TERMS OF REFERENCE FOR THE
TURFLOOP RESEARCH ETHICS COMMITTEE (TREC)

Declaration of Independence

Declaration by representatives of research ethics committees in South Africa:

In the interests of protecting human research participants, we, as representatives of the Turfloop Research Ethics Committee declare that the committee should be:-

1) autonomous and free of any conflict of interest that impact on our ethical decision making processes based on the Department of Health guidelines “Ethics in Research: Principles, Structures and Processes”, other relevant guidelines, and the Constitution of South Africa; and

2) adequately supported by the University of Limpopo in order to ensure optimal human research participants protections.

1. Composition

The key of the compositions is: “The research ethics committee should consist of members who, collectively, have the qualifications and experience to review and evaluate the science, health aspects and ethics of the proposed research. Research ethics committees should be independent, multi-disciplinary, multi-sectoral and pluralistic.” The composition of the Turfloop Research Ethics Committee (TREC), which shall not be more than 70% of either male or female, would thus be as follows:

<table>
<thead>
<tr>
<th>Composition of the Turfloop Research Ethics Committee</th>
<th>Name</th>
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<tbody>
<tr>
<td>1 DVC: Academic and Research (ex officio)</td>
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<tr>
<td>2 Registrar (ex officio)</td>
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<td>3 Layperson 1 – Community Representative</td>
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<td>4 Layperson 2 – Community Representative</td>
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<td>5 Psychologist</td>
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<td>6 Social Worker</td>
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<td>7 Nurse</td>
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<td>8 Medical Doctor</td>
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<td>9 Research Methodologies (quantitative &amp; qualitative)</td>
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<td>10 Person with legal training</td>
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<td>11 Ethicist</td>
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<td>12 Director Research (Turfloop Campus)</td>
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<td>13 Hospital Representative</td>
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<td>14 Director, School of Health Sciences</td>
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<td>15 Polokwane-Mankweng Complex Representative</td>
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<td>16 Secretary</td>
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<td>17 Dean of the Faculty of Health Sciences</td>
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<td>18 Dean of the Faculty of Humanities</td>
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<td>19 Dean of the Faculty of Management and Law</td>
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<td>20 Dean of the Faculty of Science and Agriculture</td>
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Persons 3-12 are requirements according to the Guidelines.
Layperson means a representative of the community.

Shaded rows refer to core committee members. **A quorum is determined by the core committee members.**

1.1. A Chairperson and Deputy-Chairperson should be elected from the members.
1.2. The Committee is a Research Ethics Committee for the Turfloop Campus of the University of Limpopo.
1.3. TREC functions through School Research Committees, which should screen the scientific merit of the research to be carried out.
1.4. TREC should in addition to evaluating the ethical implications also evaluate the scientific merit of the research to be carried out.
1.5. Core committee members will perform the functions of TREC on a continuous basis.
1.6. Non-core members will attend meetings when research protocols submitted from the relevant Faculty(ies) are to be evaluated.

2. **Responsibilities**

The Turfloop Research Ethics Committee should:

2.1. Safeguard the dignity, rights, safety and well-being of all subjects involved in research projects considered by this committee.

2.1.1. Special attention should be paid to projects **which** may include vulnerable participants.

2.2. Ensure that the research ethics needs of the Turfloop Campus are met.

2.3. Collaborate with the National Health Research Ethics Council for South Africa and other applicable Research Ethics Committees, nationally and provincially.

2.4. Ensure that there is proper liaison with the Medunsa Campus’ Research Ethics Committee (MREC) and the Provinces.

2.5. Ensure that there is proper liaison with the Senate Research Ethics Committee (SREC).

2.6. Obtain national accreditation.

2.7. Ensure continual international registration as an IRB.

2.8. Formulate and recommend to SREC policy in respect of research ethics.

2.8.1. This should be done in liaison with the MREC.

2.9. TREC should periodically familiarize itself with possible changes in legislation pertaining to research ethics.

2.10. Draw up, in collaboration with MREC and SREC standardized guidelines.

2.10.1. When the need may arise, inform SREC about changes in legislation pertaining to research ethics.

2.10.2. Regularly inform academics about ethical requirements regarding research and make guidelines regarding research ethics readily available.

2.11. Report to SREC on its activities.

2.12. Ensure financial and administrative independence, so as to enable it to adequately fulfil its duties.

2.13. Ensure that members of TREC undergo orientation and training in research ethics.
2.14. Protocols approved by MREC involving clinical trials to be undertaken by researchers at the Polokwane Campus, should be copied to TREC for notification, with similar notification by TREC to the Polokwane Campus of clinical trials to be conducted by staff members of the Turfloop Campus.

2.15. The Terms of Reference and composition of the TREC might change as circumstances dictate.

3. Functions

3.1. The TREC should obtain the following documents with ethical implications:

3.1.1. All contract research protocols.

3.1.2. Research protocols involving Donor Agencies.

3.1.3. Research collaboration protocols involving other institutions, national and / or international.

3.1.4. Research protocols where drugs are used which have not yet received Medicines Control Council approval (where at least one of the researchers / supervisors is a staff member of the Turfloop Campus).

