HREC Submission Guidelines

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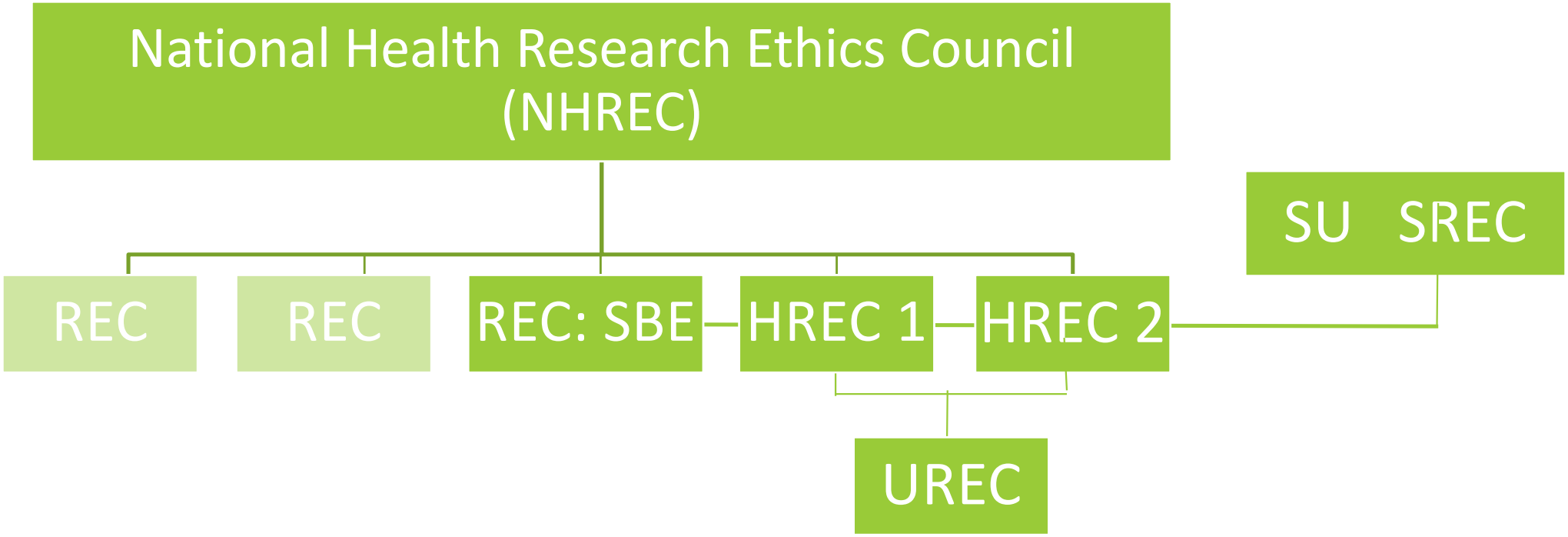
FEBRUARY 2024

OVERVIEW

1. Brief Introduction to health research structures at Stellenbosch University (SU) and the regulatory environment in South Africa (SA)
2. The primary mandate of Research Ethics Committees in SA
3. Responsible Conduct of Research
4. Navigating ethics submission at SU
5. Guidance on Submissions

Health Research Ethics Committees: South African regulatory context



What needs to be submitted to a Health Research Ethics Committee (HREC) for review?

By law, anything that can be classified as health research has to undergo formal review by a Health Research Ethics Committee

(National Health Act, 2003)

Health research involves…

As defined by the National Health Act

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, and health technologies and interventions***

REC Reviews in SA

RECs in SA are tasked with dual review process i.e.

A. **Scientific +**
B. **Ethics review**

Scientific review of research involves :

a. The scientific or scholarly validity of proposed research
b. The ethical implications of proposed research methods

Ethics review process evaluates a protocol on:

- The ability of the research to answer the proposed questions; and
- provides the REC with information it needs to determine whether regulatory criteria for approval are met (i.e. risks to participants are minimised by using procedures consistent with sound research design, and risks to participants are reasonable in relation to anticipated benefits, if any, and the important knowledge that may reasonably be expected to result)

The Primary Mandate of Research Ethics Committees in SA

PRIMARY MANDATEof RECs= protection of research participants' well-being and interests

- The objective of research is to develop generalisable knowledge to improve quality of life/health
- The aims of research are a recognised good i.e. public good

BUT

Research has the potential to inflict harms and to treat participants as "means to an end"

AIM of RESEARCH ETHICS: to treat participants with dignity and respect while they contribute to the social good

Ethics may help us find the 'least harmful' route

Responsible conduct of research (RCR)

RESEARCH ETHICS

"the ethical design of the protocol"

Thoughtful application of **research ethics principles** and **compliance** with, local and international laws, regulations and guidelines

REC review

RESEARCH INTEGRITY

"the moral conduct of the investigator"

Moral sensitivity, virtuous behaviour (*honesty*, *responsibility*, *trustworthiness*, *fairness*, *accountability* and *high regard for the scientific record)* and **professional standards**

PEER review

To which REC do I submit?

- SU RECs have developed the following helpful infographic to help researchers navigate

Click here to access this online, via http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics

To which REC do I submit?

- Per SOP any research involving health care devices/interventions to HREC

- Research to be conducted at a health facility/institution to HREC – whether public or private

- When in doubt - CONSULT

HREC Operations

Meeting dates:

- **HREC1: meets on the first (1st) Wednesday** of the month from February to December

- **HREC2: meets on the third (3rd) Wednesday** of the month from January to November

- **Both HRECs are in recess in December**

- **Researchers need to:**

(i) **Plan ahead to ensure timely submission**

(ii) **Budget sufficient time to allow for review, communication of outcomes, and for submitting responses**

HREC 1 Meetings and Submission Deadlines

SUBMISSION DEADLINE 12h00	HREC 1 MEETING 13h00
29 November 2023	07 February
31 January	06 March
28 February	10 April
27 March	08 May
02 May	05 June
29 May	03 July
26 June	07 August
31 July	04 September
28 August	02 October
25 September	06 November
27 November	**05 February 2025**

HREC 2 Meetings and Submission Deadlines

SUBMISSION DEADLINE 12h00	HREC 2 MEETING 13h00
15 November 2023	17 January
10 January	21 February
14 February	20 March
13 March	17 April
10 April	15 May
08 May	19 June
10 July	14 August
07 August	18 September
11 September	16 October
09 October	20 November
13 November	**15 January 2025**

