



JSS Dental College & Hospital Institutional Ethics Committee

CDSCO reg No: ECR/1170/Inst/KA/2019

JSS Dental College and Hospital

A Constituent college of JSS Academy of Higher Education & Research, Mysuru.

Guidelines for Submitting Serious Adverse Events

Serious Adverse Event (SAE): A serious adverse event (SAE) in human drug trials is defined as: Any untoward medical occurrence that at any dose results in

1. Death
2. Is life-threatening
3. Requires inpatient hospitalization or prolongation of existing hospitalization
4. Results in persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

Procedure for reporting:

All interventional trials approved by the JSSDCH IEC will come under the purview of this policy (drugs, devices, and behavioural 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), and the chairperson of the Institutional Ethics Committee (jssdchiec@gmail.com)**.

Within **10 days** the principal investigator must 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 OF DCGI, JSSDCH IEC, AND THE HEAD OF THE INSTITUTION (both should have a copy of the original report to the DCGI).**

The researcher is hereby requested to utilize the form named “Guidelines for Submitting Serious Adverse Events” which is available for download from the JSSDCH (IEC) website for the submitting the details of any SAE occurring during their research study.

All the faculty and students are hereby requested to contact the member secretary of JSSDCH IEC by email (jssdchdiec@gmail.com) regarding any further queries or information.