**Form FHS013: New protocol application form – Section A**

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| Instructions | | | | | | | | | | | | |
| * **Researchers must ensure that they use the current version of the application form on** [**UCT Administrative Forms**](http://forms.uct.ac.za/forms.htm#HealthSciences) **web page.** * Applicants wishing to register **databases**, **registries** or **repositories** should only fill out form [FHS020.](https://forms.uct.ac.za/fhs020.docx) | | | | | | | | | | | | |
| 1. Protocol information | | | | | | | | | | | | |
| Protocol title | |  | | | | | | | | | | |
| Protocol number  (if applicable) | |  | | | | | | | | | | |
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| 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 | | |  | |
| \* Please comment briefly on safety and efficacy findings of the existing/main study that may have relevance to this application. (Please also add a brief description in new study synopsis) | | | | | | | | | | | | |
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| 2. Investigator(s) profile | | | | | | | | | | | | |
| **Note:**  For all postgraduate student research, the **main** supervisor must be listed as PI on this form.  For all undergraduate student research please **only** complete the [FHS021](https://forms.uct.ac.za/fhs021.docx) form and not this form.  The PI or Co-PI **must** be a UCT affiliated person.  **2.1 UCT’s Principal Investigator – (PI)** | | | | | | | | | | | | |
| Title, First name, Surname |  | | | | | | | | | | | |
| Department/Division |  | | | | | | | | | | | |
| Phone |  | | | | | | | | | | | |
| Email address |  | | | | | | | | | | | |
| Department /Office Internal Mail Address for Correspondence |  | | | | | | | | | | | |
| Registration with HPCSA (tick ✓) | 🞏 Yes | | 🞏 No | | | Registration # | | |  | Expiry date | |  |
| Is the PI covered by professional liability insurance? (tick ✓) | | | | | | | | | 🞏 Yes | 🞏 No | | |
| If ***Yes*** above, please provide the liability insurance number and expiry date. | | | | Liability insurance # | | |  | | | Expiry date | |  |

**Note:** **If a non-medically trained PI is overseeing research that involves medical procedures, the application must include a medical doctor registered with the HPCSA as a Sub-investigator.**

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| **2.2 Sub-investigator(s) Note:** Staff and students involved in the research must be listed as sub-investigators | | |
| Title, First name, Surname | Department/Division | Email |
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| **2.3 Is this protocol for degree purposes? (tick** ✓**)** | | |
| 🞏 Yes | | 🞏 No |
| If yes, please specify: | | |
| Type of degree |  | |
| Student’s title, first name, surname |  | |
| Student’s email |  | |

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| **2.4 Supervisor(s)** | | |
| Title, First name, Surname | Department and University | Email |
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| **2.5 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) |  |
| Sub-investigators |  | Number of participants |  |

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| 2.6 What is the PI’s role in authoring this protocol? (tick ✓ all relevant) | | |
| Primary author |  |
| Collaborator |  |
| Supervisor |  |
| None (developed by sponsors) |  |

