UNIVERSITY OF KWAZULU-NATAL
BIOMEDICAL RESEARCH ETHICS COMMITTEE

REPORT OF PROTOCOL DEVIATION DURING DRUG TRIAL/INTERVENTIONAL STUDY

See BREC Terms of Reference and Standard Operating Procedures for guidance on submitting protocol deviations

Study Title: _____

_____

BREC Reference Number:_____Principal Investigator:_____

Investigational drug (if applicable): _____

Participant age: _____Sex: M/F_____ Participant Number: _____

Date of Deviation: _____

Date event identified: _____

Event identified by: _____

Study site: _____

BRIEF SUMMARY/DESCRIPTION OF DEVIATION:

_____

_____

_____

_____

Number of times event recorded in trial/study: _____

Corrective Actions: _____
_____

Duration of event: _____

How will you prevent future occurrences?: _____

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

Action taken with drug (circle appropriate number)

1. Drug withdrawn
2. Dose reduced
3. Dose unchanged
4. Unknown
5. N/A

Did reaction recur on re-administration: Y / N / not known

Relatedness of drug to reaction (circle appropriate number):

1. Definitely related
2. Possibly related
3. Not related
4. Unknown

The correct response to this question is usually - (4). Unknown - and numbers 1, 2 and 3 should not be used unless the relatedness of drug reaction can clearly be deemed to be *definitely related/possibly related/not related*

LIST OF ADDITIONAL FULL CASE DOCUMENTATION RETURNED WITH THIS SUMMARY:

Will event result in protocol amendment / change in information to patients: Y / N?
If yes, submit amendment to Biomedical Research Ethics Administration BREC@ukzn.ac.za or fax 031-2604609.

_____ _____

SIGNATURE (PRINCIPAL INVESTIGATOR) **DATE:**

March 2018