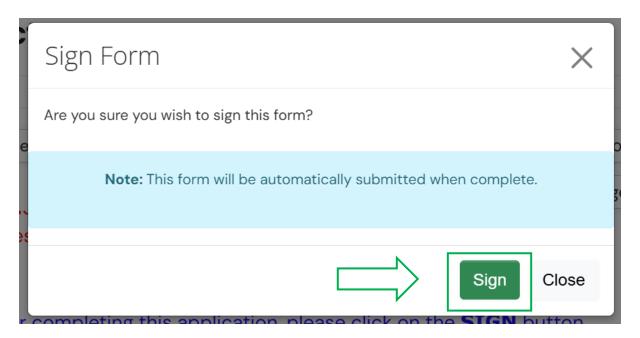


1.3.3.After uploading the response letter, please ensure that your form is signed, before submitting it. If you are the RESEARCHER, please "Sign" the form. If you are the STUDENT, please select "Request Signature".

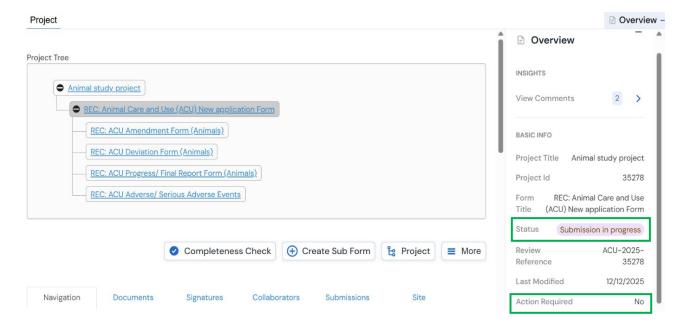
REC: Animal Care and Use (ACU) New application Form				
Section	Questions			
Section 1: Declaration	Declaration by Principal Investigator (PI)			
Section 2: Project Information	Project Information			
Section 3: Project Type	Research or Teaching			
Section 4: Investigators	Principal Investigator Co-Investigators Supervising Veterinarian (SAVC Requirements)			
Section 5: Scientific Review and Related Ethics Review	Scientific Review and Related Ethics Review			
Section 6: Study Description	Synopsis Potential benefits of this study Objectives/ Hypotheses Study Design			
Section 7: Animals Required	Animal Information Housing and Care			
Section 8: Procedures	Please select all relevant procedures			
Section 9: Monitoring and Transport	Animal Monitoring Animal transport			
Section 10: Endpoints	Humane Endpoints Ultimate fate of the animals			
Section 11: Drugs	Drugs to be used			
Section 12: Permits	Permits Required			
Section 13: Occupational Health and Safety	Occupational Health and Safety			
Section 14: Additional Documents	Additional Documents			
Declaration/Signature	Declaration/Signature			



1.3.4. After signing, your form should be submitted.



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

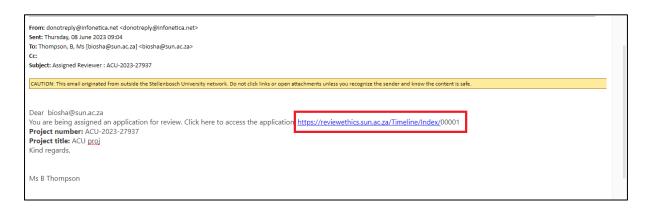


1.4. Turnaround times

- 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:

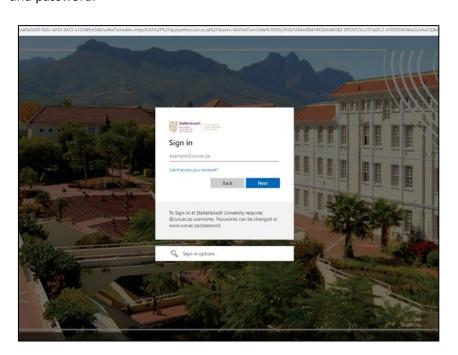


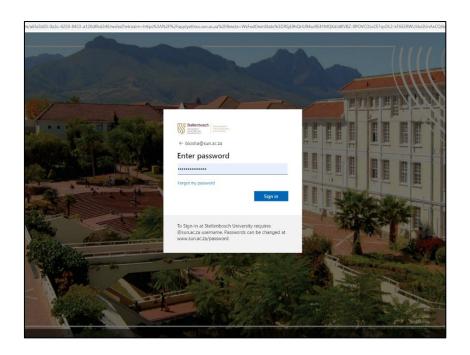
2.1.3.By clicking on the link, you will be directed to the Review Ethics site.

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.

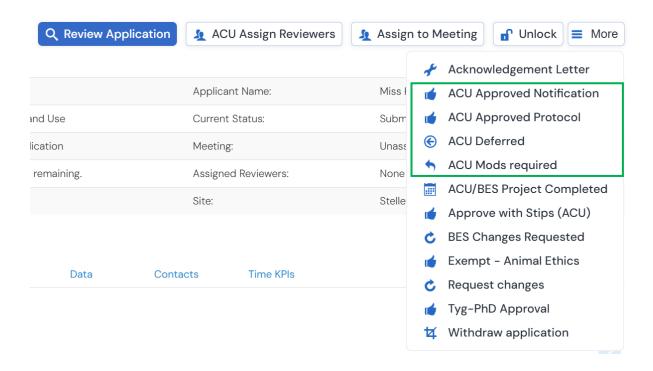




2.2.2. You will be directed to the Response to Stipulations or Modifications submission.

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.



Please indicate if the Letter is a: Response to Stipulations OR Response to Modifications

Date: ... (e.g., 6 June 2024)

Ethics Reference Number: BES-2024- ... / ACU-2024-.... (e.g., ACU-2024-12345)

PI name: ... (e.g., Dr P Adams)

Co-investigator name(s): ... (e.g., Prof S Keister, Miss L Behr).

Project title: ... (e.g. The effect of NSAID on the metamorphosis of Xenopus laevis tadpoles).

Key aspects when responding to committee feedback:

- 1. Please answer the queries from the committee in question-and-answer format.
- 2. Kindly refer to the online sections in which changes had been made.
- 3. Ensure that the PI is a permanent/senior member of staff.

Example:

1. Kindly amend the start and end dates for the project.

The start and end dates have been amended to 05/08/2024 – 25/10/2025 (section 2: Project Information).