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| 2.7 Are there any publication restrictions on the research? | |
| 🞏 Yes | 🞏 No |
| If yes, please describe and justify: | |
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| **2.8 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: | | | |
|  | | | |
| 3. Protocol profile | | | |
| **3.1 Has this protocol been submitted to another Human Research Ethics Committee? (tick** ✓**)** | | | |
| 🞏 Yes | | | 🞏 No |
| If yes, please complete: | Name of Institution | | Outcome |
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| **3.2 To your knowledge, has this protocol been rejected by another HREC? (tick** ✓**)** | | |
| 🞏 Yes | 🞏 No | 🞏 Don’t know |
| If yes, please provide the reasons: | | |
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| **3.3 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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| **3.4 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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| **3.5 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 UNDERGOING EXPEDITED REVIEW MAY NEED TO BE CONSIDERED AT A FULL COMMITTEE MEETING** | |
| **3.6 Are there additional requirements by a funder or sponsor that require the study to undergo Full Committee review? (tick** ✓**)** | |
| 🞏 Yes | 🞏 No |
| Comments | |
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| **3.7 Does this protocol comply with all the principles of the** [**Helsinki Declaration of 2013**](https://health.uct.ac.za/sites/default/files/content_migration/health_uct_ac_za/54/files/Helsinki%25202013.pdf)**, including care after research, if applicable? (tick** ✓**)** | | | | | |
| 🞏 Yes | | | 🞏 No | | |
| If no, please explain with full justification: | | | | | |
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| **3.8 No - Fault Insurance**  **Note:** Research participants should not have to bear the financial cost of remedying harms that occur when something goes wrong during a study. Consequently, the University of Cape Town requires researchers or sponsors to provide compensation to participants who suffer research-related bodily injuries during clinical studies conducted under its auspices. Although insurance is not a requirement for all research, when research-related bodily injury is foreseeable, researchers, industry and the HREC must ensure insurance cover is available.  No Fault compensation implies that participants incurring a research-related injury are not required to prove wrong-doing to be compensated.  The cover is for research participants in UCT sponsored trials who may be injured or suffer side effects or death through their direct participation in a trial. It is important that all trials have study specific insurance confirmation from the Insurance Office and the trials must be ratified by the UCT FHS HREC. All studies must be declared individually to the Insurance Office **via** [fhs.sponsorship@uct.ac.za](mailto:fhs.sponsorship@uct.ac.za) and a study specific insurance confirmation will be provided. UCT is mandated to provide a consolidated list of all its studies every 6 months to the insurers. Any injury to the participants not linked to the trial or is as a result of PI malpractice/negligence is not covered under this insurance policy (please refer to UCT Professional Indemnity Policy).  ***Please refer to the UCT Sponsorship booklet Link:*** <http://www.crc.uct.ac.za/crc/sponsorship> | | | | | | |
| ***Faculty of Health Science policy is that all clinical trial studies that involve Human Participants should have an insurance cover.***  **Does this study involve human participants? (tick✓)** | | | | | | |
| ☐ Yes | | | | ☐ No (If ‘no’, please complete 3.8.4 below) | | |
| **3.8.1 If ‘yes’, please indicate the type of insurance cover:** | | | | | | |
| ☐ ABPI-compliant sponsor’s insurance policy | | | | ☐ UCT No-Fault insurance policy  **Note:** Please liaise with the [Research](mailto:Research) Office via [fhs.sponsorship@uct.ac.za](mailto:fhs.sponsorship@uct.ac.za) to obtain an Insurance Certificate  ☐ UCT No-fault Insurance Certificate attached  ☐ N/A – Not Applicable  (**tick ✓ to confirm)** | | |
| Insurer’s name |  | | |
| Policy no |  | | |
| Coverage period |  | | |
| **Note:**   * Please use the approved HREC Insurance Clause in your Consent Form as per the [HREC SOP.](https://health.uct.ac.za/sites/default/files/media/documents/health_uct_ac_za/54/UCT%20HREC%20Standard%20Operating%20Procedures%20Version%207.0%20October%202019.pdf) * Kindly refer to [UCT Sponsorship Insurance Booklet](file:///\\Srvslsfsv003\datshr202\RG&F\3%20Merged%20Pre-%20and%20Post%20Award%20Folder\4%20Pre-Award%20Unit\Research%20Ethics%20Administration\HUMAN%20ETHICS\HREC%20FORMS\CURRENT%20WEBSITE%20FORMS\UCT%20Sponsorship%20%20Insurance%20Booklet_1.0%207%20Sep%202021_YHSigned.pdf) * Please liaise with the Research Office at [fhs.sponsorship@uct.ac.za](mailto:fhs.sponsorship@uct.ac.za) regarding the required documentation and information to be submitted in order to obtain a UCT No-fault Insurance Certificate. | | | | | | |
| **3.8.2 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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| **3.8.3 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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| **3.8.4 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: |

