

APPLYING FOR ETHICS APPROVAL FOR YOUR UNDERGRADUATE RESEARCH STUDY @ FMHS

PROCESS: HOW TO SUBMIT AN ETHICS APPLICATION to the UNDERGRADUATE RESEARCH ETHICS COMMITTEE (UREC)							
Who are we at RDS?	<p>The Research Development & Support Division (RDS) is located on the 5th floor of the teaching building. It is made up of 5 offices, two of which are concerned with supporting and reviewing undergraduate research and ethics applications:</p> <p>Undergraduate Research Office – which manages the Undergraduate Research Ethics Committee (UREC) and provides assistance to undergraduate students in putting together their ethics applications. UREC reviews all minimal risk undergraduate and honours-level ethics applications. Visit the Undergraduate Research Office website for research- and ethics-related resources: http://www.sun.ac.za/health-undergradresearch</p> <p>Health Research Ethics Office – which manages two Health Research Ethics Committees (HRECs). HREC 1 and HREC 2 both review the same sorts of studies. The Undergraduate Research Ethics Committee is a subcommittee of the Health Research Ethics Committees.</p>						
Where do I find the forms?	<p>http://www.sun.ac.za/health-undergradresearch and click on “Ethics Application Package” on right hand side, or http://www.sun.ac.za/english/faculty/healthsciences/rds/Pages/Ethics_application_package.aspx</p> <p style="color: red;">Note: Make sure you use the latest version of the forms</p>						
What forms do I submit?	<p>Your application should include all of the following:</p> <ul style="list-style-type: none"> • Completed & signed application form • Completed & signed HREC checklist • Investigator's Declarations for you, supervisors & all other involved researchers • CVs for you, supervisors and all other involved researchers • Protocol synopsis (2 page summary of your research) • Protocol, including budget, timeline and <u>all instruments</u> to be used (Include or attach the questionnaire, survey, interview guide or any other relevant measure that you will be using to collect data) • Information & consent forms (Note: There should be different forms for adults (e.g. parents) and children. These forms must be translated into all relevant languages of your study population) <p style="color: red;">Note: student applications that are for degree purposes are exempt from payment</p>						
When do I submit the application?	<p>There are usually two submission deadlines per month. The submission deadlines and meeting dates can be found here: http://www.sun.ac.za/english/faculty/healthsciences/rds/Documents/Undergraduate%20Research/UREC%20Submission%20Deadlines%202017.pdf</p>						
How do I submit the application?	<ul style="list-style-type: none"> • Submit one electronic copy of all documents, saved as individual files, to ethics@sun.ac.za. Scan signed documents & attach as PDFs, AND • Submit one hard copy of all documents to Lauren van Turha (reception) or Ashleen Fortuin, (room 5008E), 5th floor, teaching building 						
How long does it take to review?	<p>There are two types of review: minimal risk review and full committee review:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; vertical-align: top;"> <p>Minimal risk review:</p> <ul style="list-style-type: none"> • 1 reviewer + review & sign off by UREC Chair • First letter usually issued within 2-4 weeks of submission </td> <td style="width: 50%; vertical-align: top;"> <p>Full committee review (more than minimal risk):</p> <ul style="list-style-type: none"> • 2 UREC reviewers + full HREC committee discussion & vote • First letter issued within 5-6 weeks of submission (2 weeks after meeting) </td> </tr> </table>			<p>Minimal risk review:</p> <ul style="list-style-type: none"> • 1 reviewer + review & sign off by UREC Chair • First letter usually issued within 2-4 weeks of submission 	<p>Full committee review (more than minimal risk):</p> <ul style="list-style-type: none"> • 2 UREC reviewers + full HREC committee discussion & vote • First letter issued within 5-6 weeks of submission (2 weeks after meeting) 		
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What does the feedback mean?	<p style="text-align: right; color: red;">Note: correspondence will be sent to your @su email address</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; vertical-align: top;"> <p>Review decisions:</p> <p>Approved: study has ethics approval and can proceed for period of one year after date of approval.</p> </td> <td style="width: 25%; vertical-align: top;"> <p>Approved with stipulations: research can begin subject to certain conditions. The responsibility for meeting these conditions rests with the researcher.</p> </td> <td style="width: 25%; vertical-align: top;"> <p>Modifications required: changes need to be made to the application / protocol and re-submitted to HREC. The primary reviewer will review these changes and once satisfied will inform the Chairperson, who signs off on the final approval.</p> </td> <td style="width: 25%; vertical-align: top;"> <p>Deferred: significant parts of the protocol need rethinking and rewriting. Rewrite and resubmit. This will be sent for a new full committee review.</p> </td> </tr> </table>			<p>Review decisions:</p> <p>Approved: study has ethics approval and can proceed for period of one year after date of approval.</p>	<p>Approved with stipulations: research can begin subject to certain conditions. The responsibility for meeting these conditions rests with the researcher.</p>	<p>Modifications required: changes need to be made to the application / protocol and re-submitted to HREC. The primary reviewer will review these changes and once satisfied will inform the Chairperson, who signs off on the final approval.</p>	<p>Deferred: significant parts of the protocol need rethinking and rewriting. Rewrite and resubmit. This will be sent for a new full committee review.</p>
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Who can I go to for help about the application process?	<p>For advice on the application process, submission deadlines and relevant forms, you can contact: Lauren van Turha (laurenv@sun.ac.za / 0219389820) or Ashleen Fortuin (afortuin@sun.ac.za / 0219389819) or Elvira Rohland (elr@sun.ac.za / 0219389677)</p>						

