**Annual Progress Report / Renewal / Study Closure Report**

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| **Please indicate:** | |
| Annual progress report |  |
| Renewal |  |
| Study Closure Report |  |

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| **IFHREC office use only**  **This serves as notification of annual approval, including any documentation described below.** | | | | | | | | | |
| 🞏 Approved | Annual progress report | | | Approved until/next renewal date | | | |  | |
| 🞏 Not approved | See attached comments | | | | | | | | |
| Signature Chairperson of the IFHREC/ Designee | | |  | | | Date Signed | |  | |
| **Note:** Please email this form and supporting documents (if applicable) in a combined pdf-file to  [ifhrec.enquiries@uct.ac.za](mailto:ifhrec.enquiries@uct.ac.za).  Please use the latest form found on our website:  [Inter-Faculty Human Research Ethics Committee (IFHREC) | University of Cape Town (uct.ac.za)](https://uct.ac.za/research-support-hub/inter-faculty-research-ethics-committee-if-rec) | | | | | | | | | |
| Comments to PI from the IFHREC | | | | | | | | | |
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| Principal Investigator to complete the following:  **1. Project information** | | | | | | | | | |
| Date  (when submitting this form) | |  | | | | | | | |
| IFHREC REF Number | |  | Current Ethics Approval was granted until | | | | | |  |
| Project title | |  | | | | | | | |
| Project number  (if applicable) | |  | | | | | | | |
| Are there any sub-studies linked to this study? | | | | | 🞏 Yes | | 🞏 No | | |
| If yes, could you please provide the IFHREC Reference number for all sub-studies? **Note:** A separate form must be submitted for each sub-study. | | | | |  | | | | |
| Principal Investigator | |  | | | | | | | |
| Department and email address | |  | | | | | | | | |

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| **2. Project status (tick ✓)** | | |
| 🞏 | Open Enrolment | |
| 🞏 | Closed to enrolment (tick ✓) | |
| 🞏 | Research-related activities are ongoing | |
| 🞏 | Research-related activities are complete, long-term follow-up only | |
| 🞏 | Research-related activities are complete, data analysis only | |
| 🞏 | Main study is complete but sub-study research-related activities are ongoing | |
| 🞏 | Publication or thesis submitted and final completion? | |
| 🞏 | Study is closed | |
| **3. Enrolment** | | |
| Number of participants enrolled to date | |  |
| Number of participants enrolled, since last IFHREC Progress report (continuing review) | |  |
| Additional number of participants still required | |  |
| **4. Refusals** | | |
| Total number of refusals (participants invited to join the study, but refused to take part) | |  |
| **5. Cumulative summary of participants** | | |
| Total number of participants who provided consent | |  |
| Number of participants determined to be ineligible (i.e. after screening) | |  |
| Number of participants currently active on the study | |  |
| Number of participants completed study (without events leading to withdrawal) | |  |
| Number of participants withdrawn at participants’ request (i.e. changed their mind) | |  |
| Number of participants withdrawn by PI due to toxicity or adverse events | |  |
| Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance) | |  |
| Number of participants lost to follow-up.  Please comment below on reasons for loss of follow-up. | |  |
|  | | |
| Number of participants no longer taking part for reasons not listed above.  Please provide reasons below: | |  |
|  | | |
| **6. Progress of study / reason for closing the study** | | |
| Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the IFHREC.  If closing the study, please specify the reason for this. | | |
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| **7. Protocol violations and exceptions (tick ✓ all that apply)** | | |
| 🞏 | No prior violations or exceptions have occurred since the original approval | |
| 🞏 | Prior violations or exceptions have been reported since the original approval and have already been acknowledged or approved  If so, did these occur in the last review period | |
| 🞏 | Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review | |
| **8. Amendments (tick ✓ all that apply)** | | |
| 🞏 | No Prior amendments have been made since the original approval | |
| 🞏 | Prior amendments have been reported since the last review and have already been approved | |
| 🞏 | New protocol changes/ amendments are requested as part of this continuing review | |

Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

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| 9. Adverse events |
| 9.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the project and informed consent document(s) as a result (if not already reported to the IFHREC). Please comment on whether causality to any study procedure or intervention could be established. |
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| 9.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)? | | | |
| 🞏 Yes | | 🞏 No | 🞏 Not applicable |
| If yes, please describe: | | | |
|  | | | |
| 11. Level of risk (tick ✓) | | | |
| 11.1 In light of your experience of this research, please indicate whether the level of risk to participants has: | | | |
| 🞏 | Increased | | |
| 🞏 | Decreased | | |
| 🞏 | Shown no change | | |
| If there has been a change, please explain: | | | |
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| 13. Statement of conflict of interest | | | | |
| Has there been any change in the conflict-of-interest status of this project since the original approval?  (tick ✓) | | | | |
| 🞏 Yes | | 🞏 No | | |
| If yes, please explain and if necessary. | | | | |
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| 14. Signature | | | | |
| My required signature certifies that the above is complete and correct. | | | | |
| Signature of PI |  | | Date |  |