**Form FHS021: Undergraduate student research protocol application form**

**Researchers must ensure that they use the current version of the application form on** [**UCT Administrative Forms**](https://health.uct.ac.za/home/human-research-ethics) **web page.**

**Our website address:** <http://www.health.uct.ac.za/fhs/research/humanethics/forms/>

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| 1. General information | | | | | | | | |
| Protocol title |  | | | | | | | |
| Is this a sub-study or an extension study linked to an existing/main study previously approved by this Committee?  (e.g. a sub-study, follow-up study, earlier phase trial) (tick ✓) | 🞏 Yes | | | | | 🞏 No | | |
| If yes above, please provide the following with regards to the existing/main study: | HREC ref. no. | |  | | | Expiry approval date of existing/main study | |  |
| 2. Course information | | | | | | | | |
| Degree |  | | | | | | | |
| Year of study |  | | | | | | | |
| Course name |  | | | | | | | |
| Course code |  | | | | | | | |
| 3. Investigator(s) profile | | | | | | | | |
| **3.1 UCT’s principal investigator (PI)**  **Note:** For all undergraduate student research the **main** supervisor must be listed as PI. | | | | | | | | |
| Title, first name, surname |  | | | | | | | |
| Department |  | | | | | | | |
| Phone |  | | | | | | | |
| E-mail address |  | | | | | | | |
| Department /Office Internal Mail Address for Correspondence |  | | | | | | | |
| Registration with HPCSA (tick ✓) | 🞏 Yes | 🞏 No | | Registration **#** |  | | | |
| Is the PI covered by professional liability insurance? (tick **✓**) | | | | | 🞏 Yes | | 🞏 No | |
| If yes above, please provide the liability insurance number. | | | | |  | | | |

**Note:**

* If a non-medically trained PI is overseeing research which involves medical procedures, the application must include a medical doctor registered with the HPCSA as a co-investigator.
* The research must have a UCT-based principal investigator/main supervisor.

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| **3.2 How many of the following does the PI or supervisor currently oversee?**  (Total number for all research projects) | | | | | |
| Open research studies |  | | Sites (excluding this application) | |  |
| Co-investigators |  | | Number of participants | |  |
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| **3.3 Co-investigator(s)  Note:** Staff and external collaborators involved in the research must be listed as co-investigators. | | | | | |
| Title, first name, surname | | Department/Division | | E-mail | |
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| **3.4 Student(s)**  **Note:** Please list all undergraduate students involved in the research project. | | |
| Title, first name, surname | Student number | E-mail |
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| 4. Protocol profile | | | |
| **4.1 Has this protocol been submitted to another Human Research Ethics Committee? (tick** ✓**)** | | | |
| 🞏 No | | 🞏 Yes | |
| If yes, please complete: | Name of Institution | | Outcome |
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| **4.2 Does this protocol comply with the Helsinki Declaration of 2013? (tick** ✓**)** | |
| 🞏 No | 🞏 Yes |
| If no, please explain with full justification: | |
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| 4.3 Are there any publication restrictions on the research? (tick ✓) | |
| 🞏 No | 🞏 Yes |
| If yes, please describe and justify: | |
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| **4.4 Does the protocol comply with** [**UCT’s intellectual property rights policy**](https://uct.ac.za/sites/default/files/content_migration/uct_ac_za/39/files/Policy_Intellectual_Property_2011.pdf)**? (tick** ✓**)** | |
| 🞏 Yes | 🞏 No |
| If no, please justify: | |
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| **4.5 Does the protocol provide insurance for research-related adverse events (tick** ✓**)** | | | |
| 🞏 NA (e.g. minimal risk research, medical record review) | | 🞏 No | 🞏 Yes |
| If yes, please describe: | | | |
| ABPI-compliant corporate insurance policy |  | | |
| UCT’s no-fault insurance policy |  | | |
| Other. Please specify: |  | | |
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| **4.6 If UCT No-Fault insurance is required, please indicate if the study involves any of the following:** | | |
| 🞏 Pregnant women | 🞏 Minors | 🞏 Participants outside South African borders |
| If UCT No-fault insurance is required for participants outside South African borders, please specify the countries below: | | |
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| **4.7 If the research will involve participants outside South African borders and these participants are not insured by a sponsor or local mechanism in that country, please specify the study site(s):** | | |
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| **4.8 If no insurance for research-related bodily injury is required, please justify by indicating the type/nature of the proposed research:** | |
| ☐ Qualitative research study  ☐ Purely observational study  ☐ Patient folder or document review only  ☐ Questionnaires/Interviews only  ☐ Study involves secondary data analysis only  ☐ No human participants involved in the research study  ☐ Other | |
| If other, please specify: | |
| 5. Evaluation of minimal risk  Undergraduate research should involve minimal risk, which means that the probability and magnitude of harm due to participation in the research is no greater than that encountered by participants in their everyday lives. |