**4.1 Funding and grant information (Required)**

Note: A summary budget must be attached in the appendices

Please tick ✓ the appropriate box for billing purposes:

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|  | ***Submission Type*** | ***Description*** | ***New fee (Vat Incl.)*** | **tick ✓** |
| ***A.*** | ***Research funded solely from UCT departmental/ divisional/group budget*** | New applications (FHS013 Form)/ Extensions | **R0.00** | 🞏 |
| ***B.*** | ***Non-sponsored student research for degree purposes at UCT/ Other Universities or Colleges*** | New applications / Extensions | **R0.00** | 🞏 |
| ***C.*** | ***New Clinical Trial/Covid-19 Interventional application (FHS013 Form)/Full Committee Review*** | Pharmaceutical / Industry driven company sponsors an investigator to conduct a new research project | **R31 993.00** | 🞏 |
| ***D.*** | ***New application*** | International grant funded research (Total project budget above R5m) | **R22 470.00** | 🞏 |
| ***E.*** | ***New application*** | International grant funded research (Total project budget R1m to R5m) | **R14 980.00** | 🞏 |
| ***F.*** | ***New application*** | International grant funded research (Total project budget below R1m) | **R7 490.00** | 🞏 |
| ***G.*** | ***New application*** | National grant funded research (Total project budget above R5m) | **R14 980.00** | 🞏 |
| ***H.*** | ***New application*** | National grant funded research (Total project budget R1m to R5m) | **R7 490.00** | 🞏 |
| ***I.*** | ***New application*** | National grant funded research (Total project budget R500 000 < R1m) | **R3 600.00** | 🞏 |
| ***J.*** | ***Extension clinical study /Covid-19 Interventional Study/ Additional clinical site*** | Project is extended; study rolls over to open label; re-evaluation of protocol for continuation; sub-study | **R15 000.00** | 🞏 |
| *K.* | ***Extension / Additional site*** | International grant funded research - Project is extended; study rolls over to open label; re-evaluation of protocol for continuation; sub-study | **R8 000.00** | 🞏 |

**Please complete the Ethics Debit form if you ticked off between C - K.**

**Note: If a waiver is required, please send an email to** [**hrec-payments@uct.ac.za**](mailto:hrec-payments@uct.ac.za) **and advise the reason for this waiver.**

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| **4.2 What is the total sponsorship/funding for this protocol?** |  |

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| **4.3 Into what entity will the funding be paid and when?** |  |

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| **4.4 Where applicable, has the PI negotiated an agreement with the hospital or other health or laboratory services to cover the costs of interventions/ procedures/ investigations performed solely for research purposes? (**e.g. extra MRIs, CT scans, diagnostic tests, prolonged hospitalisation, use of non-research staff to collect research-related data or perform research-related procedures) **(tick** ✓**)** | | | | |
| 🞏 N/A | | 🞏 Yes | 🞏 No | |
| If no, please explain how research costs will be recovered | | | | |
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| 5. Characteristics of the protocol | | | | |
| **5.1 Category of research**  Please select an appropriate category for your protocol. If the protocol falls in more than one category, please designate a primary and secondary category by entering a ‘1’ and a ‘2’. | | | | |
| Medical intervention/ clinical trial (e.g. medicines, traditional or complementary medicines, nutriceuticals, devices or innovation) | | | |  |
| 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 | | | |  |
| Establishment of a specimen repository, medical database/ registry | | | |  |
| 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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| **5.2 BIOHAZARD STATEMENT**  **Important: All researchers must be aware of and familiar with the Material Safety Data Sheet (MSDS) Safety Sheets for each of the compounds/organisms used in this study.**  **Note:** Faculty Biosafety Committee approval is required for all projects involving biohazardous material that poses a real or potential risk to human health and/or the environment.  **Examples include:** transfer of rDNA, DNA, or RNA into whole animals or plants; use of human or animal pathogens (BSL2 and higher); use of genes encoding toxins that are lethal for vertebrates; and release of GMOs into the environment. | | |
| Will this application require **approval** by the **Faculty Biosafety Committee?**  If yes, please note that you are required to submit an application for approval to the Faculty Biosafety Committee / GMO committee. Please consult the Faculty Research webpage at:  <http://www.health.uct.ac.za/fhs/research/faculty-biosafety-committee> | 🞏 Yes | 🞏 No |

