**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. 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 |  |

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| 1. Protocol exception request
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| Please describe the anticipated exception, including the justification for the request. |
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| 1. Follow-up actions
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| 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 |  |