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# Ethics Application Guide

## for PhD students

in the Faculty of Medicine and Health Sciences

Tygerberg Doctoral Office

2024

# Contents

# 1. Ethical clearance for doctoral research in the FMHS

## 1.1 Rationale

Ethical oversight is critically important for preventing the abuse of a researcher's power of influence and for ensuring that the dignity, rights and welfare of research participants are protected, irrespective of biographical categories or socio-economic status. SU requires all researchers to apply for ethical approval of a study before commencing with their research.

The ethics process is largely student-driven, though supervisors do sign off on their students' ethics submission on the application platform, Infonetica. To make the ethics approval process as accessible as possible, and to assist students with their preparation, the Tygerberg Doctoral Office has compiled this guide.

## 1.2 From proposal development to ethics approval

Ethics applications for doctoral studies usually follow a proposal review process. The research proposal is the first deliverable that a doctoral student is expected to produce. The manuscript, typically 10 to 20 pages long, outlines the significance of the research question, details its planned execution, indicates the contribution of the study to scientific knowledge, and demonstrates that the project goals can be achieved within the available time of a further two years, and with the available resources. The Tygerberg Doctoral Office has drawn up a Proposal Writing Guide for doctoral students in the FMHS, available for download at this link. The document flags the pitfalls and delays that have been encountered by peers. It also covers key **ethical concerns that a research proposal should address**, which this process guide does not do. The norm is to submit various drafts for feedback so that supervisor comments are addressed before the proposal is presented to a review panel. This process can take five or more months. The review represents a first step in the ethics process, since a representative of the most relevant ethics committee serves on every FMHS review panel. Upon successful completion of the review process, the following documents are submitted to the Tygerberg Doctoral Office at tyg-phd@sun.ac.za:

a) Supervisor confirmation that all changes required by the panel have been made;
b) Fully completed and signed Form A3 review checklist;
c) Summary report by the panel chair OR all reviewer reports;
d) Final proposal for ethics submission;
e) Turnitin report on the final proposal, indicating a similarity score of 15% or less.

On receipt of a full set of review documents in good order, the Tygerberg Doctoral Office supplies a student with a letter to confirm their readiness to proceed with an ethics application. The application should be submitted without delay. To submit an ethics application, the following minimum set of documents will be required:

a) Confirmation of compliance with a faculty review process;
b) Final, revised research proposal / protocol for ethics submission;
c) Turnitin report on the final proposal, indicating a similarity score of 15% or less;
d) Any and all previous ethics approvals and institutional or access permission documents;
e) CVs of the student, supervisors, and all parties to be involved in the research.

# 2. Application fees

The RECs: ACU, BES and SBE do not charge application fees. The services of these committees are free of cost to students and staff. The HRECs have a graded administrative fee structure in place, which is revised annually, and applies to PhD projects that have secured funding or a sponsorship. Non-sponsored student projects for degree purposes, self-funded projects, projects funded solely from a Stellenbosch University Departmental budget, and Harry Crossley research, are exempt from HREC fees.

## 3. Which SU Research Ethics Committees will have oversight of my research?

### 3.1 Research Ethics Committees (RECs) at SU

Every PhD candidate must apply for ethics approval, to the most suitable Research Ethics Committee (REC) within Stellenbosch University:

a) Animal Care and Use (REC: ACU)
b) Biosafety and Environmental Ethics (REC: BEE)
c) Health Research Ethics Committee 1 (HREC1)
d) Health Research Ethics Committee 2 (HREC2)
e) Social, Behavioural and Education (REC: SBE)

Most PhD projects can be assessed by one, particular REC, but some projects will straddle the domain of more than one REC. A majority of FMHS doctoral research projects are considered either by the REC for Animal Care and Use, or the REC for Biosafety and Environmental Ethics, or one of the Health Research Ethics Committees.

Following successful completion of the proposal review process, candidates should allow up to three months for the ethics process of a doctoral study, from application to outcome. Ethics approval for an individual study, OR – in cases where the parent study covers the PhD study - a letter adding a student as investigator to an existing, ethics-approved study, is acceptable. In case of the latter, the original or most recent ethics approval of the larger study should also be submitted. Note that ethics approval for a parent study does not automatically cover all objectives of a PhD study.


