



आयुर्वेद शिक्षण एवं अनुसंधान संस्थान

Institute of Teaching and Research in Ayurveda

राष्ट्रीय महत्व का संस्थान, आयुष मंत्रालय, भारत सरकार

Institute of National Importance, Ministry of Ayush, Government of India

Website: <https://itra.ac.in> Email: ethics@itra.edu.in

Serious Adverse Event Reporting Format (Biomedical Health Research)

1. Title of the study:

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2. IEC ref no:

3. PI – Name, Designation and Affiliation:

4. Date of EC approval:

5. Date of Start of study:

Participant details:

Initials/ID:

Age at the time of event:

Gender: Male/Female

Weight (Kgs):

Height (Cms):

Suspected SAE diagnosis:

Date of onset of SAE:

Describe the event:

Date of reporting SAE:

Details of suspected intervention causing SAE:

Report type: Initial/Follow-up/Final

If Follow-up report, state date initial report

Have any similar SAE occurred previously in this study? Yes/No

If yes, please provide details.....

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)

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 or medical) to prevent SAE
- Event which poses threat to life
- Others

In case of death, state probable cause of death.....

- No permanent/significant functional/cosmetic impairment
- Permanent/significant functional/cosmetic impairment
- Not Applicable

Describe the medical management provided for adverse reactions (if any) to the research participant.....

.....
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(Include information on who paid, how much was paid and to whom).

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

Outcome of SAE

- Fatal
- Recovered
- Continuing
- Unknown
- Recovering
- Other (specify)

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

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

Signature of PI / Research scholar

Signature of Guide

(in case of research scholar)