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| **5.1 Is there any vulnerability associated with the proposed participant groups?  Note:** Group vulnerability refers to any potential vulnerabilities relating to pre-existing physiological or health conditions; cognitive or emotional factors; and socio-economic or legal status. | | |
| 🞏 Low | 🞏 Medium | 🞏 High |
| Please explain the group vulnerability and justify the need for research in this group of participants. | | |
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| **5.2 Please specify the level of risk associated with the proposed research.**  **Note:** Research risk refers tothe probability and magnitude of harms participants may experience as a result of the proposed research methods and/or type of data to be collected. Examples include research procedures or collection of data relating to clinical diagnoses or side effects; cognitive or emotional factors such as stress or anxiety during data collection; and socio-economic or legal consequences of research such as stigma, loss of employment, deportation, or criminal investigation. | | |
| 🞏 Low | 🞏 Medium | 🞏 High |
| Please explain the research risk and justify the need for the proposed research. | | |
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| **5.3 Is this study suitable for an expedited review? I.e. is the research considered to be minimal risk**? **(tick** ✓**)** | |
| 🞏 Yes | 🞏 No |
| If yes, please provide a motivation for expedited review: | |
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**Note: AT THE DISCRETION OF THE HREC CHAIRPERSON OR DESIGNATE, STUDIES REQUESTING EXPEDITED REVIEW MAY NEED TO BE CONSIDERED AT A FULL COMMITTEE MEETING**

**6. Funding information**

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| **6.1 What is the total sponsorship/funding for this protocol?** |  |

**Note:**

* If the undergraduate student project forms part of federally funded research, or is sponsored by foundations (excluding the MRC, NRF and CANSA) or private institutions, an Ethics Review Levy will be required. Please complete Section 4 of the [FHS013](https://health.uct.ac.za/sites/default/files/media/documents/health_uct_ac_za/54/fhs013%20New%20Protocol%20Application%20Form%2030.05.2022.docx) form and attach to this application if applicable.
* A summary budget must be attached in the appendices.

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| 7. Characteristics of the protocol | | |
| **7.1 Category of research**  Please select an appropriate category for the protocol. If the protocol falls in more than one category please designate a primary and secondary category by entering a ‘1’ and a ‘2’. | | |
| Behavioural/ psychosocial interventions (e.g. comparison of counselling programmes) | |  |
| Epidemiology/ observational study (e.g. survey, prevalence, case control, cohort studies) | |  |
| Quality improvement | |  |
| Testing new technologies | |  |
| Medical record review, audit | |  |
| Clinical laboratory studies | |  |
| Clinical laboratory studies (DNA related) | |  |
| Qualitative research (e.g. focus groups, in-depth interviewing, ethnography) | |  |
| Pilot study | |  |
| Other. Please describe: |  | |

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| **7.2 Category of participants** | 🞏 Adults | 🞏 Minors (<18 years). Please specify age range: |

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| **7.3 If conducting research with minors, please provide the justification for the proposed inclusion of minors in the study.** (**Required**) | | | |
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| **7.3.1 Is the research considered ‘non-therapeutic’ i.e. does not have a likelihood of direct benefit to the minor participants?** | 🞏 Yes | 🞏 No | 🞏 N/A |
| For “Non-therapeutic” health research with minors, as part of the statutory requirements, [Form A](https://health.uct.ac.za/sites/default/files/content_migration/health_uct_ac_za/54/files/Appendix%25203%2520Form%2520A%2520-%2520Application%2520for%2520ministerial%2520consent%2520for%2520non-therapeutic%2520research%2520with%2520minors_16.02.2022.docx) (NHREC Operational Guidelines for Ministerial Consent: v19 Feb 2015) must be completed and must accompany the FHS013 form.  **Non-therapeutic research** is classified as research that includes interventions that do not hold the prospect of direct health-related benefit to the participant but may produce results that contribute to generalisable knowledge. (Please see [SOP](https://health.uct.ac.za/sites/default/files/content_migration/health_uct_ac_za/54/files/Manual%2520of%2520UCT%2520FHS%2520HREC%2520SOPs%2520v7-1%2520October%25202019.pdf)) | | | |