Infographic from http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics

**For clinical researchers only:**

In the case of clinical trials, a separate ethics process governed by the Department of Health follows. In addition, the trial may be registered on the South African National Clinical Trials Register (SANCTR). Please see part 6 of this guide for more detail.

Next, the mandate of each REC will be discussed. This determines which committee has oversight of a specific study.

### 3.2 REC: Animal Care and Use

All activities that involve the use of live vertebrate animals (as defined by the SANS: 10386) must be reviewed by the REC: Animal Care and Use (ACU). Specific examples of such activities are:
a) Research involving wildlife, laboratory animals, farm animals, or aquaculture;
b) Teaching and practical sessions;
c) Testing of an antibody, vaccine, etc (REC: ACU, nd).

The mission of the REC: ACU is to ensure the humane care and use of animals in research, teaching and testing, in compliance with the South African National Standard for the care and use of animals for scientific purposes 10386:2008, and with the regulations contained in the Veterinary and Para-veterinary Professions Act of 1982 and the Animal Health Act of 2002.

### 3.3 REC: Biological and Environmental Safety

All research involving genetically modified organisms or research that poses a risk to the natural environment or the researcher and supporting staff, must be submitted for ethical review and approval before the REC: Biological and Environmental Safety (BES). This REC provides review and regulatory oversight of all research, teaching and testing activities using recombinant DNA, biohazardous materials, genetically modified organisms (GMOs) and nanomaterials that have the potential to negatively impact the physical, biological or spatial environment. They aim to protect the interests of researchers, the community and the environment and ensure compliance with accepted international and national guidelines on biological and environmental safety.

### 3.4 Health Research Ethics Committee 1 & 2

Health Research Ethics Committee (HREC) 1 and 2 both review health-related research involving:

- Any direct interaction with or observation of human participants in health research,
- Human progenitor or stem cells (HREC, n.d.), and
- The use of potentially identifiable health records, personal information, or tissue specimens.

The primary purpose of the HRECs is to support researchers towards compliance in the protection of the safety, rights, and welfare of every human participant in health research. The National Health Act indicates that all health research must be reviewed and approved by a REC that is registered with the National Health Research Ethics Council before the research commences.

The latest HREC Terms of Reference and Standard Operating Procedures can be found at this link. Guidance for those responding to modifications required by the HREC can be found at this link.

### 3.5 Social, Behavioural and Education REC

The Social, Behavioural and Education REC provides independent, competent, and timely reviews of ethical risks regarding research proposals relating to social, behavioural, educational, and economic research conducted at Stellenbosch University. Academic environments usually screen applications to determine their risk levels, with low-risk projects being ratified by the SBE and medium or high-risk projects being referred to the SBE for review at a convened meeting.

For research that may involve conducting research on university-held personal information and/or institutional information and recruiting SU staff, students, partners, alumni, and other stakeholders affiliated to the University, researchers should obtain institutional permission from the Division for information Governance before conducting research (SBE REC, n.d.). To apply for permission to use institutional information, visit www.sun.ac.za/permission.

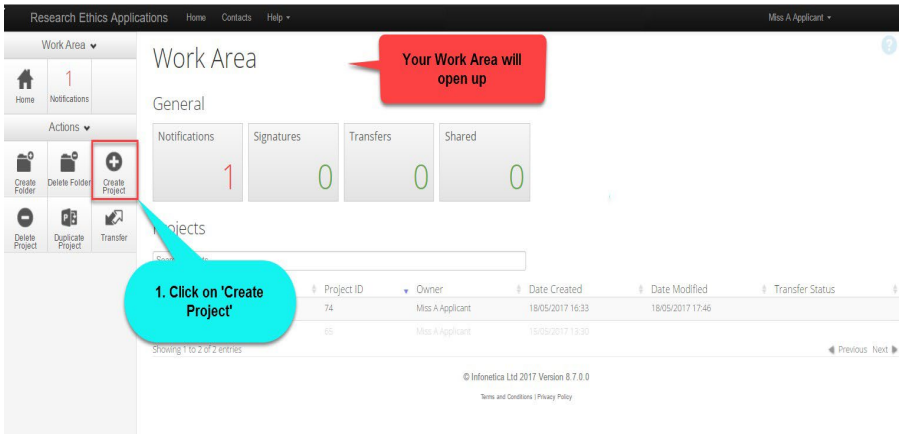
# 4. Pointers for using the online SU ethics application platform