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| **5.3 Does the study involve innovative therapy?**  Innovative therapy is a newly introduced or modified therapy with unproven effect or side effect and is being delivered in the best interest of the patient. While there are clear distinctions in the aims of research and care, innovative therapy is experimental in nature and may involve data collection, similar to that for research. The HREC needs to determine whether the planned intervention can be classed as research. | | | | 🞏 Yes | 🞏 No |
| Please describe the innovative therapy. | | | | | |
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| **5.4 Category of participants** | 🞏 Adults | 🞏 Minors (<18 years) | | | |
| Please specify age range: |  | | |

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| **5.5 If conducting research with minors, please provide the justification for the proposed inclusion of minors in the study.** (**Required**) | | | |
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| **5.5.1 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/media/documents/health_uct_ac_za/54/UCT%20HREC%20Standard%20Operating%20Procedures%20Version%207.0%20October%202019.pdf)) | | | |

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| **5.6 Estimated number of participants to be enrolled at the local site.** | Number of Adults: |  | Number of Minors: |  |

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| **5.7 Estimated duration of the study.** |  |

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| **5.8 Location(s) of the study**: (Please supply name of the Research Unit / Site and/orHospital/Institutionand particular department – if applicable) |
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| **5.9 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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| **5.10 Please describe where and how recruitment will take place; and who will be recruited?** |
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| **5.11 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 the delegated HR authority, 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 delegated HR authority, 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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| **5.12 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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| **5.13 Will human tissue samples be collected for research purposes?** | | | | 🞏 Yes | 🞏 No |
| **5.13.1 Type of samples to be collected:** | | | | | |
| 🞏 Blood | 🞏 Tissue | 🞏 Genetic material | 🞏 Other (please specify in field below) | | |
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| **5.14 Will data and/or samples be stored for future use?** | 🞏 Yes | 🞏 No |
| **5.14.1 If yes, please attach a SOP for the governance and storage of samples for future use with the protocol submission.** | | |

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| **5.15 Will data and/or samples obtained in this study be shared with other researchers and/or institutions?** | 🞏 Yes | 🞏 No |
| **5.15.1 If yes, please specify who will have access to data and/or samples from this study.** | | |
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| **5.15.2 If yes, has a Material Transfer Agreement been approved by the Research Contracts & Innovation (RC&I) office?** | 🞏 Yes | 🞏 No |

**Note: All Material Transfer Agreements (MTA’s) for incoming and outgoing data and/or samples should be approved by the Research Contracts & Innovation (RC&I) office and submitted to the HREC office for acknowledgment.**

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| **5.16 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/media/documents/health_uct_ac_za/54/UCT%20HREC%20Standard%20Operating%20Procedures%20Version%207.0%20October%202019.pdf) **for guidance: Privacy and Confidentiality and Collection and Storage of Data or Biological Specimens for Research Purposes** |
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| 6. Clinical trials | Is this protocol a clinical trial (tick ✓): | 🞏 Yes | 🞏 No (If no, please go to Q.7) |
| This section must be completed **only** if the research involves a clinical trial of drugs/ medicines, herbal, complementary indigenous therapies; or a substance testing a clinical outcome, therapeutic devices; an innovative therapy or intervention; off-label use or a departure from standard treatment or care.  The SA GCP Guidelines (2020) define a clinical trial as any investigation in human participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s) and/or to study absorption, distribution, metabolism and excretion of an investigational product(s) with the objective of ascertaining its safety and/or efficacy.  WHO: ‘a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.  Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.’ | | | |

