**FACULTY OF MEDICINE & HEALTH SCIENCES**

**HEALTH RESEARCH ETHICS COMMITTEE**

*(Adapted from Stellenbosch university & UCT)*

**INTERIM/ ANNUAL PROGRESS / FINAL REPORT FOR HEALTH RESEARCH**

(Kindly type in all the information)

***NB:*** *Submit to* [*fhsrec@wsu.ac.za*](mailto:fhsrec@wsu.ac.za)

|  |  |
| --- | --- |
| FOR WSU HREC Office only: | |
| 🞏 Type of review: Expedited |  Full committee |

**NB**: *Attach current clearance/ approval certificate*.

1. **Protocol Information**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Submission date of the form to HREC |  | | | | |
| WSU HREC Ref No: |  | | | | |
| Title of the Approved Project |  | | | | |
| Date of Approved Project |  | | | | |
| Principal Investigator |  | | | | |
| Professional Status |  | | | | |
| Department/ Organisation |  | | | | |
| Purpose of study | Degree  Non-Degree | | | | |
| Email Address |  | | | | |
| Contact Number |  | | | | |
| Duration of the current ethics approval | |  | | | |
| Reporting Period | From: | | | To: | |
| Source of funding for the study |  | | | | |
| Type of report | Interim Report | | Annual progress report(request for extension/annual renewal) | | Final report(submitted after study/site closure) |

1.2. **Collaborator/s details**

|  |  |  |  |
| --- | --- | --- | --- |
| Title, Name & Surname (*List if more than one*) | Position/Roles | Institution | Email address |
|  |  |  |  |
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1. **List of documents for approval/Motivation**

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| --- | --- | --- |
| **3. Protocol status (tick ✓)** | | |
| 🞏 | Open Enrolment | |
| 🞏 | Closed to enrolment | |
| 🞏 | Research-related activities are ongoing | |
| 🞏 | Research-related activities are complete, long-term follow-up only | |
| 🞏 | Research-related activities are complete, data analysis only | |
| 🞏 | Research-related activities are complete, writing of (mini)-dissertation only | |
| 🞏 | Main study is complete but sub-study research-related activities are ongoing | |
| 🞏 | Study is closed | |
| **4. Enrolment** | | |
| Number of participants enrolled to date | |  |
| Number of participants enrolled, since last HREC Progress report (for continuing review) | |  |
| Total number of refusals | |  |
| Additional number of participants still required | |  |
| Total number retained/ active in the study | |  |
| Total number lost to follow-up. *Please comment below on reasons for loss to follow-up* | |  |
|  | | |

**5. Progress to-date of the study**

|  |
| --- |
| Kindly provide a summary of what has been achieved to date including unanticipated challenges, negative incidents/ adverse events, positive outcomes, dissemination of results including publications, etc. |
|  |

**6. 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 last review and have already been acknowledged or approved |
| 🞏 | Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review |
| State reasons for deviation prior to REC approval: | |

**7. 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. Please fill in the Protocol Amendment Form and attach hereto. |

**8. Adverse events**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Number of SAEs for reporting period** | | |  | | | |
| **Summary of SAEs for reporting period** | | | | | | |
| Participant No. | Date | Event | | Causality (Related/ unrelated/ unknown) | Outcome (Resolved/ unresolved/ death) | Previously reported to REC (Yes/ No) |
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**9. Protocol non-compliance** (kindly attach details)

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| --- | --- | --- | --- | --- |
| **No. of protocol deviations for reporting period** | | | **Total protocol deviations** | |
|  | | |  | |
| **Summary of local site deviations for reporting period** | | | | |
| **Ref No.** | **Date** | **Event** | | **Explanation** |
|  |  |  | |  |
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**10. Summary of monitoring & audit activities** (tick ✓ all that apply)

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| --- | --- | --- |
| 10.1 Was this study monitored or audited by an external agency (e.g., SAHPRA, FDA, REC)?/ Local institutional clinical governance (attach proof) | | |
| 🞏 Yes | 🞏 No | 🞏 Not applicable |

|  |  |  |
| --- | --- | --- |
| 10.2 Did a Data and Safety Monitoring Board publish a report?/Any violation reported by the local institution? (attach proof) | | |
| 🞏 Yes | 🞏 No | 🞏 Not applicable |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 10.3 If yes, please identify the agency and attach a summary of the findings. | | | | | |
| Agency Name |  | Report attached | 🞏 Yes | 🞏 No | 🞏 Not applicable |
|  | | DSMB report attached | 🞏 Yes | 🞏 No | 🞏 Not applicable |
| 10.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team? | | | | | |
| 🞏 Yes | | 🞏 No | | | |
| If yes, please explain: | | | | | |
|  | | | | | |

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| --- | --- |
| **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: | |
|  | |
| 11.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the  level of risk. | | |
|  | | |

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| --- | --- |
| **12. Statement of conflict of interest** | |
| Has there been any change in the conflict-of-interest status of this protocol since the original approval?  (tick ✓) | |
| 🞏 Yes | 🞏 No |
| If yes, please explain: | |
|  | |

**13. Attachments**

|  |  |
| --- | --- |
| Kindly attach the following documents relevant to the reporting period | |
| Informed consent documents |  |
| Published articles or abstracts. |  |
| Protocol deviations supporting documents |  |
| Other, specify. |  |

**14. Declaration**

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| --- |
| I ………………………………………………………………… confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility of it.  ……………………………………………………………….. ……………………………….  Signature of PI Date |
| **FOR OFFICE USE** |
| Reviewer Comments & Recommendation |
| **HREC Chairperson**:  Decision:  Signature & Date: |