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 Health Research: Principles, Structures and Processes(2015)", 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 protection.

1. Composition

The key to the compositions shall: "

- Consist of members who, collectively, have the qualifications and experience to review and evaluate the science, health aspects and ethics of the proposed research.
- Be independent, multi-disciplinary, multi-sectoral and pluralistic."
- not be more than 70% of either male or female, would thus be as follows:

Composition of the Turfloop Research Ethics Committee (2019-2021)

Composition of the Turfloop Research Ethics Committee	**Division/Title**	**Name**
1.Chairperson	Natural scientist	Prof P Masoko

2. Deputy Chairperson	Nursing	Prof Mothiba
3. Ex officio Member	Director Research administration and development	Dr TE Mabila
4. Faculty Representative	Faculty of Science and Agriculture	Prof KD Monyeki
5. Faculty Representative	Faculty of Management and Law	Prof E J Van Rooyen
6. Faculty Representative	Faculty of Humanities	Prof L Rafapa
7. Faculty Representative	Faculty of Health Sciences	Prof L Mdee
8. Person with legal training Law	Law	Adv R Msaule
9. Clinical psychologist	Clinical Psychologist	Prof T Sodi
10. Polokwane /Mankweng Hospital Complex	Hospital	Dr S Maweya
11. Research Methodologist(Qualitative)	Education Studies	Prof SA Rankoana
12. Medical Doctor	Medical Doctor	DR CJ Sutton
13. Medical Doctor	Medical Doctor	Dr TA Malatji
14. Social worker	Social work	Prof JC Makhubele
15. Pharmacologist	Pharmacy	Mr MG Mohlala

16. Research Methodologist(Quantitative)	Mathematics and Computer Science	Dr D Maposa
17. Bioethicist	Nutrition and Dietetics	Prof MN Jali
18. Lay person	Community representative	Mr CFE Modiba

A quorum is determined by half of the members plus one is present.

1.1. A Chairperson and Deputy-Chairperson should be elected from the members.
1.2. Turfloop research ethics committee is based at 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 also evaluate the ethical implications as well as the scientific merit of the research to be carried out.
1.5. The committee members will perform the functions of TREC for a duration of 3 years

2. Responsibilities

The Turfloop Research Ethics Committee should:

2.1. Safeguard the dignity, rights, safety and well-being of all participants 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 University 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 a proper liaison with other registered ethics committees in the province and other the other Provinces.
2.5. Ensure that there is a proper liaison with the Senate Research Ethics Committee (SREC).
2.6. Obtain national registration.
2.7. Ensure continual registration with NHREC
2.8. Formulate and recommend to SREC policy in respect of research ethics.
2.9. TREC should periodically familiarize itself with possible changes in legislation pertaining to research ethics.
2.10. Draw up, in collaboration with other Research Ethics Committees and SREC standardised 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, to enable it to adequately fulfil its duties.

2.13. Ensure that members of TREC undergo **orientation** and training in research ethics.

2.14. 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).

3.1.4.1. Such protocols will be forwarded to TREC for review.

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 TREC for review.

3.1.5.2. Experiments involving animals will be forwarded to the Animal Research Ethics Committee, (AREC) for review.

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, TREC should determine that the proposed protocol and/or other documents (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.

3.1.9. Available safety information.

3.1.10. Information about reimbursement and compensation available to participants.

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

3.1.10.2. Reimbursement 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. TREC should ensure that information regarding payment to participants, including the methods, and schedule of project participants, as outlined 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 (independent researcher)/supervisor and/or other documentation evidencing qualifications. Supervisors must have in their possession their students' CVs.

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 fulfil 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 before 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 participants 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 an indication that the research participants, volunteers, animals or biotic/abiotic environment are at risk of harm.

4. Procedural Matters

4.1. TREC will have 10 meetings per year.

4.2. The REC 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 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. Invited researchers/supervisors may provide information on any aspect of the protocol, but should not participate in the deliberations of the committee or 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 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 direct benefits such as the provision of materials or facilities,

5.1.1.2. The support of individuals such as the 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 of 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.