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| **6.1 Is the product registered with the South African Health Products Regulatory Authority (SAHPRA)?** (tick ✓) | | | 🞏 Yes | 🞏 No |
| If yes, please provide the registration number |  | | | |
| If no, is the SAHPRA’ s approval letter for use of an unregistered medicine attached?  **Note:** HREC approval must be obtained prior to study commencement. | | 🞏 Yes | | 🞏 No |
| 🞏 Application submitted | | |
| If registered, will the product be studied for an **indication** different to that in the latest approved SA package insert? | | | 🞏 Yes | 🞏 No |
| If registered, will the product be studied using a **dose** different to that in the latest approved SA package insert? | | | 🞏 Yes | 🞏 No |
| If registered, will the product be studied using a **formulation** different to that in the latest approved SA package insert? | | | 🞏 Yes | 🞏 No |
| If registered, will the product be studied using **a route of administration** different to that in the latest approved SA package insert? | | | 🞏 Yes | 🞏 No |

**Note:** If yes to any of the above, SAHPRA approval is required.

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| **6.2 Does the study involve an FDA-monitored product (drug, device or biological)?** (tick ✓) | 🞏 Yes | 🞏 No |

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| **6.3 Is this trial registered with the South African Clinical Trial Register?** | | 🞏 Yes | 🞏 No |
| If yes, please provide the registration number |  | | |
| If no, application submitted? | | 🞏 Yes | 🞏 No |
| If no application submitted, please justify. |  | | |

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| **6.4 Is this trial registered with the Pan African Clinical Trials Registry?  (See:** [**www.pac**t**r.org**](http://www.pactr.org) **)** | | | 🞏 Yes | 🞏 No |
| If yes, please provide the registration number | |  | | |
| If no, application submitted | | | 🞏 Yes | 🞏 No |
| **6.5 Does this trial comply with the South African Good Clinical Practice (SA GCP): Clinical Trial Guidelines , 3rd Edition, 2020?** (tick ✓) | | | 🞏 Yes | 🞏 No |
| If no, please justify |  | | | |

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| **6.6 Note: The Helsinki Declaration states: ‘*The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention.’* Please describe the local and international standards of care. If appropriate, please provide a strong justification for including an intervention in this study that is different from the recognized standard of care.** |
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| **6.7 Care after research** | |
| **Please provide information about the provision of appropriate care or benefits after the study has been completed.**  **Note:** In accordance with the Helsinki Declaration of 2013, this must include provision of the investigational product once the study has been completed, for participants that benefit, or a justification as to why investigational product will not be provided.  Where relevant, consent forms should include specific information clarifying what post-trial care will be provided at the end of the study, including access to any investigational products used. If none will be provided, this should also be explicitly indicated in the consent forms. | |
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| **7. Statement of conflict of interest** | |
| The PI 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. |  |
| I, or any member of my family or business partnerships, **will not** receive any payment for enrolling participants in this study. |  |

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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 in the space 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. (see: [SOP](https://health.uct.ac.za/sites/default/files/media/documents/health_uct_ac_za/54/UCT%20HREC%20Standard%20Operating%20Procedures%20Version%207.0%20October%202019.pdf)) | | | |
| **8.1 Head of Department or Division**  My signature confirms that:   1. The researcher(s)/student(s)/supervisor(s) have the skills, training (including research ethics training), experience and time to undertake this research. 2. There are adequate resources (e.g. equipment, space, support services) to perform this research. | | | |
| Signature of Head |  | Date |  |
| Print name |  | | |

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

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| **8.2 Chairperson of the Departmental Research Committee (DRC)**  My signature confirms that:   1. This research protocol has undergone peer review by a person(s) experienced in the field of study. 2. This research is well-designed and scientifically sound. 3. Where relevant, all methodological issues have been resolved to the satisfaction of the peer reviewer(s). 4. If conducted according to the protocol, this research is expected to yield valid and useful findings. | | | |
| Signature of Chairperson |  | Date |  |
| Print name |  | | |

**Note:** Where the PI is also the Chairperson of the DRC, confirmation must be obtained from an authorised designee. PIs may not approve their own research.

