**FHS016: Annual Progress Report / Renewal**

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| **HREC office use only (FWA00001637; IRB00001938)**  **This serves as notification of annual approval, including any documentation described below.** | | | | | | | | | |
| 🞏 Approved | Annual progress report | | | Approved until/next renewal date | | | |  | |
| 🞏 Not approved | See attached comments | | | | | | | | |
| Signature Chairperson of the HREC/ Designee | | |  | | | Date Signed | |  | |
| **Note:** Please email this form and supporting documents (if applicable) in a combined pdf-file to  [hrec-enquiries@uct.ac.za](mailto:hrec-enquiries@uct.ac.za).  Please use the latest form found on our website: <http://www.health.uct.ac.za/fhs/research/humanethics/forms> | | | | | | | | | |
| Comments to PI from the HREC | | | | | | | | | |
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| Principal Investigator to complete the following:  **1. Protocol information** | | | | | | | | | |
| Date  (when submitting this form) | |  | | | | | | | |
| HREC REF Number | |  | Current Ethics Approval was granted until | | | | | |  |
| Protocol title | |  | | | | | | | |
| Protocol number  (if applicable) | |  | | | | | | | |
| Are there any sub-studies linked to this study? | | | | | 🞏 Yes | | 🞏 No | | |
| If yes, could you please provide the HREC Reference number for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study. | | | | |  | | | | |
| Principal Investigator | |  | | | | | | | |
| Department and email address | |  | | | | | | | | |

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| 1.1 Does this protocol receive US Federal funding? | | | 🞏 Yes | | 🞏 No |
| 1.2 If the study receives US Federal Funding, does the annual report require full committee approval?  **Note:** Any annual approvals for **Full Committee** review MUST be submitted on the monthly HREC submission dates.  (Please send electronic combined copy if for full committee review to  [hrec-submission@uct.ac.za](mailto:hrec-submission@uct.ac.za)) | | | 🞏 Yes | | 🞏 No |
| **If yes in 1.2 please complete section 1.3 below for invoicing purposes** | | | | | |
| **1.3 Ethics Renewal Fee** | | | | | |
| Please (tick ✓)appropriate box for billing purposes:   |  |  |  |  | | --- | --- | --- | --- | | ***Submission Type*** | ***Description*** | ***New fee (Vat Incl.)*** | ***tick ✓*** | | ***Research funded solely from UCT departmental/ divisional/group budget/self-initiated research*** | Annual evaluation of research progress report for re-certification | **R0,00** | 🞏 | | ***Non-sponsored student research for degree purposes at UCT/Other Universities & Colleges*** | Annual evaluation of research progress report for re-certification | **R0,00** | 🞏 | | ***Annual re-certification / Progress report (FHS016 Form)*** | Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Full Committee Approval | **R7700,00** | 🞏 | | ***Annual re-certification / Progress report (FHS016 Form)*** | Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Expedited review | **R3800.00** | 🞏 | | ***Annual re-certification / Progress report (FHS016 Form)*** | National grant funded research - Annual evaluation of research progress report for re-certification for Full Committee Approval | **R5000.00** | 🞏 | | ***Annual re-certification / Progress report (FHS016 Form)*** | National Grant funded research for Annual evaluation of research progress report for re-certification for Expedited review | **R1650,00** | 🞏 |   *NB: Protocols funded by UCT (e.g. departmental funding / student research) and by certain*  *grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from these charges.* | | | | | |
| **Please provide details for Invoicing, either complete section 1 or 2 :** | | | | | |
| 1. **Invoice billing – Directly to Sponsor** | | | | | |
| Sponsor’s name | |  | | | |
| Billing Address of Sponsor: | |  | | | |
| Vat Number: | |  | | | |
| Contact person | |  | | | |
| Telephone number | |  | | | |
| Email Address | |  | | | |
| 1. **Internal Journal Billing:** | | | | | |
| Fund Number: | |  | | | |
| Cost Centre Number: | |  | | | |
| Account Holder Name: | |  | | | |
| Division of Account Holder: | |  | | | |
| **2. List of documentation included to support this approval where applicable** | | | | | |
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| **3. Protocol status (tick ✓)** | | | | | |
| 🞏 | Open Enrolment | | | | |
| 🞏 | Closed to enrolment (tick ✓) | | | | |
| 🞏 | Research-related activities are ongoing | | | | |
| 🞏 | Research-related activities are complete, long-term follow-up only | | | | |
| 🞏 | Research-related activities are complete, data analysis only | | | | |
| 🞏 | Main study is complete but sub-study research-related activities are ongoing | | | | |
| 🞏 | Publication or thesis submitted and final completion? | | | | |
| 🞏 | Study is closed 🡪 Please submit a Study Closure Form ([FHS010](https://health.uct.ac.za/sites/default/files/content_migration/health_uct_ac_za/54/files/fhs010_16.02.2022.doc)) | | | | |
| **4. Enrolment** | | | | | |
| Number of participants enrolled to date | | | |  | |
| Number of participants enrolled, since last HREC Progress report (continuing review) | | | |  | |
| Additional number of participants still required | | | |  | |
| **5. Refusals** | | | | | |
| Total number of refusals (participants invited to join the study, but refused to take part) | | | |  | |
| **6. Cumulative summary of participants** | | | | | |
| Total number of participants who provided consent | | | |  | |
| Number of participants determined to be ineligible (i.e. after screening) | | | |  | |
| Number of participants currently active on the study | | | |  | |
| Number of participants completed study (without events leading to withdrawal) | | | |  | |
| Number of participants withdrawn at participants’ request (i.e. changed their mind) | | | |  | |
| Number of participants withdrawn by PI due to toxicity or adverse events | | | |  | |
| Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance) | | | |  | |
| Number of participants lost to follow-up.  Please comment below on reasons for loss of follow-up. | | | |  | |
|  | | | | | |
| Number of participants no longer taking part for reasons not listed above.  Please provide reasons below: | | | |  | |
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| **7. Progress of study** | | | | | |
| Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC: | | | | | |
|  | | | | | |
| **8. Protocol violations and exceptions (tick ✓ all that apply)** | | | | | |
| 🞏 | No prior violations or exceptions have occurred since the original approval | | | | |
| 🞏 | Prior violations or exceptions have been reported since the original approval and have already been acknowledged or approved  If so, did these occur in the last review period | | | | |
| 🞏 | Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review | | | | |
| **9. Amendments (tick ✓ all that apply)** | | | | | |
| 🞏 | No Prior amendments have been made since the original approval | | | | |
| 🞏 | Prior amendments have been reported since the last review and have already been approved | | | | |
| 🞏 | New protocol changes/ amendments are requested as part of this continuing review (See note below) | | | | |