Standard Operating Procedure of TREC

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 (research innovation and partnerships) 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 takes 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 as allocated 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.
- Maybe delegated to review protocols that should be expedited.
- Attend meetings regularly as per NHREC guidelines
- 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 and replace regularly, needed expertise or a member who is on occasion unable to attend convened meeting.
- Names of these members will be listed on the official

2.5. Secretariat

- Communicates with the researchers/supervisors concerning the outcome of the review.
- 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
- Organises 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 Administration and Development.
- Archived records will be kept for a maximum period of five years, after completion of research, after which records will be disposed of.
- The secretariat may utilise other assistance, depending on requirements and availability.
- Facilitate training for researchers

3. Conditions of office

3.1. Duration

- The duration of membership is three (3) years, and at the end of a members' term, nomination, election and co-option 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, death or long-term unavailability or any other action not commensurate with the responsibilities laid down in NHREC guidelines.
- A member can tender his / her resignation from the committee with adequate reasons.

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 a 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 who have conflicting interests are required to disclose such interest and recuse themselves from deliberations of the relevant protocol.

3.4. Compensation of members

- The University of Limpopo will not remunerate members who serve on the TREC.

- However, it is acknowledged that service on the TREC requires a significant investment of time.
- The chairperson will, at the end of the term of office provide members with formal certificates.

4. Administrative support

- The University shall, through the Deputy Vice Chancellor's office, allocate on an annual basis, sufficient resources to support the TREC.
- Directors of Schools shall assign, on an annual basis, research ethics administrative duties to one of the School's administrative staff members.
- The will:
    - Receive, document and acknowledge receipt of protocols and other documents from the researchers/supervisors.
    - 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 at least five years after completion of the project.
        - Researchers should also retain all relevant records for 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 morals.
    - 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 regularly by 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) as well as the Department of Health 2015 document.

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, *before* 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:**
- **Faculty approval letter**
  - **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**
  - **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 the 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)**
  - **The 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 South Africa Health Product (SAPRA) MCC. SAH**
  - **Investigator Declaration**
  - **Supervisor Declaration**
  - **Conflict of interest statement**
  - **Information about the reimbursement 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 reimbursement 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 the 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

- Research that involves human participants may be exempted from the 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. Submission Procedure

- **All applications, except those from external agency applying independently to TREC, must serve at the Faculty Research Committee.**
- 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 will be **four weeks before** the next meeting of the TREC. Dates are published in the **University's Important Dates Annual Schedule**.
- Monthly reminders are disseminated to the university community

10. Review procedures

- The TREC's task is to review research protocols and their supporting documents, 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

- Research involving human participants, animals or tissue modification of organisms requires full review by the TREC, at a meeting where TREC members constitute a quorum.

10.2. Expedited review

- Research protocols or responses may require expedited review procedures.
- **The process from submission will take approximately 3-4 weeks.**
- Research that may be expedited includes:
  - Researching on outbreak investigations, epidemic conditions or prospective collection of biological specimens for research purposes by non-invasive means e.g. hair and nail clippings.
  - **Undergraduate, honours and honours equivalent studies with minimal risk.**

10.3. Review process

10.3.1. Pre-review and processing of applications

- Once the TREC has 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.
- If documents are missing, forms not fully completed, the secretary will communicate electronically in writing with the researcher to rectify the problem as soon as possible.
- Only applications that have successfully pre-reviewed will be further processed.
- The Chairperson allocates reviewers among TREC members
- If a Committee member believes that they cannot be a reviewer for any reason, including lack of expertise or a conflict of interest, the administrative staff should be notified immediately.
- The Chair or designee serves as the primary reviewer for a 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 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 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 before the next meeting.

10.3.2. Responsibilities of the Reviewers

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 writing. 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. Reviewing process during a committee meeting

- The reviewer leads the discussions based on the submitted report.
- Researchers/supervisors may be invited to attend the meeting to offer clarifications on specific matters regarding their proposals.
- After providing clarifications the researcher/supervisor leaves the meeting and discussions continue with the aim of reaching a decision
- 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.
- Reviews with minor modifications can be signed off by the chairperson
- The decision of the expedited review serves at the next TREC meeting for ratification.

