**FACULTY OF MEDICINE & HEALTH SCIENCES**

**HEALTH RESEARCH ETHICS COMMITTEE**

*(Adapted from UCT & UKZN)*

**PROTOCOL DEVIATION FORM : 2024**

(Kindly type in all the information)

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

**NB**: Kindly note that incomplete submissions will not be reviewed.

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  |  |

1. **Description of Deviation**

|  |  |
| --- | --- |
| Date of deviation  |  |
| Date event identified  |  |
| Event identified by  |  |
| Study site |  |

**3. Summary about the Deviation**

|  |
| --- |
| Kindly explain below how and why the deviation occurred.  |
|   |
| **4. Corrective/ Follow up actions taken**  |
| 4.1 Kindly describe follow up actions undertaken or planned due to this deviation.  |
|  |
| 4.2 Kindly indicate actions taken or planned to prevent this deviation in the future.  |
|  |
| 4.3 Will the event lead to protocol amendment/ change in information to participants? Yes/ No If yes, kindly submit the Protocol amendment to the WSU HREC at fhsrec@wsu.ac.za  |

**5. Principal Investigator’s acknowledgement of responsibility**

|  |  |
| --- | --- |
| **Applicants’ signature**:  | **Date**:  |
| I, ......................................................................................................., the study PI confirms that I have reviewed the deviation, taken appropriate follow-up action and implemented/ plan to implement corrective action as well as preventative steps where possible.  |