

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

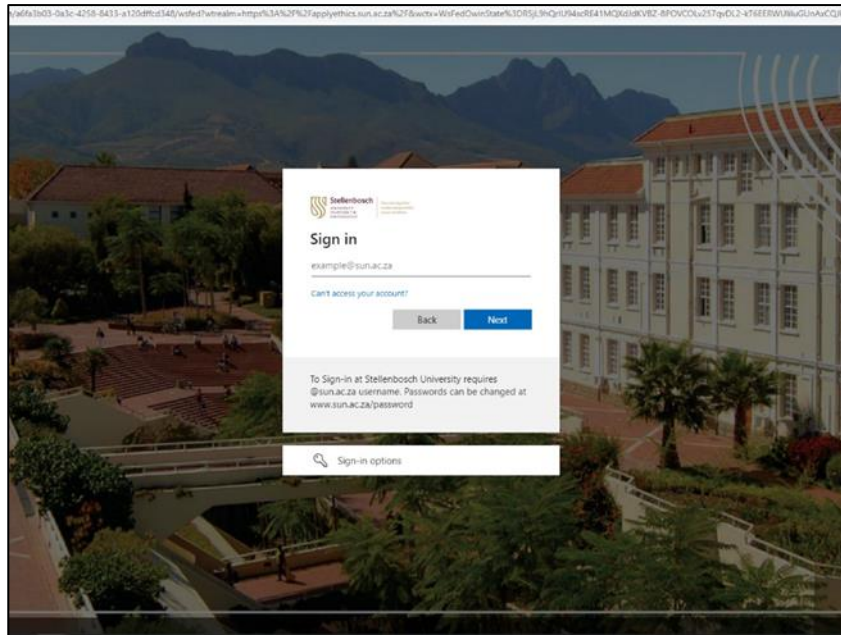
1.1.1. After you, the applicant, receives your Approval with Stipulation or Modifications

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.

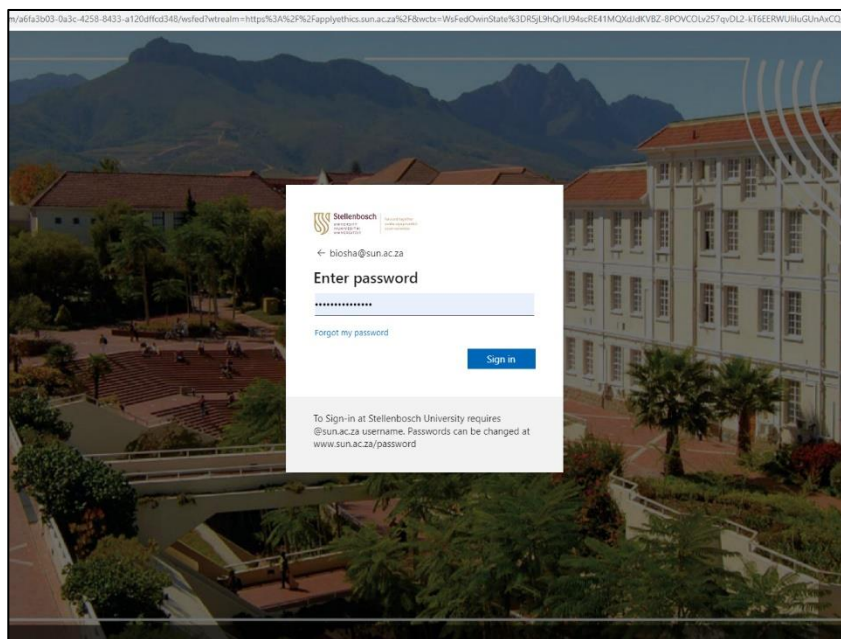
1.1.2. In order to do so, you will need to log in to the Apply Ethics website

(<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

Search 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	
gnop lab	27152	Ms B Thompson	02/02/2023 12:39	02/02/2023 12:39	

Showing 1 to 8 of 8 entries

Previous Next

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.

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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. The template for Response Letters has been made available on the REC: ACU and REC: BES websites under the 'Documents' folder.