How HREC operates at SU

Researchers submit electronic applications for review and approval via Infonetica©

The submission is categorised based on the study risk level or participant vulnerability/ capacity to consent as either:

- Expedited review; OR

- For full committee review

Important links

- The link to create and submit a new ethics application: http://applyethics.sun.ac.za
- The link to the Health Research Ethics Office where all the forms, instructions, submission dates, and resource documents can be found: www.sun.ac.za/healthresearchethics

Getting started

- Make sure you leave **enough time** to complete the online application before the submission deadline

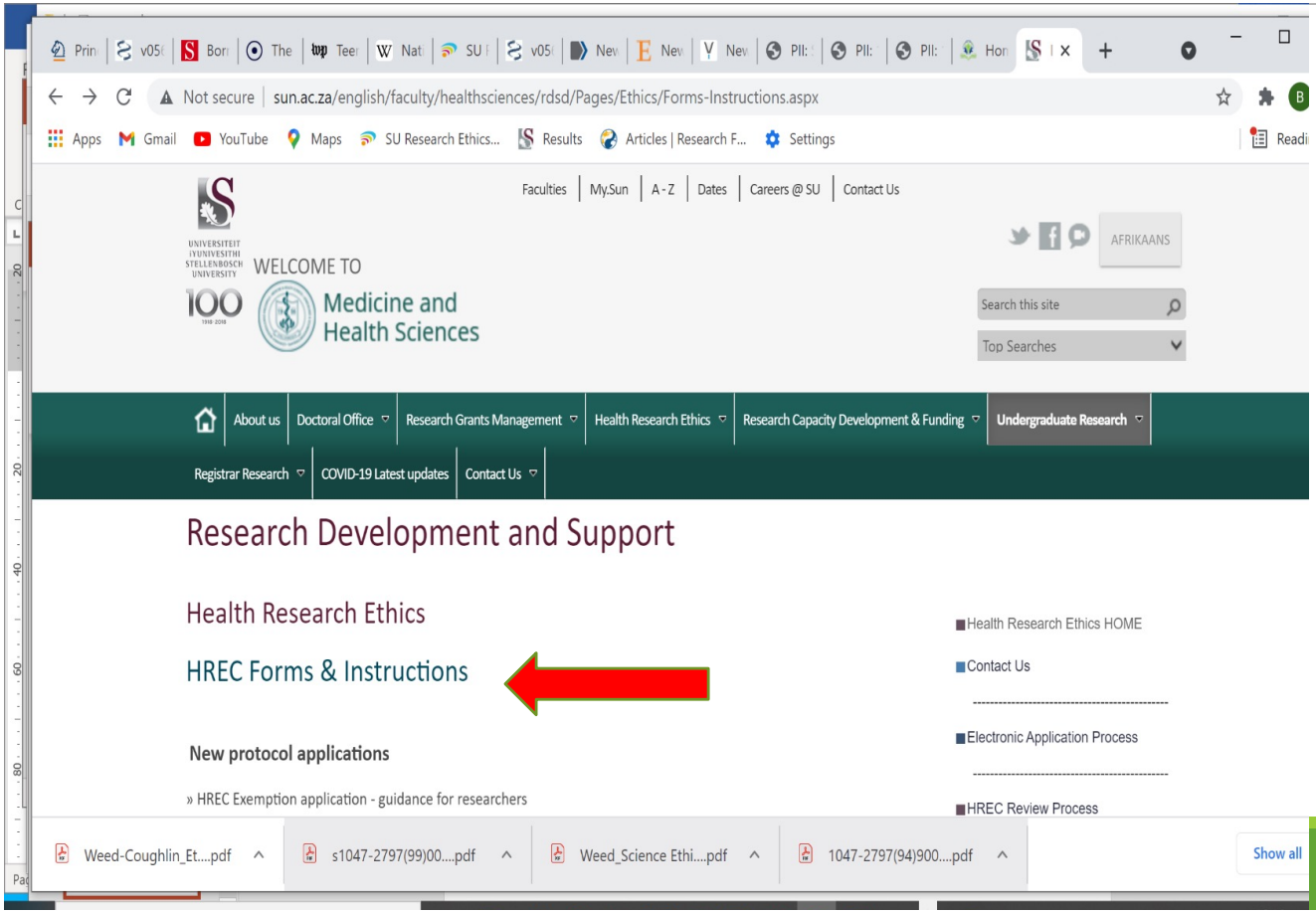
- Check the **submission deadlines** online to ensure you submit on time (see HREC website: Submission dates). Applications must be submitted by 12:00 (midday) on the deadline (HREC)

- Make sure you have active SU credentials (i.e., **SU username and password)** so that you can log on to the online application system (http://applyethics.sun.ac.za) (see below)

- Ensure that you have all the **information** you need to complete the electronic (online) application form (see below)

- Ensure you have all the **documents** you need to attach to your online application form – suggest you look at the requirements, have all your documents in a folder ready to upload

