**AX2-V6/SOP09/V6**

**Off site Safety Reports Classification Form**

**NOTE to PI:**

The following questions will act as a guide for submission of the “Safety Reports”. This form is merely providing guidance for reporting / logging of Off-Site Safety Reports’.

If the answer to all three questions is **"Yes", prompt reporting is required** and such off site safety reports need to be reported to IEC along with the log.

If any one answer is **"No", it needs to be logged as prescribed format**. (AX3-V6/SOP 09/V6). This log should be timely submitted to the IEC Secretariat

Project No. :

Project Title :

|  |  |  |
| --- | --- | --- |
| **Questions** | **Yes** | **No** |
| Is adverse event serious? |  |  |
| Is adverse event related? |  |  |
| Is adverse event unexpected? |  |  |

Date of reporting :

Signature of PI :

Name of PI :

**AX3-V6/SOP09/V6**

**Off Site Safety Reports Log**

NOTE to PI:

* 1. Please log in details of Off Site Safety Reports.
  2. The following log has to be maintained continuously until the end of the study.
  3. This log should be timely submitted to the IEC Secretariat. The log must be submitted to the IEC Secretariat immediately, if prompt reporting is required and/or if a trend related to the occurrence of SAE is observed.
  4. Please note the complete set of Off-Site Safety Reports need not be sent to IEC Secretariat as and when received. If the IEC needs to review the reports, they can request copies at any time.

|  |  |  |
| --- | --- | --- |
| Project No. | :- |  |
| Project Title | :- |  |
| Total Sample Size | :- |  |
| Total No. of patients to be enrolled | :- |  |
| No. of Participants already enrolled | :- |  |
| No. of patients active on Treatment | :- |  |
| No. of patients on FU | :- |  |
| No. of Patients lost to follow up | :- |  |
| No. of Consent Withdrawn | :- |  |
| No. of patients withdrawn by Principal Investigator | :- |  |
| No. of patients completed treatment | :- |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S. No.** | **Country** | **Date of Onset** | **Adverse event** | **Out Come** | **Remarks** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

PI Assessment:

Do you observe a trend? □ Yes □ No □ NA

Name and Signature of Principal Investigator: Date: