**FHS012: Study exception**

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| |  |  |  |  |  | | --- | --- | --- | --- | --- | | A protocol exception is a one-time, intentional action or process that departs from the HREC-approved protocol and is anticipated or known prior to the event occurring. See ‘Study Exceptions and Study Deviations ⎯ Pointers for Researchers’ on the HREC website: [**https://health.uct.ac.za/home/human-research-ethics**](https://health.uct.ac.za/home/human-research-ethics)for further information. | | | | | | **HREC office use only (FWA00001637; IRB00001938)** | | | | | | This serves as notification of approval of the study exception described below. This study exception is noted and filed. | | | | | | 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).  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. Protocol exception request |
| Please describe the anticipated exception, including the justification for the request. |
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| 1. Follow-up actions |
| 3.1 Please describe any additional action(s) already taken or planned in anticipation of this protocol exception, e.g. DSMB reporting, obtained sponsor’s approval. |
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| 3.2 Please describe if and how this exception changes the balance of risks and benefits to the participant. |
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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 |  |