3.1.4.1. Such protocols will be forwarded to MREC for reviewing.

3.1.5. Research protocols(s) / amendments forming part of self-initiated research or under – and postgraduate studies.

3.1.5.1. Research protocols involving clinical trials will be forwarded to MREC for reviewing.

3.1.5.2. Experiments involving animals will be forwarded to the Animal Ethics Committee, Medunsa Campus for reviewing.

3.1.6. Written consent form(s) and consent form updates of the researcher / supervisor proposes for use in the projects.

3.1.6.1. Where the protocol indicates prior consent of the project subject or the subject’s legally acceptable representative is not possible, the TREC should determine that the proposed protocol and / or other document(s) adequately addresses relevant ethical concerns and meets regulatory requirements of such projects.

3.1.7. Subject recruitment procedures (e.g. advertisements).

3.1.8. Written information provided to participants.


3.1.10. Information about payments and compensation available to participants.

3.1.10.1. The TREC should review both the amount and method of payment to participants.

3.1.10.2. Payments to a subject should be prorated and not wholly contingent on completion of the project by the subject.

3.1.10.2.1. The way payment will be prorated should be specified.
3.1.10.3. The TREC should ensure that information regarding payment to participants, including the methods, and schedule of project participants, is set forth in the written informed consent form and any other written information to be provided to participants.

3.1.11. Questionnaires to be used during the research.

3.1.12. A synoptic, current curriculum vitae of the researchers / supervisor and / or other documentation evidencing qualifications.

3.1.12.1. The TREC should consider the qualifications of the researchers / supervisor for the proposed research project, based on information required in clause 3.1.12, or any other relevant documentation the Committee may request.

3.1.13. Any other documents the ethics committee may need to fulfill its responsibilities.

3.2. The TREC should notify / remind researchers / supervisors that no study subject must be admitted to a project before the TREC issues its written approval (clearance certificate) of the project.

3.3. The TREC should review a proposal within a reasonable time and document its views in writing, clearly identifying the proposal, the documents reviewed and dates for:

3.3.1. Approval,

3.3.2. Modifications required prior to its approval,

3.3.3. Disapproval, and

3.3.4. Termination / suspension of any prior approval.

3.4. Together with every approval, the TREC should bring to the attention of the researcher / supervisor:

3.4.1. That no deviations from, or changes of the protocol should be initiated without prior written TREC approval of an amendment, except when necessary to eliminate immediate hazards to the participants or when the change(s) involves only logistical or administrative aspects of the research project.

3.4.2. The researchers / supervisor should promptly report to the TREC:

3.4.2.1. Deviations from, or changes of, the protocol to eliminate immediate hazards to the participants.

3.4.2.2. Changes increasing the risk to participants and / or affecting significantly the conduct of the research.

3.4.2.3. All adverse drug reactions (ADRs), physical or emotional, that are both serious and unexpected.

3.4.2.3.1. This should also be reported to the regulatory authority.

3.4.2.4. New information that may adversely affect the safety of the participants or community, or the conduct of the project.

3.4.2.5. New information that may adversely affect the reputation, or lead to stigmatization of a community.
3.5. The TREC should conduct continuing reviews of each ongoing project at intervals appropriate to the degree of risk to subjects or the biotic / abiotic environment, but at least once per year.

3.5.1. The TREC should provide opportunities, according to the applicable regulatory requirements, for the review and approval of minor change(s) to ongoing research projects that have been approved by the TREC.

3.6. The TREC has the authority to suspend and terminate research when there may be indication that the research participants, volunteers, animals or biotic / abiotic environment are at risk of harm.

4. Procedural Matters

4.1. Meeting of TREC will be held on a bimonthly basis.

4.2. The TREC should:

4.2.1. Perform its functions according to written operating procedures.

4.2.2. Maintain written records of its activities and minutes of its meetings.

4.2.3. Comply with the applicable regulatory requirement(s).

4.3. The committee should make its decisions at announced meetings during which a quorum of half of the members plus one is present.

4.3.1. However, adequate representation of professional requirements and a member representing the community must be ensured.

4.3.2. No quorum will consist entirely of members of one profession or one gender.

4.4. The Committee can co-opt members from Schools or Faculties to meet research ethics requirements.

4.5. All members have full voting powers, excluding co-opted members, and the Secretary.

4.6. Decisions at the TREC meeting will be taken by consensus after discussions, and whenever needed voting will be done.

4.7. An invited researchers / supervisors may provide information on any aspect of the protocol, but should not participate in the deliberations of the committee or in the vote / opinion of the committee.

4.8. The agenda and minutes are to be compiled by the Secretariat in consultation with the Chairperson.

4.9. TREC records should be retained as follows:

4.9.1. The committee should retain all relevant records (e.g.) written procedures, membership list, lists of occupations / affiliations of members, submitted documents, minutes of meetings and correspondence) for a period of at least five years after completion of the project.

4.9.2. Such documentation should be made available upon request from the regulatory authority(ies).

4.9.2.1. TREC may be asked by investigators, sponsors or regulatory authorities to provide its written procedures and membership lists.
5. Disclosure of potential conflict of interest

5.1. Researchers / supervisors / members of TREC must ensure disclosure of affiliation with, or financial involvement in any organization or entity with a direct interest in the subject matter of materials of the project.

5.1.1. These procedures must cover the full range of potential interests;

5.1.1.1. including the direct benefits such as the provision of materials or facilities,

5.1.1.2. or the support of individuals such as provision of travel or accommodation expenses to attend conferences.

5.1.2. Such disclosure should cover any situation in which the conflict of interest may, or may be perceived to, affect decisions regarding other people.

5.2. Researchers / supervisors have an obligation, at the time of reporting, proposing research, or seeking approval from TREC or other regulatory authorities to declare any conflict or interest which has a potential to influence the project and its conduct.

5.3. Members of TREC must withdraw from the committee when discussion of projects in which they are personally involved takes place, and must not use their membership to gain a favourable advantage.

6. Charging of fees

6.1. TREC is entitled to charge a service fee to review research proposals on behalf of other institutions, externally funded and contract research.
1. Appointment of members of TREC
   - Nominations for members of TREC are called for through a memorandum, initially from the Deputy Vice Chancellor’s office and nominations for specific member(s) and the Senate carries out elections.
   - Members will be appointed by the Deputy Vice Chancellor and approved by Senate and then the University Council.
   - Members will receive a formal notice of appointment and assurance that the University will provide legal protection in respect of liabilities that may arise in the course of bona fide conduct of their duties as committee members.

2. Roles and functions

TREC reports to the Senate Research Ethics Committee (SREC).

2.1. Deputy Vice-Chancellor
   - Facilitates the process of nomination and election of the chairperson and members, where appropriate, with the help of the outgoing chair and the TREC secretariat.
   - Ensures adequate resources for the proper functioning of the TREC.
   - Support and supervise the secretariat, but the secretariat take directions from the chairperson, TREC.

2.2. Chairperson
   - Reviews the agenda and minutes of the meeting with the secretariat.
   - Signs the minutes.
   - Signs the Research Approval Certificates.
   - Chairs the TREC meetings, and facilitate discussions.
   - Facilitate decision making of the committee.
   - Reports to the Deputy Vice-Chancellor.
   - Serves as the link between the TREC and other stakeholders.

2.3. Roles of TREC members
   - Review protocols in their area of expertise, to ensure scientific and ethical basis, with the main aim of protecting the research participants.
   - Serves as a general reviewer on all research by actively participating in the discussion of all other protocols.
   - May be delegated to review protocols that should be expedited.
   - Attend meetings regularly.
   - The chairperson can delegate members to take some of his responsibilities, if unavailable.

2.4. Co-opted / alternate members
   - The TREC or chairperson may co-opt or appoint alternative members to replace on a regular basis, needed expertise or a member who is on occasion unable to attend convened meeting.
   - Names of these members will be listed on the official committee member’s list.
2.5. Secretariat

- Communicates with the researchers / supervisors concerning review processes.
- Receives documents and acknowledges receipt of protocols and other documents from the researchers / supervisors.
- Draws up the agenda and takes / writes the minutes for the TREC meeting.
- Distributes agenda to members of TREC
- Organizes the meeting – venues.
- Word processing of all the correspondence between the TREC and researchers / supervisors, TREC members, including minutes and the agenda.
- Makes copies of all the documents.
- Keeps records of the committee, including those specified in the “Ethics in Health Research: Principles, Structures and Process”.
- Hardcopy records shall be filed systematically and stored in a locked cabinet in the Secretary’s Office.
- Electronic copies will be systematically filed on the secretary’s computer and backed-up weekly on a dedicated server of the Division for Research Development and Administration.
- Archived records will be kept for a maximum period of five years, after completion of research, after which records will be disposed off.
- The secretariat may utilize other assistance, depending on requirements and availability.

3. Conditions of office

3.1. Duration

- The duration of membership is three (3) years, and at the end of a members’ term, a nomination, election and cooption processes will be put in place, following defined procedures.
- To ensure the blending of the advantages of experience with those of new perspective, members of the TREC may be re-elected or re-appointed for two or more terms of office.
- A member can be replaced in the event of resignation or death of long-term unavailability or any other action not commensurate with the responsibilities laid down in the TREC guidelines.
- A member can tender his / her resignation from the committee with adequate reasons to do so.

3.2. Confidentiality

- All members should maintain absolute confidentiality of all discussion during the meetings and on being appointed to the TREC sign a confidentiality form declaring the fact that they will maintain absolute confidentiality.

3.3. Conflict of interest

- TREC member should declare conflict of interest, whenever applicable.
- No TREC member may participate in the review of any protocol in which a member has a conflict of interest, except to provide information that may be requested by the TREC.
- Members, or even chairperson, who have conflicting interests are required to disclose such interest and absent themselves from deliberations of the relevant protocol.

3.4. Compensation of members

- The University of Limpopo shall not remunerate members who serve on the TREC.
- However, it is acknowledged that service on the TREC requires a significant investment of time.
• The TREC chairperson shall, on an annual basis provide members with a formal letter to be included in the individual staff member’s file, describing the critical importance and extremely time-consuming nature of the TREC service.

4. **Administrative support**

• The University shall, through the Deputy Vice Chancellor’s office, allocate on an annual basis, sufficient resources to support the TREC review and record keeping responsibilities.

