

**RESEARCH ETHICS COMMITTEE: BIOSAFETY AND ENVIRONMENTAL ETHICS
STANDARD OPERATING PROCEDURES**

Purpose	Management of Biosafety and Environmental Ethics in Research at Stellenbosch University
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A. TERMS OF REFERENCE

1. Stellenbosch University (SU) is committed to the highest standards of safe and ethical research and complies with all relevant legislation, guidelines and procedures.
2. The Research Ethics Committee: Biosafety and Environmental Ethics (REC: BEE) has been instituted to protect the interests of researchers, the community and the environment and ensure that all research, teaching and testing involving hazardous organisms and materials complies with accepted international and national guidelines on biosafety and environmental ethics.
3. To prevent and to reduce exposure of laboratory workers, other persons and the environment to potential hazardous agents.
4. The REC: BEE provides review and oversight of research, teaching and testing activities utilizing recombinant DNA, biohazardous materials, genetically modified organisms (GMO's) and nanomaterials or that in any other way has

the potential to negatively impact the physical, biological and spatial environment.

5. The REC: BEE functions in compliance with, but not limited to, the following documents, guidelines and legislation (in all instances the most recent amended version will be applicable):
 - a. Constitution of the Republic of South Africa No. 108 of 1996 (section 24)
 - b. Genetically Modified Organisms Act 1997 (Act No. 15, 1997)
 - c. Genetically Modified Organisms Amendment (Act No. 23 of 2006)
 - d. The National Environmental Management Biodiversity Act (Act no. 10 of 2004; NEMBA)
 - e. National Environmental Management Act (Act no. 107 of 1998)
 - f. The [Cartagena Protocol](#) on Biosafety
 - g. The MRC Guidelines for Ethics on Medical Research: Use of Biohazards and Radiation
 - h. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ([NIH Guidelines](#))
6. The REC: BEE is registered with the United States Office of Biotechnology Activities (OBA) and reports to the Senate Research Ethics Committee (SREC).

B. COMMITTEE COMPOSITION

1. The REC: BEE shall include no fewer than five members who collectively have experience and expertise in the use of potentially hazardous organisms and materials and the capability to assess the safety of proposed research, teaching and or testing activities and to identify any potential risk to public health or the environment.
2. Membership must include, but is not limited to the following areas of expertise:
 - a. A Biosafety Officer when protocols involving BL3, BL4 and Larger Scale Research (defined as greater than 10 litres) are reviewed.
 - b. An expert in plant, plant pathogen, and/or plant pest containment principles when protocols including these organisms are reviewed.
 - c. An expert in animal containment principles when protocols including animals are reviewed.
 - d. An expert in human gene transfer when recombinant DNA protocols involving human subjects are reviewed.

- e. A nanotechnology expert when protocols involving nanomaterials are reviewed.
 - f. An expert in policies, applicable law, standards of professional conduct and practice.
 - g. An expert in research ethics (if available).
 - h. Any other expert as required for the protocol(s) being reviewed and as determined by the chairperson.
 - i. Two members not affiliated with the institution (apart from their membership on the committee) that represents the interests of the surrounding community with respect to health and protection of the environment.
3. The Manager: Research Support shall serve as an alternate member when needed to meet quorum.
 4. A non-voting representative from the Division for Research Development serves as the committee secretary and Biosafety and Environmental Ethics administrator.
 5. Members are recruited by the Senior Director: Research and Innovation with assistance from the REC: BEE chair and relevant deans.
 6. Members are appointed for a period of two years, with appointment to consecutive terms possible.
 7. Membership may be suspended by a majority vote for committee members who attend less than 50% of the scheduled meetings over a one-year period.
 8. The chairperson and Vice-chairperson of the committee will be senior researchers and are elected by the members of the committee after a formal nomination process which shall occur prior to the convened meeting where said election takes place.
 9. No member of the committee shall be held personally liable for any act committed or omitted by the committee, or member of the committee, in good faith in the course of his/her REC duties.
 10. The committee may co-opt additional affiliated or non-affiliated members when necessary.
 11. The committee may consult external experts to assist them with the review of a particular protocol, when and if necessary.
 12. An up-to-date list of committee members identified by name, earned degrees, representative capacity; indication of experience sufficient to describe each

member's chief anticipated contributions to REC: BEE deliberations; and any employment or other relationship between each member and the institution, will be retained at the administrative office and be publicly available. All members must supply the administrative office with a brief updated CV summary every year.

