**Annexure: (UOR/18-001)**

Template for notification of serious adverse event

**Serious Adverse Effect (SAE) Reporting Form**

**Faculty of Medicine, University of Ruhuna**

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| Principal Investigator :Study Title :Name of the studying medicine/herbal/device :Sponsor : | Application Number :Protocol Number :Report Date : Initial Follow upOnset Date :Date of first use : |
| Subject’s initial / number : | Age :  | Gender: Male Female |
| Subject’s history : | Laboratory findings : |
| State the SAE : | Treatment:Outcome : resolved on-going |
| **Seriousness : Relation to Drug/Device/Study** Death Not related/Possibly related/Definitely relatedLife ThreateningNot related/Possibly related/Definitely related Hospitalization Not related/Possibly related/Definitely related Disability/ Incapability Not related/Possibly related/Definitely related  Congenital Anomaly Not related/Possibly related/Definitely related  Unknown Not related/Possibly related/Definitely related  Other Not related/Possibly related/Definitely related Changes to the protocol recommended? No Yes, attach proposalChanges to the informed consent form recommended? No Yes, attach proposal |
| Reviewed by : Comment :Action : Date : |