

University of Cape Town

Institutional Biosafety Committee

Standard Operating Procedure for Managing Research Protocols

[February 2024, version 1]

Title	Institutional Biosafety Committee, Standard Operating Procedure for Managing Project Applications
Approval date	28 February 2024 (at IBC quorate meeting)
Person(s) responsible for drafting, review, and revision	Senior Administrative Officer, Animal and Biosafety Compliance Research Integrity Manager Chair, Institutional Biosafety Committee (IBC)
Next review date	February 2026 [or sooner if needed to better align with processes]
Status	Standard Operating Procedure
Approval route	Office of Research Integrity (ORI) > Institutional Biosafety Committee (IBC)
Approving body	IBC
Relevant related policies, procedures, and guidelines	<ul style="list-style-type: none"> • UCT Policy for Responsible Conduct of Research • IBC Terms of Reference • IBC Policy on Review of Research Protocols Submitted to the IBC

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1. Abbreviations and definitions

a. Abbreviations

APR	Annual Progress Report
BSL	Biosafety Level
EBE	Faculty of Engineering and the Built Environment
eRA	Electronic Research Administration
FBC	Faculty Biosafety Committee
FHS	Faculty of Health Sciences
GMO	Genetically Modified Organism
HREC	Health Research Ethics Committee
IBC	Institutional Biosafety Committee
IRB	Institutional Review Board (=REC)
NIH	National Institutes of Health, USA
ORI	Office of Research Integrity
pHBA	potentially Hazardous Biological Agent
PI	Principal Investigator
REC	Research Ethics Committee (=IRB)
SCI	Faculty of Science

b. Definitions

Biosafety Level (BSL)

- "A biosafety level is the level of the biocontainment precautions required to work with dangerous biological agents in an enclosed facility. The levels of containment range from the lowest, biosafety level 1 (BSL-1), to the highest at level 4 (BSL-4)."¹
- UCT does not conduct work which requires BSL4 facilities.

Genetically Modified Organisms (GMOs)

"Plant, animal, or microbe in which one or more changes have been made to the genome ... to alter the characteristics of an organism. Genes can be introduced, enhanced, or deleted within a species, across species, or even across kingdoms. GMOs may be used for a variety of purposes, such as making human insulin, producing fermented beverages, and developing pesticide resistance in crop plants."²

Principal Investigator (PI)

- "PI refers to the person(s) in charge of a clinical trial or a scientific research grant. The PI prepares and carries out the clinical trial protocol (plan for the study) or research paid for by the grant. The PI also analyzes the data and reports the results of the trial or grant research."³
- **"A PI is primarily responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of clinical research."**⁴
- All submissions to the IBC must be signed-off and made by the PI, even if the documentation was prepared by another member of the team. The PI is responsible for the final submission to the IBC and the conduct of the project for the duration of its activity.

¹ Taken from the NIH: <https://policymanual.nih.gov/3035>

² Taken from the NIH: <https://www.genome.gov/genetics-glossary/Genetically-Modified-Organism>

³ Taken from the NIH: <https://toolkit.ncats.nih.gov/glossary/principal-investigator/>

⁴ Taken from the NIH: <https://toolkit.ncats.nih.gov/glossary/principal-investigator/> (emphasis added)

Potentially Hazardous Biological Agents (pHBAs)

"General term used to describe recombinant and synthetic nucleic acids, toxins, human, animal and plant pathogens requiring BSL-2 and higher and Select Agents that could cause disease in humans."⁵

2. Preamble and purpose

The purpose of this document is to outline the processes and procedures for:

- submission of research protocols to the Institutional Biosafety Committee (IBC),
- review of research protocols by the IBC,
- determination of an outcome of a research protocol, including issuing of outcomes letters and/or noting research protocols, as necessary, and
- submission, review, and processing of annual progress reports (APRs) and research protocol closure reports.

This document is only intended to describe processes related to the IBC. Researchers may also be required, for a given research protocol, to make submissions to human (HREC) or animal (AEC) research ethics committees in their faculties, as outlined in the relevant policies. This document should therefore be seen as complementary to Faculty policies related to human or animal research ethics.

Disclaimer: The IBC, along with all ethics committees, are in the process of moving to the institutional electronic Research Administration (eRA) system; as this process occurs, this document will require further review and amendment.