C. MEMBER TRAINING

1. Upon appointment to the REC:BEE, new members are provided with copies of all relevant legislation, guidelines and procedures and are expected to familiarise themselves with it.
2. Members are encouraged to attend any opportunities for ongoing training in both broad and specific fields related to biosafety and environmental ethics.
3. Training will also take place through educational presentations at convened REC: BEE meetings and annual workshops.

D. COMMITTEE RESPONSIBILITIES

1. Establish standardized criteria and review procedures.
2. Perform comprehensive and timely protocols reviews, based on:
 - a. assessment of laboratory design, physical facilities and containment levels (based on risk group)
 - b. assessment of the facility's procedures and practices
 - c. assessment of the training and expertise of the Principal Investigator (PI) and all personnel involved
3. Review relevant institutional procedures and practices, including guidelines regarding the competence and training of all investigators using potentially hazardous organisms and materials and procedures for handling such organisms and materials.
4. Suspend or terminate any study where the **REC: BEE**, or the chairperson on its behalf, considers that any relevant legislation or guidelines are being breached. The chairperson/REC: BEE shall report any suspected or alleged noncompliance to institutional standards to the SU Research Integrity Officer.
5. Report its activities and decisions to the Senate Research Ethics Committee on a regular basis. (i.e. minutes of meetings to be tabled at SREC meetings)
6. Perform such other functions as may be delegated to the REC: BEE.

E. MEETING PROCEDURES

1. The committee shall meet as needed, but normally four times per year.
2. A quorum of 50% plus one must be present for the meeting to proceed.
3. Members will be requested to sign an attendance register and make apologies in advance, if unable to attend.
4. The meeting will proceed according to a formal agenda which will be distributed electronically to all members, along with copies of all relevant material, prior to the meeting.
5. Minutes documenting main decision points, will be recorded.
6. An applicant, who is also a member of the REC: BEE, may answer any specific queries that other members wish to address, but must voluntarily recuse him/herself prior to discussion and decision-making.
7. Any other conflict of interest, with regards to the protocols being reviewed, must be declared by the member concerned before an application is reviewed, duly noted by the committee and managed according to the severity of the conflict.
8. Applicants will not attend the meetings routinely, unless requested to do so by the chairperson or unless they request to appeal against a previous application rejection and this request is granted by the Chairperson.
9. Decision making will generally be by consensus. If consensus is not reached, then the members will vote on an application.
10. Applications are reviewed primarily from an ethics perspective although the scientific and methodological aspects are also taken into consideration.
11. An application will be given one of the following statuses.
 - a. **Approved**- The researcher can start the project.
 - b. **Approval with stipulations**- The researcher can start the project as soon as specified conditions have been reached.
 - c. **Modifications required**- The researcher must make and resubmit certain changes to the protocol. These changes will be reviewed by the primary and secondary reviewers and Chairperson and if accepted, a letter of approval will be issued.
 - d. **Deferred**- The project requires major changes or the committee has major concerns. Changes to the protocol must be reviewed at a convened meeting.
 - e. **Not approved**- The project cannot be resubmitted in its current form.

F. ADMINISTRATIVE SUPPORT STRUCTURE

1. The **REC: BEE** administrative office functions within the Division for Research Development at the Stellenbosch University (SU) main campus. The following staff members are appointed (proportional time commitment) to assist with the efficient running of this committee:
 - a. Administrative Officer, who also acts as Secretary to the REC: BEE.
 - b. Manager: Research Support
2. **Collective responsibilities of the administrative officer**
 - a. Ensure availability of all biosafety and environmental ethics related documents and procedures on the DRD website.
 - b. Answer all queries related to biosafety and environmental ethics at SU.
 - c. Ensure that the application process proceeds efficiently.
 - d. Schedule meetings, prepare agendas, and record minutes during meetings.
 - e. Coordinate with the chair to assign primary and secondary reviewers and facilitate reviews.
 - f. Liaise with applicants in writing with respect to all decisions taken in the meeting.
 - g. Maintain a confidential and secure database of accurate and complete records.
 - h. Facilitate the committee's monitoring role.
 - i. Submit annual reports to the NIH/OBA and NHREC.
 - j. Forward queries or complaints to the chair, when appropriate.
3. **Responsibilities of the Manager: Research Support**
 - a. Assist the chairperson and address queries or complaints.
 - b. Compile and update policy and procedure documents in conjunction with the Chairperson.
 - c. Ensure that the REC: BEE processes comply with national and international guidelines and regulations and stay abreast of changes in regulations and guidelines.
 - d. Determine and facilitate training needs of administrative staff, committee members and potential applicants.

