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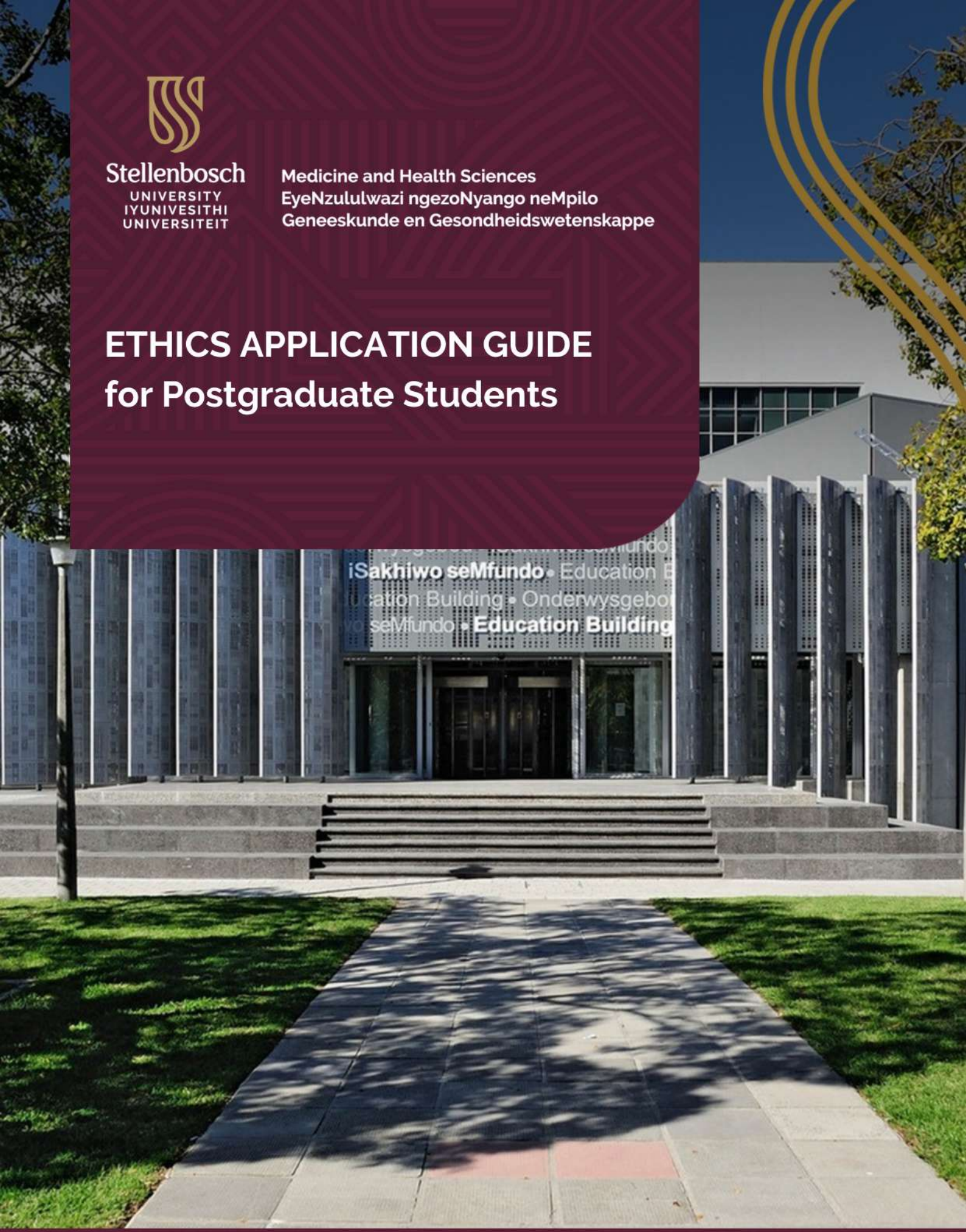
Geneeskunde en Gesondheidswetenskappe

ETHICS APPLICATION GUIDE for Postgraduate Students



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Ethics Application Guide

for Postgraduate Students

Updated 2026

Please ensure you are using the most up-to-date version of this guide, available at this link.