3. IBC servicing and administration

The IBC is serviced, administered, and supported by the Office of Research Integrity (ORI). The Senior Administrative Officer: Animal and Biosafety Compliance in the ORI is the lead contact person. However, should this person not be available, additional support is provided by the Office of Research Integrity: Servicing and Compliance team.

The IBC website can be accessed [here](#).

4. Submission procedures

[This section should be read in conjunction with the [IBC Policy on Review of Research Protocols submitted to the IBC](#)]

- i. All research protocols requiring biosafety review and approval must first be submitted to the Faculty Biosafety Committee (FBC) in which the principal investigator (PI) is based.
 - a. If the PI is based in the Faculty of Engineering and the Built Environment (EBE), they must make a submission to the Faculty of Science Biosafety Committee.
 - b. PIs based in the Faculty of Science are required to make submissions to the Faculty of Science FBC.
 - c. PIs based in the Faculty of Health Sciences are required to make submissions to the Faculty of Health Sciences FBC.

⁵ Taken from the NIH: <https://policymanual.nih.gov/3035>

- ii. Where, according to the IBC policy, a project requires review and approval by the IBC, the FBC will escalate the research protocol to the IBC and notify the PI.

The following table is a limited extract from the IBC policy mentioned above and is included here to illustrate the criteria applied in determining the potential requirement for the escalation of a research protocol. Please consult the [IBC policy document](#) for full information.

Level of Review	Example of types of research covered (refer to NIH Guidelines for more detail)
IBC	Experiments that compromise the control of disease agents in medicine through deliberate transfer of a drug resistance trait.
IBC approval and review for containment determinations	Experiments involving the cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram of body weight.
IBC and IRB (or HREC) approval and review before research participant enrolment	Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules into human research participants or gene editing of human embryos or participants.
IBC approval before initiation	Creating stable germline alterations of a microorganism, animal (insect or other species) or plant germline or testing viable recombinant or synthetically modified microorganisms on whole animals or plants where BSL-2 containment or greater is necessary. This includes gene editing. GMO work involving biological agents of risk group 2 or above and/or requiring BSL-2 containment or above. GMO work involving culture volumes greater than 10L.
	Release into the environment of any potentially hazardous biological agents (pHBAs).
	Any research involving pHBAs under BSL-3 containment.
FBC approval and recorded at IBC	Creating stable germline alterations of microorganisms, animals (insect or other species), or plants by introduction of recombinant or synthetically modified nucleic acid molecules when these experiments require BSL-1 containment. This includes gene editing.
	Purchase or transfer of transgenic rodents. GMO work involving biological agents of risk group 1 where BSL-1 containment is sufficient.
	Research with any pHBAs not covered by the NIH guidelines such as unmodified pathogens.
Approval not required	Laboratory research involving clinical trials on pHBAs that do not involve GMOs or any BSL-3 laboratory component at UCT.

a. Submission of complete applications

The IBC will only review complete applications. Complete applications are to be provided to the IBC servicing officer within the timeframe for a given meeting ([Section 5](#)) and must consist of the following documentation:

- i. The complete research protocol, on the correct application form with all necessary approvals/signatures;
- ii. Any required supporting documentation, as outlined in the application form;
- iii. A recommendation letter from the relevant FBC which first received and reviewed the application;
- iv. Any rebuttal letters or provision of additional information requested by the FBC from the submitting PI.

If the documentation listed above is not provided to the IBC servicing officer within the timeframe for a given meeting ([Section 5](#)), the research protocol application will be held over to the next available meeting to allow for the outstanding documentation to be provided. Only once all the documentation is provided, and an application is deemed complete, will it be placed on an IBC meeting agenda for review.

5. Timelines

The IBC calendar of meetings and submission deadlines is available on the [IBC website](#).

If the FBC determines that a research project needs to be escalated to the IBC for approval, this notification must be made to the IBC no later than 2 weeks prior to the date of the next scheduled or targeted IBC meeting. The IBC servicing officer will invite applications from the FBCs approximately 3 weeks prior to a scheduled meeting.

FBCs are required to determine internal submission deadlines that will allow for the receipt, review and, where necessary, revision and re-review (including discussion or provision of additional information, if required) of protocol applications in time for them to be escalated to the IBC.

Research project applications received after the IBC deadline, or applications which are incomplete, will be held over until the next IBC meeting.

6. Meetings

The IBC meets approximately 11 times per year, with no meetings held in December.

