**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 up  Onset 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 related  Life 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 proposal  Changes to the informed consent form recommended? No Yes, attach proposal | | |
| Reviewed by :  Comment :  Action :  Date : | | |