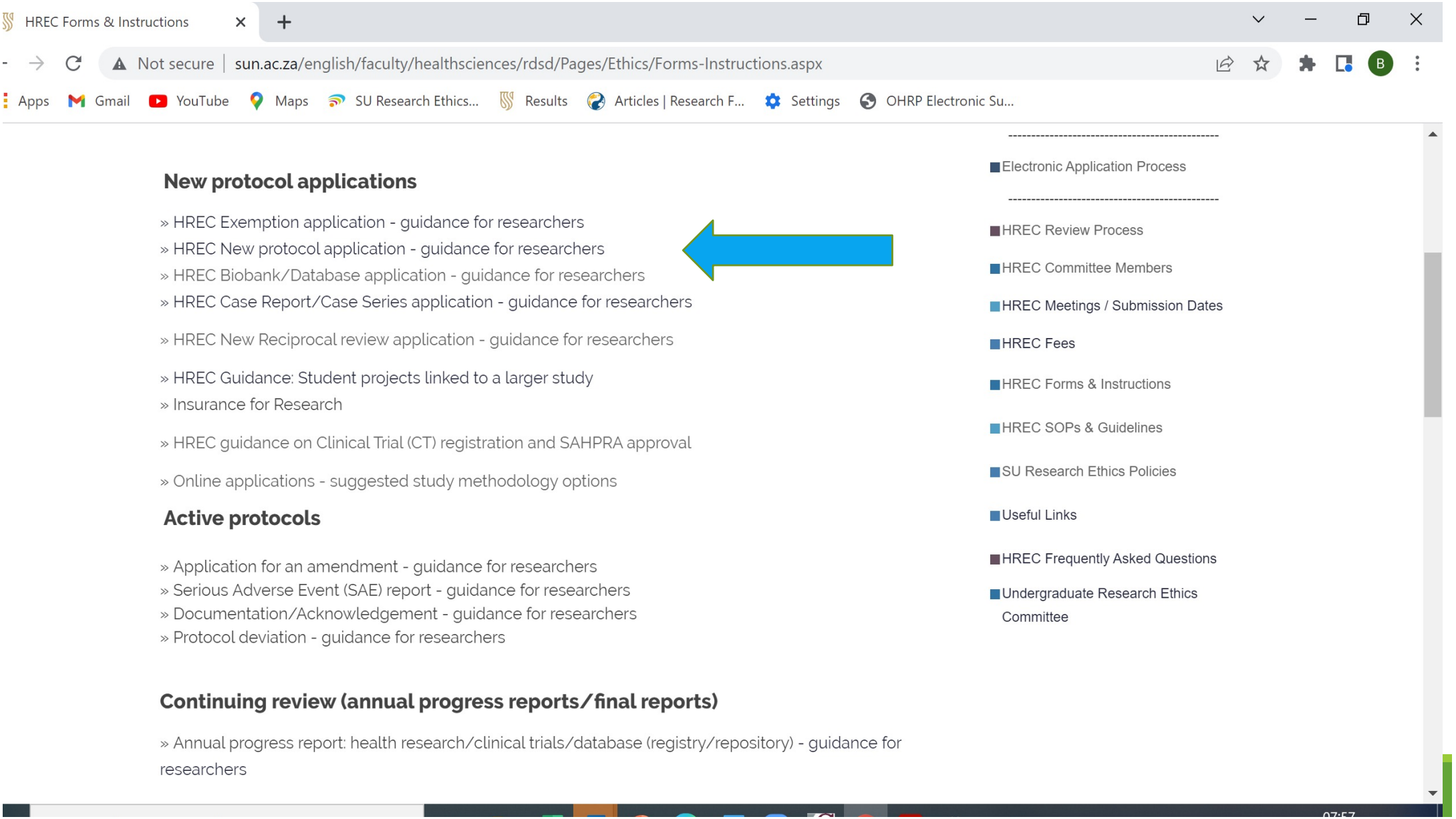
Navigating the submission process



✓Online application system via Infonetica platform

✓http://www.sun.ac.za/english/faculty/healthsciences/rdsd/ethics_application_package

- HREC Website provides submission and meeting dates:
- http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics/Meetings-Submission.aspx


HREC Forms & Instructions
Not secure | sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics/Forms-Instructions.aspx
Apps
Gmail
YouTube
Maps
SU Research Ethics...
Results
Articles | Research F...
Settings
OHRP Electronic Su...
New protocol applications
» HREC Exemption application - guidance for researchers
» HREC New protocol application - guidance for researchers
» HREC Biobank/Database application - guidance for researchers
» HREC Case Report/Case Series application - guidance for researchers
» HREC New Reciprocal review application - guidance for researchers
» HREC Guidance: Student projects linked to a larger study
» Insurance for Research
» HREC guidance on Clinical Trial (CT) registration and SAHPRA approval
» Online applications - suggested study methodology options
Active protocols
» Application for an amendment - guidance for researchers
» Serious Adverse Event (SAE) report - guidance for researchers
» Documentation/Acknowledgement - guidance for researchers
» Protocol deviation - guidance for researchers
Continuing review (annual progress reports/final reports)
» Annual progress report: health research/clinical trials/database (registry/repository) - guidance for researchers
Electronic Application Process
HREC Review Process
HREC Committee Members
HREC Meetings / Submission Dates
HREC Fees
HREC Forms & Instructions
HREC SOPs & Guidelines
SU Research Ethics Policies
Useful Links
HREC Frequently Asked Questions
Undergraduate Research Ethics Committee

Categories of Submission

New Applications

a. **Health Research Projects**

b. Clinical Trials

c. Case Reports

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d. Exemption: study involves secondary data e.g. systematic reviews, scoping reviews, re-analysis of data sets in the public domain based on new research questions, meta-analyses

