**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 reasons for the amendment. Please note that incomplete amendment submissions will not be reviewed. All amendments are reviewed subject to the study having study approval timelines. Please complete the [FHS016](http://forms.uct.ac.za/fhs016.doc) / [FHS017](http://forms.uct.ac.za/fhs017.doc) form for annual approval at least one month before study expiration.  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>   |  | | --- | | Comments from the HREC to the Principal Investigator: | |  | | **Note:** The approval of this protocol amendment does not grant annual approval. |   **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 & Email Address |  | | | | | | |
| 1.1 Is this a major or a minor amendment? (see [FHS006hlp](http://forms.uct.ac.za/fhs006hlp.doc)) 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**

|  |  |  |  |
| --- | --- | --- | --- |
| **Please itemise on the page below, all amendments with revised version numbers and dates, which need approval** Please describe your changes/amendment in this section.  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 where no fault insurance has been requested 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/ self-initiated research within UCT*** | 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 - Any changes to the protocol that requires Full Committee review | **R8 800.00** | **🞏** | | ***Protocol amendment - Major (FHS006 Form)*** | International Grant Funded Research - Any change to the protocol that requires Expedited review that does not require Full Committee Review | **R5 500,00** | **🞏** | | ***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 475,00** | **🞏** | | ***Protocol amendment - Major (FHS006 Form)*** | National grant funded research - Any change to the protocol that requires Full Committee review | **R1100,00** | **🞏** | | ***Protocol amendment - Major (FHS006 Form)*** | National grant funded research - Any change to the protocol that requires Expedited review that does not require Expedited review | **R990,00** | **🞏** | | ***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. | **R990,00** | **🞏** |   *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) |
| 🞏 | The PI has signed the form |

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>

**8. Signature**

|  |  |  |  |
| --- | --- | --- | --- |
| 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 |  |