

Division of Medical Physiology: A guide to ethics applications within the Division.

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Scope:

This document provides a brief overview of how to apply for ethics if you are associated with the Division of Medical Physiology at Stellenbosch University. This is applicable to all new projects or amendments for research that require ethical approval and will be performed either by a student or staff member registered (or affiliated in any way) with Stellenbosch University, if the research is to be performed at Stellenbosch University, or by a student/staff member at another site.

Responsibility:

It is the responsibility of all those conducting research under the auspices of Stellenbosch University (employees, students or visiting researchers at the University) irrespective of the source of funding, the field of research or the site where the research is conducted to ensure that the correct ethics approval is obtained prior to conducting the study.

REGAL-JC workstream within the Division of Medical Physiology:

The REGAL-JC workstream (Research, Ethics, Good Lab Practice and Journal club) ensures that all current research projects within the Division of Medical Physiology have the required ethical approval and provide assistance to ensure that the laboratory facilities are in line with the requirements for ethics approval. This includes, and is not limited to, ensuring that the animal holding facility complies with the South African Veterinary Council requirements, all scheduled drugs are stored in a locked safe and that human and animal blood products can be processed safely and discarded in the correct designated area. REGAL-JC also organize information sessions and provide guideline with regards to ethics. The REGAL-JC stream is being led by Dr Ingrid Webster and Dr Marguerite Blignaut. They co-lead the Research aspect of the workstream, and the Ethics aspect is headed by Dr Marguerite Blignaut.

Contact: Dr Ingrid Webster (iwebster@sun.ac.za)

Dr Marguerite Blignaut (mblignaut@sun.ac.za)

Scientific Research Overview Committee (SROC):

The Scientific Research Oversight Committee (SROC) falls under the REGAL-JC workstream and is an *internal committee tasked with reviewing research protocols* prior to submission to the designated ethics committees. Both the Ethics Committee: Animal Care and Use and Health Research Ethics Committees 1 and 2 require a signed Scientific Review Statement from the Division upon submission of an ethics application. This document can be obtained from the SROC after an internal review and implementation of the suggestions made by the reviewers.

SROC process:

It is the responsibility of the supervisor and student to identify the correct ethics committee and research protocol requirements. The student should write and complete the research protocol together with the supervisor, whereafter the supervisor should sign off on the research protocol prior to submission to the SROC. Once the SROC receives the protocol, the committee will identify two reviewers with knowledge in the specific field and submit the application to the reviewers. A minimum of two weeks and a maximum of three weeks will be allocated to identifying the reviewers and the review process. The reviewers complete an anonymous review form that evaluates the protocol and make suggestions (should it be required) to improve the protocol. The applicant will receive the reviewers' forms within 3-4 weeks after submission and will then have the opportunity to make changes. Once these have been implemented, the SROC will issue the applicant with a signed Scientific Review Statement that can be submitted together with the protocol and application.

Aim: the aim of the SROC is to improve the quality of submissions to the ethics committees and improve the chance of a successful application and approval.

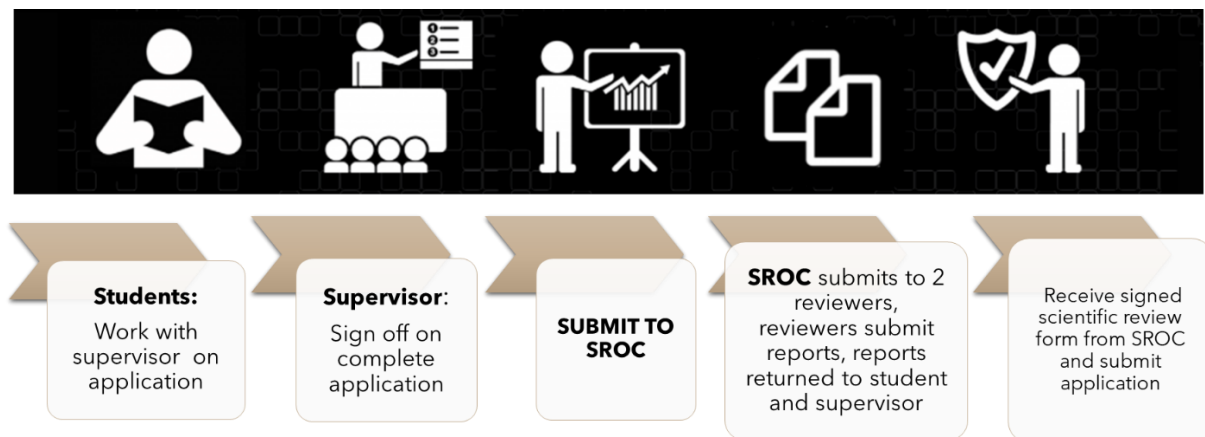


Figure: This schematic provides an overview of the SROC process.

