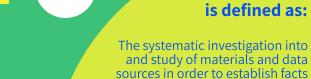
Ethics of health research at SU

Research ethics aims to protect the welfare and dignity of research participants (and their healthrelated 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.



and reach new conclusions, contributing to the body of knowledge about:

Health research

- Biological, clinical, psychological, or social processes in human beings
- Improved methods for the provision of health services
- Causes of disease

human body

 Development or new application of pharmaceuticals, medicines, health technologies and interventions

Effects of the environment on the

(National Health Act 61 of 2003)

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



Research ethics context

Important policies

and guidelines

- Why is ethics review of research important?
- What informs the work of an REC?

and Standard Operating

• Dept. of Health (2015) ethics guidelines.

Procedures.

- SU responsible research conduct policies. SU data management
- policy.

probability and magnitude

that encountered in daily life

or during routine physical or psychological examinations.

of harm is not more than

Research in which the



About UREC

- About UREC.
- **UREC** members.
- Submission deadlines.

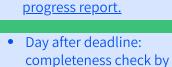


application process

ethics application. • How to submit a

How to submit a new

- response to modifications. How to submit an
- amendment. How to submit a





- UREC administrator. • Allocated to 1 reviewer by UREC coordinator.
- First feedback letter sent 1-2 weeks after deadline.

*UREC only reviews minimal risk research

Minimal risk

research*

defined as...

Online health research ethics applications



documents required

Minimum set of

- Online application form. Research protocol.
- Protocol synopsis (2-page. summary of research protocol).
- every member of research team. • CVs for all research team

Investigator's Declaration form for

- 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

an ethics application. • What UREC reviewers are

• A quick guide to submitting

- 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-Research Ethics Committee at the FMHS

I need to remunerate

research participants

• National guidance on payment of

• HREC guidance on participant

compensation (pp. 67-68).

research participants.



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
- Details about research involving children, where relevant.

records, etc.).

- 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.

ethics approval • Educational projects vs health

I don't know if I need

- research needing ethics approval. • HREC guidance on what is exempt from ethics review (pp. 21-22).
- My project is linked to

a larger project HREC guidance on whether

study is linked to a larger project. I'm doing research at a

ethics approval is needed if your

Western Cape • <u>Undergraduate studies only need</u> health facility permission, not

health facility in the

I'm doing research on

W.C. provincial Dept. of Health.

Stellenbosch University students and/or staff

Apply for permission from the <u>Division of Information</u> Governance at SU.

I'm doing quantitative

with biostatistics

research and need help

• Apply for a Biostatistics Consult



Frequently Asked Questions:

What if...

• Ethical considerations in secondary use. What consent is needed for use of

I'm using secondary data

or samples

• What to include in a protocol using secondary data/samples.

secondary data/samples.

I'm doing a systematic or scoping review

(systematic reviews and scoping reviews).

• Ethics of secondary research

report or case series • Ethical considerations in case reports/case series.

I'm doing a case

- 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.

(Watch this space!)

(free for SU students).

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UREC Frequently Asked Questions page <u>Information about HREC</u> | <u>Information about other SU RECs</u>

(Watch this space!)