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

27937

Project Create Sub Form Share

Completeness Check Refresh View as PDF

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)
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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
Drugs to be used
Permits Required
Occupational Health and Safety
Additional Documents
Declaration/Signature

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27937

Version: Beta

Compare with Previous Submission

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

Project Title: ACU proj

Previous Next Navigate

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Completeness Check

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

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 Ma B Thompson

Project Create Sub Form Share

Completteness Check Refresh View as PDF

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

☐ Show Inactive Sections

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

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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Completteness Check

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

Project Title: ACU prqj

27937 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 adress to the field (TYG-PHD@sun.ac.za)

Request Signature

1.2.4. After signing, your form should be submitted.

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

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

Project Title: ACU proj 27937 Version: Beta

Are you sure you wish to sign this form?

Note: This form will be automatically submitted when complete.

Sign Close

Supervisor's Signature

Please note that if you are a student completing this application, you must 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

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

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

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

Project Tree

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

Action Required on Form	Status	Review Reference	Date Modified
No	Submitted to ACU REC Office	ACU-2023-27937	09/06/2023 14:31

Navigation Documents Signatures Collaborators Submissions Centre History

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

Section 1: Declaration

Section 2: Project Information

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- 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

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 27937

ACU proj

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

- Section 1: Declaration
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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

ACU proj

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	09/06/2023 11:15

Navigation Documents Signatures Collaborators Submissions Centre History

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

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- Section 1: Declaration
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- Section 15: Additional Documents

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- Permits Required
- Occupational Health and Safety
- Additional Documents
- Declaration/Signature

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

Project Title: ACU proj 27937 Version: Beta

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Completeness Check

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

Previous page Next page

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”.**

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

Project Create Sub Form Share

Completeness Check Refresh View as PDF

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

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Section

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Project Title: ACU proj 27937 Version: Beta

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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 adress to the field. (TYG-PHD@sun.ac.za)

Request Signature Sign

1.3.4. After signing, your form should be submitted.

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

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

Project Title: ACU proj 27937 Version: Beta

Compare with Previous Submission

Sign Form

Are you sure you wish to sign this form?

Note: This form will be automatically submitted when complete.

Sign Close

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.

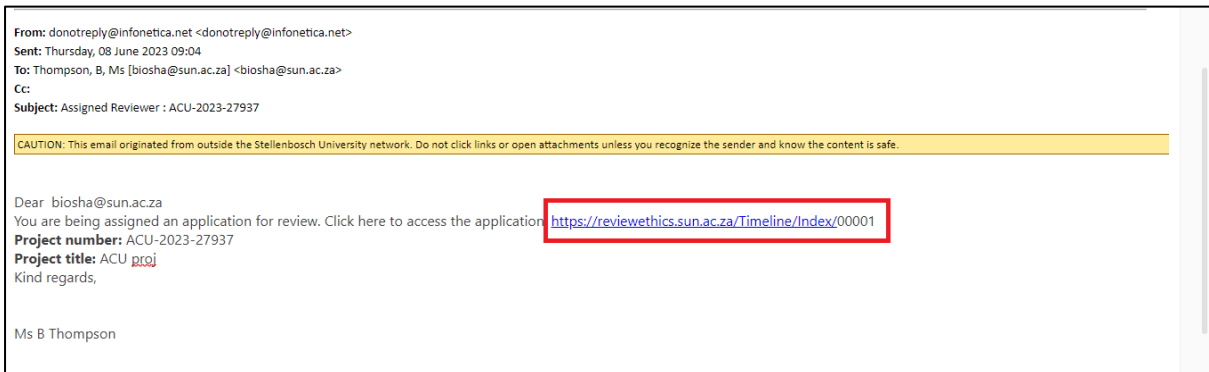
1.4.3. Once your response to stipulations or response to modifications has been approved, you will be required to submit a progress report to the committee on an annual basis. Once you have completed your project, you will be required to submit your final progress report to the committee.

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:

