SOP: 17

PROCEDURE FOR FOLLOW-UP OF RESEARCH PROJECTS WITH RESPECT TO SERIOUS ADVERSE EVENTS (SAE)

PURPOSE

To carry out follow-up of the research proposals with respect to serious adverse events

SCOPE

Applicable to the IEC of IGIDS

RESPONSIBILITY

All members of the committee and the investigators are responsible for implementing this SOP.

PROCEDURE

1. IEC will monitor the Serious Adverse Events related to the study or product/ device in the follow up of the research proposal

2. IEC will review the exact nature of Serious Adverse Event and the time of reporting by the investigators and whether the Investigator followed the procedure regarding the medical and financial management of Serious Adverse Event as mentioned in the research protocol.

3. The following events should be reported as 'Serious Adverse Events' by the investigator.

a. The death of a study subject, whether or not related to an investigational agent

b. A life-threatening adverse drug event

c. Inpatient hospitalization or prolongation of existing hospitalization for >24 hours (excluding elective hospitalization for conditions unrelated to the study)

Prepared by:	Prepared by:	Verified by:	Approved by:
Prof. Manoharan PS	Prof. Dr. Pratebha B	Prof. Dr. Aruna Sharma	Prof. Dr.R. Madhavan Nirmal
Member,IEC	Member Secretary, IEC, IGIDS	Principal-IGIDS , SBV	Chairman, IEC, IGIDS, SBV

d. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions

e. A birth defect in an offspring of a study participant, regardless of the time after the study the congenital defect is diagnosed

f. Important Medical Events (IME) that [not resulting in death, be life threatening, or require hospitalization] may be considered an SAE when, based upon medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent these events listed in the definition.

g. Any Serious Adverse Event should be reported to the sponsor within 24 hrs and to the IEC within 7 days (in the format given in Schedule Y, Appendix XI). In case of death, it should be reported to the IEC within 24 hrs

h. All other Adverse Events that are not fatal or life threatening must be filed within 14 calendar days. The details will be evaluated and discussed during the review meetings.

i. A decision of this follow up review will be issued and communicated to the applicant indicating modification/suspension/termination/continuation of the project

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