**Form FHS006: Protocol Amendment**

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| **HREC office use only (FWA00001637; IRB00001938)** |
| 🞏 Approved  | 🞏 Type of review: Expedited  | 🞏 Full committee  |
| This serves as notification that all changes and documentation described below are approved. |
| Signature HREC Chairperson / Designee  |  | Date |  |
| **Note:** All **Major** amendments must include a **Cover Letter** and a local **PI Synopsis** justifying the changes for the amendment. Please note that incomplete amendment submissions will not be reviewed. Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za with subject line: FHS006 + (HREC Reference number). The latest forms are found on our website. <http://www.health.uct.ac.za/fhs/research/humanethics/forms> Please also clarify your plan for research-related activities during COVID-19 lockdown.

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| Comments from the HREC to the Principal Investigator: |
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| **Note:** The approval of this protocol amendment does not grant annual approval. Please complete the [FHS016](https://forms.uct.ac.za/fhs016.docx) / [FHS017](https://forms.uct.ac.za/fhs017.docx) form for annual approval at least one month before study expiration.  |

**Principal Investigator to complete the following:** **1. Protocol information** |
| Date (when submitting this form) |  |
| HREC REF Number |  |
| Protocol Title  |  |
| Protocol Number (if applicable)  |  |
| Principal Investigator |  |
| Department / Office Internal Mail Address |  |
| 1.1 Is this a major or a minor amendment? (see [FHS006hlp](https://forms.uct.ac.za/fhs006hlp.docx)) Major (tick box) Minor (tick box) | 🞏 Major  | 🞏 Minor |
| 1.2 Does this protocol receive US Federal funding? | 🞏 Yes  | 🞏 No |
| 1.3 If the amendment is a major amendment and receives US Federal Funding, does the amendment require full committee approval?**Note:** Any protocol amendments for **Full Committee Review** MUST be submitted on the monthly HREC submission dates.(Please email an electronic copy to hrec-enquiries@uct.ac.za) | 🞏 Yes  | 🞏 No |
| 1.4 Did the initial study require UCT No-Fault Insurance | 🞏 Yes | 🞏 No |

**2. List of Proposed Amendments with Revised Version Numbers and Dates**

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| **Please itemise on the page below, all amendments with revised version numbers and dates, which need approval.** This page will be detached, signed and returned to the PI as notification of approval. Please add extra pages if necessary. |
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| 3. Protocol status (tick ✓) |
| 🞏 | Open to enrolment |
| 🞏 | No participants have been enrolled |
| 🞏🞏🞏 | Closed to enrolment (tick ✓)Research-related activities are ongoingResearch-related activities are complete, long-term follow-up onlyResearch-related activities are complete, data analysis only |
| 4. Proposed changes will affect: (tick ✓ all the categories that apply) |
| Protocol |
| 🞏 | Study objectives, design (including investigator’s brochure, clinical activities, study length) |
| 🞏 | Study instruments, questionnaires, interview schedules |
| 🞏 | Sample size |
| 🞏 | Recruitment methods |
| 🞏 | Eligibility criteria (inclusion and exclusion criteria) |
| 🞏 | Drug/device (composition, amount, schedule, route of administration, combination with other drugs/devices, safety information) |
| 🞏 | Data collection/ analysis |
| 🞏 | Principal Investigator. (Please attach revised conflict of interest and PI declaration statements. Refer: sections 7 and 8.4 in the New Protocol Application Form FHS013) |
| 🞏 | Consent form and information sheet |
| 🞏 | Recruitment materials (e.g. advertisements) |
| 🞏 | Administrative (e.g. change in sponsor’s name, change in contact information) |
| 🞏 | Other. Please specify: |
| *\*Note: Amendment changes involving study length, sample size, additional sites and eligibility criteria (i.e. inclusion of minors and /or pregnant woman) need to be declared to the Insurance office. Please liaise via* *fhs.sponsorship@uct.ac.za* *regarding the required documentation and information to be submitted to obtain an updated UCT No-fault Insurance Certificate- it should be included herewith* |
| 4.1 In your opinion, will there be any **increase** in risk, discomfort or inconvenience to participants? | 🞏 Yes  | 🞏 No |
| If yes, please provide a detailed justification/explanation: |  |
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| 4.2 What follow-up action do you propose for participants who are already enrolled in the study? |
| 🞏 | Inform current participants as soon as possible |
| 🞏 | Re-consent current participants with revised consent/assent forms (append) |
| 🞏 | No action required |
| 🞏 | Other. Please describe: |
| **5. Detailed description of the change(s)** |
| **Please attach, for each amendment, a summary of all changes which clearly indicates:**1. Old wording (e.g. ~~strikethrough~~ text, CHANGED FROM and CHANGED TO)
2. New wording (e.g. *italicized*, **bold**, tracked)
3. Detailed rationale/ justification/ explanation for each change
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**6. Ethics Review for Amendment Levy – cost including vat**