10.3.4. Recording and communication of the decision

- Decisions will be recorded in the minutes as one of the following:
  - Approval
  - Not approved
  - Conditional approval
- The outcome of the review shall be communicated to the researchers by the Secretariat within three weeks after the TREC meeting:
- **Steps under sections 10.3.1 and 10.3.3 are followed in placing the amended submission on a new agenda.**
- **The Secretariat shall maintain systematically, 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;**
- **The action that was 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 the case of research for non-qualification purposes, approval is given for a year or less following Ethics in Health Research: Principles, Structures and Processes (2015, Department of Health).**
- **Approval of any material changes must be sought before 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 the 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.
  - *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

I.RECs have the right to monitor the research it approves (Declaration of Helsinki 2013 par 23). Researchers should provide appropriate information to the REC to facilitate monitoring, including alerts and investigator brochures. The frequency and type of monitoring should reflect the degree and extent of risk of harm to participants or animals.

ii. RECs may recommend and adopt any additional appropriate mechanism for monitoring, including random inspection of research sites, welfare monitoring sheets, data and signed consent forms, and records of interviews. Information and consent materials should indicate that such monitoring may take place.

iii. RECs should request regular, at least annual, reports from principal investigators on matters including but not limited to progress to date, or outcome in the case of completed research

- **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 provide the full contact details of the Secretary of TREC who they contact in the event of a problem or complaint.**
- **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 a review of ethical approval of the protocol, including:**
  - **Serious or unexpected adverse effects;**
  - **Propose changes in the protocol;**
  - **Unforeseen events that might affect the 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.
- whether participant follow-up is still active or completed

iv. RECs should inform principal investigators in writing of concerns arising from such monitoring activities.

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Suspension or discontinuation of projects

i. Where circumstances indicate that a project is non-compliant with the approved protocol and the interests of participants are at risk of harm, the REC may withdraw approval after due process has been followed.

ii. A clear process should be followed that permits swift but proper investigation and decision-making to ensure protection of participants. The investigation should include interaction with the researchers and other interested parties to ensure a fair and transparent process.

iii. If the decision is to withdraw approval, the REC should inform the principal investigator and other interested parties, including the institutional authorities, and recommend suspension (temporary stoppage) or termination (permanent stoppage) of the project. It should also recommend remedial action where appropriate.

iv. In the case of suspension, the principal investigator should comply with the recommendations and any special conditions imposed by the REC.

- If TREC is 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) might affect the 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.

13. Complaints and appeals procedures

4.5.1.12 Complaints

i. Each REC should have a complaints process that is accessible to researchers and other interested persons. In principle, but subject to institutional requirements, complaints about REC-related business should be directed to the REC in the first instance. If the matter remains unresolved, it may be escalated to other specified institutional officials and then to the NHREC.

ii. A standard operating procedure should detail the procedures to be followed.

iii. The NHREC is empowered to adjudicate complaints about RECs and to hear a complaint from any researcher who believes that he has been discriminated against unfairly by a REC.

iv. A framework for the management of complaints and ethics-related health research misconduct has been developed by the Complaints and Advisory Disciplinary Committee (CADC) of the NHREC (http://nhrec.org. za).

v. The NHREC, through its CADC, adheres to the following principles when investigating a complaint: fairness, confidentiality, integrity and prevention of detriment.

vi. All information and consent documentation should include contact details for making complaints about being a research participant. Similarly, a research assistant, researcher or an interested

- 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 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 complaint directly to NHREC, if not satisfied with the decision of the internal procedures.**

14. Violations and cause of action

- **Any serious violation, which is not criminal, 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.**

15. 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 the number of complaints received and handled.**

TREC's STANDARD REVIEW CRITERIA

The following criteria are used to standardise 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. Anyone 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 , it 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 of 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 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 separate section (e.g: if sampling bias has been minimized by using random sampling, this can be mentioned under sampling).
- 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 CONSIDERATIONS:

- 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, homoeopathic, naturopathic, and 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 can be clearly understood by the prospective research participants.

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 a guarantee to the participants/participants that they will not be coerced to participate in the research.
    - The researcher shall inform participants/participants 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.
    - The researcher shall not reveal the participants'/participants' identity or any related information at any point during or after the research.
    - The researcher shall assure participants/participants 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 a guarantee that the following step shall be taken to protect participants/participants:

- 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/participants 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 quantitiative 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 date 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 regularly as changes within the Institution occur.