• Directors of Schools shall assign, on an annual basis, research ethics administrative duties to one of the School’s administrative staff members.

• Such and Administrator should:
  - Receive, document and acknowledge receipt of protocols and other documents from the researchers / supervisors.
  - Forward such documents to the Chairperson of the School’s Research Committee for review.
  - Forward approved protocols and other documents from the aforementioned committee to the secretariat of TREC for inclusion of the agenda.
  - Communicate with researchers / supervisors concerning TREC’s review process.
  - Receive, document and acknowledge receipt of reviewed protocols and other documents from the TREC Secretariat and communicate with researchers / supervisors on the outcome of the review.
  - The Administrator shall ensure accurate records are maintained of all the correspondence to and from the School’s Research Committee and the TREC.
  - The Administrator shall annually put out a call for progress reports regarding the research, which shall be forwarded to the TREC (via the Secretariat) for review by the committee.
  - The Administrator shall create a file for each protocol and its application documents submitted for review.
  - Subsequently, all correspondence related to the protocol will be filed in the respective file.
  - These would, in addition to the complete protocol include documents such as, recruiting material, all versions of the informed consent forms, protocol amendments, progress reports, serious adverse event reports and any other documentation.
  - The School should retain all relevant records for a period of at least five years after completion of the project.
  - Researchers should also retain all relevant records for a period of at least five years after completion of the project.

5. **Induction, orientation and training of members**

• At the start of a new member’s term, before a member participates in TREC activities, the following induction and orientation will be provided:
  - The ethicist will present a brief overview of the principles of ethics and morels.
  - The secretary will make available the TOR and SOP, legislation and guidelines documents and explain the administrative procedures which a member must be familiar with.
  - The chairperson will introduce the member to the responsibilities, functions, procedural matters and operations of TREC and what is expected of TREC members.

• All members will be required to attend at least one ethics training workshop paid for by the University.
• TREC will endeavour to keep members up to date on any new developments on a regular basis by regularly making available any new information, inviting experts to address TREC, or paying for members to attend seminars or workshops on recent ethics developments.
• TREC will endeavour to develop and update a dedicated website containing all relevant ethics documents and information.

6. Ethical guidelines
• The TREC follows the Helsinki Declaration, the Department of Health, South Africa Clinical Trials Guidelines 2000 (Good Clinical Practice), Ethics in Health Research: Principles, Structures and Processes, Guidelines from the MRC and the new rules and regulations that follow the New Health Act (Act 61 of 2003).

7. Protocols for review

7.1. Types of protocols
All research that includes human participants, animals or genetic modification of organisms must be submitted for review, prior to initiation of such research.

7.2. The research protocol and supporting documents
The research protocol should:
• Follow an acceptable standardised format.
• Clearly identify the title, properly dated together with supporting documents and annexes, where applicable, such as:
  ▪ Questionnaires, or data collection sheets
  ▪ General Informed consent
  ▪ Informed consent for case reports
  ▪ Informed consent genetics studies
  ▪ Consent to participate in the Research
  ▪ Minors (under 18) including other vulnerable groups informed consent from parent/legal guardians
  ▪ Informed Assent for children
  ▪ Completed Reg 4 and Reg 5 forms
  ▪ written approvals (from the chairperson of SRC, the director of the school and the Dean)
  ▪ Completed Application for Human Experimentation Part 1
  ▪ Completed Application for Human Experimentation Part 2
  ▪ Request Letter (or granted permission) to access premises where research will be conducted
  ▪ Request Letter (or granted permission) to conduct research from an institution / authority
  ▪ Request Letter (or granted permission) to assess records from an institution / authority
  ▪ Request Letter (or granted permission) to relevant authority
  ▪ Synoptic current CV of supervisor (internal student projects) or researcher(s) (for external projects) evidencing that the person(s) is qualified in the area in which the research will be conducted (supervisor(s) for student research)
  ▪ Written consent and synoptic current CV of all researchers who will be involved in the research. Specify which specific research area(s) in the project they will be responsible for.
If a new drug (as yet unregistered), compound or medical device is researched, approval of the protocol is subject to approval from the MRC.

- Investigator Declaration
- Supervisor Declaration
- Conflict of interest statement
- Information about the payments and compensation available to participants
- Any other written document, leaflet which will be provided to the participants
- Available safety information for participants, where applicable
- Document regarding funding, sponsors and payments for the project.
- Advertisement for recruitment of participants

### Additional documents required for clinical trials:
- Cover Letter
- Insurance
- Financial Agreement
- MCC approval (if available, otherwise proof of application to MCC)
- Letter of Indemnity
- Proof of GCP training
- Investigator Brochure

- The researcher / supervisor is responsible for submission of all documents via the structures expanded under section 9.

#### 7.3. Forms and other standardised declaration documents
- The required forms are available electronically from the Secretariat’s e-mail or can be accessed from the intranet.

#### 7.4. Completion of forms
- Forms must be duly completed and signed, where indicated.
- Omission of signatures and / or incomplete applications delay(s) the review process.