G. APPLICATION PROCEDURES

1. All research, teaching and testing activities at SU involving recombinant DNA, genetically modified organisms, infectious agents, select agents and cultured cell lines that fall into risk group 2-4 and are NOT classified as exempt in section III-F and Appendix C of the NIH Guidelines, or that in any other way can pose a risk to the physical, biological and spatial environment, must be approved by the REC:BEE before protocol initiation.
2. Application guidelines are available on the Division for Research Development website at www.sun.ac.za/research
3. Applications are submitted electronically on the SU Research Information Management Systems (RIMS). A reference number is allocated to all new applications. This number is then recorded on all correspondence and additional attachments/amendments.
4. Applications must be submitted at least 14 days prior to the agenda closing date.
5. Agenda closing dates and dates of meetings are available from the secretary of the REC: BEE and on the DRD website.
6. The application and supporting documentation will be checked for completeness by the administrative team. Incomplete applications will NOT be reviewed.
7. Decisions taken at the REC:BEE meeting with respect to each submission will be communicated in writing to the applicant.
8. It is not unusual for the REC:BEE to request changes to a protocol, or clarification of certain issues. Only once these requirements are fulfilled can a formal letter of approval be issued. It is the responsibility of the investigator to comply with all requests and return the requested documentation to the REC:BEE. All requested alterations/documentation must preferably be returned together.
9. Once approved, Investigators are responsible for conducting the protocol as described in the approved application and for submitting all revisions to the protocol, describing any departures from the original, before revisions are implemented.
10. All protocols are subject to inspection or audit.
11. **The committee has the authority to place restrictions on, suspend, or terminate any study in which the investigator fails to comply with the**

review process, specified conditions OR where such actions are deemed appropriate and justified by a fully convened meeting.

12. Protocols that, for any reason, have been approved by an appropriate research ethics committee of another university or institution, but that will be conducted under the auspices of, or on any campus of SU, must also receive approval by the REC: BEE. This can be done via expedited review and by submission of the application pack as submitted to the other committee and the approval letter and any feedback received from said committee.

H. GUIDELINES FOR ROUTINE CONTINUING REVIEW

1. **NB: All ethics approvals expire after one year, unless renewed.**
2. An application for renewal of approval is made by submitting a progress report to the REC: BEE before the approval expires. It is the responsibility of the investigator to submit this report in good time to ensure that the approval of an active research project or teaching programme does not lapse.
3. Protocols will only be re-approved annually for a further two years after which a new application must be submitted.

I. PROCESS OF APPEAL

The Senate Research Ethics Committee approved a standard process of appeal on 9 February 2011. This process will be followed in all instances and is attached as Annexure A.

J. GUIDELINES FOR REPORTING SERIOUS ADVERSE EVENTS/INCIDENTS.

1. It is the responsibility of the PI to report any serious adverse events or incidents that occur during the course of a protocol, including any occupational health and safety hazard, to the REC: BEE, and, if applicable, to the relevant regulatory authorities.
2. Significant reportable events include:
 - a. Spills or accidents in BL2 laboratories resulting in an exposure to hazardous organisms or materials, e.g. a skin puncture
 - b. Spills in BL3 laboratories resulting in an exposure or potential exposure to hazardous organisms or materials, e.g. outside of a containment device such as a biosafety cabinet or safety centrifuge cup

- c. The escape of a transgenic animal or improper disposition such that it enters the food chain
- d. A release of transgenic pollen, seed, or plants through failure of biological or physical containment
3. An incident report form must be completed and submitted within one week of the incident and will be tabled at the next meeting for discussion.
4. The safety officer of the relevant facility must co-sign the incident report or submit an independent incident report to the REC: BEE.
5. The REC: BEE, or a mandated subcommittee consisting of the chairperson and at least two other scientific members has the authority to take immediate appropriate emergency action e.g. to suspend all further study related activities, if circumstances indicate that such action is warranted.

K. OVERSIGHT AND MONITORING OF RESEARCH FACILITIES BY THE REC: BEE

1. International and national practices and guidelines emphasise the active monitoring role the committee must play in ensuring that all laboratory facilities using potentially hazardous organisms and materials comply with prescribed safety precautions.
2. All such facilities must thus be registered with the committee through a formal application process and the committee will regularly assess these facilities.
3. Inspections may take place unannounced.

L. DEFINITIONS AND ACRONYMS

1. **Biosafety Level (BSL)** is a description of the degree of physical containment being employed to confine parasites, infectious agents or organisms containing recombinant DNA molecules and to reduce the potential for exposure of laboratory workers, persons outside of the laboratory, and the environment. There are four Biosafety Levels which consist of a combination of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the operations performed the documented or suspected routes of transmission of the infectious agents, and the laboratory function or activity.
2. **Environmental ethics** is a sub-discipline of applied ethics. It entails the outcome of a systematic reflection on the norms and values that determine

human responsibility for the sustenance and protection of the environment in which all living beings need to survive. It also develops and critically reflects on morally accountable strategies for ensuring current and future environmental sustainability.

