



**Standard Operating Procedures:  
Instructions on submission of a protocol for approval by the  
Faculty of Health Sciences Biosafety Committee (FBC)**

## 1. Background

The Faculty Biosafety Committee (FBC) reports to the Deanery in the Faculty of Health Sciences and to the UCT Institutional Biosafety Committee (IBC). The IBC is a Senate-level committee and is registered with the National Institutes of Health (NIH) USA.

As stated in the UCT IBC Policy on research protocols submitted to the IBC, the IBC is constituted to protect the interests and integrity of UCT-based researchers (staff and students), the community and the environment, by ensuring that all research and related activities involving **genetically modified organisms (GMOs)**, recombinant or synthetic nucleic molecules as well as other **potentially hazardous biological agents (pHBAs)** complies with national legislation and national and international guidelines on biosafety and environmental ethics<sup>1</sup>.

This Standard Operating Procedure (SOP) provides an overview of the types of research that require FBC and/or IBC approval. In some cases, and according to the biosafety risks inherent in a project, the FBC will issue recommendations (not approvals) which will be escalated to the IBC for final consideration and approval.

## 2. Role of the Principal Investigator (PI)

- The PI is responsible for compliance with UCT IBC policy as well as national (e.g., SAMRC Guidelines for Ethics in Medical Research: Use of Biohazards & Radiation) and international guidelines (e.g., NIH Guidelines on Research Involving Recombinant or Synthetic Nucleic Acid Molecules (including Human Gene Transfer Research)).
- The PI must ensure that no research involving genetically modified organisms or potentially hazardous biological agents (pHBAs) including recombinant or synthetic nucleic acid molecules may be initiated prior to approval by the F/IBC.
- The PI must ensure that all procedures are implemented in line with acceptable biosafety standards.
- The PI should ensure that any significant problems, or violations of the biosafety guidelines, or any significant research-related accidents are reported immediately to the F/IBC and/or other appropriate authorities.
- The PI must ensure adequate and up-to-date biosafety training.

## 2. Steps to be taken before submitting a New Protocol

- Researchers submitting a new application to conduct research utilizing genetically modified organisms (GMOs) or potentially hazardous biological agents (pHBAs) must

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<sup>1</sup> UCT IBC Policy on research protocols submitted to the IBC was approved by the Senate Executive Committee on 18 November 2020.

complete a new Protocol Application Form available on the FHS FBC webpage at <http://www.health.uct.ac.za/fhs/research/faculty-biosafety-committee>.

- The protocol has to go through a scientific review in the relevant Department and the signature of the Head of Department (HoD) is required before it can be submitted to the FBC for review.

### 3. New Protocol Submission

- Upon receiving the approval from the HoD, **ONE typed** copy of the protocol application form in a Word document or PDF format (not an image file) with the HoD approval signature **or** approval letter, can then be emailed to [fhs.fbc@uct.ac.za](mailto:fhs.fbc@uct.ac.za).
- An acknowledgement letter or email will be issued to acknowledge receipt of the application.
- The IBC does not accept direct submissions of applications. All applications requiring IBC. Approval must be submitted to the FBC for initial review. The FBC will refer or escalate an application to the IBC for review as appropriate.

### 4. Responding to FBC full review comments

- The full committee of the FBC will review the application. For all applications received, a preliminary review may be conducted by the Chair of the FBC before sending the application for full FBC review.
- An FBC Approval Letter or FBC Decision Letter may be issued.
- In case of an FBC Decision Letter, further changes to the protocol are required. These changes must be implemented, and the protocol resubmitted via email to the FHS Research Ethics Office (REO) incorporating these additional changes
- The revised application may require final consideration by the UCT IBC. This will be indicated in the FBC Decision Letter. In such cases, the FHS REO will refer or escalate the revised application to the Secretariat of the IBC. The Secretariat of the IBC is located in the Office of Research Integrity (ORI). The Secretariat will assign the revised application to an agenda of the IBC meeting.
- After the IBC meeting, the IBC Secretariat will inform the PI of the outcome.

### 5. Amendments to approved protocols

- The amendment application form is available on the FBC webpage at: <http://www.health.uct.ac.za/fhs/research/faculty-biosafety-committee>
- Researchers must apply for approval of any minor or major amendment(s) to an approved protocol.
- Upon receipt of an amendment application, the FHS REO will issue an Acknowledgement of receipt via email.
- In cases where the amendment does not affect the biosafety aspects of the protocol, the FBC Secretariat in the FHS REO will issue an FBC Acknowledgment Letter in consultation with the FBC Chair. Such an amendment application may be referred to the IBC for ratification, where appropriate.
- In some cases, an amendment may require further and final approval from the UCT IBC. The FBC Secretariat will then refer the amendment application to the IBC Secretariat for review and approval.

## 6. Annual Progress Reports (Continuing Review of on-going Research)

- PIs are required to submit annual progress reports on:
  - (i) FBC-approved studies – directly to the FBC Secretariat; or
  - (ii) IBC-approved studies – directly to the IBC Secretariat in the Office of Research Integrity.
- The due date of annual progress reports is listed either in the FBC approval letter or IBC approval letter.
- The Annual Progress Report application form is available on the FBC webpage at: <http://www.health.uct.ac.za/fhs/research/faculty-biosafety-committee>.
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## 7. Final Reports

- The Final Report application form is available on the FBC webpage at: <http://www.health.uct.ac.za/fhs/research/faculty-biosafety-committee>
- The PI is responsible for submitting a final report to the FBC.
- A Final report is for the closure of the study prior to or on its expiry date.

## 8. Signatures

- The applicant's and HoD's signatures (section 10 of the application form – in the table below) are required before an application is submitted to the FBC. If no signatures are appended, then the application is deemed incomplete and will be returned to the applicant.

**Kindly Note:** No application will be reviewed without HoD signature!

DECLARATION BY APPLICANT'S HEAD OF DEPARTMENT	
<p><b>I confirm that I have read and understood the risk assessment relating to this project;</b> in my opinion the Principal Investigator is competent to perform and oversee the work described and I thus support this application.</p>	
HoD Signature: _____	Date _____
Department: _____	

## 9. Compliance certificates and Checklist

These are the compliance certificates that must be submitted along with the final application:

STATUTORY AND OTHER EXTERNAL APPROVALS				
<i>Legally you are obliged to obtain certain certificates and permits before you may commence with your research, please answer the following questions so that the committee may ascertain the status/need of your applications.</i>				
	YES (If yes, please include a copy of the permit/ approval)	NO	NOT APPLICABLE	PENDING (If pending, please include proof of application)

Department of Agriculture, Land Reform and Rural Development (Section 20)				
Department of Agriculture, Forestry and Fisheries (GMO)				
Department of Agriculture, Forestry and Fisheries (Release Form)				
SAPHRA- South African Health Products Regulatory Authority				
Nature Conservation Permits for Wildlife Research (e.g. SANParks, Cape Nature)				
Relevant Committee approval (with biological/biosafety oversight)				

- Checklist to be consulted before submitting an application to the FBC.

<b>CHECKLIST</b>				
<b>Item</b>	<b>Required</b>	<b>Submitted</b>	<b>Not applicable</b>	<b>If not included, will be sent by</b>
Application form complete and signed				
Listed SOPs included				
University approvals (animal/human ethics)				
Statutory/External approval letters or proof of application				
<b>PLEASE NOTE: DO NOT ATTACH STANDARD OPERATING PROCEDURES (SOPs). SOPs SHOULD BE AVAILABLE ON REQUEST.</b>				