#### 8. Exempt research
- “Even if the research is suspected to be exempt, if the project meets the definition of research and if human participants, animals or genetic modification of organisms are involved, the research protocol must be submitted to the TREC”
- Some research that involves human participants may be exempted from TREC review. Examples include:
  - Literature review and theoretical analysis.
  - Evaluation studies of intervention programmes.
  - Research using existing data, documents and other specimens where no identifying information will be recorded that can link participants to the data.

#### 9. Procedures of submission
- All applications, except those from external agency applying independently to TREC, must serve at the School Research Committee.
- Once approved, a letter of approval from SRC chairperson accompanying the application is sent to the director of the school and the Dean of the faculty, respectively, to sign off the application.
• After approval by the School Research Committee one copy of the research protocol with all applicable documents should be submitted to the TREC’s Secretariat.
• The deadline for submission is four weeks prior to the next meeting of the TREC. Dates are published in the University’s Important Dates Annual Schedule.

10. Review procedures

• The TREC’s task is to review research protocols and their supporting documents, in order to make recommendations regarding the issuing of a clearance certificate allowing the research to proceed.
• The review process should not be obstructive, and clearance certificates should not be withheld for minor issues.

The type of review depends upon the protocol.

10.1. Full committee review

• All research involving human participants, animals or genetic modification of organisms requires full review by the TREC, at meeting where TREC members constitute a quorum.

10.2. Expedited review

• Some types of research protocols or responses may require expedited review procedures.
• The total process from submission to approval should take approximately 2-3 weeks.
• The types of research which may be expedited include:
  ▪ researching sudden epidemic conditions or prospective collection of biological specimens for research purposes by non-invasive means e.g. hair and nail clippings.
  ▪ Undergraduate, and course work with mini-dissertation master’s studies with minimal risk.

10.3. Review process

10.3.1. Pre-review and processing of applications

• Once the TREC is in possession of all the necessary documentation, these are pre-reviewed at the secretariat level.
• The secretariat uses a standardised checklist to ensure that the application form is fully completed and accompanied by all relevant documents. This checking should be done immediately upon receiving an application.
• In the event that documents are missing, forms not full completed, etc., the secretary will communicate telephonically and in writing with the researcher to rectify the problem as soon as possible.
• Only applications which have successfully passed the pre-review will be further processed.
• The Chairperson selects primary reviewers among its members for reviews requiring full committee review based on members’ knowledge, experience or expertise. If a Committee member believes that he or she cannot be a reviewer for any reason, including lack of expertise or a conflict of interest, the administrative staff should be notified immediately.
• If no Committee members have the required expertise, a consultant will be invited to perform the review.
• The Chair or designee serves as primary reviewer for research meeting the criteria for expedited review.
• The Secretariat presents the primary reviewer or consultant with the completed checklist, the standardized criteria used for review, the application and all documents within two to three days after having received the application.
• The primary reviewer is requested to review the application and present a one to two page review report to the Secretariat within 10 (ten) days.
• The Secretariat ensures placement of the primary reviewer’s report, the checklist, the research protocol and all accompanying documents in the agenda of TREC for distribution to the committee members one week prior to the next meeting.

10.3.2. Responsibilities of the Primary Reviewers

Primary reviewers must:

• Conduct an in-depth review of the protocol and accompanying documents using the standardised review criteria.
• At reviewers’ discretion, contact investigators directly or via the Secretariat to clarify issues identified during the review.
• At reviewers’ discretion, make ‘editing’ recommendations directly onto documents in legible handwriting. Documents with suggested changes can be returned to investigators.
• Submit a written report for inclusion in the agenda. The report must conclude with a recommendation (Approved, Approved with stipulations, Conditional approval – minor changes, deferred – major modifications required (resubmission), rejected) supported by sound reasons.
• Make a decision for expedited reviews (approve, require revisions, send for full committee review).
• Lead the discussion on the initial or ongoing reviews at full committee meetings.

10.3.3. Reviews at a full committee meeting

• The primary reviewer leads the discussions based on the submitted report.
• Researchers / supervisors will be invited to offer clarifications on specific matters regarding their proposals, if need be asked to attend the TREC meeting.
• After offering clarifications the researcher / supervisor leaves the meeting and discussions with the aim of reaching a decision continue.
• Committee members should pay particular attention to study design and ethical issues, as these two elements decide whether a protocol is approved, or not.
• Decisions at the TREC meeting will be taken by consensus after discussions, and whenever needed voting by a show of hands will be done.
• If the requested modification of the protocol is minor, the meeting will indicate that should the researcher / supervisor respond quickly, the modification may be reviewed by an expedited review through identified reviewer(s), signed off by the Chairperson and a clearance certificate issued. The decision of the expedited review serves at the next TREC meeting for ratification.
10.3.4. Recording and communication of decision

