**Serious Adverse Events (SAE) report form (version 2 effective from August 2019)**

**Research Ethics Committee, FMS, USJ.**

|  |  |  |
| --- | --- | --- |
| Principal Investigator:  Study title:  Name of the study medicine/device:  Sponsor | Application number:  Protocol number:  Report date  Initial follow up  Onset date:  Date of first use: | |
| Subjects initial number: | Age | Male female |
| Subjects history: | Laboratory findings: | |
| SAE: | Management if any:  Outcome: resolved  on going | |
| Seriousness   |  |  | | --- | --- | | Seriousness | Relation to drug/device/study | | * death | * not related | | * Life threatening | * Possibly | | * Hospitalization initial/prolong | * Probably | | * Disability/incapacity | * Definitely related | | * Congenital anomaly | * Unknown | | * Other |  |   Changes in the protocol recommended?  No Yes, attach proposal  Changes in the informed consent form recommended  No  Yes, attach proposal | | |
| Received by………………………… Date………………………  Comment…………………………….. Action …………………….. | | |