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| Amendment Review Costs including VATPlease tick amount to be billed:

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| ***Submission Type*** | ***Description*** | ***New fee (Vat Incl.)*** | ***tick ✓*** |
| ***Research funded solely from UCT departmental/ divisional/group budget*** | Major/ Minor Amendments | **R0,00** | **🞏** |
| ***Non-sponsored student research for degree purposes at UCT/Other Universities & Colleges*** | Major/ Minor Amendments | **R0,00** | **🞏** |
| ***Protocol amendment - Major (FHS006 Form)*** | Clinical Trial & International Grant Funded Research - Any changes to the protocol that requires Full Committee review | **R8 000.00** | **🞏** |
| ***Protocol amendment - Major (FHS006 Form)*** | Clinical Trial & International Grant Funded Research - Any change to the protocol that requires Expedited review that does not require Full Committee Review | **R5 000,00** | **🞏** |
| ***Protocol amendment - Minor (FHS006 Form)*** | Clinical Trial & International Grant Funded Research - Minor amendments, administrative changes that do not affect study design e.g. changes to informed consent form, changes in study staff, etc. | **R2 250,00** | **🞏** |
| ***Protocol amendment - Major (FHS006 Form)*** | National grant funded research - Any change to the protocol that requires Full Committee review | **R7 000,00** | **🞏** |
| ***Protocol amendment - Major (FHS006 Form)*** | National grant funded research - Any change to the protocol that requires Expedited review that does not require Full Committee review | **R2 500,00** | **🞏** |
| ***Protocol amendment - Minor (FHS006 Form)*** | National grant funded research - Minor amendments, administrative changes that do not affect study design e.g. changes to informed consent form, changes in study staff, etc. | **R1 000,00** | **🞏** |

*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:**
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| Fund Number: |  |
| Cost Centre Number: |  |
| Account Holder Name: |  |
| Division of Account Holder: |  |

**7. Amendment Submission checklist (tick ✓)**

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| 7.1 Please tick that all the documents are attached before submitting to the HREC.NB: Incomplete submissions will not be processed |
| 🞏 | Latest FHS006 form completed with all sections completed as per our website |
| 🞏 | Cover Letter |
| 🞏 | PI Justification/ Summary for the reasons for the amendment |
| 🞏 | Protocol - Track changes & Clean Copy (where necessary) |
| 🞏 | Informed Consent Forms (ICF), if applicable (Any changes made to ICF tracked & clean copy) |
| 🞏 | Any other additional documentation in support of amendment |
| 🞏 | Updated no fault insurance certificate (if applicable)  |

Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za with subject line: FHS006 + (HREC Reference number). The latest forms are found on our website.

**8. Signature**

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| My signature certifies that I will maintain the anonymity and/ or confidentiality of information collected in this research. If at any time I want to share or re-use the information for purposes other than those disclosed in the original approval, I will seek further approval from the HREC. |
| Signature of PI |  | Date |  |