e. Databases/registries/bio-banks

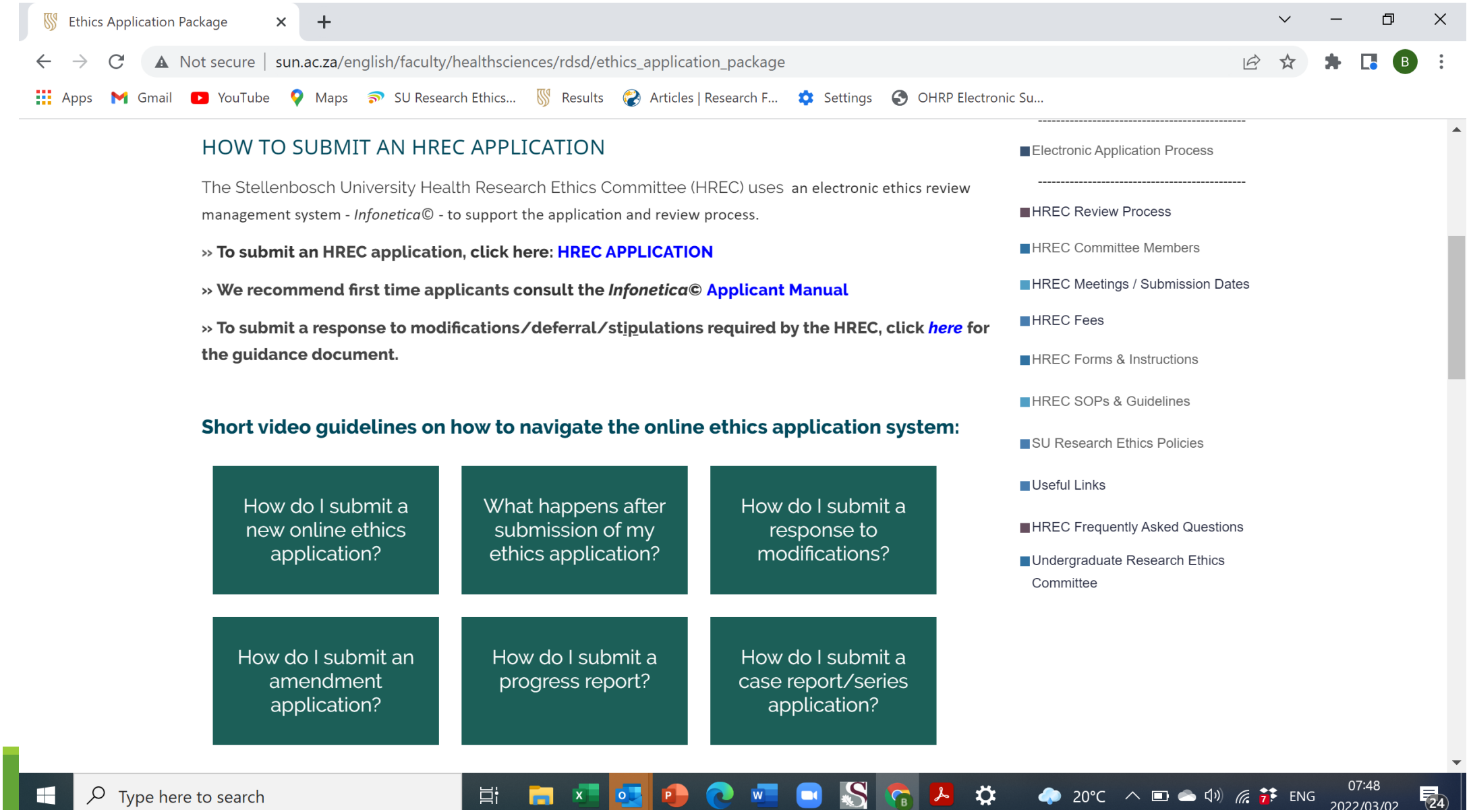
Ongoing Submissions

(i) **Amendments**

(ii) **Annual Progress Reports (PR) (in SA research is approved for 1 year and then based on PR continued ethics approval each year until Final Report upon completion of study)**

(iii) **Protocol Deviations**

(iv) Adverse Events


Ethics Application Package
Not secure | sun.ac.za/english/faculty/healthsciences/rdsd/ethics_application_package
Apps
Gmail
YouTube
Maps
SU Research Ethics...
Results
Articles | Research F...
Settings
OHRP Electronic Su...
HOW TO SUBMIT AN HREC APPLICATION
The Stellenbosch University Health Research Ethics Committee (HREC) uses an electronic ethics review management system - Infonetica© - to support the application and review process.
» To submit an HREC application, click here: HREC APPLICATION
» We recommend first time applicants consult the Infonetica© Applicant Manual
» To submit a response to modifications/deferral/stipulations required by the HREC, click here for the guidance document.
Short video guidelines on how to navigate the online ethics application system:
How do I submit a new online ethics application?
What happens after submission of my ethics application?
How do I submit a response to modifications?
How do I submit an amendment application?
How do I submit a progress report?
How do I submit a case report/series application?
Electronic Application Process
HREC Review Process
HREC Committee Members
HREC Meetings / Submission Dates
HREC Fees
HREC Forms & Instructions
HREC SOPs & Guidelines
SU Research Ethics Policies
Useful Links
HREC Frequently Asked Questions
Undergraduate Research Ethics Committee
Type here to search
20°C
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2022/03/02

Review Outcomes

i. Approved

ii. Approved with stipulations

iii. Approved with modifications (minor or significant)

iv. Deferred

v. Rejected or

vi. Referred to Committee Meeting

(in the case of expedited reviews where reviewer feels that additional input of the committee is required to reach a decision)

Review decisions: what do they mean?

Approved	Approved with stipulations	Modifications required	Deferred
Study has ethics approval and can proceed for period of one year after date of approval.	Research can begin subject to certain conditions. The responsibility for meeting these conditions rests with the researcher. The stipulations must be submitted to the ethics committee to keep on file.	Changes need to be made to the application / protocol and re-submitted to HREC, BEFORE data collection can proceed. The primary reviewer will review these changes and once satisfied will inform the Chair, who signs off on the final approval.	Significant parts of the protocol need rethinking and rewriting. Rewrite and resubmit. This will be sent for a new full committee review.

FEEDBACK ON REVIEW OUTCOMES: CHECK STATUS of SUBMISSION

HREC1 Co-ordinator:

Ms Melody Shana

melodys@sun.ac.za

HREC2 Co-ordinator:

Ms Brightness Nxumalo

brightness@sun.ac.za

Creating the online application form

- Log in to the *Infonetica* ethics application site using your SU username and password: http://applyethics.sun.ac.za
- Only applicants with an active SU username and password will be able to access the online ethics application system with their SU username and password
- If you experience problems with your SU username and password, contact the SU IT Service Desk. (You can reset your SU password by way of the SU password self-help app).
- For external collaborators: It is a department/division's responsibility to create an SU engagement via SUNid and request an SU username and password for external collaborators. This cannot be done by the ethics office.

Why is it important to have an active SU username and password?

- When you log in with your SU credentials – i.e. your SU username and password - the *Infonetica* system automatically pulls in your contact information from other SU systems.

- ***N.B.*** **The SU email address that is pulled in from the relevant source system will be the one that is used by the ethics office to communicate all feedback regarding your ethics application. The relevant department that you are registered with must also be correct.**

- It is therefore essential that you ensure that your correct department and contact details are loaded on the HR, Student Information or SUNid systems of identity, in order for the correct information to be populated on *Infonetica*

Assistance with SUN-IDs, usernames & passwords

- SUN-ID guidance:
  http://www0.sun.ac.za/itservices/useradm/sunid.htm
- Username guidance:
  http://infoteg.sun.ac.za/useradm/usernames.htm
- Password guidance:
  http://infoteg.sun.ac.za/useradm/passwords.htm
- Password self-help:
  https://web-apps.sun.ac.za/user-password-manage/#/home

“Ethics” is not just a section at the end!