- The IBC has 4 quarterly meetings per year, these are generally scheduled in the last weeks of March, June, September, and November. Quarterly meetings are convened to consider policy and other related matters and any protocols which may have been received. Quarterly meetings will be hosted in-person in UCT's Research Office, Mowbray. Members are expected to attend quarterly meetings in person at the Research Office, Mowbray, or send apologies to the servicing officer.
- In addition to quarterly meetings, the IBC makes provision for monthly meetings during which *only protocols* are reviewed. These meetings are generally scheduled in the last weeks of January, February, April, May, July, August, and October. If FBCs do not have any protocols to escalate to the IBC for a given monthly meeting, the IBC Chair may take the decision to cancel the monthly meeting. Monthly meetings will be hosted virtually using Zoom as a meeting platform. The general expectation is that members will attend monthly meetings virtually.
- The IBC may also call special meetings if urgent business needs to be considered. Special meetings will generally be hosted virtually, unless prior agreement of the committee is secured to convene in-person.
- A Chair's Circular may also be issued in place of a special meeting. A Chair's Circular will have a comment period of two weeks to allow members sufficient time to consider the documentation.

All meetings will be scheduled as early as possible in the year and placed in the committee members' diaries to secure the time.

Agendas will be drafted and distributed to the IBC by the Servicing Officer no later than one (1) week prior to a scheduled meeting.

7. Review procedures and delegation of authority

Protocols received by the IBC will be included in an agenda pack which will be distributed one (1) week in advance of a given meeting. At the meeting, the following will take place:

- i. The Chair of the FBC which escalated the application will present the research protocol to the IBC, including any communications with the PI, provision of additional supporting information, and the rationale for FBC's recommendation for a project outcome/decision.
- ii. The IBC will discuss the application and any concerns arising in relation to the protocol.
- iii. If the IBC is satisfied with the application, it may choose to approve it. This decision must be clearly documented by the Servicing Officer in the minutes of the meeting and communicated to the PI.

- iv. If the IBC is not satisfied with the application, the committee may choose NOT to approve it. This decision must be clearly documented by the Servicing Officer in the minutes of the meeting and communicated to the PI.
- v. If the IBC has queries about an application, the committee may delay making a final decision until the Chair and Servicing Officer have been able to communicate with the PI to provide additional information for the committee to consider.
 - a. The committee may choose to reconsider the application, in its entirety, following the provision of additional information, at a convened meeting. This decision must be clearly documented by the Servicing Officer in the minutes of the meeting and communicated to the PI.
 - b. The committee may delegate the final decision-making authority to the Chair, following provision of additional information by the PI. This decision must be clearly documented by the Servicing Officer for the minutes of the meeting. Following the provision of the additional information, if the Chair is satisfied, they may approve the project using the delegated authority of the IBC. If the Chair determines that the IBC should review the additional information provided, it may be placed on a forthcoming meeting agenda. This will be communicated to the PI and IBC by the Servicing Officer.

8. Types and communication of outcomes

Applications may receive one of the following outcomes:

- i. Not approved: the project may not commence. In this case, the PI may submit a revised application to the FBC reflecting a genuine attempt to implement IBC and FBC recommendations.
- ii. Approved: project may commence.
- iii. Approved with conditions: project may only commence after a specific condition(s) has been met. The PI should provide evidence of having met the condition(s) to the IBC Servicing Officer and Chair.
- iv. IBC notes research protocol. This outcome is used where the FBC has escalated an application to the IBC for noting. In this case, the IBC Servicing Officer will record the outcome for the minutes and communicate the outcome with the FBC Chair and Servicing Officer via email. For IBC notes protocols, it is the duty of the FBC to issue an outcome letter to the PI.

In the case of outcomes i – iii (above), the IBC Servicing Officer will draft an outcome letter for review, approval, and signature of the IBC Chair. The Servicing Officer will send the outcome letter to the relevant PI (and appropriate project management staff associated with the project). All active projects will be recorded on the IBC database for record-keeping purposes and to allow for subsequent follow-up activities.

In all cases of projects approved by the IBC, approval will be granted for one (1) year with the condition of submission of an annual progress report. Annual reports are discussed [below](#).

In the case of outcome iv (listed above), it is the duty of the relevant FBC to communicate the outcome with the PI and relevant project staff, in line with their internal procedures.

