**Date: ………………………………………**

**Prof. T. Rossouw**

Chair: University of Pretoria

Faculty of Health Sciences Research Ethics Committee

Pretoria

**Cover letter: Serious Adverse Event**

|  |  |
| --- | --- |
| **Ethics number** |  |
| **Protocol title** |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Event** | **Causality** | **Site (country in which SAE occurred)** |
| Participant Number:  Date report:  Report: |  | * Related * Unrelated * Expected * Unexpected |  |

Suggested action to be taken by the Ethics Committee: -

…………………………………………………….

Yours sincerely,

Name of researcher…………………………………………

Signature of researcher…………………………………………