

Ethics of health research at SU

Health research is defined as:

The systematic investigation into and study of materials and data sources in order to establish facts and reach new conclusions, contributing to the body of knowledge about:

- Biological, clinical, psychological, or social processes in human beings
- Improved methods for the provision of health services
- Causes of disease
- Effects of the environment on the human body
- Development or new application of pharmaceuticals, medicines, health technologies and interventions

(National Health Act 61 of 2003)

Research ethics aims to protect the welfare and dignity of research participants (and their health-related information/biological materials) while facilitating socially valuable research.

All health research, as defined by the National Health Act (61 of 2003), must undergo formal ethics review by a Research Ethics Committee (REC).

This infographic aims to simplify the process of applying for approval from the Undergraduate Research Ethics Committee for undergraduate and honours students at Stellenbosch University.

Undergraduate Research Ethics Committee (UREC) and the research ethics context



Research ethics context

- [Why is ethics review of research important?](#)
- [What informs the work of an REC?](#)



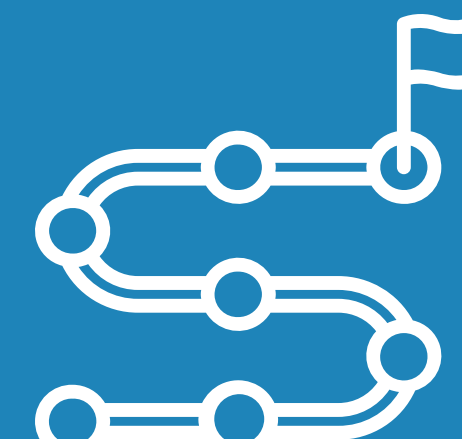
About UREC

- [About UREC.](#)
- [UREC members.](#)
- [Submission deadlines.](#)



Important policies and guidelines

- [HREC Terms of Reference and Standard Operating Procedures.](#)
- [Dept. of Health \(2015\) ethics guidelines.](#)
- [SU responsible research conduct policies.](#)
- [SU data management policy.](#)



About the online application process

- [How to submit a new ethics application.](#)
- [How to submit a response to modifications.](#)
- [How to submit an amendment.](#)
- [How to submit a progress report.](#)



Minimal risk research* defined as...

Research in which the probability and magnitude of harm is not more than that encountered in daily life or during routine physical or psychological examinations.



About UREC's review process

- Day after deadline: completeness check by UREC administrator.
- Allocated to 1 reviewer by UREC coordinator.
- First feedback letter sent 1-2 weeks after deadline.

*UREC only reviews minimal risk research

Online health research ethics applications



Minimum set of documents required

- [Online application form.](#)
- [Research protocol.](#)
- Protocol synopsis (2-page, summary of research protocol).
- [Budget.](#)
- [Investigator's Declaration form for every member of research team.](#)
- CVs for all research team members.
- [HoD signature form.](#)
- [HREC payment instruction form.](#)
- Data recruitment and collection materials.
- [Informed consent/assent forms OR waiver of consent request letter.](#)



Important information about the content of applications

- [A quick guide to submitting an ethics application.](#)
- [What UREC reviewers are looking for in an ethics application.](#)
- [Review criteria used by UREC.](#)
- [Link to online application site.](#)
- [What happens after submission of an application.](#)

Undergraduate and honours students' ethics applications will automatically be routed to UREC, which is a sub-committee of the Health Research Ethics Committee at the FMHS



Basic information for application form

- Degree information.
- Contact information of all members of your research team (students, supervisor/s, etc.).
- Details about linked projects and applications where relevant.
- General information about the project (title, objectives, research design, etc.).
- What type of sample/s your study includes (human participants, medical records, etc.).
- Details about research involving children, where relevant.
- Whether you'll be testing any medicines, devices, etc.
- Whether you'll be using diagnostic tests.
- Data management plan and privacy / confidentiality protections.
- Payment of participants.
- Disclosures of any conflicts of interest.
- You and your supervisor's sign off.

I don't know if I need ethics approval

- [Educational projects vs health research needing ethics approval.](#)
- [HREC guidance on what is exempt from ethics review \(pp. 21-22\).](#)

I need to remunerate research participants

- [National guidance on payment of research participants.](#)
- [HREC guidance on participant compensation \(pp. 67-68\).](#)

I'm doing a systematic or scoping review

- [Ethics of secondary research \(systematic reviews and scoping reviews\).](#)

My project is linked to a larger project

- [HREC guidance on whether ethics approval is needed if your study is linked to a larger project.](#)

I'm doing research at a health facility in the Western Cape

- [Undergraduate studies only need health facility permission, not W.C. provincial Dept. of Health.](#)

I'm doing research on Stellenbosch University students and/or staff

- [Apply for permission from the Division of Information Governance at SU.](#)

I'm doing quantitative research and need help with biostatistics

- [Apply for a Biostatistics Consult \(free for SU students\).](#)

I'm using secondary data or samples

- [Ethical considerations in secondary use.](#)
- [What consent is needed for use of secondary data/samples.](#)
- [What to include in a protocol using secondary data/samples.](#)

I need to ensure that my research is POPIA-compliant

- [Protection of Personal Information Act \(POPIA\) and research data management](#)

I'm doing a case report or case series

- [Ethical considerations in case reports/case series.](#)
- [Consent form for case reports/series.](#)
- [Submit a case report application.](#)

I'm doing qualitative interviews and am using a translator/transcriber

- [Get translators and transcribers to sign a confidentiality agreement.](#)

I need to apply for a waiver of consent

- [Conditions for applying for a waiver of individual consent.](#)

Frequently Asked Questions: What if...

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[UREC Frequently Asked Questions page](#)
[Information about HREC](#) | [Information about other SU RECs](#)

(Watch this space!)