8 benchmarks of ethical research	Where should these feature in the research protocol?
1 Community participation	1. Research methods section
2 Social value	2. Background/literature review
3 Scientific validity	3. Research methods section
4 Fair selection of participants	4. Research methods section
5 Favourable risk / benefit ratio	5. Ethics section
6 Independent review	6. Ethics section (mention)
7 Adequate informed consent	7. Research methods section
8 Ongoing respect for dignity	8. Multiple sections
8.1 Confidentiality	8.1 Ethics section
8.2 Feasible budget	8.2 Budget section
8.3 Dissemination of findings	8.3 Ethics section

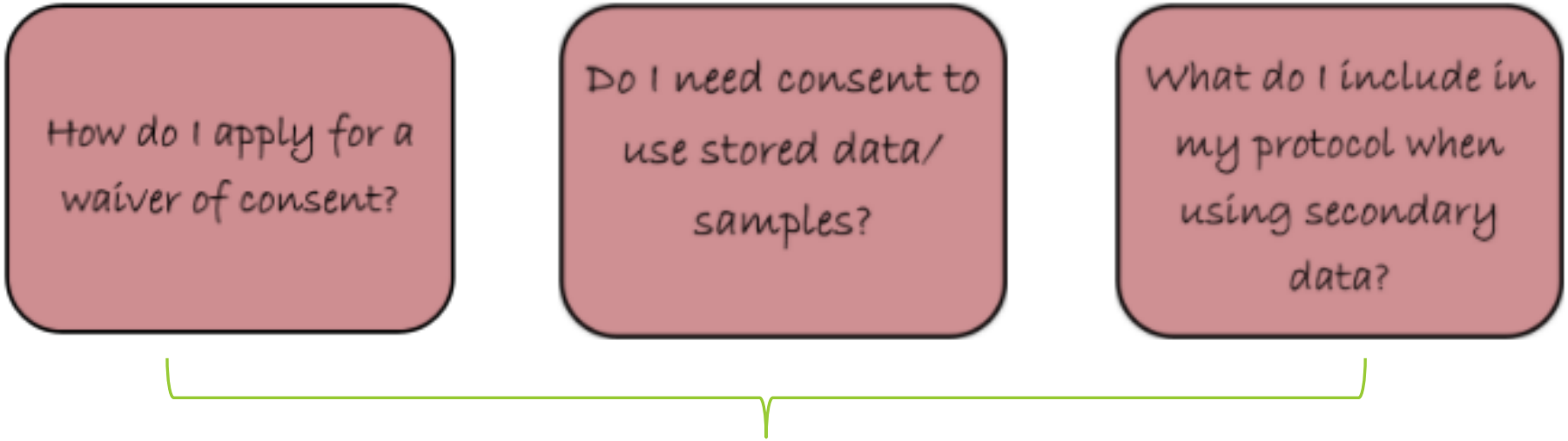
Frequently asked questions resources

Doing quantitative research

Doing research involving SU staff or students

Doing research in health facilities

Frequently asked questions resources



Documents required for health/student ethics applications *(1)*

This is the **minimum set of documents** you need to have prepared to attach to your online application form. Additional documents may be required that pertain to specific aspects of your study.

- **Research protocol** (also called a research proposal)
- **Protocol synopsis** (a 2-page summary of your research protocol)
- **Two page CV** for all members of the research team (students and staff)
- Completed and signed **Investigators' Declaration forms** for all members of the research team (can be found on the HREC Forms and Instructions webpage)
- **Research budget** (including whatever costs you anticipate in your study)

Documents required for health/student ethics applications *(2)*

- **HREC payment instruction form** (can be found on the HREC Forms and Instructions webpage. Must be uploaded even for student projects that are exempt from payment of fees)
- **Informed consent and assent forms** if research involves human participants
- Formal **waiver of consent request letter** if research involves record review and other relevant types of research that may qualify
- **Data collection materials** (e.g. questionnaire, interview guide, data extraction sheet) and recruitment materials where relevant (e.g. emails, posters, podcasts and so forth)
- **Signature page signed by the HoD** of your department (this can be found on the HREC Forms and Instructions webpage)

Ethics of health research at SU

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.

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)

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

Frequently Asked Questions: What if...

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

THE INFORMED CONSENT PROCESS

Minimal risk health research brief guide

Informed consent is a conversation and a process, not simply the signing of an informed consent form. The process continues throughout and beyond the research study.

Informed consent is made up of 5 components: information, understanding, voluntariness, competence/capacity, and documentation of consent. Respect for autonomy and dignity must be upheld during and after the research is completed.

1 INFORMATION

Information that should be included on the information and consent form minimally includes:

- What the activity is that they are being asked to participate in.
- The purpose of the activity, making it clear that this is for research purposes.
- Where and when it is being conducted and the duration of the activity.
- A clear description of what their participation will involve and how long it will take.
- A clear description of the potential risks and benefits of participation.
- What will be done with and who will have access to the information they provide.

WRITTEN

- Have a conversation with potential participants to explain what the research is about, what their participation would entail, and that they have the right to choose not to participate or to withdraw with no negative consequences.
- Give time to ask questions and reflect on whether they would like to participate.
- Check in and allow for questions throughout data collection.
- Download informed consent templates from the HREC Forms & Instructions page.

VERBAL

2 UNDERSTANDING

WRITTEN

- The information leaflet should be written in simple (grade 8 level) language. Refer to consent form readability guidance and summary.
- The information sheet should be written in a conversational style, as if you are speaking to the participant and explaining the research to them.
- Information and consent sheets should be available in the first language of all relevant participant groups.

- Encourage conversation and questions as this helps you to check understanding.
- Allow for time for people to reflect and consider whether participation is consistent with their values and interests.
- Observe verbal and non-verbal cues of understanding.
- Consider issues of first/second language and the need for interpreters.

VERBAL

3 VOLUNTARINESS

WRITTEN

Depending on what information is - or is not - included in the information and consent sheet, participants may understand the information provided but still may not feel free to choose. For example:

- Being promised undue incentives

People may not feel free to choose because of implicit or explicit actions of researchers, including:

- Coercion to participate (threat of negative/punitive consequences).
- Undue influence to participate. This may be because of perceived authority and

POPIA AND RESEARCH DATA MANAGEMENT

This infographic was created by the Undergraduate Research Ethics Committee (UREC) for **undergraduate and honours student researchers** conducting **minimal risk research**. It aims to provide a bird's-eye-view summary of the application of the Protection of Personal Information Act (POPIA) to the processing of personal information for research purposes.

Student researchers should complete the Division for Information Governance's **privacy impact self-assessment** to determine the risk level of the data they will be collecting. Some conditions that apply to more than minimal risk-level data are not addressed in this infographic; in such cases, researchers should consult the ASSAf POPIA Code of Conduct for Research for information pertinent to their research.

Student researchers are advised to read this document in conjunction with the ASSAf POPIA Code of Conduct for Research and guidance from SU's Division for Information Governance.

