**Form FHS010: Study Closure Report**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **HREC office use only (FWA00001637; IRB00001938)** | | | | | | | |
| **Noted and filed**. This serves as acknowledgement that this study is closed. | | | | | | | |
| 🞏 Approved | Study closure report | | | | | | |
| 🞏 Not Approved | Study closure report | | | | | | |
| Chairperson of the HREC signature/Designee | |  | | | Date | |  |
| **HREC Website:** [**https://health.uct.ac.za/home/human-research-ethics**](https://health.uct.ac.za/home/human-research-ethics)  **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).   1. Principal Investigator to complete the following: | | | | | | | |
| Date  (when submitting this form) | | |  | | | | |
| HREC REF Number | | |  | | | | |
| Protocol Title | | |  | | | | |
| Protocol number  (if applicable) | | |  | | | | |
| Principal Investigator | | |  | | | | |
| Department & Email Address | | |  | | | | |
| 1. Please confirm (tick ✓) | | | | | | | |
| This study is closed to enrolment | | | | 🞏 Yes | | 🞏 No | |
| Participants have completed all research-related interventions | | | | 🞏 Yes | | 🞏 No | |
| Participants have completed all research-related follow-up | | | | 🞏 Yes | | 🞏 No | |
| Data analysis is complete | | | | 🞏 Yes | | 🞏 No | |
| Publication or thesis submitted and final completion? | | | | 🞏 Yes | | 🞏 No | |
| Your sponsored protocol is closed | | | | 🞏 Yes | | 🞏 No | |
| If you answered ‘no’ to any of the above questions, you must keep your study open until all research activity is completed. Please complete the FHS 016 or FHS 017 annual progress report form | | | | | | | |

1. **What is the reason for closing the study? (tick ✓)**

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| Research completed |  | No time |  |
| Terminated due to toxicity/adverse event |  | PI left UCT or affiliated sites |  |
| Slow accrual |  | Insufficient funding |  |
| Loss of interest |  | Research never began |  |
| Other. Please specify: | | | |
|  | | | |
| 1. For clinical trials, please describe the arrangements for provision of care after research, including (where applicable) post-trial access to the investigational product. | | | |
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1. **Please explain how the research findings have been disseminated to participants, communities, and/or stakeholders.**

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| 1. Please confirm (tick ✓) | | | | | | |
| Have you submitted a final report to the Provincial Health Research Committee? | |   Yes | |   No | |  N/A |
| **Please note**: Researchers must submit final reports to the relevant research co-ordinator/research directorate at City Health Department, GSH, RXH, TBH, PGWC (for non-tertiary hospitals) within six months of completion of the study and may be required to report the findings of the study to other relevant authorities including the PHRC. | | | | | | |
| 1. **Please indicate how, and for how long, the data will be stored and protected.** | | | | | | |
|  | | | | | | |
| 1. **Please list or attach any papers, abstracts, presentations or other outputs generated from this study.** | | | | | | |
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| 1. **Signatures (It is important that the PI signs this form before submitting to the HREC)** | | | | | | |
| Signature of PI |  | | Date | |  | |