**Note:** For multidisciplinary and interdepartmental research, the signing DRC Chairperson need to confirm that there has been appropriate consultation with the DRC from the relevant departments.

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| **8.3 Principal Investigator**  My signature confirms that:   1. Information in this application is true and accurate. 2. I will begin the research only after written HREC approval is obtained. 3. I accept full responsibility for the conduct of this research and the protection of participants’ rights and welfare. 4. I will conduct the research according to all ethical, regulatory and legal requirements stipulated in the HREC’s Standard Operating Procedures; as well as national and international guidelines/regulations. 5. I will provide annual progress reports to the HREC as requested, including a final closing report at the end of the research. 6. I will notify the HREC in writing if any change to the research is proposed and await approval before proceeding with the proposed change except when urgently necessary to protect participants’ safety. 7. I will notify the HREC in writing immediately if any adverse event or unanticipated problem occurs during the research. 8. I will allow an audit of my research if requested by the HREC. 9. I have the time, training, experience and resources to oversee this research. 10. I will endeavour to publish and disseminate the findings of the study. | | | |
| Signature of Principal Investigator |  | Date |  |
| Print name |  | | |

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| **8.4 Student supervisor (if research is for a degree)**  My signature confirms that:   1. The student researcher has adequate training and resources to complete the research in the allocated timeframe. 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. I will meet the student on a regular basis to monitor progress and address any problems that may arise during the study. 6. 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. 7. If applicable, I will ensure that I report unanticipated problems or serious adverse events to the HREC. 8. I will arrange for an alternative faculty supervisor to take responsibility for this research during periods of absence such as sabbatical or annual leave. | | | |
| Signature of Supervisor |  | Date |  |
| Print name: |  | | |

**Note:** The supervisor and student researcher are jointly responsible for the ethical conduct of this research from inception to dissemination of findings.

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| **8.5 Student (if research is for a degree)**  My signature confirms that:   1. Information in this application is true and accurate. 2. I will begin the research only after written HREC approval is obtained. 3. I accept full responsibility for the conduct of this research and the protection of participants’ rights and welfare. 4. I will conduct the research according to all ethical, regulatory and legal requirements as stipulated in the HREC’s Standard Operating Procedures. | | | |
| Signature of Student |  | Date |  |
| Print name |  | | |

**HREC - Debit Order Form**

**Please complete the Ethics Debit form if you ticked off between C - K.**

**To be Completed by the Ethics Office:**

Reference number of Study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person Completed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| ***Research Ethics Committee Fee Structure – New Application*** | | | |
| ***Submission Type*** | ***Description*** | ***New fee (Vat Incl.)*** | **tick ✓** |
| ***New Clinical Trial/Covid Interventional application (FHS013 Form)/ Full Committee Review*** | Pharmaceutical / Industry driven company sponsors an investigator to conduct a new research project | **R31 993.00** | 🞏 |
| ***New application*** | International grant funded research (Total project budget above R5m) | **R22 470.00** | 🞏 |
| ***New application*** | International grant funded research (Total project budget R1m to R5m) | **R14 980.00** | 🞏 |
| ***New application*** | International grant funded research (Total project budget below R1m) | **R7 490.00** | 🞏 |
| ***New application*** | National grant funded research (Total project budget above R5m) | **R14 980.00** | 🞏 |
| ***New application*** | National grant funded research (Total project budget R1m to R5m) | **R7 490.00** | 🞏 |
| ***New application*** | National grant funded research (Total project budget less than R1m to R500 000) | **R3 600.00** | 🞏 |
| ***Extension clinical study / COVID-19 study / Additional clinical site*** | Project is extended; study rolls over to open label; re-evaluation of protocol for continuation; sub-study | **R15 000.00** | 🞏 |
| ***Extension / Additional site*** | International grant funded research - Project is extended; study rolls over to open label; re-evaluation of protocol for continuation; sub-study | **R8 000.00** | 🞏 |

