**FACULTY OF MEDICINE & HEALTH SCIENCES**

**HEALTH RESEARCH ETHICS COMMITTEE**

*(Adapted from UCT)*

**PROTOCOL AMENDMENT FORM : 2024**

(Kindly type in all the information)

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

**NB**: **All amendments must include:**

* Signed and dated cover letter from local PI itemizing ALL proposed amendments with justifications.
* Copy of the proposal/protocol with tracked changes of proposed amendments.
* Clean copy of proposed amended proposal/protocol.
* Copy of Ethical clearance certificate for proposal/protocol to be amended.
* For multi-site studies, evidence of approval of proposed amendments of proposal/protocol.
* Evidence of sponsor approval of proposed amendments where applicable.
* Submit to [fhsrec@wsu.ac.za](mailto:fhsrec@wsu.ac.za).

Incomplete amendment submissions will not be reviewed. Approval of the amendment does NOT grant annual approval. Annual report forms must be completed and submitted yearly, a month before current Ethical clearance certificate expires.

1. **Protocol Information**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Submission date of the form to HREC |  | | | |
| WSU HREC Ref No: |  | | | |
| Title of the Approved Project |  | | | |
| Principal Investigator |  | | | |
| Professional Status |  | | | |
| Department/ Organisation |  | | | |
| Email Address |  | | | |
| Contact Number |  | | | |
| Is this a minor or major amendment? | 🞏 Major | | 🞏 Minor | |
| Source of funding for the study |  | | | |
| Does the amendment require full committee approval? | | 🞏 Yes | | 🞏 No |

**2. List of Proposed Amendments with Revised Version Numbers and Dates**

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| **Please itemise on the page below, all amendments with revised version numbers and dates, which need approval.** |
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| **3. Proposed changes will affect:** (tick ✓ all the categories that apply) | | | | |
| **Protocol** | | | | |
| 🞏 | Title | | | |
| 🞏 | Study objectives | | | |
| 🞏 | Study design | | | |
| 🞏 | Study instruments | | | |
| 🞏 | Sample size | | | |
| 🞏 | Recruitment methods | | | |
| 🞏 | Eligibility criteria (inclusion and exclusion criteria) | | | |
| 🞏 | Drug/device (composition, amount, schedule, route of administration, combination with other drugs/devices, safety information) | | | |
| 🞏 | Data collection/ analysis | | | |
| 🞏 | Consent form and information sheet | | | |
| 🞏 | Recruitment materials (e.g., advertisements) | | | |
| 🞏 | Change in investigators | | | |
| 🞏 | Administrative (e.g., change in sponsor’s name, change in contact information) | | | |
| 🞏 | Other. Please specify: | | | |
| 3.1 In your opinion, will there be any **increase** in risk, discomfort or inconvenience to participants? | | | 🞏 Yes | 🞏 No |
| If yes, please provide a detailed explanation: | | |  | |
|  | | | | |
| What follow up action do you propose for participants already enrolled in the study? Please explain. | |  | | |
| **4. Reasons for amendment** (Provide justification for the proposed amendment) | | | | |
|  | | | | |
| **5. Details of Amendment** (Give a concise description of proposed change(s) in the protocol, highlighting how the new methods differ from the already approved protocol and what new information will be generated). | | | | |
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|  | | | | |
| **6. Progress to date**(Provide a detailed account of work that has been done to date- include participant recruitment, retention, unanticipated changes, positive outcomes, negative incidents, adverse events, dissemination of information, etc.) | | | | |
|  | | | | |
| 7. What is the impact of proposed amendment on the participants already enrolled and data already collected? | | | | |
|  | | | | |
| **8. Sponsor Approval** (Provide evidence of sponsor approval of the proposed changes | | | | |
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**9. Amendment Submission checklist (tick ✓)**

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| --- | --- |
| 9.1 Please tick that all the documents are attached before submitting to the WSU HREC.  NB: Incomplete submissions will not be processed | |
| 🞏 | Protocol amendment form completed with all sections completed |
| 🞏 | Cover Letter |
| 🞏 | Copy of the previous approval certificate by the WSU HREC |
| 🞏 | PI Justification/ Summary for the reasons for the amendment |
| 🞏 | Protocol - Track changes & Clean Copy (where necessary) |
| 🞏 | Informed Consent Forms (ICF), if applicable (Any changes made to ICF tracked & clean copy) |
| 🞏 | Any other additional documentation in support of amendment |

**10. Signature**

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| **Applicants’ signature**: | **Date**: |
| **Undertaking by the supervisor** (if PI is a student):  I, ...................................................................................... have read, passed the proposal/protocol amendment herewith submitted. I am satisfied with the quality of this work and therefore do consent to the submission thereof for scientific and/or ethical review.  **Signature and Date**: **Qualification(s)**:  **Email address**: | |
| **Head/Research Coordinator of Department/ in which study will be conducted:**  **Name**: **Signature and Date**: | |