## 4.1 Infonetica platform

Applications to any of the five SU ethics committees are submitted online, on the Infonetica platform at https://applyethics.sun.ac.za/. An active SU profile is required for logging into Infonetica. It is not acceptable to use someone else's login details to submit an ethics application. A student should take responsibility for their application via their own SU profile, and their ethics clearance letter must bear their name. Please refer to the How-To Video's at this link for step-by-step guidance on the application process.

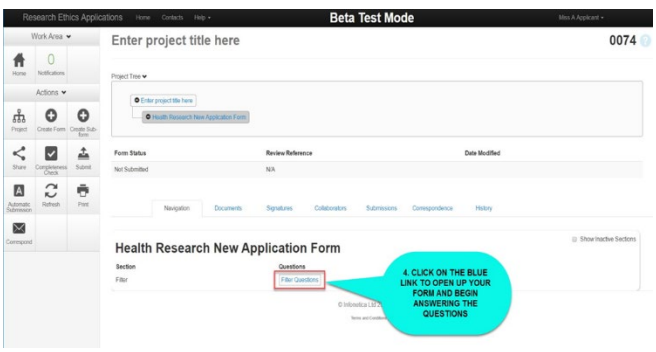
a) Login at https://applyethics.sun.ac.za/


b) Create your Project

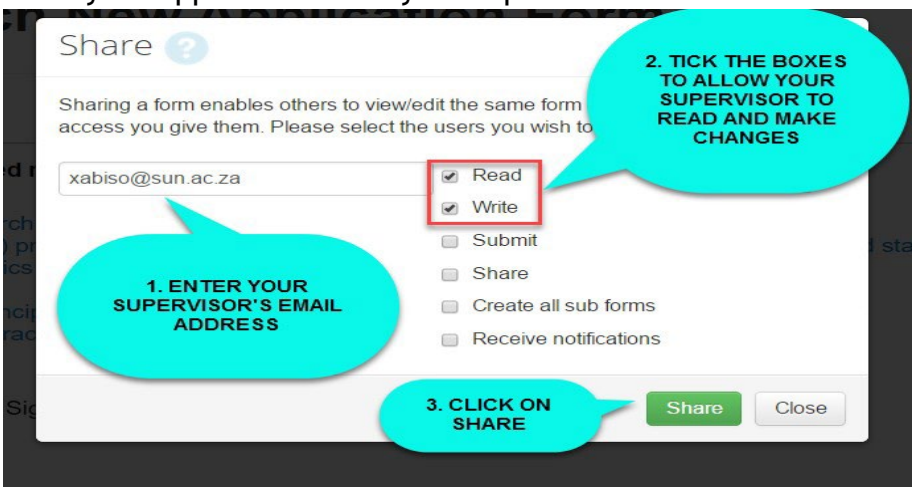



NB: Select the correct application form

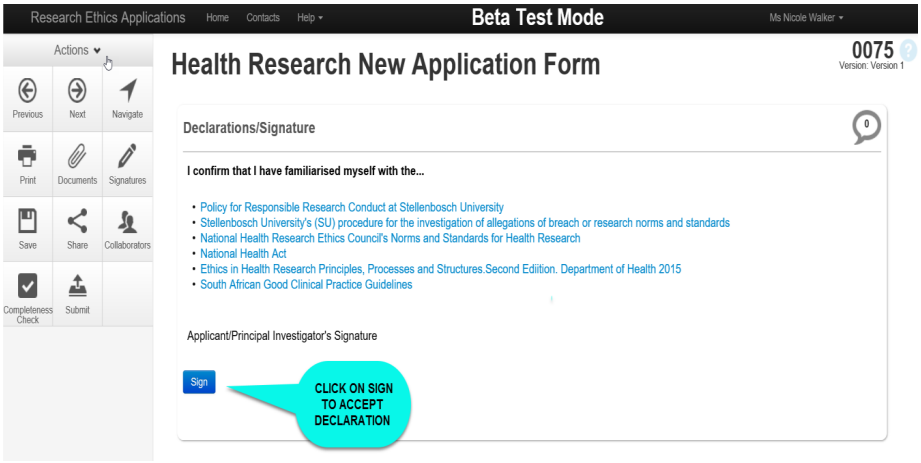
c) Complete the online form answering all questions




d) Share your application with your supervisor



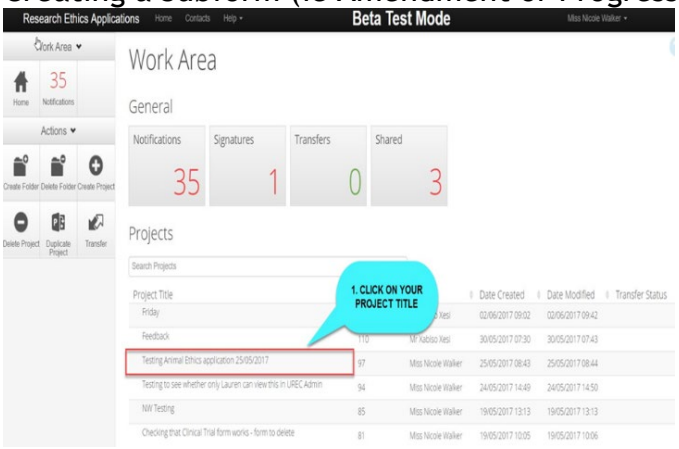

e) Sign and Submit your application




f) Changes requested

Login and click on your project list. Make your necessary changes, save and then click on submit to resubmit your application.

g) Creating a Subform (ie Amendment or Progress Report)



## 4.2 Lone-standing studies

Each REC has a manual on Infonetica that has been adapted from a general manual created by the SU Division for Research Development (DRD). Please see links below to the respective REC application manuals for Infonetica.

a) REC: ACU Manual
b) REC: BES Manual
c) HREC Manual
d) SBE REC Manual

## 4.3 Studies that form part of a larger project

Ethics applications for projects that form part of a larger study, may proceed in one of two ways:

a) A student may submit a new application on https://applyethics.sun.ac.za and indicate on the online form that their project is linked to another project which has been approved by the committee. The project reference and approval letter should be added to the submission.