9. Amendments to active applications

Where a research protocol requires changes or amendments post IBC approval, these must be described in an amendment application which must be submitted to the relevant FBC. Amendment applications must contain the following:

- i. PIs are expected to submit a cover letter describing the amendment as well as a completed application form highlighting the proposed changes in the context of the entire project.
- ii. PIs are also expected to submit any additional supporting documentation, where relevant.
- iii. PIs must make applications for amendments to their respective FBC, as outlined in [section 3 above](#).

- iv. Amendments will be reviewed by the IBC using the same process described in [section 7 above](#).
- v. Outcomes of amendment applications will be the same as those described in [section 8 above](#).

10. Reporting

a. Annual progress reports

- An annual progress report (APR) must be submitted for each active, approved IBC research protocol. It is expected that PIs or appropriate project staff make one APR submission per project.
- The deadline for APRs is 30 September every year (or the last working day in September where the 30th falls on a weekend).
- The date will be clearly communicated by the IBC Servicing Officer who will send PIs and project staff a reminder to submit APRs approximately 4 weeks prior to the submission date; follow-up reminders (2 weeks, 1 week, and 1 day) will also be sent closer to the deadline.
- APRs are submitted digitally via an MS Form. The link to the form will be provided in the call for APRs and all subsequent reminders.
- Projects reviewed and approved at an FBC level (*i.e.*, NOT projects escalated to the IBC), will follow the FBC annual reporting requirements.
- During the APR submission, PIs will be asked if they want to renew/extend their IBC approval or close out the study. PIs are asked to make the relevant selection so that the appropriate letters can be issued by the IBC.

APRs will generally be considered during the October monthly meeting of the IBC. If it is not possible to consider the APRs in this meeting, the Chair may call a special meeting or issue a Chair's Circular to manage the review of APRs.

- i. At the meeting, the IBC will consider the APRs in two (2) separate batches.
 - a. The first batch will be projects requesting renewal or continuation of a project.
 - b. The second batch will be projects requesting closure.
- ii. After reviewing the relevant APRs, the IBC may recommend the following outcomes:
 - a. For projects requesting renewal or continuation
 - i. Approve the continuation request and grant approval for an additional year (until 31 December of the following year).
 - ii. Require further information in the case of any biosafety incidents reported. The IBC may delay a decision on the outcome of any such projects until it is satisfied that the biosafety incident was appropriately addressed, and sufficient mitigating measures have been put in place to limit future incidents. The IBC may decide to renew the project approval for an additional year, or may halt the project if the biosafety risk is considered too great.
 - b. For projects requesting closure
 - i. Approval of the closure.
 - ii. Require further information in the case of any biosafety incidents reported. The IBC may delay formally closing such projects until it is satisfied that the biosafety incident was appropriately addressed.
- iii. Once the IBC has made a decision on each of the APRs submitted for active projects, the Servicing Officer will record the decision in the minutes.
- iv. In collaboration with the IBC Chair, the Servicing Officer will prepare the appropriate letters for the APR submissions.
 - a. For projects requesting renewal or continuation
 - i. A continuation letter will be issued granting the study approval until 31 December of the following year; the letter will also outline the requirement to submit an APR in the following year.
 - ii. Any conditions placed on the continuation of the project will be noted in the letter.

- iii. The IBC's database will be updated to reflect the new study approval/expiration date and the subsequent APR date.
- b. For projects requesting closure
 - i. A closure letter will be issued to the study.
 - ii. The study will be closed and removed from the IBC's active protocols database.

b. Research protocol closure reports

Should a PI of an active protocol wish to make a study closure application outside of the annual reporting period, they should contact the IBC Servicing Officer directly (Ms Suraya Azam, suraya.azam@uct.ac.za). PIs will be required to complete a form similar to the APR form (the link will be supplied by the Servicing Officer at the time of the request) and submit a covering letter. The Servicing Officer will place the item on the next available meeting agenda.

11. Monitoring of this SOP

The SOP should be viewed as a living document, which describes active processes and procedures. It will be purposefully reviewed for possible updates every two years, following approval by the IBC.

It may also be the case that processes and procedures change outside of the regular review process; if this is the case, this SOP will be updated as needed.

The IBC Servicing Officer, in collaboration with the IBC Chair and ORI Servicing and Compliance team, is responsible for reviewing and updating this document.

12. Authorship and attribution

This document was originally authored by Mrs Paula Saner (Manager, Office of Research Integrity, Servicing and Compliance team). It was reviewed and edited by the IBC to make it fit-for-purpose and, finally, approved by the IBC.