University of Cape Town
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)
TERMS OF REFERENCE

Status
A Senate-level committee to provide review and oversight of research protocols and related activities conducted at the University of Cape Town involving recombinant or synthetic nucleic acid molecules as well as potentially hazardous biological agents.

Approval date and Implementation date
(a) Date of Approval: Senate, via PC06/2016 dated 29 June 2016; Senate, via PC08/2018 dated 19 September 2018
(b) Approved by: Senate
(c) Date of Implementation: 26 September 2018
(d) Revision date: 19 September 2018

1.

2. Definitions
Biological safety (biosafety) encompasses the safe handling, manipulation, containment and disposal of infectious microorganisms and hazardous biological agents and materials. The guiding principles of biosafety are (i) to ensure appropriate containment, and (ii)to ensure that all potential risks are identified through comprehensive risk assessment processes and appropriately mitigated.

1.1 **Recombinant and synthetic nucleic acids** are defined as:
(i) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids;
(ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids; or
(iii) molecules that result from the replication of those described in (i) or (ii) above.

1.2 **Hazardous biological agent (HBA)** is defined as;
Any microorganism, pathogen, cell culture, nucleic acid or parasite, recombinant and synthetic nucleic acids as defined in 1.1 above, and GMO as defined in 1.3 below, and all biological materials including those that have been genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human, animal or plant health or to the environment.

1.3 **Genetically Modified Organisms (GMOs)** are defined as:
'an organism, the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or *both, and "genetic modification" shall have a corresponding meaning'* (Genetically Modified Organisms Act (15 of 1997).

1.4 **Standard precautions** are:

'a synthesis of the major features of Universal Precautions and Body substance Isolation, and apply to all persons coming into contact with potentially infected persons, animals or animal products, and potentially contaminated blood and other body fluids in health care facilities or elsewhere and (a) apply to: (i) all blood; (ii) all body fluids, secretions and excretions, except sweat, regardless of whether they contain visible blood or not; (iii) non-intact skin; (iv) mucous membranes; (v) tissues; and (b) are designed to reduce the risk of transmission of HBA from both recognised and unrecognised sources of infection in work-places' (Occupational Health and Safety Act (85 of 1993), Regulations for Hazardous Biological Agents (2001))

3. Purpose

3.1. Consistent with its commitment to the responsible conduct of research and teaching, the University of Cape Town (UCT) is committed to safe and ethical science, and this extends to the use of potentially hazardous biological agents (pHBAs), as defined above.

3.2. Activities involving HBAs are subject to the Regulations on Hazardous Biological Agents of the Occupational Health and Safety Act 85 of 1993. Activities involving genetically modified organisms (GMOs) are subject to the Regulations under Section 20 of the GMO Act (Genetically Modified Organisms Act 15 of 1997) and the Genetically Modified Organisms Amendment Act 23 of 2006. Furthermore, UCT's Institutional Biosafety Committee (IBC) aims to comply with, and is not limited to, other relevant national and international acts, guidelines, and protocols such as the National Environment Management Act (Act no.107 of 1998), the Cartegena protocol on biosafety, the SA MRC Guidelines for Ethics in Medical Research: Use of Biohazards and Radiation, and the NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules.

3.3. To ensure safety, ethics, and compliance, the IBC, as a Senate-level committee, will have oversight of Faculty-level Biosafety Committees (FBCs) to which it may delegate reviews of specific projects or project types (non-compliance, study closure reports).

3.4. The IBC will provide protocol-level review and monitoring support to UCT-based activities[1] when necessitated by funding requirements or other imperatives. The university requires that all activities using pHBAs are reviewed to the satisfaction of applicable regulatory and compliance requirements. If a project or protocol involves the use of animals and pHBAs, approval by the appropriate Animal Ethics Committee will also be required. Further approval may be required under Section 20 of the Animal Diseases Act (Act 35 of 1984). Human gene transfer projects will require Faculty Research Ethics Committee (REC) approval, which is contingent on approval by the IBC. The testing of any pHBAs in humans will require faculty REC approval, which is contingent on approval by IBC. Further approval for both human, plant and animal testing may be required under the GMO Act.

