

SERIOUS ADVERSE EVENTS/SAFETY REPORTS

- Serious adverse events log.
- Investigator safety reports to Sponsor (per protocol instructions, report to IRB if required).
- IND safety reports received from Sponsor (report to IRB).

Alternate location(s) if not filed in this binder

Item	Location
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

SERIOUS ADVERSE EVENTS LOG

Investigator: _____

Project: _____

Study Site: _____

Sponsor: _____

DATE SAE OCCURRED	DATE LEARNED OF EVENT	PATIENT NUMBER	EVENT	SAE FORM COMPLETED (Y/N)	DATE REPORTED TO SPONSOR	DATE REPORTED TO IRB*	IRB RESPONSE*

*File correspondence regarding IRB reports in the IRB Correspondence Log