

UNIVERSITY OF LIMPOPO



I) PASSIVE MONITORING OF RESEARCH PROGRESS

The TREC monitoring process will be done as follows:

- Through reports from school senior degrees' committees as well as faculty of higher degrees' committees.
- Progress of all studies will be reported to TREC from the time the decision was taken until the finalisation of the research.
- Supervisors and students will be required to submit annual progress reports to keep the committee abreast of the research protocols. Independent researchers will also be required to do likewise.

Lines of communication between TREC and the applicant will be clearly specified in the communication of the review result of the applicant to outline how monitoring will be conducted

The following will be outlined on the clearance certificate:

1. Ethically approved studies must apply for renewal annually
2. Ethics approval will not be valid when an annual renewal if not granted by TREC
3. Applications for annual renewal must be made a month before the expiry date stipulated on the clearance certificate.
4. Undergraduate and honours-degree research need to be submitted to TREC for consideration and approval.

II) ACTIVE MONITORING

This will apply mostly to high-risk research. Faculties will be expected to classify protocols as to whether they are low or high risk. Those classified as high risk will require a full review by TREC before approval is granted. Low risk and minimal risk protocols will be identified at the faculty and clearance will be approved by TREC.

The follow-up procedure will consider the following:

- The requirements laid down for follow-up reviews, the reviews, and the communication procedure may vary from the requirements and procedure for the initial decision on an application.
- The follow-up review intervals are determined by nature and events expected about particular research projects, though each research project should undergo a follow-up review at least once a year.

Events leading to indications for a follow-up review of a study

Indications that will make TREC decide to make a follow-up or monitoring visits of a project include:

- Any protocol likely to affect the right, safety, and /or well-being of the research participants or the conduct of the study
- Serious and unexpected adverse event related to the conduct of the study or study results, and the response taken by investigators, sponsors, and regulatory agencies, when applicable
- Any event or new information that may affect the benefit/risk ratio of the study
- A decision of a follow-up review will be issued and communicated to the applicant, indicating a modification, suspension, or termination of the TREC's original decision or confirmation that the decision is still valid

NOTE:

In the case of the premature suspension/ termination of a research project that was approved by TREC, the applicant should notify the TREC immediately of the suspension/ termination

The outcome of the review

- A summary of results obtained in a study prematurely suspended/terminated should be communicated immediately to TREC