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1. Ethical approval for postgraduate studies

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 of a postgraduate student should ultimately sign off on their students' submission on the ethics application platform, Infonetica. To assist students enrolled for a postgraduate degree with their preparation - in collaboration with their supervisor/s - and to make the ethics application process accessible and transparent, this guide has been compiled with the generous inputs of colleagues affiliated to the ethics committees and academic environments (see section 11). Kindly note that the official communication from an SU ethics committee is the authoritative communication on the matter; and supersedes this guide.

1.2 From proposal development to ethics approval

Ethics applications for postgraduate studies usually follow a proposal review process. The research proposal is the first deliverable that a thesis or dissertation student is expected to produce. The document, typically 10 pages (up to master's level) to 20 pages (at doctoral Level) 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, and with the available resources, for a specific degree. Following successful completion of the proposal review process and ethics approval process, the practical research may commence.

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 postgraduate student conducting research must apply for ethics approval to the most suitable SU Research Ethics Committee:

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

Most postgraduate projects can be assessed by one, particular REC, but some projects will straddle the domain of more than one REC. Applications to more than one REC may be submitted simultaneously. Note that ethics approval for a parent study does not automatically cover all objectives of a postgraduate 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 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.

2.3 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.

2.4 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.

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.

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

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, postgraduates secure funding which requires HREC fee payment.

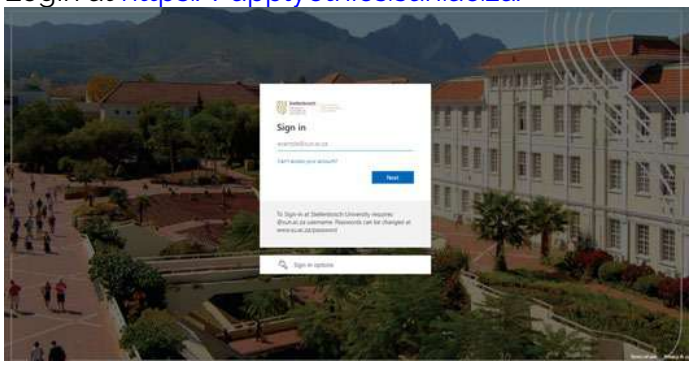
The relevant payment instruction form (Payment instruction form: Clinical trial OR Payment instruction form: Health/human research) can be accessed on the HREC Fees page. The HREC will consider a well-motivated written request for reduction of fees. A decision will be made and communicated to the researcher 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.

4. Pointers for using the online SU ethics application platform

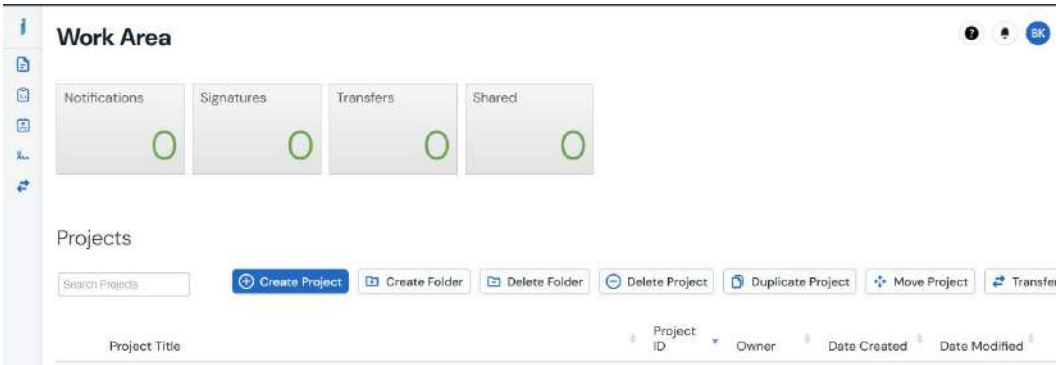
4.1 Infonetica platform

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 informing the relevant parties such as their supervisor, with the ethics approval letter. To apply for ethics approval, follow the steps below.