**Note:** If new protocol changes are being requested in this review, please complete an amendment form [(FHS006](http://forms.uct.ac.za/fhs006.doc)).

Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

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| 10. Adverse events |
| 10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established. |
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| 10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)? | | |
| 🞏 Yes | 🞏 No | 🞏 Not applicable |
| If yes, please describe: | | |
|  | | |
| 11. Summary of Monitoring and Audit Activities (tick ✓) | | |
| 11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)? | | |
| 🞏 Yes | 🞏 No | 🞏 Not applicable |

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| 11.2 Did a Data and Safety Monitoring Board publish a report? | | |
| 🞏 Yes | 🞏 No | 🞏 Not applicable |

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| 11.3 If yes, please identify the agency and attach a summary of the findings. | | | | | |
| Agency Name |  | Report attached | 🞏 Yes | 🞏 No | 🞏 Not applicable |
|  | | DSMB report attached | 🞏 Yes | 🞏 No | 🞏 Not applicable |

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| 11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team? | | |
| 🞏 Yes | | 🞏 No |
| If yes, please explain: | | |
|  | | |
| 12. Level of risk (tick ✓) | | |
| 12.1 In light of your experience of this research, please indicate whether the level of risk to participants has: | | |
| 🞏 | Increased | |
| 🞏 | Decreased | |
| 🞏 | Shown no change | |
| If there has been a change, please explain: | | |
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| 12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the  level of risk. | | | | |
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| 13. Insurance   |  |  |  |  | | --- | --- | --- | --- | | Please confirm that valid no fault insurance is still in place? (tick ✓) | | | | | 🞏 Yes | | 🞏 No | | | If yes, please complete the following: | | | | | Insurer’s name: |  | | | | Policy no. |  | \*Coverage Period: |  | | *For UCT sponsored studies please liaise the Insurance office via* [fhs.sponsorship@uct.ac.za](mailto:fhs.sponsorship@uct.ac.za) *regarding the required documentation and information required obtain a renewed UCT No-fault Insurance Certificate.* | | | |   14. Statement of conflict of interest | | | | |
| Has there been any change in the conflict of interest status of this protocol since the original approval?  (tick ✓) | | | | |
| 🞏 Yes | | 🞏 No | | |
| If yes, please explain and if necessary, attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form [FHS013](http://forms.uct.ac.za/fhs013.doc)): | | | | |
|  | | | | |
| 15. Signature | | | | |
| My required signature certifies that the above is complete and correct. | | | | |
| Signature of PI |  | | Date |  |