Members of SROC:

Dr Shantal Windvogel: Dr Windvogel leads the SROC committee and has many years of experience as a committee member of the SU REC: Animal Care and Use.

shantalw@sun.ac.za

Prof Barbara Huisamen: Prof Huisamen has many years of experience with animal ethics and has previously served as a chair for Ethics Committee: Animal Care and Use.

Bh3@sun.ac.za

Dr Lihle Qulu: Dr Qulu has experience with both animal and human ethics, established, and leads an animal behavior laboratory, and is currently involved with several human research projects.

qulul@sun.ac.za

Research protocol and ethics application reviewers:

The reviewers of the research protocol submitted to SROC are recruited from the staff and post-doctoral fellows within the Division of Medical Physiology. All staff are required to complete at least one review annually. The review entails thoroughly reading the research protocol and providing detailed answers on the review form in a timely manner or within the time specified by the SROC. Should a reviewer not be able to review the application at the time of the request, the reviewer needs to inform the SROC immediately in order to identify an alternative reviewer. The reviewer's identity will always remain anonymous. The form should be completed in such a manner as to improve the quality of the research protocol and the applicant's chances of a successful application.

DIFFERENT ETHICS COMMITTEES AT STELLENBOSCH UNIVERSITY:

Stellenbosch University has five research ethics committees that all function under the Senate Research Ethics Committee. Links to the ethics committees are provided below. These pages include the submission process, submission dates and other information specific to the committee.

1. [Research Ethics Committee: Social, Behavioural and Education Research \(REC: SBE\)](#)
2. [Health Research Ethics Committee 1](#)
3. [Health Research Ethics Committee 2](#)
4. [Research Ethics Committee: Animal Care and Use \(REC: ACU\)](#)
5. [Research Ethics Committee: Biosafety and Environmental Ethics \(REC: BEE\)](#)
6. [Undergraduate-Research-Ethics-Committee \(UREC\)](#)

IMPORTANT: *The researcher/principal investigator/supervisor and student must identify the correct ethics committee and ensure that the submission is prepared sufficiently in advance to allow for the additional review time required by SROC. **Submissions to UREC (hons projects), REC: ACU and HREC needs to be submitted to SROC 1 month prior to the committee deadline.***

The infographic on page 4 of this document (also available at <http://www.sun.ac.za/english/research-innovation/Research-Development/Documents/Integrity%20and%20Ethics/ETHICS%20AT%20SU.pdf>) provides detailed information and contact details for each ethics committee.

NAVIGATING THE ETHICS APPROVAL PROCESS

RESEARCH ETHICS COMMITTEES (RECS)

Research Ethics Committees (RECs), under oversight of the Senate Research Ethics Committee include:



REC: ACU - RESEARCH ETHICS COMMITTEE: ANIMAL CARE & USE



REC: SBER - RESEARCH ETHICS COMMITTEE: SOCIAL SCIENCES, BEHAVIOURAL & EDUCATION RESEARCH



REC: BES - RESEARCH ETHICS COMMITTEE: BIOLOGICAL & ENVIRONMENTAL SAFETY



HREC - HEALTH RESEARCH ETHICS COMMITTEES 1 & 2

WHAT IS THE MANDATE OF EACH REC?

Research Ethics Committees at SU have distinct mandates for the review of ethics considerations in research, & are constituted in terms of legislation and regulations, and in compliance with national and international ethics guidelines.

REC: ACU

is mandated to review research and teaching activities that involve the use of live, non-human vertebrates and higher invertebrates such as advanced members of the Cephalopoda and Decapoda, including eggs, fetuses and embryos (where development of an integrated nervous system is evident).

REC: BES

reviews research that is potentially hazardous to humans, animals, or the environment (such as research that may involve work related to recombinant DNA, pathogens and infectious agents, biological toxins or engineered nanomaterials).

HREC

(and sub-committee Undergraduate Research Ethics Committee (UREC)) reviews research protocols to ensure compliance in the protection of human participant safety, rights, and welfare in health research. UREC is responsible for ethics review of research undertaken by undergraduate and Honours students whilst HREC manages submissions from postgraduate students and staff.

REC: SBER

reviews research that involves human participation in social science, behavioural, economic and education disciplines.

