

## APPLYING FOR ETHICS APPROVAL FOR YOUR UNDERGRADUATE RESEARCH STUDY @ FMHS

PROCESS: HOW TO SUBMIT AN ETHICS APPLICATION to the UNDERGRADUATE RESEARCH ETHICS COMMITTEE (UREC)			
<b>Who are we at RDSD?</b>	<p>The <b>Research Development &amp; Support Division (RDSD)</b> is located on the 5<sup>th</sup> 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><b>Undergraduate Research Office</b> – which manages the <b>Undergraduate Research Ethics Committee (UREC)</b> 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: <a href="http://www.sun.ac.za/health-undergradresearch">http://www.sun.ac.za/health-undergradresearch</a></p> <p><b>Health Research Ethics Office</b> – 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>		
<b>Where do I find the forms?</b>	<p>The Health Research Ethics Committee and Undergraduate Research Ethics Committee use an electronic ethics review management system, <i>Infonetica</i>® to manage the application and review process.</p> <p>To access the <a href="#">electronic submission platform</a>, you can go to</p> <ul style="list-style-type: none"> <li>• <a href="http://www.sun.ac.za/health-undergradresearch">http://www.sun.ac.za/health-undergradresearch</a> and click on “Ethics Application Package” on right hand side, OR</li> <li>• <a href="http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics_application_package.aspx">http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics_application_package.aspx</a></li> </ul> <p><b>Note:</b> Make sure you use the latest version of the all the required forms that you need to attach along with your application, which can be found here: <a href="http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics/Forms-Instructions.aspx">http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics/Forms-Instructions.aspx</a></p>		
<b>What forms do I submit?</b>	<p>Your application should include all of the following:</p> <ul style="list-style-type: none"> <li>• Completed &amp; signed <a href="#">e-form application form</a>. <b>Guidance</b> on completing this e-form application form is <a href="#">available here</a> and the <a href="#">manual is available here</a>. <b>Note:</b> You need to ensure that you are registered on SUNId (i.e. your student number and password) in order to be able to log into and use the electronic application system.</li> <li>• <a href="#">Investigator's Declarations</a> for you, supervisors &amp; all other involved researchers</li> <li>• <b>CVs</b> for you, supervisors and all other involved researchers</li> <li>• <b>Protocol synopsis</b> (2-page summary of your research)</li> <li>• <b>Protocol</b>, 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)</li> <li>• <b>Information &amp; consent forms</b> (Note: There should be different forms for adults (e.g. parents) and children. <b>These forms must be translated into all relevant languages of your study population</b>). You can find a template of these forms on the <a href="#">HREC forms and instructions webpages</a></li> </ul> <p><b>Note:</b> student applications that are for degree purposes are exempt from payment</p>		
<b>When do I submit the application?</b>	<p>There are usually two submission deadlines per month. The <b>submission deadlines and meeting dates</b> can be found here: <a href="http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Documents/Undergraduate%20Research/UREC%20Submission%20Deadlines%202021.pdf">http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Documents/Undergraduate%20Research/UREC%20Submission%20Deadlines%202021.pdf</a></p>		
<b>How do I submit the application?</b>	<p>The Health Research Ethics Committee and Undergraduate Research Ethics Committee use an electronic ethics review management system, <i>Infonetica</i>® to manage the application and review process. <b>Note:</b> <b>Hard copies of applications are no longer required.</b></p> <p>To access the <a href="#">electronic submission platform</a>, you can go to</p> <ul style="list-style-type: none"> <li>• <a href="http://www.sun.ac.za/health-undergradresearch">http://www.sun.ac.za/health-undergradresearch</a> and click on “Ethics Application Package” on right hand side, OR</li> <li>• <a href="http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics_application_package.aspx">http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics_application_package.aspx</a></li> </ul>		
<b>How long does it take to review?</b>	<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><b>Minimal risk review:</b></p> <ul style="list-style-type: none"> <li>• 1 reviewer + review &amp; sign off by UREC Chair</li> <li>• First letter usually issued within 2-4 weeks of submission</li> </ul> </td> <td style="width: 50%; vertical-align: top;"> <p><b>Full committee review (more than minimal risk):</b></p> <ul style="list-style-type: none"> <li>• 2 UREC reviewers + full HREC committee discussion &amp; vote</li> <li>• First letter issued within 5-6 weeks of submission (2 weeks after meeting)</li> </ul> </td> </tr> </table>	<p><b>Minimal risk review:</b></p> <ul style="list-style-type: none"> <li>• 1 reviewer + review &amp; sign off by UREC Chair</li> <li>• First letter usually issued within 2-4 weeks of submission</li> </ul>	<p><b>Full committee review (more than minimal risk):</b></p> <ul style="list-style-type: none"> <li>• 2 UREC reviewers + full HREC committee discussion &amp; vote</li> <li>• First letter issued within 5-6 weeks of submission (2 weeks after meeting)</li> </ul>
<p><b>Minimal risk review:</b></p> <ul style="list-style-type: none"> <li>• 1 reviewer + review &amp; sign off by UREC Chair</li> <li>• First letter usually issued within 2-4 weeks of submission</li> </ul>	<p><b>Full committee review (more than minimal risk):</b></p> <ul style="list-style-type: none"> <li>• 2 UREC reviewers + full HREC committee discussion &amp; vote</li> <li>• First letter issued within 5-6 weeks of submission (2 weeks after meeting)</li> </ul>		

<b>What does the feedback mean?</b>	<b>Review decisions:</b>				<b>Note: correspondence will be sent to your @sun SU email address</b>
	<b>Approved:</b> study has ethics approval and can proceed for period of one year after date of approval.	<b>Approved with stipulations:</b> research can begin subject to certain conditions. The responsibility for meeting these conditions rests with the researcher.	<b>Modifications required:</b> 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.	<b>Deferred:</b> significant parts of the protocol need rethinking and rewriting. Rewrite and resubmit. This will be sent for a new full committee review.	
<b>Who can I go to for help about the application process?</b>	For advice on the application process, submission deadlines and relevant forms, you can contact: Lauren Hendricks ( <a href="mailto:laurenv@sun.ac.za">laurenv@sun.ac.za</a> / 0219389820) or Debbie Marais ( <a href="mailto:debbiem@sun.ac.za">debbiem@sun.ac.za</a> / 0219839181)				
<b>CONTENT: WHAT TO CONSIDER IN YOUR PROPOSAL &amp; ETHICS APPLICATION</b>					
<b>Administrative</b>	<ul style="list-style-type: none"> <li>• Make sure all required documents are included and signed where necessary</li> <li>• Make sure protocol synopsis matches protocol</li> <li>• Feasible timeline and budget</li> <li>• Are you and research team adequately qualified to carry out research? State if you'll need to consult with an expert during research</li> </ul>				
<b>Research design</b>	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. <b>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!</b>				
<b>Ethical principles</b>	<ul style="list-style-type: none"> <li>• Respect for autonomy (voluntariness)</li> <li>• Privacy (access to the person) &amp; confidentiality (access to the data)</li> <li>• Fairness (justice)</li> <li>• Balancing risks versus benefits</li> </ul>				
<b>Participant selection &amp; recruitment</b>	<ul style="list-style-type: none"> <li>• Fair selection &amp; sampling</li> <li>• Justify inclusion &amp; exclusion criteria</li> <li>• Detail the informed consent process in your recruitment procedures</li> <li>• Show understanding that getting a signed informed consent form does not equal informed consent! (it's a process, not a once-off)</li> </ul>				
<b>Data collection procedures</b>	Explain how you will <b>protect participant privacy &amp; confidentiality</b> during data collection Explain <b>exactly what you plan to do</b> , 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				
<b>Data management</b>	Explain how data will be managed to protect confidentiality <b>There is a difference between data that is anonymised and data that is de-identified</b>				
<b>Ethical considerations section</b>	Acknowledge <b>risks and benefits</b> and how these will be managed Acknowledge and address any potential for <b>undue influence</b> (e.g. if you are treating the same patients you ask to participate)				
<b>Information &amp; consent sheets</b>	<ul style="list-style-type: none"> <li>• Information provided on informed consent form must match what is detailed in protocol</li> <li>• Imagine you are speaking to the participant</li> <li>• Briefly but clearly describe what research is about</li> <li>• Highlight voluntariness &amp; right to withdraw</li> <li>• Outline what their participation involves</li> </ul>	<ul style="list-style-type: none"> <li>• Highlight risks and benefits</li> <li>• Explain what will be done with 1) personal info and 2) their data</li> <li>• Give information about where to go if 'harmed'</li> <li>• Include your, supervisor's &amp; HREC contact details</li> <li>• Simple language - 'grade 8 level'</li> <li>• Translated into all relevant languages</li> </ul>			
<b>Participant compensation</b>	Will participants be compensated? ( <b>time, inconvenience, expense</b> )				
<b>Who can I go to for help about the content of my application and review feedback?</b>	Debbie Marais (Head: Undergraduate Research Office & UREC coordinator) ( <a href="mailto:debbiem@sun.ac.za">debbiem@sun.ac.za</a> / 021 938 9181)				