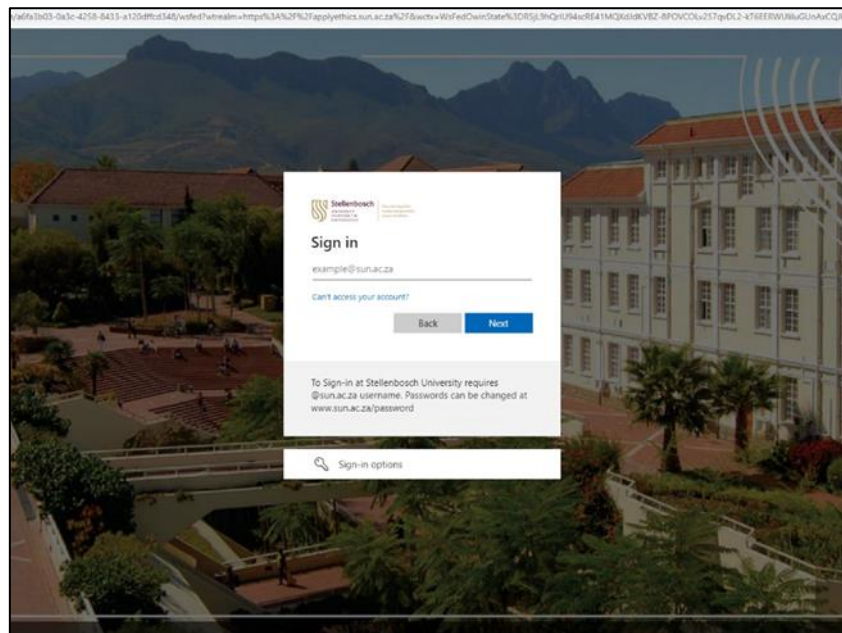


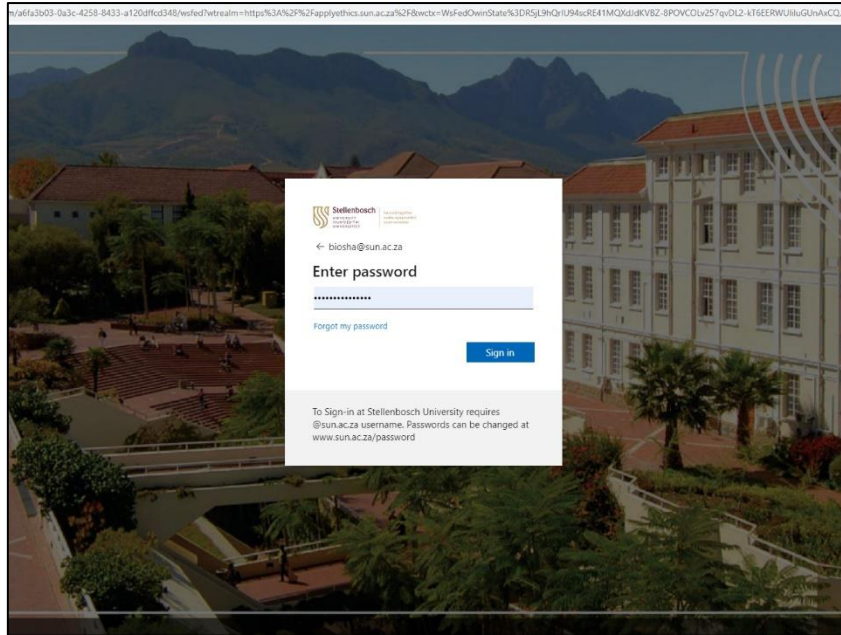
2.1.3. By clicking on the link, you will be directed to the Review Ethics site.

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.



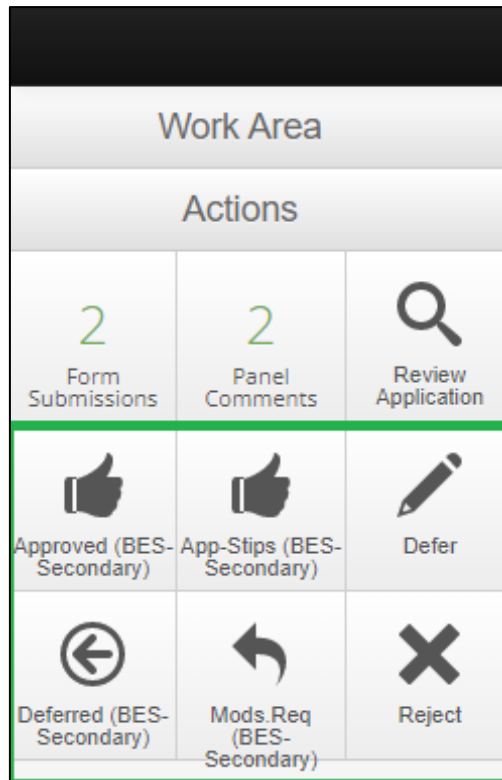


2.2.2. You will be directed to the Response to Stipulations or Modifications submission.

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.

Appendix A. Template for Response to Stipulations and Modifications



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).