CONTENT: WHAT TO CONSIDER IN YOUR PROPOSAL & ETHICS APPLICATION

Administrative	<ul style="list-style-type: none"> • Make sure all required documents are included and signed where necessary • Make sure protocol synopsis matches protocol • Feasible timeline and budget • Are you and research team adequately qualified to carry out research? State if you'll need to consult with an expert during research 		
Research design	<p>Research that is of no benefit to society or that is poorly designed and conducted exposes participants to risks and inconveniences for no purpose. This makes it unethical. HREC will not approve research that is regarded as scientifically flawed, nor a research proposal that is poorly written. Science and ethics cannot be separated!</p>		
Ethical principles	<ul style="list-style-type: none"> • Respect for autonomy (voluntariness) • Privacy (access to the person) & confidentiality (access to the data) • Fairness (justice) • Balancing risks versus benefits 		
Participant selection & recruitment	<ul style="list-style-type: none"> • Fair selection & sampling • Justify inclusion & exclusion criteria • Detail the informed consent process in your recruitment procedures • Show understanding that getting a signed informed consent form does not equal informed consent! (it's a process, not a once-off) 		
Data collection procedures	<p>Explain how you will protect participant privacy & confidentiality during data collection</p> <p>Explain exactly what you plan to do, how long it will take, where it will take place, what participants will be expected to do. Make sure this information appears in the information & consent sheets</p>		
Data management	<p>Explain how data will be managed to protect confidentiality</p> <p>There is a difference between data that is anonymised and data that is de-identified</p>		
Ethical considerations section	<p>Acknowledge risks and benefits and how these will be managed</p> <p>Acknowledge and address any potential for undue influence (e.g. if you are treating the same patients you ask to participate)</p>		
Information & consent sheets	<ul style="list-style-type: none"> • Information provided on informed consent form must match what is detailed in protocol • Imagine you are speaking to the participant • Briefly but clearly describe what research is about • Highlight voluntariness & right to withdraw • Outline what their participation involves 	<ul style="list-style-type: none"> • Highlight risks and benefits • Explain what will be done with 1) personal info and 2) their data • Give information about where to go if 'harmed' • Include your, supervisor's & HREC contact details • Simple language - 'grade 8 level' • Translated into all relevant languages 	
Participant compensation	<p>Will participants be compensated? (time, inconvenience, expense)</p>		
Who can I go to for help about the content of my application and review feedback?	<p>Debbie Marais (Head: Undergraduate Research Office & UREC coordinator) (debbiem@sun.ac.za / 021 938 9181)</p> <p>Franklin Weber (HREC 1 coordinator) (fweb@sun.ac.za / 021 938 9657);</p> <p>Francis Masiye (HREC 2 coordinator) (fmasiye@sun.ac.za / 021 938 9207)</p>		
What other permissions do I need?	<p>If your study includes Stellenbosch University students, staff or alumni:</p> <p>Division for Institutional Research & Planning @ SU:</p> <p>Cover letter outlining recruitment procedures & plans for data management, together with protocol</p> <p>Allison Mlitwa: amlitwa@sun.ac.za</p> <p>If you are doing research on FMHS students, remember to also get permission from the relevant programme committee (e.g. MBChB programme committee).</p>	<p>If you intend to recruit Western Cape government facility staff and/or patients as participants (e.g. from clinics):</p> <p>Western Cape Provincial Research Committee:</p> <p>Charlene Roderick, 021 483 9319, health.research@westerncape.gov.za https://www.westerncape.gov.za/general-publication/health-research-approval-process</p>	<p>If you intend to recruit school learners or teachers:</p> <p>Western Cape Department of Education</p>