

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 one week of when the PI becomes aware of event