**FACULTY OF MEDICINE & HEALTH SCIENCES**

**HEALTH RESEARCH ETHICS COMMITTEE**

*(Adapted from UKZN)*

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**SERIOUS ADVERSE EVENT REPORTING FORM FOR DRUG TRIAL/STUDY**

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| --- |
| **SECTION A** |
| REC Reference Number: |
| Principal Investigator:  |
| Study Title:  |
| SAHPRA approval number: |
| Investigational drug/s (if applicable):  |
| Study site: |
| **SECTION B** |
| Participant Number (PID): |
| Gender: |
| Participant age: |
| Relevant pre-medical history summary: |
| **SECTION B** |
| Type of report (*initial, follow-up, final*): |
| Onset date of event: |
| Event stop date:  |
| Reaction/event/diagnosis: |
| BRIEF SUMMARY/DESCRIPTION OF AE EVENT: |
| Time interval between suspect drug administration and start of reaction/event:  |
| Describe steps taken to manage AE/Drugs administered to treat AE: |
| Date of initiation of treatment: |
| Action taken with drug (circle appropriate number)1. drug withdrawn 2. dose reduced

3. dose unchanged 4. Unknown5. Stopped and re-administration 6. None7. discontinued  |
| Explain outcome from action selected above? |
| Outcome/Seriousness criteria (Select appropriate)1. Death 2. Life threatening

3. Hospitalisation/prolongation of hospitalisation 4. Persistent/significant disability1. Congenital birth defect 6. Other
 |
| Relatedness of drug to reaction (circle/ tick appropriate number):1. definitely related 2. possibly related

3. not related 4. unknown  |
| Crucial additional information:  |
| **SECTION D** |
| list of suspected drugs:  |
| Doses:  |
| Action: |

**LIST OF ADDITIONAL FULL CASE DOCUMENTATION RETURNED WITH THIS SUMMARY:**

1.
2.
3.
4.
5.

Is protocol amendment required due to the event: Y / N?

If yes, submit the amendment to Health Research Ethics office to fhsrec@wsu.ac.za .

|  |
| --- |
| Name and designation of person completing the form: |
| Signature and date:  |

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**SIGNATURE (PRINCIPAL INVESTIGATOR): DATE:**

**FOR WSU HREC OFFICE ONLY:**

|  |
| --- |
| **Reviewers’ comments:** |
|  |
| **Reviewer recommendation:** |
|  |
| Reviewers signature: |
| Date:  |
| **Chairpersons’ decision:** |
|  |
| Chairpersons’ signature: |
| Date:  |