ANNEXURE: 01 **AF/IEC/01/15/V7.1**

Serious Event Report

Project No.:

Study Title:

Name of the study medicine/device:

Report Date:

☐ **Initial** ☐ **Follow-up**

Onset date:

Subject's initial/number: : Age: ….. Yrs. ☐ Male ☐ Female

Subject's history: Laboratory findings: ----------

SAE: Treatment: ----------

Outcome: ☐ resolved ☐ on-going

Seriousness:

☐ Death
☐ Life Threatening
☐ Hospitalization –○ initial ○ prolong
☐ Disability / Incapacity
☐ Congenital Anomaly
☐ Other……

Relation to ○ Drug ○ Device ○ study

☐ Not related ☐ Possibly ☐ Probably ☐ Definitely related ☐ Unknown

Changes to the protocol recommended? ☐ No ☐ Yes , attach proposal

Changes to the informed consent form recommended?

☐ No ☐ Yes, attach proposal

Reviewed by:_____

Comment:_____

Date:

Action:_____

ANNEXURE: 02 **AF/IEC/02/15/V7.1**

Unexpected Adverse Event Summary Report

Principal Investigator:…….

Study Title...

Name of the studied medicine/device……..

Sponsor:……...

#	Description of Unexpected Adverse Events	Date of Event (D/M/Y)	Date start and end of Tx (D/M/Y)	F or M	Initial	Age (Y)	Serious Yes No	Related to Study Yes No	Concomitant medication	Inter-vention

Comment:

Reviewed by**:**

Date: