

All researchers applying for ethics must read the following document carefully and ensure that they are thoroughly prepared for the online submission process.

The following is based off of guidelines and SOPs of the Research Ethics Committee (REC):

<https://www.up.ac.za/healthethics>

1. General Ethics Application Information – Researchers’ Responsibilities

- The Principle Investigator (PI) is the *only person* that can submit the research proposal and supporting documents electronically, as this ensures that the PI takes full responsibility for all documents submitted and also for all research done.
- The researchers’ responsibility is to take note of application status. Comments made by the REC after the Preliminary Committee and the Main Committee meetings will be forwarded to **project supervisors**.
- Note your **protocol number (xxx/year)** upon the initiation of your application as this number is used to access your application / track your application progress. It is also to be included in cover letter/ patient ID protection letter.

2. Who should apply?

- **All individuals** wishing to initiate postgraduate research projects, research fellows, intern medical biological scientists as well as departmental researchers **must apply** for ethical approval from the REC in order to commence with a research project.
- A full protocol needs to be submitted for consideration by the REC for all research studies to be conducted with commercial cell lines, blood samples, human tissues, human bodily products and/or “in vitro” work as well as for systematic reviews.
- The REC is required to evaluate all research proposals/protocols even if the project is a **pilot study** or **subset of another study** (sub-study/ under the umbrella of another study), which has already been approved by the Ethics Committee.
 - Please indicate clearly and refer to the umbrella study title and protocol number **in your cover letter with your application**.
 - As the latter submission needs to refer to the study already approved, it may consequently be less comprehensive (for example, the previously approved Participant Information and Consent Documents may suffice).
- If the research is classified as a clinical trial or is case reports/case studies another subset of permission documents are required.
- Researchers who are not UP staff members, students or affiliates may submit ethics applications at the discretion of the REC.

3. What is required?

- Ethics application must follow the receipt of an **approval letter** from the MSc/PhD Committees, Postgraduate Committee School of Healthcare Sciences, Academic Advisory Committee, and Academic Programme Committee *where the research is for degree purposes*. This is not necessary for applications that are not for degree purposes.
- On the electronic ethics application form (generated on PeopleSoft platform) the researcher needs to indicate that he/she will abide by the principles of the **Declaration of Helsinki***. In addition the **Declaration of Storage*** needs to be completed.

Furthermore the PI needs to complete the **PI's commitment section** within the application (declaration of commitment). *Documents can be found under the research tab on the Department of Obstetrics and Gynaecology website.

4. When should you submit?

- Researchers need to take note of the **submission deadline** for a specific monthly meeting. These are available on the [REC website \(www.up.ac.za/healthethics\)](http://www.up.ac.za/healthethics).
 - No late submissions will be accepted by the REC secretariat for evaluation for a specific REC meeting. The PeopleSoft system has a cut-off-date and will automatically allocate late submissions to the next REC meeting for evaluation.
 - Please note that the researcher, Head of Department and the student supervisor (where applicable) need to sign the electronic application form on the PeopleSoft electronic submission system, before the electronic system will forward it to the REC secretariat. Allow sufficient time for all signatures to be added to the application.

5. How to Apply

- In preparation of your research protocol you will acquire a lot of the information necessary for the ethics application. However, additional information/documentation will be required.
 - A comprehensive description of the process of preparing for the ethics submission is described in **Figure 1a** and **Figure 1b**.
 - **Figure 1a** contains a breakdown of all the documentation and additional information that will be required of you for your submission and is printable to act as a checklist for your submission process.
- Ensure that all relevant documents are compiled timeously. Additionally, ensure that your research protocol contains all the relevant sections by referring to **Figure 2**.
- Any information regarding fees can be obtained here: <https://www.up.ac.za/healthethics/article/2847135/application-fees-2020>
- To begin your application:
 - [Access the UP portal login page and log in with your UP details at www.up.ac.za.](http://www.up.ac.za)
 - [Log on to UP Portal \(www.up.ac.za\) - My TUKS Login - Login with Username and Password - Select "Research Grants & Ethics" - Click on "Research Grants & Ethics" link → Click on 'My Ethics Application/Proposal' → Add new value to add your new application](http://www.up.ac.za)
- **Ethics applications will only be processed once a hard copy has been submitted** to the REC secretariat: *Mrs M Smith (manda.smith@up.ac.za) and/or Mrs Deepeka Behari (deepeka.behari@up.ac.za) and/or Mrs Carika Swart (carika.botha@up.ac.za) at the Faculty of Health Sciences Research Ethics Committee, Tswelopele Building, Level 4, Rooms 4-59; 4-60 and 4-61.* Please submit the hard copy as soon as possible after uploading your documents on the PeopleSoft system.

Preparing for 1st Ethics Submission:

Check Ethics Submission Deadlines online at:
<https://www.up.ac.za/healthethics/article/54107/submission-dates>

Prepare the following documents and information
in both .doc and .pdf formats (where applicable):

- Approval letter from scientific or academic advisory committee
- Letter: Cover letter (addressed to ethics committee, signed by researcher and all supervisors)
- Letter: Participant Information Protection/ Ethical Waiver Request
- Ethics Application Document consisting of the following sections:
 - Project title
 - Short description of project
 - Aims and objectives of project
 - Duration of project
 - Research environment
 - Research team
 - Agreements between researchers (rights to use results)
 - Funding of the project
 - Involvement of participants (participants and description of methods)
 - PI declaration for storage of data (read policy on data storage) – indicate period of study and period of storage
 - Categorization and description of risk associated with study [1 – 2 paragraphs]
 - Benefits associated with research [1-2 paragraphs]
 - Planned application of results
- Signed Declaration of Helsinki
- Research Protocol (see figure 2 for checklist)
- Research synopsis/summary [1-3 paragraphs]
- Participants Information Consent Document (Read through: Permission to access files/records [Promotion of Access to Information: Act No.2 of 2000])
- Separate Curriculum Vitae of all investigators
- Statistical support letter
- Datasheet of all variables to be collected
- Institutional Permission (only attainable after ethics application)
- Participant recruitment tools/gifts
- Advertisements for patient recruitment
- Questionnaires
- Any other relevant documents

