**Form FHS011: Study deviation**

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| **HREC office use only (FWA00001637; IRB00001938)** |
| This serves as acknowledgement of a protocol deviation as described below. |
| 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. Our website address: <https://health.uct.ac.za/home/human-research-ethics> 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. Protocol deviation description |
| Please describe the deviation below, including the reason why the deviation has occurred. |
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| 3. Follow-up actions  |
| 3.1 Please describe any follow-up action(s) taken or planned as a result of this deviation e.g. DSMB reporting, report to sponsor, informing participants. |
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| 3.2 Please describe what action(s) have or will be taken to prevent similar deviations in future.  |
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**4. Principal Investigator’s acknowledgement of responsibility**

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| The required signature indicates the PI has reviewed the deviation, taken appropriate follow-up action and implemented or plans to implement preventative steps where possible. |
| Signature of PI |  | Date |  |