

APPLYING FOR ETHICS APPROVAL FOR YOUR UNDERGRADUATE RESEARCH STUDY @ FMHS

PROCESS: HOW TO SUBMIT AN APPLICATION TO THE UNDERGRADUATE RESEARCH ETHICS COMMITTEE (UREC)							
Who are we at RDSD?	<p>The Research Development & Support Division (RDSD) is located on the 5th floor of the teaching building. It is made up of 4 offices, two of which are concerned with supporting and reviewing undergraduate research:</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. They divide the applications between them.</p> <p>Undergraduate Research Office – provides assistance to undergraduate students conducting research. It also manages the Undergraduate Research Ethics Committee (UREC) which is a subcommittee of HREC and reviews all undergraduate and honours-level ethics applications.</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/rdsd/Pages/Ethics_application_package.aspx</p> <p>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. You can submit these in English, but be aware that they will need to be translated into all relevant languages of your study population before you start data collection.) <p>Note: student applications that are for degree purposes are exempt from payment.</p>						
When do I submit the application?	<p>There are two submission deadlines each month. The submission deadlines and meeting dates can be found here: http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Documents/Undergraduate%20Research/UREC%20Submission%20Deadlines%202016.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 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 reviewers + full committee discussion & vote @ HREC meeting • First letter issued within 5-6 weeks of submission (2 weeks after mtg) </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 reviewers + full committee discussion & vote @ HREC meeting • First letter issued within 5-6 weeks of submission (2 weeks after mtg) 		
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What does the feedback mean?	<p style="text-align: right;">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 Chair, 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 Chair, 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: Ashleen Fortuin (afortuin@sun.ac.za / 021 938 9819)</p>						

CONTENT: WHAT TO CONSIDER IN YOUR PROPOSAL & 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. UREC and HREC will not approve research that is regarded as scientifically flawed. 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 (beneficence). 		
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 and confidentiality during data collection. 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. 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. 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 & <u>HREC</u> 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 9181/5th floor teaching block)</p>		
What other permissions do I need?	<p>If your study includes Stellenbosch University students, staff or alumni: Division for Institutional Research & Planning @ SU: Cover letter outlining recruitment procedures & plans for data management, together with protocol Allison Mlitwa: amlitwa@sun.ac.za</p>	<p>If you intend to recruit Western Cape government facility staff and/or patients as participants (e.g. from clinics): Western Cape Provincial Research Committee: 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: Western Cape Department of Education</p>