Note: POPIA guidance is still evolving so check [illegible] regularly for infographic updates

Definitions

- **Personal information:** includes information about a person's demographics, background, biometrics, contact details, identifiers (e.g., ID number, photos), opinions and preferences, financial information, correspondence, and criminal record.
- **Special personal information:** includes information about children, and information about a person's race or ethnic origin, health, DNA, religious or philosophical beliefs, political opinions, sex life, and criminal behaviour.
- **Data subject:** the research participant whose information is being processed during the research project.
- **Principal Investigator:** the leading researcher on a project who takes responsibility for the research.
- **Responsible party:** Practically, the responsibilities of the responsible party outlined in POPIA will fall on the researchers designing and leading the research study. Legally, ultimate responsibility lies with the research institution with which the Principal Investigator is employed or affiliated.
- **Information Officer:** The designated individual assigned by the university to ensure compliance with POPIA.

POPIA's 8 conditions for lawful processing

1. **Accountability** (POPIA Chapter 3, Part A, section 8)
2. **Limit processing** (POPIA Chapter 3, Part A, sections 9-12)
3. **Specify the purpose** (POPIA Chapter 3, Part A, sections 13-14)
4. **Limit further processing** (POPIA Chapter 3, Part A, section 15)
5. **Ensure quality of information** (POPIA Chapter 3, Part A, section 16)
6. **Openness** (POPIA Chapter 3, Part A, sections 17-18)
7. **Safeguard confidentiality** (POPIA Chapter 3, Part A, sections 19-22)
8. **Allow data subject participation** (POPIA Chapter 3, Part A, sections 23-25)

Undergraduate Research

Ethics Review

COVID-19: **Guidance** on how to do or amend your research during the embargo on face-to-face research activities

Important notice: Due to the demand that the COVID-19 pandemic is placing on our health care system, the Western Cape provincial Department of Health has advised that access to health care workers as research participants is currently restricted. Please take this into account when planning your research.

Frequently Asked Questions: General (see below for online application FAQS)

- Why is ethics review of health research important?
- What does an ethics application entail?
- What are UREC reviewers looking for in my ethics application?
- How do I apply for a waiver of consent?
- Do I need consent to use stored data/ samples?
- What criteria does UREC use to review my ethics application?
- How do I apply for institutional approval to conduct research at SU?
- How do I get help with my biostatistics before submitting for ethics approval?
- Does my class project/assignment need ethics approval?
- What are the ethical issues in case reports & case series?
- Do I need provincial Dept. of Health approval?
- How do I ensure that translators/transcribers keep participant information confidential?
- Do I apply for ethics if my project is linked to a larger study?
- What do I include in my protocol when using secondary data?
- What's ethics got to do with systematic & scoping reviews? (secondary research)

■ Useful Links

****Important notice****

Literature review sections included in protocols submitted for ethics review should be a maximum of 3-5 pages. Literature reviews exceeding this length will be returned to applicants for editing prior to review.

ETHICS REVIEW

- Quick Guide to Applying for Ethics Approval
- Ethics Application Package
- Forms & Instructions
- UREC Submission Dates
- UREC Members
- Frequently Asked Questions
- Health Research Ethics Office

Undergraduate Research

Ethics Review

Frequently Asked Questions: General (see below for online application FAQS)

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- What criteria does UREC use to review my ethics application?
- How do I apply for institutional approval to conduct research at SU?
- How do I get help with my biostatistics before submitting for ethics approval?
- Do I need provincial Dept. of Health approval?
- How do I ensure that translators/transcribers keep participant information confidential?
- Do I apply for ethics if my project is linked to a larger study?

Undergraduate Research

Ethics Review

Frequently Asked Questions: General (see below for online a

- Why is ethics review of health research important?
- Wh[illegible] does an [illegible]thics application entail?
- What are UREC reviewers looking for in my ethics application?
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- How do I apply for institutional approval to conduct research at SU?
- How do I get help with my biostatistics before submitting for ethics approval?
- Do I need provincial Dept. of Health approval?
- How do I ensure that translators/transcribers keep participant information confidential?
- Do I apply for ethics if my project is linked to a larger study?

Health Research Ethics Committee (HREC) /

Undergraduate Research Ethics Committee (UREC)

REVIEW GUIDE

1. INTRODUCTION, SPECIFIC AIMS, LITERATURE REVIEW

Is the literature review adequate?

[illegible]re the study aims and objectives clearly specified?

[illegible]ere appropriate justification for this study protocol? Is there adequate preliminary data to justify the study?

[illegible]y is it important to conduct this study? Will it add important knowledge to the field?

Why is this study worth doing in this particular setting?

Are adequate references provided? (Where possible, the literature review should include pertinent references to local research in the proposed field of study).

Is there a mechanism for those affected by the study to express their views, clarify their needs and contribute to the research?

2. SCIENTIFIC DESIGN

Is the selected scientific design appropriate to answer the study question(s)?

Is the scientific design adequately described and justified?

Does the study involve a placebo? If so, is there a persuasive justification for using a placebo? Could the study be done without a placebo?

Are study aims and objectives achievable in the given time frame?

Do the principal and co-investigators have appropriate academic and clinical credentials and experience to conduct this study?

Qualitative research:

Is the selected scientific design appropriate to answer the study question(s)?

Is the scientific design adequately described and justified?

Are study aims and objectives achievable in the given time frame?

Does the researcher and/or their supervisor/co-investigators have experience in conducting qualitative research?

Does the researcher demonstrate an understanding of the qualitative paradigm and method chosen?

3. SELECTION OF PARTICIPANTS

Is the selection of participants appropriate for the study question being asked?

Is the rationale for the proposed number of participants reasonable?

Is participant selection equitable?

Are inclusion and exclusion criteria clearly stated and reasonable?

Is the inclusion of children, pregnant women or other vulnerable groups adequately justified?

Are adequate safeguards in place to protect the rights and welfare of these vulnerable groups?