b) The PI of the larger study may submit an amendment form requesting the addition to the larger project of the student researcher as well as the smaller project or additional objectives. A full project proposal will need to be submitted as part of the amendment form for the new study.

## 4.4 Applications for exemption

Certain studies may qualify for exemption from a full, formal ethics review. Exemption is the subject of an application and may not be assumed. Exemption does not imply that overarching ethical concerns such as authorship, copyright, intellectual property rights, representation, etc, can be neglected. The specific requirements of the respective RECs differ with respect to applications for exemption.

The specifications for exemption from an application to the REC: BES, may be found at this link. An applicant who believes their project qualifies for exemption, is requested to send the relevant Ethics office their full project proposal with accompanying safety datasheets. Once reviewed, the REC Manager will confirm whether or not the project is exempt from REC: ACU or REC: BES approval. If so, an exemption letter and reference number is issued to the candidate.

For projects that fall in the domain of the HREC, apply via the electronic portal, click 'Create a new project', and select the HREC Exemption Form. Consult the HREC Ethics Exemption Application SOP for guidance.

The Health Research Ethics Office (HREO) accepts new exempt research applications at any time, on a rolling basis, for review by an administrator. The application for an HREC exemption letter is submitted via Infonetica together with:

a) Protocol synopsis – strictly max 2 pages; and
b) When the HREC letter is required for publication purposes, a copy of the submitted manuscript.