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

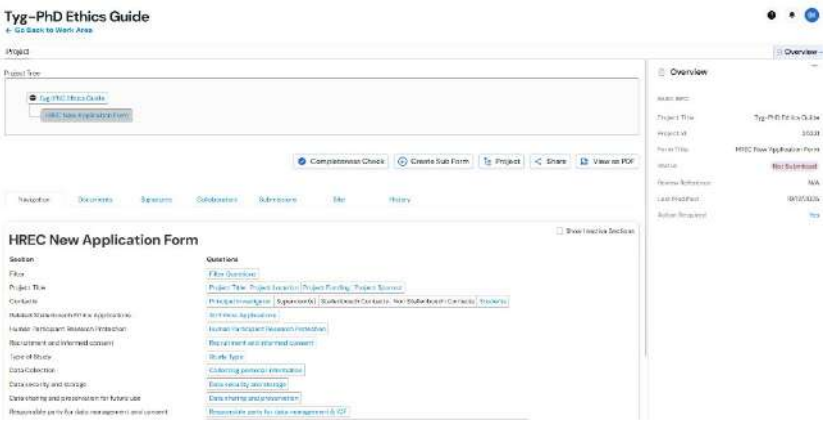


b) Create your Project

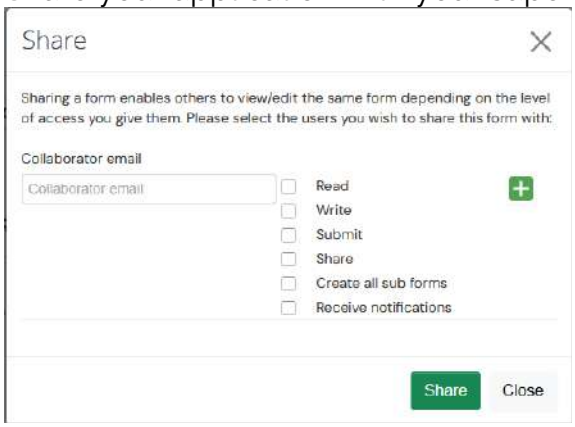


NB: Select the correct application form for the specific REC to which you need to apply.

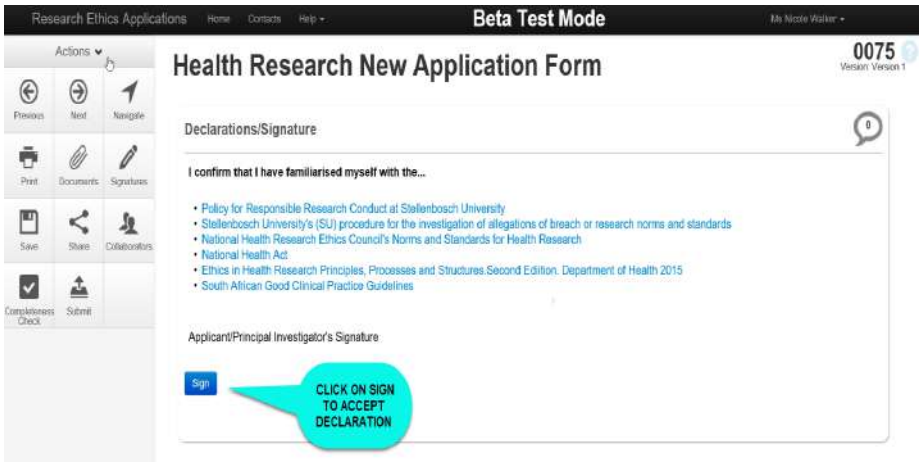
c) Complete the online form in full and upload all required documents



d) Share your application with your supervisor



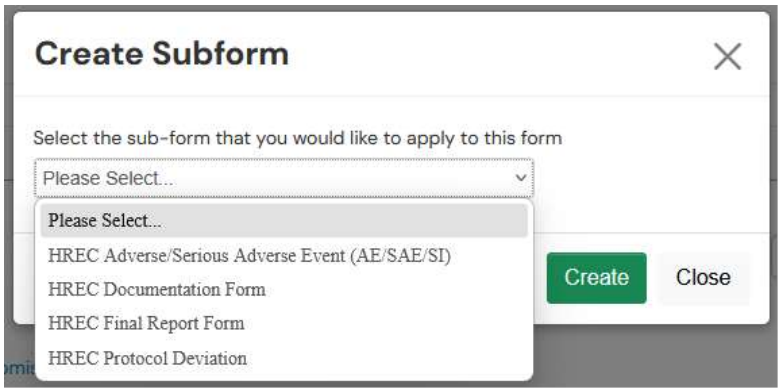
e) Sign and Submit your application



f) Ethics review outcome: Changes requested

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. (See link to HREC-specific guidance under 2.4 above.)

