



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

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Protocol Violation/Deviation Reporting Form (Reporting by Case)

1. Title of the study:

2. IEC ref no:

3. PI – Name, Designation and Affiliation:

4. Date of EC approval:

5. Date of Start of study:

6. Participant ID:

Total number of deviations /violations reported till date in the study:

Deviation/Violation identified by- Principal Investigator/study team/ Sponsor/Monitor/SAE
Sub Committee/IEC

Is the deviation related to (Tick the appropriate box):

Consenting

Source documentation

Enrolment

Staff

Laboratory assessment

Participant non-compliance

Investigational Product

Safety Reporting

Others(specify)

Provide details of Deviation/Violation:

Corrective action taken by PI/Co-I: Impact on (if any):.....

Study participant/Quality of data Are any changes to the study/protocol required? Yes/No If yes, give details

Signature of PI / Research scholar

Signature of Guide

(in case of research scholar)