FDA studies *do not qualify* for exemption. The following types of research may be exempt from an HREC review:

a) Systematic reviews using information that is available in the public domain;
b) Research involving the collection or study of existing data, documents, records and/or pathological specimens that are publicly available;
c) Research on commercial cell lines;
d) Quality assurance audits (no intention to publicly present or publish).

Once a decision has been made, an HREC notification is sent to the investigator.

## 4.5 Applications for expedited review

An REC may consider a request for using expedited or minimal risk review procedures to assess a specific ethics application. Projects that are deemed 'minimal risk' are eligible for expedited review.

Minimal risk research is defined by the HREC as 'the probability and magnitude of harm or discomfort anticipated in the research, is not greater, in and of itself, than that ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations or tests'.

Before submitting such an application, researchers should notify the relevant REC office that they will be requesting an expedited review. Only the first submission to an REC is eligible for an expedited review request.

Where studies are categorised as 'more than minimal risk', final approval can only be issued with full committee ratification. Projects that are not suitable for minimal risk reviews, include:

- All clinical trials involving drugs/medical devices or other therapeutic interventions;
- Multi-institutional and/or multi-site collaborative research projects;
- International grant funded research; and
- Studies involving children.

A new HREC application can be submitted in the case of an expedited review. The turnaround time for review is 3 to 5 weeks after the submission deadline for minimal risk projects as compared to 5 to 6 weeks for more than minimal risk projects. The applicant can request an expedited review of the project in the cover letter. Please refer to the HREC Terms of Reference and SOP for more information regarding HREC expedited reviews and the information at this link.

For urgent/rapid HREC reviews, researchers should send an email to the Head: Health Research Ethics Office, via ethics@sun.ac.za with a cover letter attached outlining the time frames involved, approved protocols (if applicable), informed consent forms, DTA/MTA pertaining to previous studies as well as HREC reference numbers.

A proposal outlining the interface with human participants should also be developed, or in the case of reuse of data from a previously approved study or studies, provide the originally approved protocol and informed consent documentation. In cases where amendments have subsequently approved, the most recently approved documentation should also be appended.

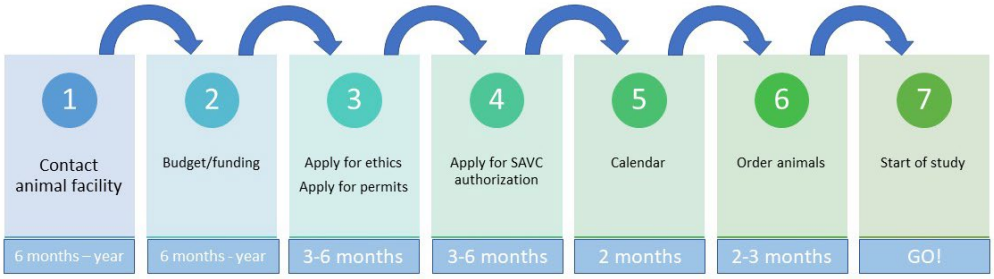
Submit the application with all supporting documentation via Infonetica **as soon as possible**. Once your application has been submitted, to enable HREC co-ordinators to assign reviewers, inform the HREO (ethics@sun.ac.za) and copy Ms Elvira Rohland at elr@sun.ac.za.