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

Postgraduate research may consist of more than one individual study. 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.

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.

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.

Certain studies, such as studies related to the USA Food and Drug Administration, *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 (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.

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

Note: It is highly unlikely that a request for a rapid/urgent review will be considered for degree studies.

5. Deadlines and turnaround times

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

Postgraduates 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:

6. Requirements for clinical research and research in clinical facilities

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.

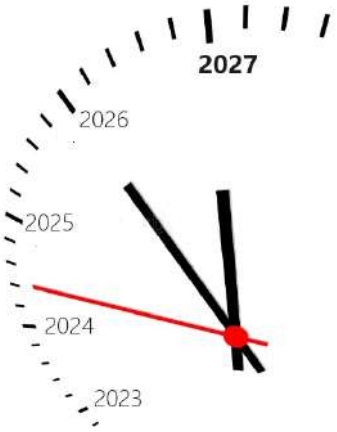
Where participants need to travel or use transport for research purposes, the researcher would be responsible for arranging such provision by contacting Mr Wium van Kerwel (wvankerwel@sun.ac.za).

7. Next steps and progress reporting

After receiving ethics approval, postgraduate students may commence with their practical research, reporting to their supervisor/s on a regular basis.

In the case of PhD students, an evidence pack is prepared for consideration of your research project by the relevant Faculty Board, and finally by Senate. This approval of a doctoral study by the highest academic governance body of the institution, is common across South African universities. 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 requiring the letter of institutional approval.

A doctoral dissertation must also bear the exact title as contained in the letter from Senate. 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 need to be repeated. Therefore, it is critical to take care with the accurate and eloquent articulation of the 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 two 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.

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. The aim was to bring together the diffused resources relating to ethics applications in a single resource. The communication directly from each REC supersedes this guide. When sharing or distributing this resource, please provide recipients with this permanent link to ensure that the latest version of this document is referenced, rather than to share the PDF file.

Postgraduate students should make contact with their academic environment and supervisor as soon as possible after successful admission; and familiarise themselves with the specific Guidelines applicable to their studies. Each academic environment has a specific approach and requirements for students enrolled in its programmes. The academic environment is also responsible for allocating a supervisor. A positive supervision relationship is the bedrock of a successful postgraduate research journey, along with sound project management, for which you should take personal responsibility.

Best wishes for your study!

9. Where to get further help with ethics applications

Unit	Contact person	Email	Telephone
Ethics Desk	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
SBE REC	Ms Melody Shana	✉ applyethics@sun.ac.za	☎ 021 808 9183
HREC application and review process	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

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11. Acknowledgements

We would like to express our sincere appreciation to the following colleagues for their informative and insightful responses to our enquiries as well as draft versions of this guide:

- Mr Winston Beukes, SU REC Animal Care and Use (REC ACU)
- Prof Marelize Burger, SU Health Research Ethics Committee 1 (HREC 1)
- Ms Charmaine Khumalo, SU Health Research Ethics Office (HREO)
- Prof Marianna Kruger, SU Health Research Ethics Committee 2 (HREC2)
- Prof Lieketseng Ned, SU Division of Disability and Rehabilitation Studies
- Ms Brightness Nxumalo, SU Health Research Ethics Office (HREO)
- Dr Emmanuel Obasa, FMHS Research and Internationalisation Development and Support (RIDS)
- Ms Clarissa Robertson, SU REC Social, Behavioural and Educational Research (REC SBE)
- Prof Carin Smith, SU Division of Pharmacology
- Dr Esté Spies, SU Principal Veterinarian
- Prof Hans Strijdom, SU Division of Medical Physiology
- Ms Biosha Thompson, Ethics office, SU Division for Research Development (DRD)
- Prof Evette van Niekerk, SU Division of Human Nutrition
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February 2024

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