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| **7.4 Estimated number of participants** |  |

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| **7.5 Estimated duration of the study** |  |

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| **7.6 Location(s) of the study**: (Please supply name of the research unit / site and/orhospital/institutionand particular department as applicable) |
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| **7.7 Which authority will be approached for institutional approval?**  **Note**: Institutional approval/permission must be obtained before study commencement and must be obtained from the institution where the research data is being collected e.g. Hospital, School, Clinic, Department of Education, Provincial Department etc. prior to starting the project |
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| **7.8 Please describe where and how recruitment will take place; and who will be recruited?** |
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| **7.9 Who will be responsible for recruiting participants in this study?**  **Note:** If the clinician involved in standard of care will be involved in this study and the recruitment of participants, please explain how the potential for therapeutic misconception will be minimized or avoided. |
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**Note:**

* **If including UCT staff:** Please obtain permission from Ms. Miriam Hoosain, the Executive Director of Human Resources, when including UCT staff as research participants. (This is a University-wide requirement): Use forms [HR194](https://health.uct.ac.za/sites/default/files/content_migration/uct_ac_za/87/files/hr194a.docx) and [HR190](https://health.uct.ac.za/sites/default/files/content_migration/uct_ac_za/87/files/hr194b.docx).
* **If including UCT students:** Please obtain permission from Dr Moonira Khan, the Executive Director, Department of Student Affairs when including students as research participants. (This is a University-wide requirement): Use form [DSA 100](https://health.uct.ac.za/sites/default/files/content_migration/health_uct_ac_za/54/files/DSA%2520100.%25202021.docx)

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| **7.10 Will non-English speaking/non-English fluent participants be enrolled in the study? (tick** ✓**)** | | | | | | |
| 🞏 Yes | 🞏 No | | | | 🞏 N/a | |
| If Yes, please **tick ✓** what measures will be used to promote participants’ and families’ understanding: | | | | | | |
| Written translation of consent/assent forms into a local language? | | 🞏 Afrikaans | | 🞏 IsiXhosa | | 🞏 Other (specify): |
| Use of trained translator(s)/ interpreter(s) | | |  | | | |
| Other. Please specify below and describe how the investigators intend to explain the study to potential participants and ensure their understanding: | | | | | | |
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| **7.11 What measures will be taken to protect individual privacy and the confidentiality of data?**  **Please see related** [**SOPs**](https://health.uct.ac.za/sites/default/files/content_migration/health_uct_ac_za/54/files/Manual%2520of%2520UCT%2520FHS%2520HREC%2520SOPs%2520v7-1%2520October%25202019.pdf) **for guidance: Privacy and Confidentiality and Collection and Storage of Data or Biological Specimens for Research Purposes** | | | |
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| **8. Statement of conflict of interest** | | | |
| The Principal Investigator is expected to declare any existing or potential conflict of interest that may affect the scientific integrity and ethical conduct of this research. For purposes of this section, ‘immediate family’ means the PI’s spouse or domestic partner and dependent children. **Please tick** ✓ **all that apply:** | | | |
| **8.1 No conflict of interest declared:** | | | |
| I, or any member of my immediate family, **do not** have any interest related to this research (e.g. financial interest in the sponsor of the research or intervention being tested.) | |  | |
| I, or any member of my immediate family, **do not** have a proprietary interest in the product being tested in this research (e.g. patent, trademark, copyright, licensing agreement). | |  | |
| I, or any member of my immediate family, **do not** have any relationships related to this research (e.g. board membership, consultative, executive, employment) or any entity with an ownership interest in the research other than the relationship of sponsor-investigator. | |  | |
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| **8.2 Conflict of interest declared:** | | | |
| As Principal Investigator of this research **I am aware** **of a potential conflict of interest**. Please describe and provide a plan to manage the conflict of interest below: | |  | |
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| 9. Declarations and signatures | | | |
| This application will not be processed unless all the required declarations and signatures are completed according to the Committee’s Standard Operating Procedures. ([SOP](https://health.uct.ac.za/sites/default/files/content_migration/health_uct_ac_za/54/files/Manual%2520of%2520UCT%2520FHS%2520HREC%2520SOPs%2520v7-1%2520October%25202019.pdf)) | | | |
| **9.1 Head of Department or Division**  My signature confirms that:   1. This research protocol has undergone peer review by a person(s) experienced in the field of study. 2. The researcher(s)/student(s)/supervisor(s) have the skills, training, experience and time to undertake this research. 3. There are adequate resources (e.g. equipment, space, support services) to perform this research. | | | |
| Signature of Head |  | Date |  |
| Print name |  | | |

**Note:** Where the main supervisor is also Head of Department, confirmation must be obtained from an authorised designee. Principal investigators may not approve their own research.

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| **9.2 Principal investigator**  My signature confirms that:   1. Information in this application is true and accurate. 2. The research has scholarly merit. 3. The level of risk inherent in the study is commensurate with the student researcher’s experience and the extent of oversight that I will provide. 4. I have time, training, experience and resources to oversee this research. 5. The student researcher has adequate training and resources to complete the research in the allocated timeframe. 6. I will meet the student on a regular basis to monitor progress and address any problems that may arise during the study. 7. The research will begin only after HREC approval is obtained. 8. I accept full responsibility for the conduct of this research and the protection of participants’ rights and welfare. 9. I will conduct the research according to all ethical, regulatory and legal requirements stipulated in the HREC’s Standard Operating Procedures. 10. I will ensure that the research undergoes continuing review as required by the HREC, including annual progress reports, protocol amendments and a final closing report at the end of the research. 11. If applicable, I will ensure that I report unanticipated problems or serious adverse events to the HREC. 12. I will arrange for an alternative faculty supervisor to take responsibility for this research during periods of absence such as sabbatical or annual leave. | | | |
| Required Signature of  Principal Investigator |  | Date |  |
| Print name |  | | |

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| **9.3 Student(s)**  My/our signature(s) confirm that:   1. Information in this application is true and accurate. 2. I/we will begin the research only after HREC approval is obtained. 3. I/we accept full responsibility for the conduct of this research and the protection of participants’ rights and welfare. 4. I/we will conduct the research according to all ethical, regulatory and legal requirements as stipulated in the HREC’s Standard Operating Procedures. | | | |
| Name and signature of Student |  | Date |  |
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**Note:** The supervisor and student researchers are jointly responsible for the ethical conduct of this research from inception to dissemination of findings.

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| New protocol submission checklist | |
| Please ensure that all the applicable sections are fully completed and included in the submission. Missing information will delay the review process as the application will be returned to the PI. | |
| **Instruction for expedited review:**   * Please submit a single PDF to [hrec-submissions@uct.ac.za](mailto:hrec-submissions@uct.ac.za) * Please provide a covering letter clearly indicating that the submission is for an undergraduate student research project.   **Please provide one copy of the protocol application form and all supporting documents:**   1. Covering letter 2. Completed undergraduate student research protocol application form (FHS021) 3. Research protocol (please refer to the FHS015hlp for guidance: <http://www.health.uct.ac.za/fhs/research/humanethics/forms/>) 4. Budget summary 5. Informed consent documents (see the [HREC SOP](https://health.uct.ac.za/sites/default/files/content_migration/health_uct_ac_za/54/files/Manual%2520of%2520UCT%2520FHS%2520HREC%2520SOPs%2520v7-1%2520October%25202019.pdf) for Informed Consent for guidance) 6. Letters of authorization from institutions such as hospitals, clinics and schools (where necessary) 7. Measurement instruments (e.g., surveys, questionnaires, interview schedules) (where necessary) 8. Recruitment material (e.g., advertisements, flyers, posters) (where necessary) 9. Materials for participants (e.g. participant diaries, identification cards) (where necessary) | |
| Please submit the form to: | [hrec-submissions@uct.ac.za](mailto:hrec-submissions@uct.ac.za) |