- Decisions, which may be approval, revision of the protocol or rejection, will be recorded in the minutes. Specific suggestions for modifications and reasons for rejection should be given.
- The outcome of the review shall be communicated to the investigators by the Secretariat within two weeks after the TREC meeting:
  - The minutes of the meeting is checked by the Chairperson.
  - The decision, with reasons in case of revision of the protocol or rejection is recorded using the standardised template letters of TREC.
  - In the case of approved protocols the letter is deemed a clearance certificate.
  - The letter will, among others, state the conditions for approval (section 11).
  - The letter is sent to the researcher / supervisor and copied to the HoD, the Director of the School, and the Dean.
- In cases where amendments should be affected or additional information required, amended documents should be directed to the School’s Administrator for forwarding to the TREC Secretariat, four weeks before the next TREC meeting.
- Steps under sections 10.3.1 and 10.3.3 are followed in placing the amended submission on the new agenda.
- The Secretariat shall maintain in a systematic manner, all correspondence w.r.t a submission and decisions, including:
  - Project identification number;
  - Details of the principal investigators;
  - Title of the project;
  - Date of ethical approval or non-approval;
  - Approval or non-approval of changes to the protocol;
  - Approval or non-approval of changes to the information sheets and informed consent forms;
  - Approval or non-approval of changes to advertising materials, letters and notices;
  - Complaints and Appeals from researchers;
  - Terms and conditions of the approval of any protocol;
  - Whether approval was by expedited review;
  - Whether the ethics committee used a consultant for a particular review;
  - Action taken by the ethics committee to monitor the conduct.
  - Details regarding approval for multi-centred research.

11. Conditions for approval

- In the case of postgraduate research approval is given for the minimum duration of the qualification, if an extension is necessary this must be requested in writing.
- In case of research for non-qualification purposes, approval is given for a year or less in accordance with Ethics in Health Research: Principles, Structures and Processes (2004, Department of Health).
- Approval of any material changes must be sought prior to their implementation.
- Notify the TREC within seven days of any adverse events which may occur in conducting the study.
- TREC has the right to suspend or terminate a study, see section on suspension and termination.
• Annual and final reports must be lodged with the TREC.
• A period of three (3) months is allowed for researchers / supervisors to respond to inquiries from TREC.
  o If no response is received, the protocol must be resubmitted and is deemed a new one.

12. Monitoring of approved protocols and reporting of adverse effects
• According to legislation ethics committees must monitor adherence to approved protocols to minimise risks and protect participants. The frequency and type of monitoring must be in accordance with the degree of anticipated risk to participants.
• Each protocol must be reviewed at least annually until the research is closed. The principal investigator / supervisor must submit an annual report to TREC on matters including:
  ▪ Progress to date, or outcomes in the case of completed research;
  ▪ Information concerning maintenance and security of records;
  ▪ Evidence of compliance with the approved protocol;
  ▪ Evidence of compliance with any conditions of approval.
• The process underlined under section 10 will be followed to assess the report.
• TREC may adopt, depending on capacity and degree potential risks of a project to conduct random inspection of the research sites, data and signed consents forms, and records of interviews, with the prior consent of research participants.
• The consent form and information given to the participants must clearly provide the full contact details of the Secretary of TREC who they contact in the event of a problem or compliant.
• Under the terms and conditions in the approval letter, it shall be stated that a researcher immediately (not later than three (3) days) report anything that might warrant review of ethical approval of the protocol, including:
  ▪ Serious or unexpected adverse effects;
  ▪ Propose changes in the protocol;
  ▪ Unforeseen events that might affect continued ethical acceptability of the project.
• Researchers must provide a report to TREC with seven (7) days giving reasons why a project was discontinued before the expected date of completion.
• If the research project takes longer than the specified period to complete, a request for extension of the ethics clearance should be sought.

13. Suspension and termination of projects
• TREC if satisfied that there are sound reasons, including the following, may suspend or terminate a project:
  ▪ Research is not being conducted in accordance with the approved protocol, as a result the welfare and rights of the participants are not or will not be protected. Approval is withdrawn.
  ▪ Evidence of serious or unexpected adverse effects. Immediate suspension of any further research and full investigation to determine if the research should be terminated or not. A sub-committee may be appointed to investigate problems and file a report with TREC.
  ▪ Evidence events (unforeseen at the stage of proposal approval) that might affect continued ethical acceptability of the project. Immediate suspension of any further research and full investigation to determine if the research should be terminated or not. A sub-committee may be appointed to investigate problems and file a report with TREC.
Immediately upon being aware of any violation or problem and having studied the evidence TREC will write to the researcher instructing him or her of suspending or terminating the project and providing the reasons for its decision. The letter will be copied to the HoD, the director of the school and the Dean and Senate Research Ethics Committee (SREC).

- The Researcher must suspend or terminate the project immediately on instruction from TREC should such a need occur.
- Proper care of human participants or animals must be ensured following such an event.

14. Complaints and appeals procedures

- In cases where the researcher / supervisor disagrees with the suggestions, recommendations or decision of the TREC, a written appeal (at least two weeks before the next TREC meeting) may be made directly to the TREC.
- The item will be placed on the agenda, discussed at TREC and the decision of TREC communicated to the researcher in writing within two weeks. The letter will be copied to the HoD, the director of the school, the Dean and SREC.
- If the researcher is still not satisfied with TREC’s decision he or she may lodge an appeal with SREC.
- SREC may appoint a subcommittee of outside reviewers to re-examine the decisions made by the TREC. The decision derived from the outside reviewer’s report will be communicated in writing to the researcher with seven (7) days of the report having been received.
- SREC’s decision will be final.
- Notwithstanding these internal complaints and appeals procedures, according to legislation, the researcher or any person participating in the research has the right to forward a compliant directly to NHREC, if not satisfied with the decision of the internal procedures.

