FORMAT FOR REPORTING SERIOUS ADVERSE EVENTS

(Biomedical research involving human participants)

Terminology:

- A Serious Adverse Event (SAE) is any untoward medical occurrence in a study participant or investigation subject that is associated with death, inpatient hospitalisation, prolongation of hospitalisation, persistent or significant disability or incapacity, a congenital anomaly or birth defect or is otherwise life threatening.
- An Adverse Event (AE) can be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporarily associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

Reporting Requirement:

- **Principal Investigator:** Within 24hours of learning about an unanticipated or SAE, the principal investigator is responsible to report to the Institutional Ethics Committee (IEC) Secretariat (iec@iitm.ac.in).
- Within 10 days the principal investigator needs to submit a follow up report to the **Chairperson, IEC** and to the **Head of the Institution**.
- **Ethics Committee:** Member Secretary puts the adverse events report for discussion at full board or circulate it among the members for suggestions and recommendations for further action.
- **IEC Secretariat:** A hard copy of this report must be sent to the IEC Secretariat operating at Room no. BT101, Block-1, Department of Biotechnology, IIT Madras for records. For any clarifications contact IEC Office: 044 – 2257 4929.

FORMAT FOR REPORTING SERIOUS ADVERSE EVENTS (SAE)

Title of Study: _____

Proposal No: _____

Principal Investigator: _____
(Name, Designation and Department)

1. Date of IEC approval:

2. Date of start of study:

3. Participant details:

   Initials / ID:
   Age (at the time of event):
   Gender: Male/Female
   Weight (kg):
   Height (cm):

4. Suspected SAE diagnosis:

5. Date of onset of SAE:

6. Describe the event:
   (Duration, setting, site, signs, symptoms and severity of the event)

7. Date of reporting SAE:

8. Details of suspected intervention causing SAE:

9. Report type: Initial / Follow-up / Final

10. If Follow-up report, state date initial report:

11. Have any similar SAE occurred previously in this study? YES/NO
    If yes, please provide details.

12. In case of a multi-centric study, have any of the other study sites reported similar SAEs?
    (Please list number of cases with details if available)

13. Tick whichever is applicable for the SAE: (Kindly note that this refers to the intervention being evaluated and NOT disease process)

    A. Expected event/ Unexpected event

B. Hospitalization
□ Increased Hospital Stay
□ Death
□ Congenital anomaly/birth defects
□ Persistent or significant disability/ incapacity
□ Event requiring intervention (surgical / medical)
□ Event which poses threat to life
□ Others

14. In case of death, state probable cause of death:
No permanent / significant functional / cosmetic impairment □
Permanent / significant functional / cosmetic impairment □
Not Applicable □

15. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom):

16. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much and to whom:

17. Outcome of SAE:

Fatal	□	Recovered	□
Continuing	□	Unknown	□
Recovering	□	Other *(specify)*	□

18. Provide any other relevant information that can facilitate assessment of the case such as medical history:

19. Provide details about PI's final assessment of SAE relatedness to research:

20. Signature of PI with date: