Study Specific Event Reporting Plan

		Reporting Timeframe	Mechanism
1	Participant screening Enrollment and attrition	• Bi-monthly; evaluate for trends	• Study database • Team meetings
2	Participant complaints not associated with potential for increased risk profile or changes to research	• **Not reported to IRB** • Evaluate for trends	• Study database
	Participant complaints associated with potential for increased risk profile or changes to research	• Serious events within 7 days • Non-serious events within 14 days	• Report to IRB
3	Protocol deviations not associated with potential for increased risk profile or changes to research	• **Not reported to IRB** • Evaluate for trends	• Study database • Team meetings
	Protocol deviations associated with potential for increased risk profile or changes to research	• **Serious events within 7 days** • **Non-serious events within 14 days**	• Report to IRB
4	Expected (given the patient population) abnormal clinical findings secondary to any research procedures	• **Not reported to IRB** • Reported to subject as soon as possible	• Study database • AE report • Phone call to subject
	Expected or unexpected clinical complications that are not related to any research procedures	• **Not reported to IRB**	• Study database
	Unexpected (not typically associated with the patient population) abnormal clinical findings secondary to any research procedures	• **Not reported to IRB** • Evaluate for trends	• Study database • Team meetings
5	Expected events that are related to the research	• **Serious events within 14 days** • **Non-serious events not reported to IRB** • Evaluate for trends	• AE report • Study database
	Unexpected events that are related to the research	• **Life threatening events within 7 days** • **Serious events within 14 days** • Non-serious events at time of SCR • Evaluate for trends	• AE report • Study database

6	Unexpected events that not related to the research	• **Not reported to IRB** • Evaluate for trends	• Study database
7	Unanticipated problem that is unexpected, related to the research & associated with increased risk profile	• Describe as "Potential UaP" in report • **Within 14 days**	• AE report depending on problem

Summary of non-reportable events:

- Participant complaints not associated with potential for increased risk profile or changes to research
- Protocol deviations not associated with potential for increased risk profile or changes to research
- Unexpected abnormal clinical findings secondary to any research procedures
- Clinical complications not related to research procedures
- Non-serious expected events that are related to the research
- Unexpected events that not related to the research

For more information:

See your institutional specific guidelines.