**Please note: Completion of this form is crucial and must be included in all the submissions submitted.**

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| **Section A: Fund Deduction** | |
| **Project name** |  |
| **Principal Investigator – (PI)** |  |
| **Fund Number & Cost Centre** |  |
| **Fund Holder** |  |
| **Contact Person for payment queries** |  |
| **Contact number for payment queries** |  |
| **Amount to be deducted:**  (Refer to Addendum A – attached Fee Structure) | **R** |

**Note: If fund provided has insufficient funds, a miscellaneous fund will be allocated automatically.**

***If fund is not applicable and Sponsor should be billed, Please complete Section B.***

|  |  |
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| Section B: Sponsor Details / Biller to be invoiced directly | |
| For invoices to be generated correctly, kindly complete below: | |
| **Sponsor’s name** |  |
| **SAP Customer number** |  |
| **Contact person** |  |
| **Address** |  |
| **Vat number** |  |
| **Telephone number** |  |
| **Email Address** |  |
| **Amount to Be Billed**  (Refer to Addendum A – attached Fee Structure) | **R** |

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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. Sections A-C must be included. Instructions for submission of new applications are posted on the HREC website.** |

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| **Note:** There are two categories for submissions of studies – those that are reviewed by the full HREC committee and those that are expedited i.e. are reviewed outside the full HREC meeting.  Upon receipt of the protocol application, an assessment of the likely risks to participants will be undertaken and a decision will be made by the HREC EXCO as to whether a protocol may be expedited. **All expedited protocols are still subject to full review; and are not subject to any timeline advantage.** |

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| **Category 1: For Industry/ Pharmaceutical / Grant / Donor Sponsored Clinical Trials involving Drugs / Devices** |
| **Instruction for full committee review:**   * Please make sure the study is submitted on or before submission day link:   <https://health.uct.ac.za/sites/default/files/media/documents/health_uct_ac_za/54/HREC%20Meeting%20Dates%20for%202023.pdf>   * Submission format can be found on the following link:   <https://health.uct.ac.za/sites/default/files/media/documents/health_uct_ac_za/54/HREC%20-%20Electronic%20submission%20process.pdf>   * Please make sure the study has all signatures required, as incomplete documents will not be processed. * Please email all documents for full committee review to [hrec-submissions@uct.ac.za](mailto:hrec-submissions@uct.ac.za) |

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| **Category 2: For Expedited Studies** |
| Protocols may be potentially reviewed using an expedited review process if they meet the following criteria [45 CFR 46.110(b)(1)]:  a. Research poses no more than minimal risk to subjects; AND  b. Research for which each of the procedures falls within one of the following expedited review categories outlined by the Office for Human Research Protections (OHRP) [45 CFR 46.110] and the Food and Drug Administration (FDA) [21 CFR 56.110]: [Eligibility for Expedited Review of US Federally-funded Research – Pointers for Researchers](file:///C:\sites\default\files\media\documents\health_uct_ac_za\54\Expedited_Review_of_US_Federally_Funded_Research_%2016.02.2022.docx). Also see see ‘eligibility for expedited review’ in the HREC SOP for the [Protocol Review Process](file:///C:\sites\default\files\media\documents\health_uct_ac_za\54\HREC%20SOPs%20v7.1%20October%202019%20-%20Protocol%20Review%20Process.pdf)).  **Instruction for expedited review:**   * Please prepare your submission pack in the order specified below. * Please motivate fully for an expedited review using the eligibility criteria above * Please note that after receiving your submission, the HREC Chairperson or designee might determine that your study falls in more than minimal risk to subjects and does require full committee review; the HREC Office will request additional copies of the documents for circulation among Committee members before the next HREC meeting. * Submission format can be found on the following link: <https://health.uct.ac.za/sites/default/files/media/documents/health_uct_ac_za/54/HREC%20-%20Electronic%20submission%20process.pdf> * Please email your submission to [hrec-submissions@uct.ac.za](mailto:hrec-submissions@uct.ac.za) in one single PDF |