DO I NEED ETHICS CLEARANCE FROM MORE THAN ONE COMMITTEE FOR MY STUDY?

Generally, research projects are submitted only to a single REC. However, there are instances where, due to the nature of the study, a study may be subject to different regulatory compliance frameworks, and thus need review by more than one REC.

Please feel free to discuss your project with a representative of the REC to determine whether approval by another REC might be required and to not delay the process of obtaining ethics approval.

WHO DO I CONTACT FOR FURTHER INFORMATION?

If you have any questions regarding which committee to submit your study to, please contact one of the following representatives who can answer your questions **before** you submit an application. The RECs each have different application forms that are designed to obtain the specific information that the relevant committee must review and report on, so your application cannot simply be rerouted

- **REC: ACU - Research Ethics Committee: Animal Care and Use**
Mr Winston Beukes | wabeukes@sun.ac.za
- **REC: BES - Research Ethics Committee: Biological & Environmental Safety**
Mr Winston Beukes | wabeukes@sun.ac.za
- **REC: SBER - Research Ethics Committee: Social Science, Behavioural & Education Research**
Ms Clarissa Graham | cgraham@sun.ac.za
- **HREC - Health Research Ethics Committees 1 & 2**
General enquiries: ethics@sun.ac.za

DO I NEED ETHICS?

Oftentimes the aim of a specific study will fall under the umbrella of a “parent” study that has ethical approval and will not require new ethics approval or an amendment. However, if the study includes new or different aims, or address a new question within the current study an amendment to the “parent” study or new approval will be required.

The schematic on page 6, as provided by HREC, gives a detailed approach to determining whether a new ethics application is required within a current study. Currently no such schematic is available for animal ethics approval, and it would therefore be advised to contact Mr Winston Beukes.

If a Hons study will utilize human samples from a previous study, UREC approval MUST be obtained. This requires submission to SROC before submission to UREC.

Importantly, the MRC will accept ethics that were obtained at SU or other institutions to prevent duplication of applications. However, these approvals must be submitted to the MRC ethics committee as well. As per the SAMRC procedures, Research conducted for Masters and PhD degree purposes should first obtain approval from a registered research ethics committee of the institution where the degree will be obtained (i. e. Stellenbosch University), before the application is sent to the SAMRC-HREC for noting (see Scenario 1). This information was kindly provided by Dr S Koali, Research Integrity officer at SAMRC.

Scenario 1

- Where a student is registered with Stellenbosch University but based at the MRC, then Stellenbosch University will award the ethics clearance letter as per its statutes, but the students will be required to submit proof of ethics clearance letter and executive summary that was approved by Stellenbosch University or any other institution that has a registered REC to the SAMRC-HREC for noting/record. In this scenario, there is no dual ethics applications.

Scenario 2

- However, a different approach will occur whereby a registered student with Stellenbosch University wants to collect data at the SAMRC or the students wants to interview staff members at SAMRC, and/or the student wants to use animal facilities at SAMRC. Then in this case, dual ethics application will be required, because the student ought to obtain both Ethics approval and institutional approval.

HONOURS projects:

In the event where an honours student will make use of human samples that have previously obtained HREC approval (irrespective of institution), the application must be submitted to UREC. They will communicate with HREC (please see the link below for their internal procedures) and provide the required approval in the event where an amendment is not required with HREC. In the event where the student will work with previously frozen animal samples, a tissue notification must be submitted to REC: ACU with the ethics number with which the animal tissue was obtained.

Important: *If in doubt whether a new application, amendment or waiver is required, please contact the relevant ethics committee at the email addresses below:*

Research Ethics Committee: Animal Care and Use (REC:ACU)

Mr Winston Beukes: wabeukes@sun.ac.za

Research Ethics Committee: Biosafety and Environmental Safety (REC:BES)

Mr Winston Beukes: wabeukes@sun.ac.za

Human Research Ethics Committee 1 and 2 (HREC)

General enquiries: ethics@sun.ac.za

Research Ethics Committee: Social, Behavioural and Education Research (REC: SBE)

Ms Clarissa Graham: cgraham@sun.ac.za

Research Ethics Committee: Undergraduate research Ethics Committee (and hons studies working on human samples)

Dr Debbie Marais (Head: Undergraduate Research): debbiem@sun.ac.za

Does my MSc or PhD student need a separate HREC approval?

Case-by-case consideration is required for each student project according to the logic below

Core principles:

1. SU's ethical obligations to study participants, staff, and students must not be compromised.
2. Redundant review of the same research question and methods needs to be avoided, especially if the parent study has approval.

