

**REPORT OF SERIOUS ADVERSE EVENT DURING STUDY**

Protocol Approval number:

Principal Investigator:

Study title

|  |  |
| --- | --- |
| **Participant Age** |  |
| **Sex** |  |
| **Participant Number** |  |
| **Date of Adverse event** |  |

**Brief Summary of Adverse event:**

**Seriousness of Criteria (Circle appropriate)**

*Emotional Distress Personal or Cultural embarssemet*

*Breach of Confidentiality Economic Harm*

*Legal Jeopardy Physical pain or injury*

*Other (Give a brief description below)*

**Will this even event in a result of protocol amendment or change in participants?**

|  |  |
| --- | --- |
| **Yes** |  |
| **No** |  |

If yes, please complete an amendment form and submit it to the CUT HREC.

Signature of PI:

Date:

All report must be submitted within 7 days of occurrence of the adverse event.