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

| **PROCESS: HOW TO SUBMIT AN ETHICS APPLICATION to the UNDERGRADUATE RESEARCH ETHICS COMMITTEE (UREC)** <br> (last updated: December 2022) ||
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| **Who are we at RDSD?** | The **Research Development & Support Division (RDSD)** 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: <br> **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** <br> **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. |
| **Where do I find the forms?** | The Health Research Ethics Committee and Undergraduate Research Ethics Committee use an electronic ethics review management system, *Infonetica©* to manage the application and review process. <br> To access the electronic submission platform, you can go to <br> • http://www.sun.ac.za/health-undergradresearch and click on "Ethics Application Package" on right hand side, OR <br> • http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics_application_package.aspx <br> **Note**: 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: http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics/Forms-Instructions.aspx |
| **What forms do I submit?** | Your application should include all of the following: <br> • Completed & signed **e-form application form**. **Guidance** on completing this e-form application form is **available here** and the **manual is available here**. **Note**: 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. <br> • **Investigator's Declarations** for you, supervisors & all other involved researchers <br> • **CV**s for you, supervisors and all other involved researchers <br> • **Protocol synopsis** (2-page summary of your research) <br> • **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) <br> • **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). You can find a template of these forms on the HREC forms and instructions webpages <br> **Note**: student applications that are for degree purposes are exempt from payment but must still complete the payment instruction form. |
| **When do I submit the application?** | There are usually two submission deadlines per month. The **2023 submission deadlines and meeting dates** can be found here. |
| **How do I submit the application?** | The Health Research Ethics Committee and Undergraduate Research Ethics Committee use an electronic ethics review management system, *Infonetica©* to manage the application and review process. **Note:** Hard copies of applications are no longer required. <br> To access the electronic submission platform, you can go to <br> • http://www.sun.ac.za/health-undergradresearch and click on "Ethics Application Package" on right hand side, OR <br> • http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics_application_package.aspx |
| **How long does it take to review?** | There are two types of review: minimal risk review and full committee review: |

| **How long does it take to review?** (cont.) | **Minimal risk review**: <br> • 1 reviewer + review & sign off by UREC Chair <br> • First letter usually issued within 2-4 weeks of submission | **Full committee review (more than minimal risk)**: <br> • 2 UREC reviewers + full HREC committee discussion & vote <br> • First letter issued within 5-6 weeks of submission (2 weeks after meeting) |
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| What does the feedback mean? | Review decisions: | | | Note: correspondence will be sent to your @sun SU email address |
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| | **Approved:** study has ethics approval and can proceed for period of one year after date of approval. | **Approved with stipulations:** research can begin subject to certain conditions. The responsibility for meeting these conditions rests with the researcher and the stipulations must be submitted to UREC. | **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. | **Deferred:** significant parts of the protocol need rethinking and rewriting. Rewrite and resubmit. This will be sent for a new full committee review. |
| **Who can I go to for help about the application process?** | For advice on the application process, submission deadlines and relevant forms, you can contact: Lauren Hendricks (laurenv@sun.ac.za / 0219389820) or Debbie Marais (debbiem@sun.ac.za / 0219839181) | | | |

<div align="center"><strong>CONTENT: WHAT TO CONSIDER IN YOUR PROPOSAL & ETHICS APPLICATION</strong></div>

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| **Administrative** | <ul><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> |
| **Research design** | 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! |
| **Ethical principles** | <ul><li>Respect for autonomy (voluntariness)</li><li>Privacy (access to the person) & confidentiality (access to the data)</li><li>Fairness (justice)</li><li>Balancing risks versus benefits</li></ul> |
| **Participant selection & recruitment** | <ul><li>Fair selection & sampling</li><li>Justify inclusion & 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> |
| **Data collection procedures** | Explain how you will **protect participant privacy & confidentiality** during data collection<br>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 |
| **Data management** | Explain how data will be managed to protect confidentiality<br>There is a difference between data that is **anonymised** and data that is **de-identified** |
| **Ethical considerations section** | Acknowledge **risks and benefits** and how these will be managed<br>Acknowledge and address any potential for **undue influence** (e.g. if you are treating the same patients you ask to participate) |
| **Information & consent sheets** | <table><tr><td><ul><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 & right to withdraw</li><li>Outline what their participation involves</li></ul></td><td><ul><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 & HREC contact details</li><li>Simple language - 'grade 8 level'</li><li>Translated into all relevant languages</li></ul></td></tr></table> |
| **Participant compensation** | Will participants be compensated? (**time, inconvenience, expense**) |
| **Who can I go to for help about the content of my application and review feedback?** | Debbie Marais (Head: Undergraduate Research Office & UREC coordinator) (debbiem@sun.ac.za / 021 938 9181)<br>Also check out our navigating the ethics process infographic. |