**FHS008: Internal Adverse Event or Unanticipated Problem reporting**

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| **HREC office use only (FWA00001637; IRB00001938)** | | | | | | | |
| 🞏 Report is noted and filed - no further action required. | | | | | | | |
| This serves as notification that all changes and documentation described below are noted and approved. | | | | | | | |
| Chairperson of the HREC signature/ Designee | | |  | | Date |  | |
| **Note:** Please note that incomplete 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).  HREC 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 | |  | | | | | |
| Project Title | |  | | | | | |
| Protocol number  (if applicable) | |  | | | | | |
| Principal Investigator (PI) | |  | | | | | |
| Department & Email Address | |  | | | | | |
| 1. Documents for acknowledgement | | | | | | | |
| **Please itemise on the page below, all documents including revised version numbers and dates, which need to be noted or acknowledged.** This page will be detached, signed and returned to the PI as notification of the HREC’s approval. (If any protocol amendments occur please separately complete the Amendment Form ([FHS006](http://forms.uct.ac.za/fhs006.doc) ) | | | | | | | |
|  | | | | | | | |
| 1. **Follow-up actions** | | | | | | | |
| 1. SAHPRA notified | | | | 🞏 Yes | | | 🞏 No |
| 1. Are any protocol revisions required? If yes, please also complete the FHS 006 | | | | 🞏 Yes | | | 🞏 No |
| 1. Should the consent/assent form(s) be amended? If yes, please also complete the FHS 006 | | | | 🞏 Yes | | | 🞏 No |
| 1. Will currently enrolled participants be notified of this event? | | | | 🞏 Yes | | | 🞏 No |
| **Note: If yes** to any of the above (points b-d), please submit an Amendment Form ([FHS006](http://forms.uct.ac.za/fhs006.doc)) and revised documents with all revisions highlighted in bold or italics. | | | | | | | |
| 1. Description of Internal Adverse Event (tick ✓)   Definitions and timelines for reporting internal (on site) adverse events and unanticipated problems are posted on the HREC website. | | | | | | | |
| 🞏 | Fatal | | | | | | |
| 🞏 | Life-threatening adverse event or drug reaction | | | | | | |
| 🞏 | Serious and unexpected, non-fatal adverse event or drug reaction | | | | | | |
| 🞏 | Expected adverse event or drug reaction occurring at a greater than expected frequency or severity | | | | | | |
| 🞏 | Serious and unanticipated adverse device reaction | | | | | | |
| 🞏 | Unanticipated problem that increases risk of harm to participants | | | | | | |
| 🞏 | New information that might impact the conduct of a clinical study | | | | | | |

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| 4.1 Please provide a brief description of the event | | | |
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| 4.2 This report is | | 🞏 Initial | 🞏 Follow up |
|  | | | |
| 4.3 In the opinion of the local PI, is this event related to the study drug, device, or procedure? (tick ✓ one) | | | |
| 🞏 | Not related | | |
| 🞏 | Unlikely | | |
| 🞏 | Possibly | | |
| 🞏 | Probably | | |
| 🞏 | Definitely | | |
|  | | | |
| 4.4 Action taken (tick ✓ all that apply) | | | |
| 🞏 | Hospitalisation | | |
| 🞏 | Study treatment altered (e.g. drug dose changed) | | |
| 🞏 | Study treatment stopped/ device removed | | |
| 🞏 | Study blind broken | | |
| 🞏 | Monitoring progress | | |
| 🞏 | Removed from study | | |
| 🞏 | Other. Describe in Section 4.1 | | |
|  | | | |
| 4.5 Outcome (tick ✓ all that apply) | | | |
| 🞏 | Complete resolution | | |
| 🞏 | Ongoing/ unresolved | | |
| 🞏 | Partial recovery | | |
| 🞏 | Disability or impairment (permanent) | | |
| 🞏 | Disability or impairment (may improve with time) | | |
| 🞏 | Death | | |
| 🞏 | Other. Describe in Section 4.1 | | |

1. Signature

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| --- | --- | --- | --- |
| 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. | | | |
| Signature of PI |  | Date |  |