| | |
|---|---|
| a | •Written request to Head: HREO who discusses with HREC Chairpersons to determine optimal path for assigning to HREC 1 or 2. Such consideration will be based on, amongst others: timing of the request vi-a-vis the scheduled meeting cycle, review expertise required and availaiblity, the feasilibity of the urgent/rapid review within the required timeframe, and so forth. |
| b | •Discuss with the Chairpersons, assess the request for urgent/rapid review, assess risk category, and assign reviewers accordingly. |
| c | • Assignment by Senior Health Ethics Administrator to the relevant committee HREC1 or 2 based on discussion with the Chairpersons. |
| d | • Table request at the closest meeting if more than minimal risk study and requires meeting deliberation and recommendation (e.g., CT, and vulnerable participants) i. Ad hoc meeting: at the Chairperson's discretion, where required to deliberate any challenges identified before feedback is provided to the applicant, an ad hoc meeting can be considered. Members of the ad hoc meeting shall include the Chairperson, Vice-Chairpersons, reviewers, Head: HREO and HREC co-ordinator. The Chairperson shall also have recourse to invite additional members or experts as provided for in the HREC SOP. ii. The feedback from the ad hoc meeting and reviews will be shared with the researcher/research team to ensure that any modifications requested by HREC can be attended to. iii. The decision of the ad hoc committee is ratified at the next scheduled meeting and final approval issued or approval with stipulations (to ensure administrative requirements (e.g., institutional permissions, DTA/MTA finalisation etc.) are met by the researcher/research team. |
| e | •To ensure the integrity of the ethics review process, a turnaround of 7-10 workingdays can be expected, in line with rapid review processes as outlined in the Research in Emergencies SOP (kindly refer to section 24 of HREC SOP). |

## 5. Deadlines and turnaround times

Each REC publishes its own meeting dates and deadlines: ACU | BES | HREC | SBE

Doctoral students should allow two to three months for the ethics application process, from first submission by a meeting deadline, to receipt of a letter of approval. Low-risk studies may receive approval faster, while any required modifications may extend the time to attain ethics approval. Animal studies require additional time. Estimated timelines for the REC: ACU are as follows:




## 6. Additional approvals for Clinical studies

### 6.1 Regulatory Authorities' Roles and Responsibilities

In the case of clinical trials, The SU ethics process is followed by a separate ethics process governed by the Department of Health. The trial may also be registered on the South African National Clinical Trials Register (SANCTR), hosted on the website of the Medical Research Council.

The National Health Research Ethics Council (NHREC) is the national statutory body established in terms of the National Health Act (NHA). The NHREC's core responsibilities are to advise the Minister of Health, to set ethical norms and standards for health research, including clinical trials, and to advance research ethics in South Africa by promoting compliance by researchers and RECs using existing and new regulations and guidelines.

The South African Health Products Regulatory Authority (SAHPRA) is a statutory body established in 2018 in terms of the Medicines and Related Substances Act 101 of 1965 (the "Medicines Act") for the purpose to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of health products, including medicines, scheduled substances, medical devices, in vitro diagnostics, clinical trials and related matters in the public interest.

The Department of Health has established the South African National Clinical Trials Register (SANCTR), a web-based publicly accessible clinical trial register (www.sanctr.gov.za). Sponsors/Applicants must register all South Africa-based trials on the SANCTR. If there is no Sponsor, the PI must register the trial. Entry of the SAHPRA and REC approvals triggers allocation of a unique study number for each trial. No trial may commence without this DoH number.

The NHRC is a national legislative body responsible for the nature, scope and coordination of health research conducted by public health agencies. Its role is to ensure that priority health problems and needs receive sufficient attention and resources, and to advise the Minister of Health on the implementation of a comprehensive strategy for national health research. In determining priority targets, the NHRC considers the burden of disease, the cost-effectiveness of disease-related interventions, the impact of resources (especially at the lowest levels of health care), and the health needs of vulnerable individuals, including women, the elderly, children and the disabled. The health needs of entire communities may also be relevant.

The Provincial Health Research Committees (PHRC) collect and transmit information about local health needs and resource constraints to the NHRC. They are gatekeepers for public health care delivery sites. Only PHRC's registered with NHREC may also do ethics review of protocols.

## 6.2 Requirement of GCP certification

To obtain GCP certification, clinicians need to complete the relevant course. One option for obtaining GCP certification is CREDE (Clinical Research Education and Development): https://crede.co.za/.

The Enhancing Research Ethics Capacity and Compliance in Africa (ERECCA) course is also being hosted on the SUNOnline platform. The course is registered as an official short course with Stellenbosch University. The duration and content of the courses follow guidelines from the National Health Research Ethics Council. There are 12 offerings per year (one per month). Delegates who complete the course will be issued with a temporary certificate upon completion as the official SU certificate can only be issued at the end of the enrolled short course offering date. The course is CPD accredited with 10 Ethics and 2 General CPD points. For registration and further information on the ERECCA course please email bioethics@sun.ac.za or call 0219389600 ("GCP Courses - Clinical Research Training", n.d.)