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| **Checklist – FHS013 submissions** | | |
| **For Full Committee Review** |  | **For Expedited Review - Category 2** |
| 1. Completed Protocol Application Form |  | 1. Completed Protocol Application Form |
| 1. Cover letter listing all submitted docs with version numbers and version dates |  | 1. Cover letter listing all submitted docs with version numbers and version dates |
| 1. PI Generated Synopsis (see FHS014) (**Required**) 2. Debit Form   (**Required**) |  | 1. PI Generated Synopsis (see FHS014) (**Required**) 2. Debit Form   (**Required – When Applicable**) |
| 1. Sponsor’s Synopsis (if applicable) |  | 1. Motivation for Expedited Review |
| 1. Research Protocol (see FHS015hlp) |  | 1. Research Protocol (see FHS015hlp) |
| 1. Consent and assent forms (English versions/and translated into local language) |  | 1. Consent and assent forms (English versions/and translated into local language) |
| 1. Sponsor’s Protocol |  | 1. NIH or other US federal grant application  (if PI is primary awardee) |
| 1. NIH or other US federal grant application (if PI is primary awardee) |  | 1. Surveys, questionnaires, interview schedules |
| 1. If an application has been submitted to the SAHPRA, a copy of (Ethical Issues) extracted from the CTF1 application form |  | 1. Recruitment materials: advertisements, flyers, posters |
| 1. Surveys, questionnaires, interview schedules |  | 1. Materials for participants: diaries, patient identification cards |
| 1. Recruitment materials: advertisements, flyers, posters |  | 1. Letters of authorisation from institutions such as hospitals, clinics and schools |
| 1. Materials for participants: diaries, patient identification cards |  | 1. No- Fault Insurance Certificate (where applicable) |
| 1. Letters of authorisation from institutions such as hospitals, clinics and schools |  | 1. Budget summary |
| 1. Post-trial care/Care after research justification |  | 1. Post-trial care/Care after research justification |
| 1. A summary of Phase III efficacy and safety data if this is an application for an open label or extension study |  | 16. If Minors are involved, please attach **FORM A** found on the HREC website |
| 1. No-Fault Insurance Certificate (If applicable) |  | 17. SOP for governance and storage of samples; and MTA’s (where applicable) |
| 1. Budget summary |  | 18. Other relevant documentation and appendices |
| 1. SAHPRA letter of approval, if available |  | 19. SOP for research-related activities during COVID-19 lockdown |
| 1. Investigator’s brochure and package inserts |  |  |
| 1. In the case of clinical trials, PI’s declaration, CVs and GCP certificates for PI and co-investigators |  |  |
| 1. If Minors are involved, please attach FORM A found on the website |  |  |
| 1. SOP for governance and storage of samples; and MTA’s (where applicable) |  |  |
| 1. Other relevant documentation and appendices |  |  |
| 1. SOP for research-related activities during COVID-19 lockdown |  |  |

**Note:**

* Clearly list all documents with version numbers and dates on the cover letter.
* Please submit the application form to [hrec-submissions@uct.ac.za](mailto:hrec-submissions@uct.ac.za)
* Documents under 35MB kindly send in one single PDF
* Large documents can you kindly send in a PDF portfolio via Dropbox

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| Please submit the completed form together with the supporting documents by hand delivery or registered mail to | **FHS Human Research Ethics Admin Office**  **c/o the secretary – HREC Office Address:**  Human Research Ethics Committee  E 53, Room 46, Old Main Building, Groote Schuur Hospital, Observatory  Office Contacts: 021 406 6492; 021 404 7682; 021 406 7260  **Electronic copy of your submission to be emailed to:** hrec-submissions@uct.ac.za  Invoice queries: [hrec-payments@uct.ac.za](mailto:hrec-payments@uct.ac.za)  **Website:** <http://www.health.uct.ac.za/fhs/research/humanethics/forms/> |