[illegible]

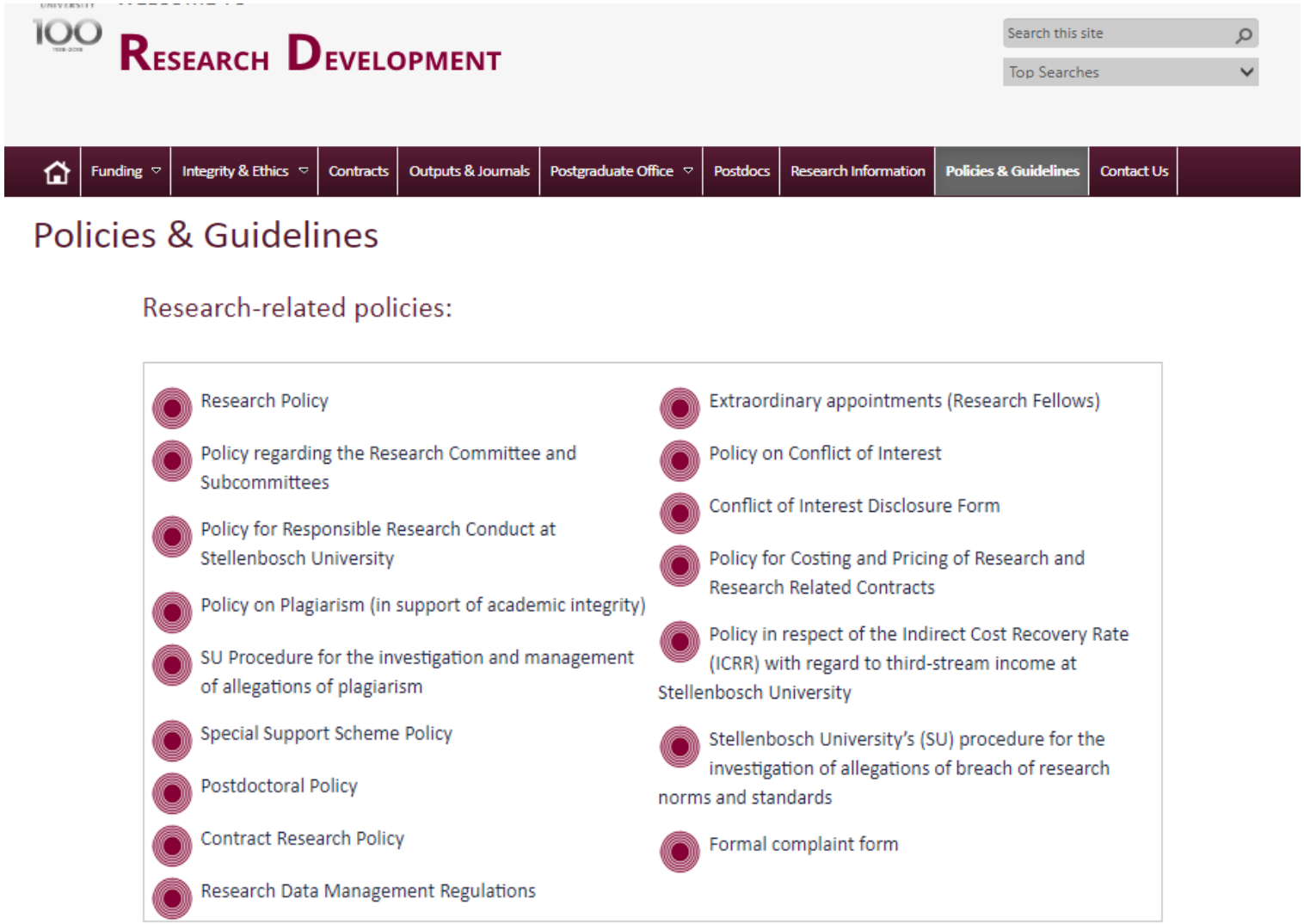
In summary, what is HREC expecting in protocol/proposal

- A study that demonstrates that the researcher has reviewed the relevant literature - in other words what is the current state of affairs/"state of the art" in the field?
- What is the study's relevance to the local/SAfrican/LMIC communities?
- Is the study design robust – will the study achieve what it intends to deliver?

- ✓Have the risks and benefits to participants been carefully considered?
- ✓Has the researcher carefully considered the impacts on participants' privacy?
- ✓Is there a clear data management plan?
- ✓Where appropriate, how will feedback be provided to participants?

What happens after submission to HREC?

- Once you submit the application, it gets routed online to your supervisor to sign off. Make sure they have received it and submitted it
- You should get an automated system email once the application has been received by HREC
- Application will be admin checked. If any missing documents, changes will be requested immediately by the HREC Administrators
- Thereafter, application is forwarded to the HREC 1 or 2 co-ordinator
- The co-ordinator allocates it to an HREC reviewer for review


RESEARCH DEVELOPMENT
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Policies & Guidelines
Research-related policies:
Research Policy
Policy regarding the Research Committee and Subcommittees
Policy for Responsible Research Conduct at Stellenbosch University
Policy on Plagiarism (in support of academic integrity)
SU Procedure for the investigation and management of allegations of plagiarism
Special Support Scheme Policy
Postdoctoral Policy
Contract Research Policy
Research Data Management Regulations
Extraordinary appointments (Research Fellows)
Policy on Conflict of Interest
Conflict of Interest Disclosure Form
Policy for Costing and Pricing of Research and Research Related Contracts
Policy in respect of the Indirect Cost Recovery Rate (ICRR) with regard to third-stream income at Stellenbosch University
Stellenbosch University's (SU) procedure for the investigation of allegations of breach of research norms and standards
Formal complaint form

SU Research Data Management Regulations

Data acquisition and management

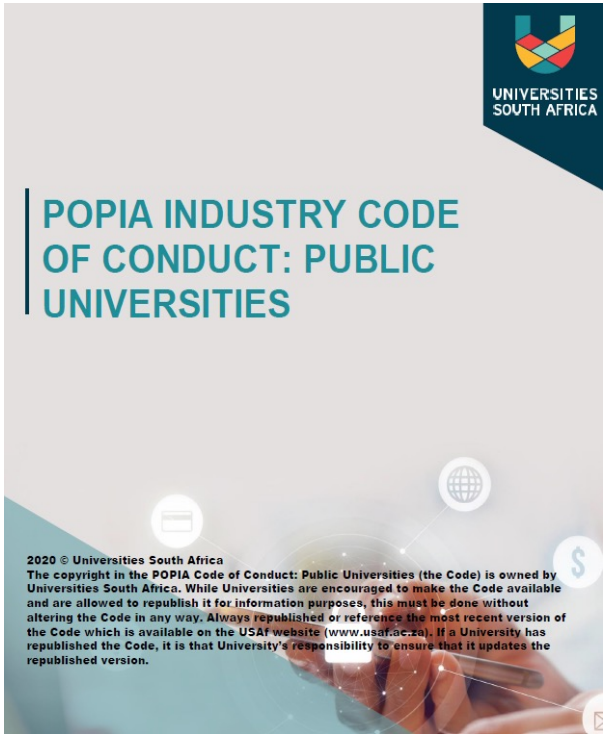
- Institutional requirements
- Institutional ownership of research data
- Data sharing
- Data dissemination
- Data categories and storage requirements
- Levels of access