15. Violations and cause of action

- Any serious violation, which are not of a criminal nature, by the researcher (academic or student) of ethics or TREC’s decisions and terms and conditions will be dealt with in accordance with, staff and student disciplinary procedures of the University, respectively.

16. Audits and compliance reporting to the National Health Research Ethics Council

- The NHREC has the right to assess and audit research ethics committees. TREC will comply accordingly.
- TREC shall report annually to the NHREC information relevant to its procedures, including:
  - Membership and membership changes;
  - The number of meetings held;
  - Confirmation of participation by the required categories of members;
  - The number of protocols presented, the number approved and the number rejected;
  - Complaint procedures and number of complaints received and handled.

17. Charging of fees

- TREC is entitled to charge a service fee to review research proposals on behalf of other institutions, externally funded and contract research.
- Fee charges will be according to a transparent set fee structure.
- Money will be paid directly into a TREC cost centre in the Finance Division.
- Funds will be used to supplement TREC’s budget to pay for external reviewers, training, administrative costs or any other costs associated with TREC activities and functions.
• Processing of transactions from these funds will follow official policy and procedures of the University.
• Income and expense reports will be available to NHREC for audit purposes.
TREC's STANDARDISED REVIEW CRITERIA

The following are criteria used to standardize the review process:

1. **TITLE**
   - The title should describe the study as succinctly as possible.
   - There should be no abbreviations in the title.
   - The title should place the study geographically if necessary. For example, a prevalence study must be placed geographically, but a study evaluating a new laboratory method does not need to be placed geographically.
   - An incorrectly worded title on its own is not sufficient grounds for withholding a clearance certificate, if all other elements of the proposal are in order. A clearance certificate should be issued with provisos / recommendations.

2. **STUDY PROBLEM:**
   - If there is no separate section headed “Study Problem”, this is acceptable, as long as the study problem is clearly explained under the section headed “Introduction / Background to the study / Rationale for the study / Motivation to do the study / etc.”
   - If the study problem is not clear to the reviewer, and there is no research question to help clarify what the study problem is, then the reviewer should consider withholding the clearance certificate for the study.

3. **LITERATURE REVIEW:**
   - Sometimes undergraduate research has this as a heading, but the literature review is generally dealt with under Introduction / Background to the study / etc. Any one of these headings is acceptable.
   - The protocol is not the dissertation, thus only a short, to the point, literature review is required. However, if the literature review rambles, or is not particularly well written, the reviewer should not withhold the clearance certificate if the other elements of the protocol are in order. The clearance certificate should be issued with provisos / recommendations.
   - Sources should be acknowledged in the literature review, according to either the Vancouver or Harvard methods.
   - However, if this is not done, the reviewer should not withhold the clearance certificate if the other elements of the protocol are in order. The clearance certificate should be issued with provisos / recommendations.

4. **PURPOSE OF THE STUDY:**
   - This refers to the aim and objectives of the study. These should be clearly stated, and should flow from the study problem.
   - There should be one aim, and all the objectives should fit under the “umbrella” of the aim.
   - A clearance certificate should not be issued if the aim and objectives are not clear, or are not addressed by the study design.

5. **RESEARCH QUESTION:**
   - It is not necessary to state this, but if the study problem has not been well formulated, and it is clear that the researcher is unsure of what the study problem is, if would be of help to the researcher to formulate...
a research question. As under point 2, the reviewer should consider withholding the clearance certificate under these circumstances.

6. **STUDY DESIGN:**
   - This refers to the overall design of the study, and the question that must be answered is: “Is this study well designed?” It is not a test to see if the researcher knows whether the study is a retrospective cohort study or a prospective case control study, etc. A clearance certificate must not be withheld if the design “label” is not included in the description of the study design.
   - The study must be designed to address the aim and all the objectives. Thus the methods, data collection, and data analysis must address the aim and all the objectives. A clearance certificate should be withheld if this is not the case.

7. **SAMPLE / STUDY POPULATION:**
   - It is always necessary to have a separate section for this.
   - The study population must be described.
   - The sampling procedure must be described, and it must be appropriate for the study. It is not always necessary (or appropriate) to name the sampling procedure, but when it is named, the procedure must fit the name (e.g.: if random sampling is named as the sampling procedure, the process described must be true random sampling). If the researcher has not named the sampling procedure, but has described a procedure that is appropriate for the study, a clearance certificate should not be withheld. It is not sufficient, however, to name a sampling procedure, but not describe it – a clearance certificate should not be issued in this case.
   - Sample size should be calculated for statistical power if the results are to be generalized to the target population. However, when this is not the case, for example in qualitative descriptive studies, this is not necessary.
   - If help is needed to calculate sample size, the reviewer should recommend that a statistician be consulted, and the clearance certificate must be withheld. If the researcher has worked out the sample size already, it is not necessary to refer the researcher to a statistician, and a clearance certificate must not be withheld.

