**Form FHS009: Reporting Form for Safety Information**

**Investigator Brochure, Safety Information, DSMB Report, Hold on Study Activity**

|  |  |  |  |
| --- | --- | --- | --- |
| **HREC office use only (FWA00001637; IRB00001938)** | | | |
| 🞏 Report is noted and filed. | | | |
| Signature of HREC Chair/ 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).

**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 |  | | |
| Department and Email address |  | | |
| 2. Type of submission (tick ✓) 3. Evaluation of information (tick ✓)   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | 🞏 | Investigator Brochure Version #: |  | Information in this report changes the study risk | 🞏 Yes | 🞏 No | | 🞏 | Data Safety Monitoring Board Report |  | Information in this report requires an amendment to the study protocol | 🞏 Yes | 🞏 No | | 🞏 | Safety Information or Publication |  | Information in this report requires an amendment to the informed consent/assent forms | 🞏 Yes | 🞏 No | | 🞏 | Audit Report (with significant findings) |  | Information in this report includes a significant new finding which may affect participants’ willingness to take part | 🞏 Yes | 🞏 No | | 🞏 | Hold on Study Activity initiated by: |  | **(If yes to any of these questions please see note below)** | | | | 🞏 | SAHPRA/FDA/EMEA |  |  |  |  | | 🞏 | Sponsor |  |  |  |  | | 🞏 | PI |  |  |  |  | | | | |
| **Note:** Please attach this report to an appropriate amendment application form ([FHS006](http://forms.uct.ac.za/fhs006.doc)) where relevant with the required protocol and consent/assent revisions. The amendment application form must include a clean copy of the revised documentation and a copy with changes highlighted in bold or italics. | | | |
|  | | | |
| **4. Please provide a brief description of all potential changes in study risk or benefit arising from this submission:** | | | |
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|  | | | |
| **5. List of Proposed Documents with Revised Version Numbers and Dates**  (If any protocol amendments occur, please separately complete form [FHS006](http://forms.uct.ac.za/fhs006.doc)). | | | |
|  | | | |

**6. Signature**

|  |  |  |  |
| --- | --- | --- | --- |
| My required signature certifies that the above is complete and correct. | | | |
| Signature of PI |  | Date |  |