Data retention and data destruction

Ethical considerations in use of data

- Ethical use
- Sensitive data should be managed accordingly
- Ethical reporting of research data
- Secondary use
- Fair use
- Informed consent
- Cultural sensitivities and indigenous knowledge

Protection of Personal Information Act (POPIA)



Information Governance

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Framework for Governance of Personal Information

Policies and Regulations

- Data Privacy Regulation

Incident and breach reporting

If you suspect a potential incident involving personal information or a breach of personal information, please report it through:

- Service desk (internal users); or
- By e-mail

Tools

- Online Privacy Impact Self-Assessment. Quickly assess the value of and risks involved with personal information you plan to collect or process. For internal users only.

Guidance Notes

- What is Personal Information?
- Privacy Considerations for Teaching Online
- Universities South Africa (USAf) POPIA Code of Conduct

Ask for Help

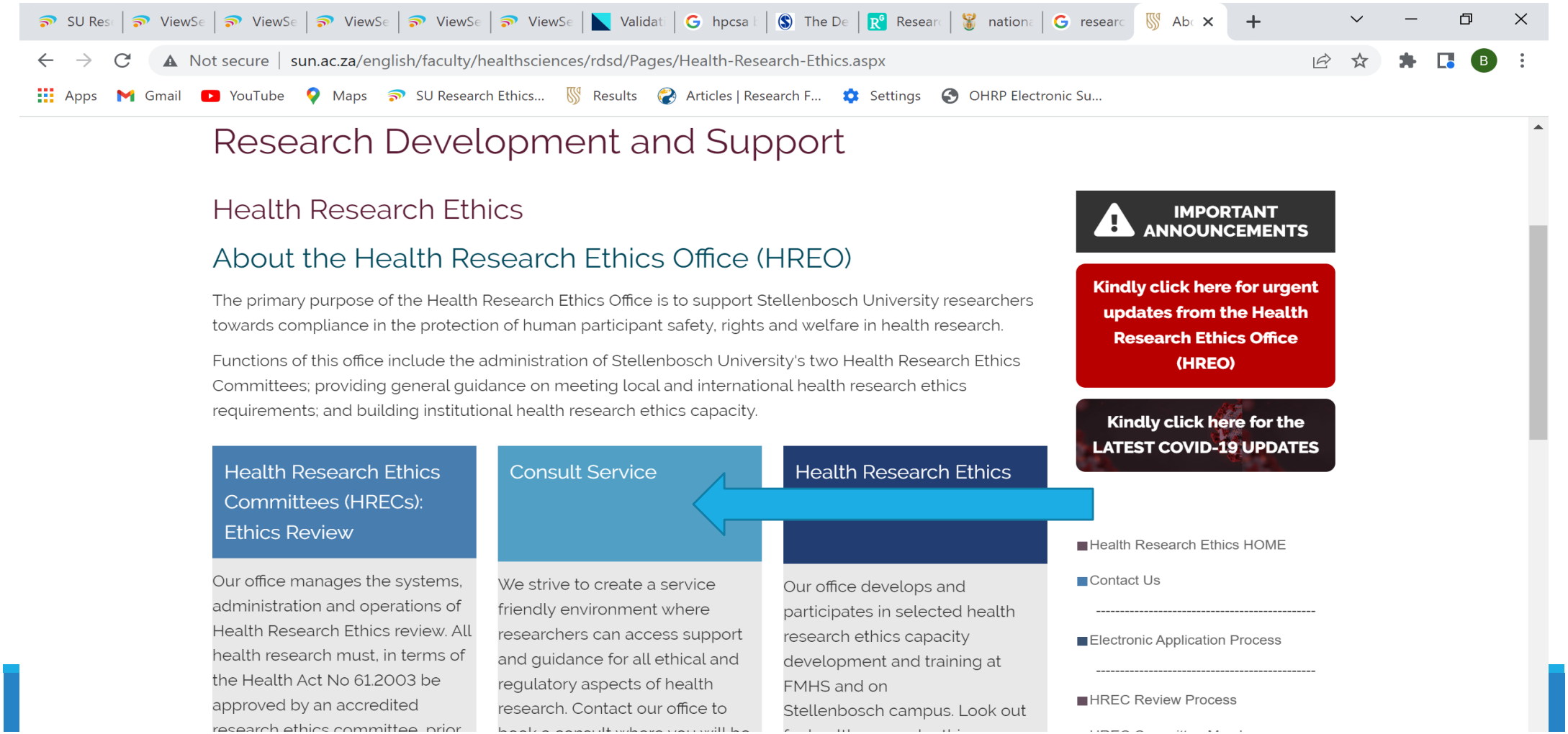
WHO TO CONTACT FOR HELP

Enquiries about the HREC application and review process:

ethics@sun.ac.za

Telephone: 021 938 9677

Ask for Help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Research Development and Support
Health Research Ethics
About the Health Research Ethics Office (HREO)
The primary purpose of the Health Research Ethics Office is to support Stellenbosch University researchers towards compliance in the protection of human participant safety, rights and welfare in health research.
Functions of this office include the administration of Stellenbosch University's two Health Research Ethics Committees; providing general guidance on meeting local and international health research ethics requirements; and building institutional health research ethics capacity.
IMPORTANT ANNOUNCEMENTS
Kindly click here for urgent updates from the Health Research Ethics Office (HREO)
Kindly click here for the LATEST COVID-19 UPDATES
Health Research Ethics Committees (HRECs): Ethics Review
Our office manages the systems, administration and operations of Health Research Ethics review. All health research must, in terms of the Health Act No 61.2003 be approved by an accredited
Consult Service
We strive to create a service friendly environment where researchers can access support and guidance for all ethical and regulatory aspects of health research. Contact our office to
Health Research Ethics
Our office develops and participates in selected health research ethics capacity development and training at FMHS and on Stellenbosch campus. Look out
Health Research Ethics HOME
Contact Us
Electronic Application Process
HREC Review Process

Thank you | Dankie | Enkosi


ANY
Questions?