**Form FHS007: Amendment – study staff**

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| --- |
| **HREC office use only (FWA00001637; IRB00001938)** |
| 🞏 Approved  |
| This serves as notification that all changes to the study staff and documentation described below are approved. |
| Chairperson of the HREC signature/ Designee |  | Date |  |

**Note:** Please note that incomplete amendment submissions will not be reviewed.

Please email this form with supporting documentation (where applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.Our website address: <http://www.health.uct.ac.za/fhs/research/humanethics/forms>

**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 and Email address |  |
| 1.1 Does this protocol receive US Federal funding? | 🞏 Yes  | 🞏 No |

**2.1 Staff changes (tick ✓)**

|  |  |  |
| --- | --- | --- |
| Are new personnel being added to this research? | 🞏 Yes  | 🞏 No |
| Are current personnel being removed from this research? | 🞏 Yes  | 🞏 No |
| Is the principal investigator for this research being changed?If yes, please attach revised conflict of interest and PI declaration statements. (Refer: sections 7 and 8.3 in the New Protocol Application Form - FHS013) | 🞏 Yes  | 🞏 No |
| Do the consent and assent forms need modification to reflect these staff changes?If yes, please attach copies of these revised forms, with all changes highlighted or tracked.  | 🞏 Yes  | 🞏 No |

**2.2 Amended study staff details**

|  |  |  |  |
| --- | --- | --- | --- |
| **Title, first name, surname** | **Department/Division** | **E-mail** | **Role of new staff member** |
|  |  |  |  |
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|  |  |  |  |
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**3. List of documentation for approval**

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| --- |
| Please list below all staff documentation such as CVs, declarations, GCP certificates and revised consent forms which need approval. This information must correspond to all ‘yes’ answers in [2.1 above](#staff_changes). This form will be signed and returned to the PI as notification of approval. Please add extra pages if necessary. |
|   |

**4. Signature**

**Current PI Signature**

|  |
| --- |
| My required 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.  |
| Current PI Signature |  | Date |  |

**New PI Signature (If Applicable)**

|  |
| --- |
| My required 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.  |
| New PI Signature |  | Date |  |