If applicable
to your study

Documents required vary depending on scope of the project. To
find out which documents are applicable to your application as
well as access templates visit:

<https://www.up.ac.za/healthethics/article/54116/which-documents>

Figure 1a: Preparing for ethics submission (<https://www.up.ac.za/healthethics/article/54116/which-documents>)



- Book an appointment with Terri-Ann de Jager: terri-ann.dejager@up.ac.za **4 weeks before** Ethics Submission deadline at which you would like to submit.
- Email all completed documents beforehand for check using the following naming system for all files:
surname_initial_title of document_date_file version
- You will then be allocated an appointment to upload documents in person **2 weeks before** your submission deadline of choice



- Arrive at appointment (Room 72402) with all relevant documents sent via email/ brought on a memory stick to submit application online in person.
- Researcher must then ensure that a hard copy is delivered to REC secretariat within 24 hours post online submission.
- Ensure sufficient time for the application process [2 hours]

Figure 1b: Preparing for ethics submission

Research Protocol Checklist:

- Introduction and relevance of the proposed research study
- Executive summary of research
- Background and problem statement (Literature references)
- Hypothesis / Aims
- Objectives (primary / secondary)
- Methodology
 - Sample size and population-please explain in detail the recruitment process, control group and experimental group where applicable
 - Randomisation process: Explain in detail
 - Exclusion criteria / inclusion criteria
 - Procedures / frequency of visits
 - Quality assurance of specific tools to be used; and
 - Data collection and analysis
- Ethical aspects e.g. anonymising of data and participants
- Assurance of data anonymity must be given. Details on how this will be done, must be written in the protocol under "Ethics."
- Statistical analysis with a statistical letter of support
- Budget and funds allocated
- Limitations of study
- Table of authorship/contributions
- Gantt timetable with correct/updated dates
- References

Figure 2: Research protocol checklist

6. Post submission process

- Supervisors and Head of Department will need to approve the submission before it goes through to the REC. Supervisors and HOD can follow the steps below to approve submissions:
 - There are Ethics Application(s) on your desk for approval.** - Log on to UP Portal (www.up.ac.za) - My TUKS Login - Login with Username and Password - Select "Research Grants & Ethics" - Click on "Research Grants & Ethics" link - Click on the "Ethics Application & Approval" Tile Go to function: 1) Ethics Approvals 2) Search (without completing any fields) - to find a list of applications on your desk for approval.
- See **Figure 3** for flow diagram of the post submission process including approximate timeline of process (Adapted from <https://www.up.ac.za/healthethics/article/24821/overview-of-review-process>)
- The system (PeopleSoft) will also forward an e-mail to the researcher/supervisor to alert the researcher that comments made by the REC need to be addressed.
- Researchers need to respond with a cover letter that addresses the REC comments in a point-by-point letter format. This needs to be submitted before the deadline stipulated on the comments letter. All amended documents should be attached.

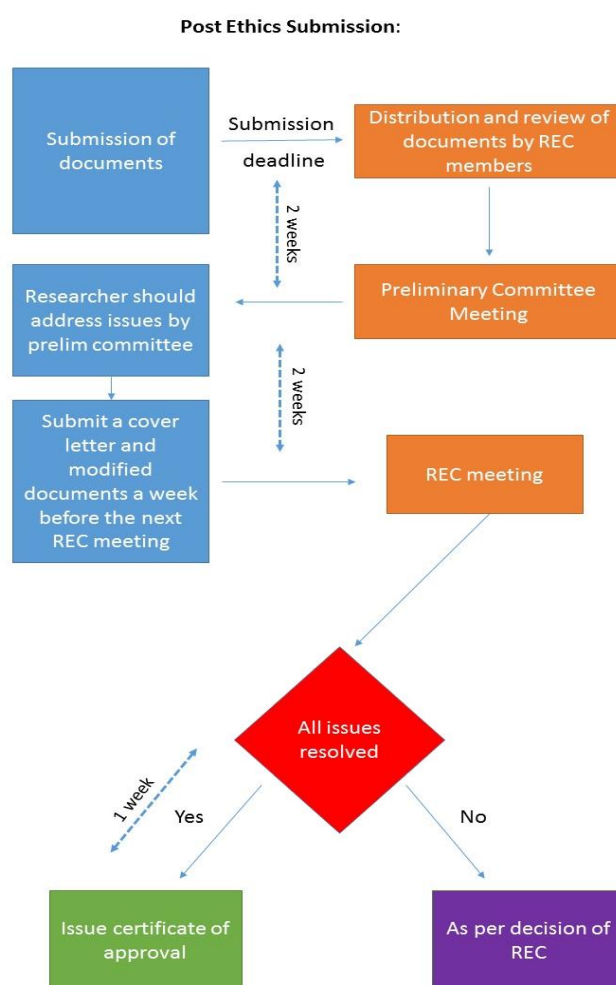


Figure 3: Overview of review process: post submission (adapted from <https://www.up.ac.za/healthethics>)

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