8. **DATA COLLECTION:**
   - The data to be collected must address the aim and objectives of the study. A clearance certificate should be withheld if this is not the case.
   - In the case of questionnaires, no question should be included that does not address the aim and objectives of the study.
   - In the case of laboratory studies, no tests should be included that do not address the aims and objectives of the study.
   - It is always necessary to have a separate section for data collection.

9. **DATA ANALYSIS:**
   - Data analysis must address the aim and objectives of the study. A clearance certificate should be withheld if this is not the case.
   - It is always necessary to have a separate section for data analysis.
   - If it is clear that the researcher needs help from a statistician, this should be recommended. However, a clearance certificate should not be withheld if the help is needed with analysis only, and not with sample size calculation. A clearance certificate should be issued with provisos / recommendations.

10. **BIAS:**
    - If the researcher has taken steps to minimize bias, this should be mentioned, but not necessarily as a
If bias is potentially present, but the researcher has not recognized it and has taken no steps to eliminate or minimize it, the reviewer should alert the researcher to the type of bias that study is subject to, and recommend that steps be taken to minimize or eliminate this bias. In this case, a clearance certificate should be withheld.

If the study is not subject to bias, there is obviously no need for bias to be mentioned. The reviewer should never withhold a clearance certificate if bias is not mentioned, and the reviewer cannot identify any bias.

If bias is present but is unavoidable (such as the bias present in all studies that use volunteers, as volunteers are different from those who do not volunteer), and the researcher does not mention this, a clearance certificate should not be withheld.

**11. ETHICAL CONSIDRATIONS:**

- There should be a separate section for this.
- It must be clearly stated that a clearance certificate from the TREC will be obtained before commencing with the study.
- However, if a protocol lacks the above statement and there are no other problems with the protocol, a clearance certificate should be issued with provisos / recommendations, in studies that do not use human or animal participants.
- When human participants are used, a consent form must be included.
- When human participants are used, and the study is an experimental one using medication (allopathic, homeopathic, naturopathic, traditional) / vaccines / etc, a consent form and a patient information leaflet must be included.
- The protocol must explain the process of obtaining informed consent.
- In non-experimental studies using human participants, an edited version of the TREC consent form is acceptable.
- In experimental studies using human participants as outlined above, both the consent form and the patient information leaflet must comply with all the elements of informed consent outlined in the Helsinki Declaration. The TREC consent form is not adequate in this instance.
- Patient information leaflets and consent forms must be free from grammatical errors and spelling mistakes, and must be written in a language that is able to be clearly understood by the prospective research participants.
- In studies using animals, approval from the Medunsa Campus’s Animal Research Ethics Committee must first be obtained.

**12. GUIDELINES FOR REFERRAL OF DISTRESSES PARTICIPANTS:**

There shall be a separate section for this:

- The research is conducted within ethical guidelines; to this effect the following directives shall be adhered to:
  - The researcher shall write consent letters which shall include all the information about the study with, clearly stated objectives.
  - The letter shall be signed by respondents before participation in the research.
  - The researcher shall give guarantee to the participants/subjects that they will not be coerced to participate in the research.
  - The researcher shall inform participants/subjects that they should feel free to withdraw at any time before or during the study and/or when they start to feel uncomfortable about their
participation.
  o The researcher shall not reveal the participants’/subjects’ identity or any related information at any point during or after the research.
  o The researcher shall assure participants/subjects that the information they share during the interviews will remain confidential unless the participants give consent that it can be revealed.
• The researcher shall give guarantee that the following step shall be taken in order to protect participants/subjects:
  • Facilitate prompt professional referral of those who become emotionally or otherwise distressed as a direct or indirect result of their participation in the research. The researcher must include in the proposal and the consent letter the addresses and contact details of professional agencies to whom distressed participants/subjects will be referred to.

13. DATA COLLECTION FORMS / QUESTIONNAIRES:
• In quantitative socio-behavioural studies using questionnaires, these should always be included as an appendix.
• In quantitative laboratory studies, data collection forms must be included as an appendix.
• In qualitative descriptive studies, there is usually no need for data collection forms.

14. REFERENCES:
• Either the Harvard or Vancouver methods of referencing is acceptable.
• If the method of referencing is the only problem with the protocol, a clearance certificate can be issued with provisos/recommendations.

15. OTHER COMMENTS:
• A clearance certificate should be withheld if the application form has not been filled in correctly, especially if the relevant signatures are missing.
• School Research Committees are responsible for ensuring that all application forms are in order before the data of the next TREC meeting.
• Lack of semantic hygiene on its own, (unless the protocol is incoherent) should not be a reason for withholding a clearance certificate (except for the Informed Consent, see point 12). The clearance certificate should be issued with provisos/recommendations.

16. RECOMMENDATIONS:
• Recommendations should be recorded in full by the Secretariat during TREC meetings.
• The names of the researcher, the number of the protocol as listed on the agenda, and the data of the TREC meeting, must be included on the protocol feedback sheet.
• When a clearance certificate is issued with provisos/recommendations, the researcher must submit the corrected protocol to the TREC by the following TREC submission date (the date must be stipulated in the letter of recommendation). However, the researcher may proceed with the study immediately.

This document will be reviewed and updated on a regular basis as changes within the Institution occur.