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

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

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| --- | --- |
| Principal Investigator:Study title:Name of the study medicine/device:Sponsor | Application number:Protocol number:Report dateInitial follow upOnset 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 proposalChanges in the informed consent form recommended  No  Yes, attach proposal |
| Received by………………………… Date………………………Comment…………………………….. Action …………………….. |