

SCRIHS Adverse Event Reporting Table

	Event	Reporting Status	Time Frame to Report
LOCAL EVENTS	Expected Serious Adverse Event	Reportable	Within 5 working days of the PI becoming aware
	Unexpected Serious Adverse Event	Reportable	Within 48 hours of time of the PI becoming aware
	Expected Non-Serious Adverse Event	Not Reportable	---
	Unexpected Non-Serious Adverse Event	Reportable if Definitely or Probably Related	Within 5 working days of the PI becoming aware
MINIMAL RISK STUDIES	Any adverse event	Not Reportable unless directly related to study	---
NON-LOCAL EVENTS	Any Category	Reportable if determination that event meets criteria for an unanticipated problem (see AE reference sheet or information could be listed here)	Within 5 working days of when the PI becomes aware of event