4. Terms of Reference

The IBC is constituted to protect the interests of UCT-based activity, as well as the community and the environment, by ensuring that all activity involving pHBAs complies with national legislation and national and international guidelines on biosafety and environmental ethics. To this end, the IBC will:

[1] "UCT-based activities" includes off-site studies, performed by UCT personnel

4.1 Develop and approve policies and define standards for activities performed at UCT involving pHBAs;

4.2 Provide guidance and support to the relevant university Health and Safety (H&S) Committees to ensure broad awareness of biosafety policies and practices within the University, and to assist the relevant H&S Committees to implement these policies;

4.3 Provide protocol level review for all faculties doing work involving pHBAs;
This will include issuing authorisation for specific projects. The initial review will be done by the relevant FBC and then by IBC or by an external biosafety committee with appropriate expertise (approved by the IBC, University of Cape Town) before the research activity may commence. The IBC will define which work on pHBAs is exempt from this process or will be managed by the FBC.

4.4 As a registered Institutional Biosafety Committee (IBC) with the US National Institutes of Health's (NIH) Office of Biotechnology Activities, the UCT IBC will provide review, monitoring and oversight of NIH-funded research in accordance with NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2016) as well as the GMO Act for the review of research involving recombinant or synthetic nucleic acid molecules.

4.5 The IBC will employ an Independent External Biosafety Officer (IBSO) who will conduct regular audits of projects and laboratories utilizing pHBAs. The audits, which will involve on-site inspections and will include the relevant Faculty Health & Safety Committee, will take place at least every two years in order to ensure that there is adequate standardised risk assessment and protocol compliance in place for such research across all relevant University faculties. The IBC will define the scope and focus of these audits and may, as required, develop or identify suitable audit tools or checklists to be used by the IBSO. After each audit, the IBSO will issue a report detailing all findings, including evidence of compliance or non-compliance with IBC accepted standards.

4.6 The Principal Investigator responsible for each approved protocol will submit an annual report to the relevant FBC. The FBC will submit an annual summary report to the IBC listing all protocols that have been approved and any other information that is relevant to the IBC.

4.7 The IBC will make its activities and determinations (approval, approval with modifications required, rejection, suspension, termination, closure, non-compliance, *etc*.) available to Faculty Deans, the URC through the Research Office, and to the Physical Risk Coordinating Committee in order to ensure broad awareness of all work (undertaken and proposed) throughout the University involving pHBAs.

5. Meeting Procedures

5.1 The IBC will meet quarterly and on an *ad hoc* basis for project and protocol review purposes, and to ensure timely continuing review of ongoing projects.

5.2 Members will be requested to sign an attendance register, and make apologies in advance if unable to attend. Apologies should be made to the IBC Servicing Officer based in the Office of Research Integrity (ORI).

5.3 A formal agenda will be distributed electronically to all members, along with copies of all relevant material, two weeks prior to the meeting.

5.4 Minutes documenting main decision points will be recorded.

5.5 A Principal Investigator (PI) who is also a member of the IBC may answer any specific queries that other members wish to address, but must recuse him/herself prior to discussion of and/ or decision-making about a protocol submitted by or involving him/her in his/her capacity as PI.

5.6 Any PI may attend a meeting if requested to do so by the Chair or if s/he requests leave to appeal against a previous application rejection and this request is granted by the Chair. The IBC recognizes that PI participation in any IBC meeting will not only enrich the discussion of the research at hand, but also raise the profile of the IBC within the investigator community. PI attendance might be particularly useful where the project is novel or complex and the IBC would benefit from a full description of the proposed activities and the associated biosafety risks.

5.7 Any conflict of interest with regard to the protocols being reviewed must be declared by the Member concerned before an application is reviewed, and duly noted by the Chairperson and managed according to the severity of the conflict. Decision-making will follow from the deliberations of the committee members. Deliberations can be supported by technologies enabling remote participation in meetings. Decisions about the approvability of a project or protocol shall generally be made by consensus. If consensus is not reached, then the members will vote on an application. Decisions will be taken by a simple majority.

5.8 An application will be given one of the following statuses:

a. *approved as is* – the research may commence;
b. *conditional approval* – changes must be implemented, and the IBC notified prior to study commencing;
c. *major changes required* – a resubmission is required, in line with the concerns raised by the IBC, and research cannot commence;
d. *not approved/rejected* – a new or materially revised submission is required.

5.9 Appropriate to its function, the IBC may make other determinations including but not limited to: suspension, termination, closure, and non-compliance.

5. Composition

At least five (5) members with relevant experience and expertise in the use of potentially hazardous organisms and materials.