3. The **National Health Research Ethics Council (NHREC)**
4. **The National Institutes of Health (NIH)** is an agency of the United States Department of Health and Human Services and is the primary agency of the United States government responsible for biomedical and health-related research. It is also a major funder of biomedical research at SU.
5. The **NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)** outlines principles for the safe conduct of research employing recombinant DNA technology. The NIH Guidelines detail practices and procedures for the containment of various forms of recombinant DNA research, for the proper conduct of research involving genetically modified plants and animals, and for the safe conduct of human gene transfer research. As a “living” document, it is periodically revised to keep pace with the changing state of science.
6. The **Office of Biotechnology Activities (OBA)** is the NIH office responsible for developing, implementing and monitoring NIH policies and procedures for the safe conduct of recombinant DNA activities, including human gene transfer.
7. **Recombinant and synthetic nucleic acids (rDNA and sNA)** are defined by the NIH as:
 - a. molecules that i) are constructed by joining nucleic acid molecules and ii) that can replicate in a living cell, i.e., recombinant nucleic acids;
 - b. 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
 - c. molecules that result from the replication of those described in (a) or (b) above.
8. **Risk groups (RG)** are a method used to classify human etiological agents based on hazard to both the individual and to the community. There are four risk groups (RG1-RG4). These correlate to but are not equivalent to biosafety levels. Determining the risk group of a biological agent can be part of the

biosafety risk assessment and helps in assigning the correct biosafety level for containment. The *severity* of potential harmful effects to human health or the environment, along with the *likelihood* of those events occurring should be considered.

9. **The Senate Research Ethics Committee (SREC)** reports to the SU Senate and is mandated to provide broad leadership on research ethics policy and to ensure the effective functioning of the SU Research Ethics Committees.

M. RELATED DOCUMENTS

Significant related documents include:

Name	Status	Owner
Policy for Responsible Research Conduct at Stellenbosch University	Approved	Division for Research Development
Policy on Conflict of Interest	Approved	Division for Research Development
SU Policy on Academic Integrity: The Prevention and Handling of Plagiarism	Approved	Division for Research Development
Procedure for the Investigation of Research Misconduct at Stellenbosch University	Approved	Division for Research Development
Health Research Ethics Committees Human Research: Standard Operating Procedures and Guidelines	Approved	Division Research Development and Support, Faculty Medicine and Health Sciences
Research Ethics Committee: Human Research (Humanities) Standard Operating Procedure	Approved	Division for Research Development
Research Ethics Committee: Animal Care and Use Standard Operating Procedures and Guidelines	Approved	Division for Research Development

RESEARCH ETHICS COMMITTEES: APPEALS AND COMPLAINTS

Generic Standard Operating Procedure

Approved by the Senate Research Ethics Committee 9th February 2011

A. DEFINITIONS

Appeals arise because a Research Ethics Committee¹ (REC) rejects a research proposal, adjudges a protocol deviation or violation to be sufficiently serious to merit calling a halt to the research, or requires additional protections or conditions before approving a protocol and the Principal Investigator (PI) objects to the decision of the REC and wishes to appeal.

An appeal **must** be directed to the chairperson of the relevant REC. A researcher may not appeal directly to the Senate Research Ethics Committee (SREC).

Complaints arise because of alleged REC procedural irregularities, breach of researcher confidentiality, unacceptable delays or conflict of interest.

Complaints should be directed, in the first instance, to the chair of the relevant REC. However if the researcher deems the matter extremely serious and urgent, the complaint can be submitted directly, in writing, to the chairperson of the SREC.

B. APPEAL PROCESS

The process described below may be a two stage process involving first the REC against which the appeal has been lodged. If the REC agrees or prefers, the matter can be referred to the Senate Research Ethics Committee to be finalised. However, in order to retain the decisional integrity and independence of a REC within its own institution, PI's may not appeal directly to the SREC. The researcher retains the right to appeal or complain to the National Health Research Ethics Council, if the research falls under the jurisdiction of this council i.e. fulfils the definition of Health Research as defined in the National health Act No.61.2003.

