FORMAT FOR REPORTING UNANTICIPATED OR SERIOUS ADVERSE EVENTS IN HUMAN RESEARCH PARTICIPANTS AT IIT MADRAS

(Please do not delete the headings and subheadings in the attached form)

Terminology:

Serious Adverse Event (SAE): A serious adverse event (SAE) in human drug trials are defined as:

1. Any untoward medical occurrence that at any dose results in
2. Death
3. Is life-threatening
4. Requires inpatient hospitalization or prolongation of existing hospitalization
5. Results in persistent or significant disability/incapacity, or
6. Is a congenital anomaly/birth defect.

Procedure for reporting:
All the research proposals approved by the institute Human Ethics Committee of IITM will come under the purview of this policy (drugs, devices, and behavioral or educational interventions; single or multiple armed trials, randomized or non-randomized).

For all SAE reports: Within **24 hours** of learning about an unanticipated or serious adverse event, the principal investigator is responsible for notifying the **DCGI, the Study Sponsor (if external), the Institute Human Ethics Committee (iec@iitm.ac.in)with a cc to ----------.** A hard copy of this document must also be sent to IEC Secretariat, Institutional Ethics Committee Office, Block 1, 1st Floor Room no BT 101, Dept of Biotechnology, IIT Madras.

Within **10 days** the principal investigator is to submit a follow up report to the same list of people as above. **IF IT IS A DEATH REPORT THEN THIS MUST ALSO BE SENT TO THE EXPERT COMMITTEE AND THE HEAD OF THE INSTITUTION (both should have a copy of the original report to the DCGI).**

Expert Committee address:

Chairman,Expert Committee,
The Drug Controller General of India,
FDA Bhavan, ITO,Kotla Road,
New Delhi -110002

Within 10 days the completed access database should be sent to ----------.

SERIOUS ADVERSE EVENT FORM

PROTOCOL TITLE:	**Protocol ID No.:**	**Centre:**

Subject's Study No.	**Investigation Product:**	**Report type** ☐☐☐ **1.0 = Initial** **2.1 = follow up 1** **2.2 = follow up 2 etc**
Occupation:		

Patient Initials: ☐☐☐	**Date of birth dd/mm/yy** ☐☐☐☐☐☐☐☐	**Age Years** ☐☐	**Sex** ☐	**Height (cm)** ☐☐☐	**Weight (Kg)** ☐☐

Event onset (dd/mm/yy) ☐☐☐☐☐☐☐☐	**Adverse Event in MEDICAL TERMS:**

Tick ✓ all appropriate to the Event

Patient Died ☐ **Date: dd/mm/yy** ☐☐☐☐☐☐☐☐	**Life Threatening** ☐	**Prolonged Hospitalization** ☐	**Significant Disability** ☐	**Congenital Abnormality** ☐	**Other SAE** ☐

Description:

Suspected Product(s):	**Daily Dose at onset of event:**	**Route of Administration:**

Indication for use:

Therapy dates (from/to), dd/mm/yy):

Therapy duration until onset of SAE

Was the product stopped? Yes / No **If yes, did the event abate after stopping the product? Yes / No/ Not Applicable**

Report Form Contn.		

Were Relevant Concomitant Drugs administered? Yes / No
If Yes, give names and details:

Drug Name	Dose & Route	Date Started (dd/mm/yy)	Continued Y or N	Date Discontinued (dd/mm/yy)	Reason For use

Other Relevant History, laboratory findings and action taken.
Medical History (please attach an additional sheet if this space is inadequate):

Relevant test / Laboratory findings

Laboratory test	Unit	Date	Value	Comments on laboratory finding

Serious Adverse Event Report Form Contn.	Protocol ID No.:	Patient ID No.:

Action taken by the Investigator: Please tick appropriate box

	None		Concomitant drug discontinued
	Trial dosage changed		New drug therapy added
	Trial drug discontinued		Prolonged hospitalization
	Non-drug Therapy		

Outcome: Please tick appropriate box

	Completely recovered on (dd/mm/yy)		Condition deteriorated
	Recovered with sequel		Death, autopsy done (attach summary)
	Condition improving		Death, autopsy not done
	Condition still unchanged		

Casuality Assessment by investigator (is there any relationship with the test product?):

	Not related		Probable
	Unlikely		Most probably
	Possible		Insufficient data to assess

Could the SAE be related to the study procedure?:

	Not related		Probable

	Unlikely		Most probably
	Possible		Insufficient data to assess

What is the long-term prognosis for the patient and will the patient continue to receive treatment? Will the costs of treatment be covered by insurance or other arrangements? (Please describe in detail the arrangements that will be made)

Was the protocol followed in recruitment of the participant? Yes / No

Did the participant meet the exclusion / inclusion criteria of the protocol? Yes / No

Was informed consent obtained as outlined in the protocol? Yes / No …… If no please explain:

In your opinion, does this report require that the consent form for participants to be revised? Yes / No

If Yes, submit **two** revised consent forms (one soft copy of each and one hard copy). One with the proposed changes emphasized in some fashion (highlighter, bolded, etc.) and another clean copy.

Name, address, telephone and e-mail address of the investigator

Name:_____ Profession (speciality):
_____

Department:
_____

Tel: _____ e-mail:
_____

Signature of the Investigator reporting the event:
_____

Reporting date (dd/mm/yy) PLEASE NOTE THAT THIS DATE MUST BE COMPLETED ON THE FORM _____
Date Received by the Research Office, CMC: _____ Signature of the receiver: _____