**Form FHS038: Honours student research project application form to apply for ethics approval**

**NOTE:**

* **This form is for seeking HREC approval for honours students research projects ONLY.**
* **This form must be completed even if the honours student has been added as a co-investigator on another main study.**
* **If the honours student project will only be using cell lines for their research, the form for Health Research Using Cell Lines** [**(FHS036)**](https://forms.uct.ac.za/fhs036.docx) **should be used instead.**
* **Researchers must ensure that they use the current version of the application form on the
HREC webpage:** <https://health.uct.ac.za/home/human-research-ethics>
* **Please submit your signed completed application with supporting documents to hrec-submissions@uct.ac.za**

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| 1. Protocol information |
| Honours research project title |  |
| Is this a sub-study or an extension study linked to an existing/main study previously approved by the HREC? (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 |
| Honours Degree e.g. BMedSc (honours) |   |
| Honours stream /subjecte.g. Cell biology  |  |
| Course code |  |
| 3. Investigator(s) profile |
| **3.1 UCT’s principal investigator (PI)** **Note:** For all honours 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 Honours Student(s)** Please add rows as required *for joint projects* involving multiple students, if applicable. |
| 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** ✓**)** |
| 🞏 N/A (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 below:** |
| ☐ 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 risk Honours research should involve no more than 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 the proposed honours student research project. |
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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. **Please be reminded that honours student research should involve only minimal risk.** |
| 🞏 Low | 🞏 Medium | 🞏 High |
| Please explain and justify the level of risk associated with the research. |
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| 6. Characteristics of the protocol |
| **6.1 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 |  |
| Laboratory studies |  |
| Laboratory studies (DNA related) |  |
| Qualitative research (e.g. focus groups, in-depth interviewing, ethnography) |  |
| Pilot study |  |
| Other. Please describe: |  |

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| **6.2 Category of participants /source of participant samples** | 🞏 Adults | 🞏 Minors (<18 years). Please specify age range:  |

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| **6.3 If conducting research with minors, please provide the justification for the proposed inclusion of minors in the study.** (**Required**)  |
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| **6.3.1 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 this application form. **Non-therapeutic research** is classified as research that does 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/media/277740)) |

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| **6.4 Estimated number of participants/ participant samples** |  |

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| **6.5 Estimated duration of the study** |  |

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| **6.6 Location(s) of the study**: (Please supply name of the research unit / site and/orhospital/institutionand particular department as applicable) |
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| **6.7 Which authority will be approached for institutional approval, if applicable?****Note**: Institutional approval/permission must be obtained, if applicable, 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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| **6.8 Please describe where and how recruitment will take place; and who will be recruited?** |
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| **6.9 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.The therapeutic misconception is when a patient/participant does not distinguish between research and care. |
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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 [HR194a](https://forms.uct.ac.za/hr194a.docx) and [HR194b](https://forms.uct.ac.za/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 [DSA100a](https://forms.uct.ac.za/studentadmin/dsa100a.docx) & [DSA100b](https://forms.uct.ac.za/studentadmin/dsa100b.docx).

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| **6.10 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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| **6.11 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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| **6.12 If using previously collected samples or data, was consent obtained from participants for use in research?**  |
| 🞏 Yes 🞏 No 🞏 N/A |
| **6.13 If using previously collected samples or data, is the honours project research consistent with the consent previously obtained?** (please provide previous consent wording with relevant sections highlighted) |
| 🞏 Yes 🞏 No 🞏 N/A |
| **7. 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:** |
| **7.1 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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| **7.2 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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| 8. 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)).  |
| **8.1 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.
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| 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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| **8.2 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.
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| Required Signature of Principal Investigator |  | Date |  |
| Print name |  |

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| **8.3 Honours Student** Please add additional signature boxes as required for *joint honours projects* involving multiple students, if applicable. All students must sign the declaration.My signature confirms 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.
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| Name and signature of Student |  | Date |  |

**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
* Please provide a covering letter clearly indicating that the submission is for an honours student research project.

**Please provide one copy of the protocol application form and all supporting documents in one single PDF:**1. Covering letter
2. Completed honours student research protocol application form (FHS038)
3. Research protocol (please refer to the FHS015hlp for guidance: <http://www.health.uct.ac.za/fhs/research/humanethics/forms/>)
4. 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)
5. Letters of authorization from institutions such as hospitals, clinics and schools (where necessary)
6. Measurement instruments (e.g., surveys, questionnaires, interview schedules) (where necessary)
7. Recruitment material (e.g., advertisements, flyers, posters) (where necessary)
8. Materials for participants (e.g. participant diaries, identification cards) (where necessary)
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| Please submit the form to:  |  hrec-submissions@uct.ac.za   |