If you have successfully completed the Division of Medical Ethics and Law (CMEL) Refresher GCP course (ERECCA) in 2019, 2020, 2021 and have a certificate that has not expired as yet, you are invited to access the GCP 2020. To view the video clip, please forward an Email to bioethics@sun.ac.za requesting the link. For further information please contact Ms Michelle Padiachee at the CMEL – 021 938 9600.

For more information about Good Clinical Practice course and certification please follow this link: http://www.sun.ac.za/english/faculty/healthsciences/cmel/Pages/CPD_Activities/GCP_training_courses.aspx.

## 6.3 Clinical / hospital process

When applying for the HREC for clinical trials, follow this advice for protocols:

1) Give as much detail as possible regarding the randomisation process. HREC prefers the randomisation to be done by a biostatistician.
2) Go into detail regarding each step from identifying patients to consent and how each arm of the clinical trial will be carried out.
3) Always state that your final publication will follow the PRISMA guidelines and distribution of data will follow the CONSORT guidelines.
4) When speaking about how you will store your collected data always state that it will be as per the latest GCP guidelines. These guidelines should be available once you complete your GCP course. (Crede is the HREC-preferred GCP course provider).
5) Make use of Stellenbosch language centre to edit your consent to a grade 8 level as this is the education level that HREC prefers; and to translate it to both Afrikaans and isiXhosa.
6) You do not have to agree with every modification request by HREC, as long as you respond why you disagree in your response letter.

Once your Protocol has been submitted to HREC and you receive your HREC number you can then apply to register your clinical trial at https://sanctr.samrc.ac.za**.** An HREC number is needed in order to register, but not yet HREC approval.

Do use the WHO IPD statement to word the last part of entering your trial, or your trial will be noted as incomplete. This statement can be found online in the WHO guidelines.

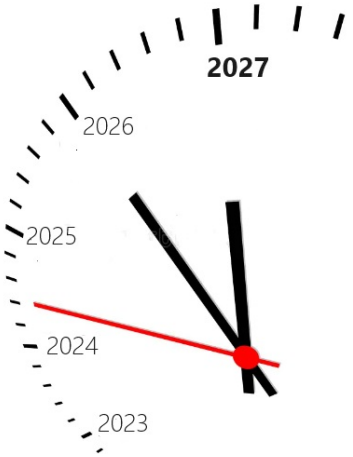
For provincial and institutional approval, you can apply at https://nhrd.health.gov.za. This website also alerts the institution about your trial, and you will be required to hand in a hard copy at Dawn Marwood's office (room 82 1st floor Tygerberg Admin).

Once approval has been obtained from all three bodies, the clinical trial can commence.

## 7. Next steps and progress reporting

As soon as the ethics approval letter bearing a student's name is submitted to tyg-phd@sun.ac.za, an evidence pack is prepared for consideration of your research project by the FMHS Committee for Postgraduate Research (CPR), thereafter by the Faculty Board, and finally by Senate. This process culminates in confirmation that a student may be registered for the PhD. This approval of a doctoral study by the highest academic governance body of the institution, is common across South African universities. No further action is required from the student, supervisor, or environment, in order to attain this. The Tygerberg Doctoral Office handles the submission for this governance process on your behalf. The committees involved in the governance process meet quarterly. The process can be expected to take about three months. Do heed this timeline, should you want to apply for a bursary for which the letter of institutional approval is required, as this item cannot be expedited.

A student will receive official notification from a faculty officer, once Senate approval is attained, approximately three months down the line from ethics approval. The dissertation that is eventually submitted for examination should bear the exact title as contained in the letter of Senate approval. Should a student want to modify their project, add objectives, or change the title to reflect a change of scope, focus, or level of the research, the entire review and ethics approval process may likely need to be repeated. Therefore, it is critical to take care with the accurate and eloquent articulation of your title, together with appropriate language usage, as much as all information included in the proposal and application documents.




Ethics approval is valid for a limited period depending on the level of risk of the project. A progress report for the renewal or reapproval of a project must be submitted to the REC by 2 months before the expiration of ethics approval, so that the submission can be reviewed prior to the expiry date. If the required information is not received by the deadline date, the application may not be reviewed and reapproved in time, leading to noncompliance with SOPs and suspension of the study until the protocol is re-certified. Ethics progress reports are focused on the practical execution of your research. Therefore, they differ from annual supervisor progress reports to the Tygerberg Doctoral Office and to your possible sponsors, who require information about your progress towards submitting a dissertation.

To fill out an ethics progress report, follow these steps:

Step 1: Click on your project ID
Step 2: Click on the project title
Step 3: Click create sub-form and select the relevant Progress Report Form
Step 4: Complete all the questions and upload the mandatory documents.

Remember to sign both signatures to submit the form.

Finally, please inform the relevant ethics committee once your project has been completed.

## 8. Conclusion

Along with a positive supervision relationship, project management is a prominent feature of a successful doctoral journey. Ideally, a doctoral student should aim to complete their practical research in 12 to 18 months following the receipt of ethics approval; and should submit a dissertation for examination by two years from the date of receipt of ethics approval. Students who are engaged in full-time employment may aim to spread this research and writing over three years, rather than two. Please reach out to the Tygerberg Doctoral Office for any support at all that you may require during the course of studies towards this advanced degree. You are invited to visit Office 1073 on the first floor of the Clinical Building from 9AM to noon, call 021 938 9813, or email tyg-phd@sun.ac.za. Our best wishes for your study!

## 9. Where to get further help with ethics applications

| | |
|---|---|
| Submit your review documents | Ms Brigitta Kepkey<br>Tygerberg Doctoral Office<br>Email tyg-phd@sun.ac.za<br>Tel 021 938 9813 |
| REC Helpdesk | Ms Biosha Thompson<br>Email biosha@sun.ac.za<br>Tel 021 808 9241 |
| REC: ACU and REC: BES | Mr Winston Beukes<br>Email wabeukes@sun.ac.za<br>Tel 021 808 9003 |
| REC: Social, Behavioural and Education Research (SBE) | Ms Clarissa Robertson<br>Email cgraham@sun.ac.za<br>Tel 021 808 9183 |
| HREC application and review process | Ms Elvira Rohland<br>Principal HREO Administrator<br>Email ethics@sun.ac.za or elr@sun.ac.za<br>Tel 021 938 9677 |
| Coordinator: HREC 1 | Ms Melody Shana<br>Email melodys@sun.ac.za<br>Tel 021 938 9657 |
| Coordinator: HREC 2 | Ms Brightness Nxumalo<br>Email brightness@sun.ac.za<br>Tel 021 938 9207 |
| Technical difficulties with Infonetica | Ms Jennifer de Beer<br>Functional Systems Custodian<br>Email jad@sun.ac.za<br>Tel 021 808 9444 |
| Submit your ethics approval letter | Ms Brigitta Kepkey<br>Tygerberg Doctoral Office<br>Email tyg-phd@sun.ac.za<br>Tel 021 938 9813 |

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World Medical Association. 2013. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. Accessed 5 December 2023, https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.


## 11. Acknowledgements


We would like to express our sincere appreciation to the following colleagues for their informative and helpful responses to our enquiries during the preparation of this guide:

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- Ms Biosha Thompson, SU Division for Research Development (DRD)
- Prof Ian Vlok, SU Division of Neurosurgery

Compiled by Liela Groenewald, Brigitta Kepkey & Chloë Krieger

## Tygerberg Doctoral Office

**www.sun.ac.za/fmhsdoctoraloffice**

Office 1073, Clinical Building, Tygerberg Campus

Research & Internationalisation Development & Support (RIDS)

Faculty of Medicine and Health Sciences

Stellenbosch University

Franci van Zijl Ave, 7505 Cape Town

PO Box 241, 8000 Cape Town

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Contact us:

Email **tyg-phd@sun.ac.za**

Tel 021 938 9813