**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](mailto: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.   |  | | --- | | Comments from the HREC to the Principal Investigator: | |  | | **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](mailto: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. | | | |
|  | | | |
| 3. Protocol status (tick ✓) | | | |
| 🞏 | Open to enrolment | | |
| 🞏 | No participants have been enrolled | | |
| 🞏  🞏  🞏 | 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 | | |
| 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*](mailto: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 | |

**6. Ethics Review for Amendment Levy – cost including vat**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Amendment Review Costs including VAT  Please tick amount to be billed:   |  |  |  |  | | --- | --- | --- | --- | | ***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:** | |
| 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](mailto: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 |  |