TO: UNIVERSITY OF KWAZULU-NATAL, HUMANITIES AND SOCIAL SCIENCES RESEARCH ETHICS COMMITTEE

REPORT OF SERIOUS ADVERSE EVENT DURING STUDY

Study Title:

HSSREC Reference Number:\_\_\_\_\_\_\_\_Principal Investigator:

Participant age: \_\_\_\_\_\_\_\_\_\_Sex: M/F\_\_\_\_\_\_\_\_\_ Participant Number: \_\_\_\_\_\_\_\_\_\_\_\_

Date of adverse event:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study site:

**Reaction/event/:**

**BRIEF SUMMARY/DESCRIPTION OF SAE EVENT AND OUTCOME:**

Seriousness criteria (circle appropriate number)

1. Death 2. Life threatening

3. Hospitalisation/prolongation of hospitalisation 4. Persistent/significant disability

1. Congenital birth defect 6. Other

Duration of event:

Time interval between suspect drug administration and start of reaction/event:

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

Will event result in protocol amendment / change in information to participants: Y / N?

If yes, submit amendment to Humanities and Social Sciences Research Ethics Administration:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

**SIGNATURE (PRINCIPAL INVESTIGATOR) DATE:**

\*All reports must be submitted as soon as possible or within 7 days of occurrence.

Updated 07 April 2014