¹ Health Research Ethics Committee (REC) 1 and 2, Non-medical REC; Animal Care and Use REC; Biosafety REC

B1. APPEAL PROCESS (REC LEVEL)

1. Where a PI is dissatisfied with a REC decision, he or she has the right to obtain from the REC written reasons for its decision and should exercise this right before launching an appeal.
2. Each committee is expected to have a mechanism whereby a PI may appeal the REC's decision. The chairperson of the REC must appoint a subcommittee to revisit the substance of the application together with any additional information put forward by the PI. The subcommittee must obtain at least one independent, external, expert review of the research project and the substance of the appeal. Additional reviews should be obtained if deemed appropriate. The subcommittee may have the same powers as the REC, if so constituted by the REC concerned.
3. The appeal is usually considered on the grounds of written submission only. However the chairperson of the appeal subcommittee may invite the PI to provide an additional oral submission to the subcommittee and answer questions.
4. After deliberation of all the information placed before it, the subcommittee must either
 - a. Uphold the appeal
 - b. Reject the appeal
 - c. Refer the matter to the Senate REC.
5. In the event of an (a) or (b) outcome, the decision of the REC (or REC-subcommittee) is final.
6. If the REC or REC-subcommittee refers the matter to the Senate Research Ethics Committee (SREC) it undertakes to adhere to any decision taken by the SREC, regarding the matter.

7. Researchers conducting 'health research' retain the right to complain or appeal to the National Health Research Ethics Council in the event that they remain dissatisfied with the outcome of the appeal².

B2. APPEAL PROCESS (SENATE RESEARCH ETHICS COMMITTEE LEVEL)

1. Notice in writing of the intention to refer the matter must be given by the chair of the research ethics committee (REC) to the chair of the Senate Research Ethics Committee. The PI must also be notified of this decision. The chair of the SREC must notify the Vice-Rector Research of the receipt of the appeal.
2. The basis of the appeal and all the relevant documentation must be submitted in writing to the chair of the Senate REC within seven (7) days of the notice in 1) above.
3. The matter is usually heard on the basis of written submissions only, that is, no oral evidence is led. It is therefore important that the chair of the REC ensure that all the information that is relevant is before the Appeal Panel of the Senate REC. The PI, the REC and other interested parties may make submissions to augment the existing record, in accordance with the time lines set out by the chair of Senate REC (see below under Appointment of Appeal Panel).

B2.1 Composition of Appeal Panel

The appeal will be heard by an independent panel made up of 3 – 5 members, who will ordinarily be members of the Senate REC, but may be other persons if deemed necessary by the chair of the Senate REC.

The members of the panel must include one member from the Faculty concerned. The members of the panel must not be members of the REC.

In the case where special expertise might be needed to deal with technical aspects of the substance of the appeal, then such expertise should be sought without compromising the independence of the panel.

² The National Health Research Ethics Council has been given the mandate by the National Health Act No.61. 1983 (NHA) to investigate and manage complaints related to the review and approval of 'health research' as defined in the NHA, by research ethics committees.

B2.2 Appointment of Appeal Panel

The panel must be appointed by the chair of the Senate REC who must draw up timelines for the submission of documentation, for the hearing of the appeal and for delivery of the panel's decision.

B2.3 Powers of Appeal Panel

The appeal panel is empowered

- to request further information if needed;
- to interview the parties; but if it does so, it must be in the presence of both parties, failing which, it must report to the other party the substance of the submissions or answers given and allow an opportunity to rebut;
- to require the parties to seek to resolve the matter through mediation or seek some other route as to a possible resolution of the dispute; and
- to recommend to the REC that the appeal be upheld; or
- to recommend to the REC that the appeal be dismissed.

As previously stated, researchers conducting 'health research' as defined by the SA National Health Act No.61.2003, retain the right to submit an appeal or complaint to the National Health Research Ethics Council if unsatisfied with the outcome of the process

C. COMPLAINTS PROCESS

1. All complaints against an REC, for matters as described above, should be submitted directly to the REC chairperson, who should make every effort to investigate the complaint thoroughly, resolve the issue and communicate the outcome of the investigation to the complainant.
2. Only complaints that cannot be resolved effectively by the REC chair, or that are deemed to be irresolvable by either the researcher or REC chair, should be submitted to the SREC.
3. The chair of the SREC shall notify the chair of the REC that a complaint has been made against the REC, inform him/her of the nature and substance of the complaint and request that he/she responds in writing to the complaint, providing sufficient detail.

4. The chairperson of the SREC shall appoint an ad-hoc committee to investigate the complaint and report back to the full SREC at a forthcoming meeting. Where necessary the subcommittee may need to interview the complainant, the chair and/or other persons.
5. The SREC shall compile a report of its findings and recommended action. The report shall be submitted to the Vice Rector: Research, the chair of the REC and other parties if deemed necessary by the SREC.
6. The PI shall be notified of the outcome of the SREC investigation.

Research Ethics Committee: Biosafety & Environmental Ethics Application Process:

