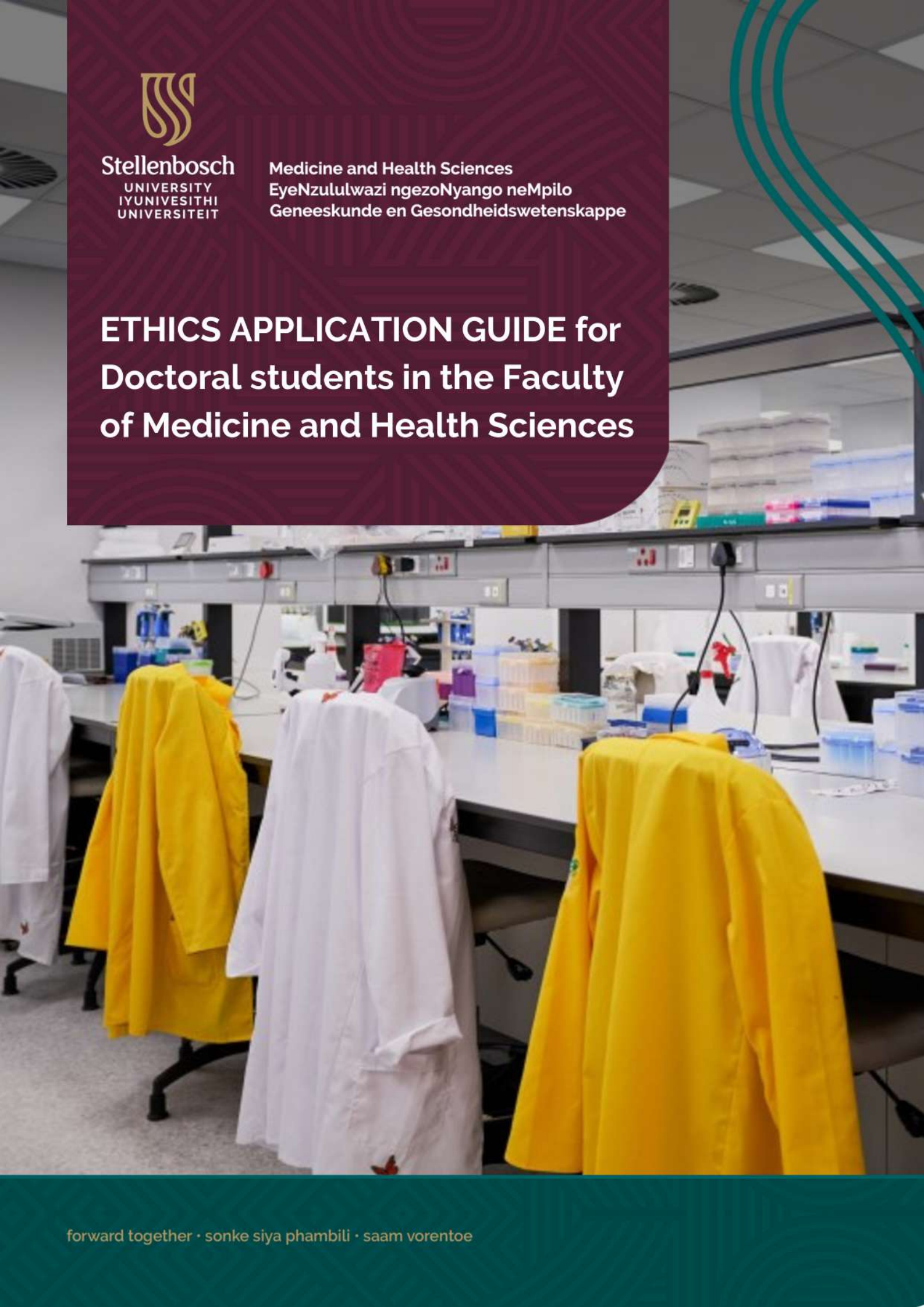**Stellenbosch**
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Medicine and Health Sciences
EyeNzululwazi ngezoNyango neMpilo
Geneeskunde en Gesondheidswetenskappe

ETHICS APPLICATION GUIDE for Doctoral students in the Faculty of Medicine and Health Sciences

Ethics Application Guide

for PhD students

in the Faculty of Medicine and Health Sciences

Tygerberg Doctoral Office
Updated 2026

Contents

Note to readers: The most up-to-date version of this guide is always available at this link.

1. Ethical approval for doctoral research in the FMHS

1.1 Introduction and rationale

Ethical oversight is critically important for ensuring respect for the dignity, rights and welfare of research participants and subjects, irrespective of biographical categories or socio-economic status; for the welfare of animals used in research; for the well-being and beneficence of affected communities and the environment; and for preventing the abuse of a researcher's power of influence. SU expects all researchers to "conduct a self-critical ethical appraisal of their own research and to obtain ethics approval from an appropriate university research ethics committee" if required by the Policy for Responsible Research Conduct at Stellenbosch University or other ethics policies and norms. Formal ethics approval is required for all (a) health research, (b) research involving interaction with or observation of human participants, (c) animal research, (d) research involving environmental and biological safety concerns, and (e) any other research that requires informed consent from individuals or permission from organisations or institutions.

The administrative aspect of the ethics process is largely student-driven, though the supervisor should provide mentorship and oversight, and should ultimately sign off on their students' submission on the ethics application platform, Infonetica. To assist students with their preparation (in collaboration with their supervisor/s), and to make the ethics application process accessible and transparent, the Tygerberg Doctoral Office has compiled this guide, with the generous inputs of colleagues affiliated to the ethics committees and various academic environments (see section 11). Kindly note that the SU policy, together with the official communication from an REC, is the authoritative communication on the matter; and supersedes 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 document, 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 three 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. That document outlines 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 <u>not</u> do. It is required to engage with the supervisor frequently, often via several drafts, to ensure that all supervisor feedback is addressed before the proposal is presented to the review panel. The review represents a first step in the ethics process, since it is a requirement that a representative of the most relevant ethics committee serves on every FMHS doctoral review panel. Upon successful completion of the review process, the following documents are submitted to 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) List of all reviewer comments with indication of how each has been addressed;
   d) Final proposal for ethics submission with review changes highlighted (not tracked);
   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. Timelines for meeting these milestones are specified in the FMHS Doctoral Guidelines. The application should be submitted without delay. Various documents are required to accompany an ethics application, including but not limited to:
   a) Confirmation of compliance with a faculty proposal review process;
   b) All reviewer comments together with an indication of where and how each comment was addressed;
   c) Final, revised research proposal / protocol for ethics submission and Synopsis;
   d) Any and all previous ethics approvals and institutional or access permission documents;
   e) CVs of the student, supervisor/s, and all parties to be involved in the research;
   f) Additional documents depending on the individual study and the relevant ethics committee.

1.3   Division for Information Governance

Before submitting an application for ethics approval 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, please use the service desk.

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

2.1   Research Ethics Committees (RECs) at SU

Every PhD candidate must apply for ethics approval to the most suitable SU Research Ethics Committee:
   a) Health Research Ethics Committee 1 (HREC1)
   b) Health Research Ethics Committee 2 (HREC2)
   c) Animal Care and Use (REC: ACU)
   d) Biological and Environmental Safety (REC: BES)
   e) Social, Behavioural and Education (REC: SBE)

Many PhD projects can be assessed by one, particular REC, but some projects will straddle the domain of more than one REC. The majority of FMHS doctoral research projects are considered either by the REC for Animal Care and Use, or the REC for Biological and Environmental Safety, or the Health Research Ethics Committees, or a comination of these, depending on the scope of the project. Applications to more than one REC may be submitted simultaneously.

Following successful completion of the PhD proposal review process (see 1.2, above) by the review panel, candidates should allow up to three months for the separate ethics process of a doctoral study, from application to outcome. Ethics approval for an individual study, OR – in cases where a parent study covers the PhD study - a letter adding a student as investigator to an existing, ethics-approved study, is accepted for the purpose of Senate admission. In case of the latter, the original or most recent ethics approval of the larger study should be submitted to the Tygerberg Doctoral Office (tyg-phd@sun.ac.za) as well. Note that ethics approval for a parent study does not automatically cover all objectives of a PhD study. In the case of complex project structures, students or their supervisors are invited to contact the REC representatives for advice individually before submitting an application to the REC.
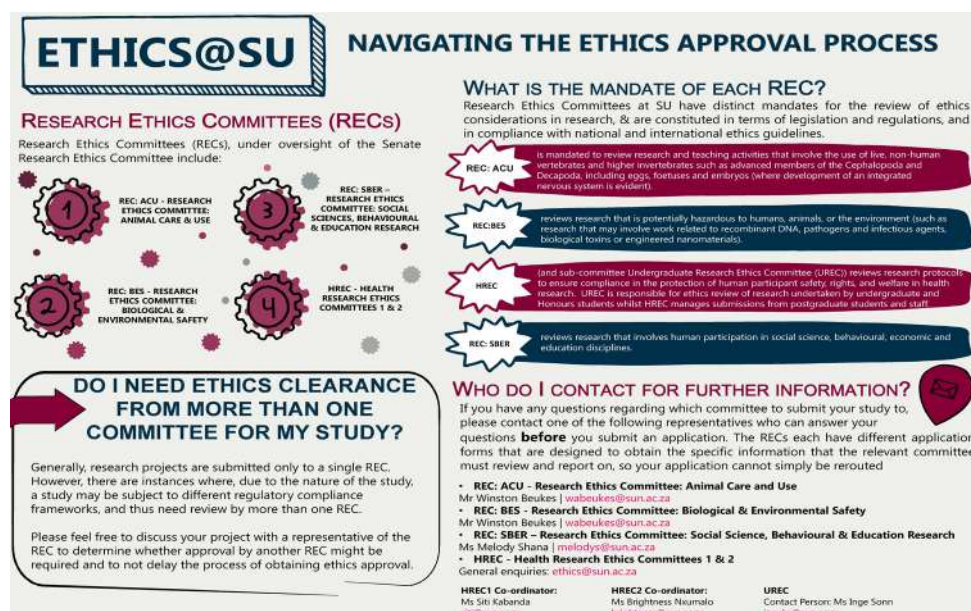
Infographic adapted from https://www.su.ac.za/en/research/research-development/integrity-ethics

RECs at SU are independent committees that are expected to review research proposals competently and in a timely manner. Next, the mandate of each REC will be discussed. This determines which committee has oversight of a specific study.

2.2   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.

For clinical trials only:

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

2.3   REC: Animal Care and Use

All activities that involve the use of live vertebrate animals (as defined by the SANS 10386: 2021) 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 REC: ACU is mandated by the National Health Research Ethics Council (NHREC), National Department of Health and the Senate Research Ethics Committee (SREC) of SU to function as an independent REC under the auspices of the SREC for the purposes of reviewing and approving all research and teaching activities involving animals, taking into consideration ethical and welfare aspects as well as scientific or educational value in accordance with accepted and applicable national and international normative and procedural standards.

2.4   REC: Biological and Environmental Safety

The REC: Biological and Environmental Safety (BES) provides review and regulatory oversight of all relevant research, teaching and testing activities at SU that involve recombinant DNA, genetically modified organisms (GMOs), infectious agents, select agents, biological toxins or cultured cell lines that fall into Hazard groups 2 to 4, and are not classified as exempt in section III-F and Appendix C of the NIH Guidelines, or that in any other way can pose a risk to the physical and biological environment, and to individuals. These activities must be approved by the REC: BES before protocol initiation.

2.5   Social, Behavioural and Education REC

The Social, Behavioural and Education (SBE) 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.

3. Application fees

The HRECs have a graded administrative fee structure in place, which is revised annually. Non-sponsored student projects for degree purposes, self-funded projects, projects funded solely from an SU departmental budget, Harry Crossley research, and studies funded with an NRF-bursary, are exempt from HREC fees. In some cases, PhDs secures funding which requires HREC fee payment.

The relevant payment instruction form (Payment instruction form: Clinical trial OR Payment instruction form: Health/human research) can be accessed on the HREC Fees page. The HREC will consider a well-motivated written request for reduction of fees. A decision will be made and communicated to the researcher in writing. Decisions taken should be viewed as final. HREC reserves the right to not review a research application, or to withhold an HREC letter, if administrative fees are outstanding.

The RECs: ACU, BES and SBE do not charge application fees in the case of researchers who are SU students or staff members.

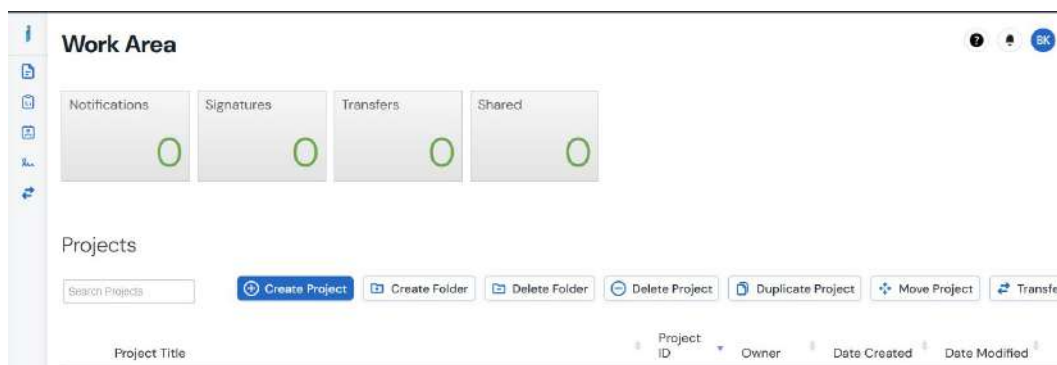## 4. Pointers for using the online SU ethics application platform

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 (a) submitting their application via their own SU profile, (b) monitoring their SU **student** email account throughout, and (c) as soon as possible after receiving ethics approval, for ensuring that the Tygerberg Doctoral Office (tyg-phd@sun.ac.za) has received an ethics letter bearing their name. To apply for ethics approval, follow the steps below.

a)   Login at https://applyethics.sun.ac.za/
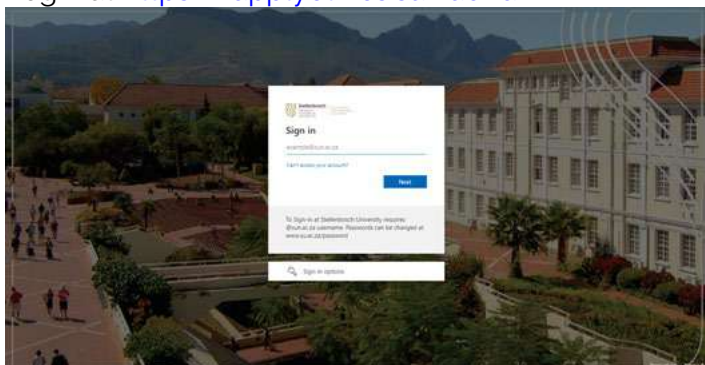
b)   Create your Project

NB: Select the correct application form for the specific REC to which you need to apply.

c) Complete the online form in full and upload all required documents

d) Share your application with your supervisor

e) Sign and Submit your application

f) Ethics review outcome: Changes required

Login and click on your project list. Where changes are requested, refer to the website or coordinator of the relevant REC. Make the necessary changes, save, and click on 'Submit' to resubmit your application.

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

4.2   Lone-standing studies

Below, please find a link to the general manual for loading an online ethics application on the Infonetica platform as created by the SU Division for Research Development (DRD).

https://files.su.ac.za/public/division-research-development/documents/2025-09/infonetica-quick-manual-researchers.pdf

PhDs may consist of several individual studies. Where the details of the later studies are to be informed by the results of the earlier studies, amendments need to be submitted for the later studies. An REC will only provide approval in the case of studies for which the methodology and all other aspects have been fully developed at the time of submitting an application for ethics approval.

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.
c) The roles of the researchers should be included to clearly delineate who is doing what research.

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.

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. The 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.

Certain studies, such as studies related to the South African Health Products Regulatory Authority (SAHPRA) or the USA Food and Drug Administration (FDA), *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 deemed BSL1 – whereas BLS2 and higher requires REC BES approval;
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.

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. The specifications for exemption from an application to the REC: BES, may be found at this link.

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. A wide range of projects are not suitable for minimal risk reviews. This list includes, but is not limited to (and the view of the REC will be definitive in this respect):
- 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.

Expedited reviews are also submitted as a new HREC application, with the request for an expedited review repeated in the cover letter. The turnaround time for review is 5 weeks after the submission deadline for minimal risk projects, though complex reviews may take longer. Please refer to the HREC Terms of Reference and SOP for more information.

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, kindly inform the HREO at ethics@sun.ac.za.

Note: It is highly unlikely that a request for a rapid/urgent review will be considered at PhD level.

5.   Deadlines and turnaround times

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

Doctoral students should allow three months for the ethics application process, from first submission by a meeting deadline, to receipt of a letter of approval. This is due to the various possible outcomes, ranging from approval, through approval with stipulationss, required modificationss, deferral, or rejection. More time may be needed in the case of a possible re-review by the full committee.

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:

1	2	3	4	5	6	7
Contact animal facility	Budget/funding	Apply for ethics Apply for permits	Apply for SAVC authorization	Calendar	Order animals	Start of study
6 months – year	6 months - year	3-6 months	3-6 months	2 months	2-3 months	GO!

6. Requirements for research in clinical facilities, clinical studies, and related experimental studies

6.1 Clinical studies and research in clinical facilities

South African's National Health Act, no 61 of 2003, requires all institutions to ensure the existence of an ethics review committee with compulsory ethics review of all health research involving humans.

When applying for the HREC – which has oversight of all clinical research and research in clinical facilities - 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 the final publication will follow the PRISMA guidelines and distribution of data will follow the CONSORT guidelines.
4) When speaking about how collected data will be stored, always state that it will be as per the latest GCP guidelines. These guidelines should be available once a GCP course has been completed. (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) A researcher does not have to agree with every modification request by HREC, as long as they indicate why they disagree in their response letter.

Once a Protocol has been submitted to HREC and an HREC number has been received, the application to register a clinical trial at https://sanctr.samrc.ac.za **can proceed.** 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, apply at https://nhrd.health.gov.za. This website also alerts the institution about your trial. In the case of studies based at Tygerberg Hospital, do also submit a hard copy to Ms Dawn Marwood, room 82, 1st floor, Tygerberg Hospital Admin, for evaluation by the Tygerberg Clinical Ethics Committee.

6.2 Roles and Responsibilities of regulatory authorities

In the case of clinical trials, the SU ethics process is followed by an ethics process governed by the Department of Health. The trial must 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 (https://sanctr.samrc.ac.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.

6.3 Clinical trials: Requirement of GCP certification

To obtain Good Clinical Practice (GCP) certification, clinicians must complete an accredited GCP course. First-time certification requires in-person attendance of a basic or beginner's course, such as those offered by CREDE (Clinical Research Education and Development).

Basic GCP certification is valid for three years. To maintain certification, clinicians must complete a GCP Refresher Course every three years. A GCP Refresher Course is available on the SUNOnline platform as a registered short course of Stellenbosch University. The course duration and content comply with guidelines from the National Health Research Ethics Council (NHREC). The course is offered twelve times per year, once per month. Participants who successfully complete the course receive an official Stellenbosch University certificate and transcript, issued at the end of the registered course period. The course is submitted annually for CPD accreditation. For registration and further information, email gcpcourse@sun.ac.za or call 021 9389074.

For more information, visit:

- Good Clinical Practice Refresher Short Course (SUNOnline)
- Clinical Research Education and Development (CREDE)

6.4 Research Insurance

All health research projects are automatically covered by SU insurance and there is no separate process for registering individual projects. In the case of contract and sponsored studies, sponsors are responsible for providing insurance.

Where research participants make use of their personal equipment, this must be stated clearly in the informed consent form (ICF) to ensure the participant has recourse to claim from SU insurance should there be damage to such personal equipment.

Where participants need to travel or use transport for research purposes, the researcher would be responsible for arranging such provision by contacting Mr Wium van Kerwel (wvankerwel@sun.ac.za).

7. Next steps and progress reporting

Each student is responsible for submitting their ethics approval letter to the Tygerberg Doctoral Office on receipt. As soon as the ethics approval letter bearing a student's name is submitted to tyg-phd@sun.ac.za, the research may commence.

At this point, the Tygerberg Doctoral Office prepares an evidence pack 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 easily be expedited.

A student will receive official notification from a faculty officer, once Senate approval is attained, approximately one term down the line from receipt of 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.

Annual progress reporting:
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. Any data collected whilst approval had lapsed, may not be used in the study and needs to be discarded. Ethics progress reports are focused on the practical execution of your research. Therefore, they differ from annual supervisor progress reports required by the faculty, which the Tygerberg Doctoral Office will request in October, and to your possible sponsors, who require information about your progress towards submitting a dissertation.

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

8. Conclusion

This guide has focused on the technical steps involved in ethics applications, and not on their substance. When sharing or distributing this resource, please provide this permanent link to the latest version of this document, rather than the PDF file. For a version more suitable for all other postgraduate students and researchers, please click here.

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 aim to 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!
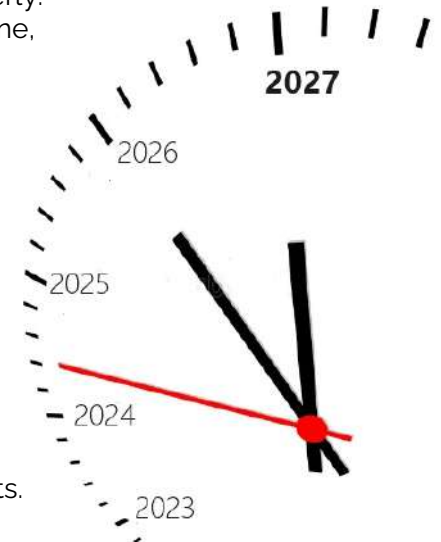
9. Where to get further help with ethics applications

Submit your proposal review documents	Ms Brigitta Kepkey Tygerberg Doctoral Office ✉ tyg-phd@sun.ac.za ☎ 021 938 9813
Ethics Helpdesk	Ms Biosha Thompson ✉ biosha@sun.ac.za ☎ 021 808 9241
REC: ACU and REC: BES	Mr Winston Beukes ✉ wabeukes@sun.ac.za ☎ 021 808 9003
Social, Behavioural and Education (SBE) REC	Ms Melody Shana ✉ applyethics@sun.ac.za ☎ 021 808 9183
HREC application and review process Infonetica technical queries (from HREC applicants)	HREO Administrator ✉ ethics@sun.ac.za ☎ 021 938 9677
Coordinators: HREC 1	Ms Siti Kabanda ✉ siti@sun.ac.za ☎ 021 938 9989
Coordinator: HREC 2	Ms Brightness Nxumalo ✉ brightness@sun.ac.za ☎ 021 938 9207
Submit your ethics approval letter	Ms Brigitta Kepkey Tygerberg Doctoral Office ✉ tyg-phd@sun.ac.za ☎ 021 938 9813

10. References

Animal Care and Use [Online]. 2023. Accessed 30 November 2023, http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics/animal-ethics.

Biosafety @ SU [Online]. 2023. Accessed 30 November 2023, http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics/biosafety-environmental-ethics.

Department of Health. 2020. *South African Good Clinical Practice: Clinical Trial Guidelines* [Online]. Accessed 12 March 2025, https://www.sahpra.org.za/wp-content/uploads/2021/06/SA-GCP-2020_Final.pdf.

GCP Courses - Clinical Research Training. [Online]. 2023. Accessed 30 November 2023, http://www.sun.ac.za/english/faculty/healthsciences/cmel/Pages/CPD_Activities/GCP_training_courses.aspx.

Health Research Ethics Office. About the Health Research Ethics Office (HREO) [Online]. 2023. Accessed 30 November 2023, http://www.sun.ac.za/english/faculty/healthsciences/rdsd/health-research-ethics.

Stellenbosch University. 2013. 'Policy on the Responsible Conduct of Research at Stellenbosch University'. Accessed 31 October 2025, https://files.su.ac.za/public/division-research-development/documents/2025-10/su-research-ethics-policy-v3-approved-council-28nov2022pdf.pdf.

Spies, E. 2023. 'A guide to planning a study involving animals'. Presentation in the DRD Research Ethics series, February 2024.

Stellenbosch University Research Information Management System Infonetica. [Online]. 2021. Accessed 30 November 2023, http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Documents/Ethics/20220516%20HREC%20Applicant%20Manual_SUNid%20info.pdf.

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

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Tygerberg Doctoral Office

www.su.ac.za/en/faculties/medicine/doctoral-office

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Research & Internationalisation Development & Support (RIDS)

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