The following persons are required:

5.1. The Vice-Chancellor (*ex officio*)

5.2. The Deputy Vice-Chancellors (*ex officio*)

5.3. An expert in plant, plant pathogen or plant pest containment when protocols require approval from the IBC

5.4. A person with expertise in animal containment principles when protocols require approval from the IBC

5.5. A person with expertise to assess research involving human research participants

5.6. A designated institutional official responsible for biosafety if the University conducts pHBAs research at Large scale (>10 L) and/or High containment (Biosafety Level (BSL) BSL3 or BSL4); this individual shall be the Biosafety Officer or the Environmental Risk Officer.

5.7. Any other expert as may be required for the protocol(s) being reviewed and as determined by the chairperson (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or

persons active in medical, occupational health, or environmental concerns in the community).

5.8. At least two members with appropriate expertise who are not affiliated with the institution.

5.9. The Chair of each Faculty Biosafety Committee.

5.10. UCT representative from each faculty conducting work which falls into the scope of the IBC.

5.11.

5.12. Assessor members

5.12.1. Director, Office of Research Integrity

5.12.2. Director, Environmental Sustainability

5.12.3. Faculty Representative from Engineering and the Built Environment.

6. Chair/Deputy Chair:

6.1. Chair: The Vice-Chancellor's nominee

6.2. Deputy Chair: The Committee elects a Deputy Chair from its members

7. Executive Committee (EXCO)

EXCO comprises the Chair, Deputy Chair, Chair of each Faculty Biosafety Committees and the Senior Manager of the Office of Research Integrity to deal with urgent matters that arise between meetings of the IBC. All decisions of the EXCO must be tabled at the following meeting of IBC.

8. Quorum and Attendance Rules

8.1. For meetings of the committee where project applications are to be reviewed, a quorum shall meet the minimum requirements set out by the NIH.

8.2. For meetings of the committee where policies are to be reviewed and discussed, a quorum shall consist of more than 50% of the non-*ex officio* members of the committee.

8.3. Assessor members will count towards a quorum, should they be in attendance.

8.4. Regular attendance of IBC meetings is essential in order to maintain continuity and cohesion in the execution of the committee's responsibilities. Committee members are expected to demonstrate their commitment to the IBC by regularly attending meetings, except when prevented by unforeseeable events or on official leave.

8.5. The Chairs of the respective FBCs are responsible for ensuring that at least one representative from their faculties is present at each IBC meeting.

8.6. Where committee members are prevented from attending any committee meeting they should notify the Chair and Servicing Officer of their expected absence.

8.7. If a committee member is absent for two consecutive meetings without first notifying the chair or servicing officer of their absence, or if a committee member is absent for three consecutive meetings having notified the chair of their absence, that committee member is in breach of their obligations and is liable be removed from the committee, subject to IBC approval and endorsement by the IBC Chair.

9. Terms of Office

Members are appointed for a period of three years, with appointment to consecutive terms (if required).

10. Institutional Biosafety Committee members should

10.1. Have an understanding of the risks to human health, animal health and the environment that may arise from the proposed GMO/HBA activity.

10.2. Seek confidential technical advice from sources outside the committee as needed.

10.3. Check the accuracy of the risk assessment and risk mitigation presented to the committee and that the applicants have an appropriate level of training and competence. This includes assessment of containment levels and the facilities, including relevant procedures.

10.4. Review in detail GMO/HBA risk assessments highlighted by the Faculty Biological Safety Committee as non-compliant and advise accordingly.

10.5. Ensure risk assessments are completed in accordance with the GMO (Contained Use) Regulations and the Occupational Health and Safety Act (85 of 1993), Regulations for Hazardous Biological Agents (2001).

10.6. Keep deliberations of the Committee confidential.

10.7. Declare when they have a conflict of interest in protocol review or committee decisions. This includes financial, personal and professional (e.g. engagement in the protocol) conflicts.

11. Annual Reports from Faculty Biosafety Committees

Each Faculty Biosafety Committee should submit an Annual Report to the IBC for approval. The Annual Report should indicate the number of applications reviewed and approved during the period in question; meetings held; title of projects; PI name; review and approval processes including risk assessment; documentation of facility registrations and/or GMO or BSL3/4 certifications (e.g. certifications issued by the Department of Agriculture, Forestry, and Fisheries) and/or permits (e.g. permits issued under Section 20 of the Animal Diseases Act).

12. Administrative Support/Servicing Officer of the IBC

The IBC Servicing Officer operates within the Office of Research Integrity under the Research Office of the University of Cape Town in Mowbray, Cape Town.