Reporting to the REB - Safety and other reports

Project Info

File No:
PI:
Project Title:
Submitted:
Submitted by:

Event Info

Event No:
Notes:

Common Questions

1. Describe Event

#	Question	Answer
1.1	Event being reported:	
1.2	Type of document being attached (please attach using the Attachments tab, and include document name and version number/date):	
1.3	Date sponsor notified (if applicable):	
1.4	Date of event or onset:	
1.5	Report type:	
1.6	If follow up report, please provide date of initial report:	
1.7	Participants affected (by ID number only):	

1.8	Are participants still enrolled in the study?	
1.9	Seriousness of event (please check all that apply):	
1.10	If other, please describe:	
1.11	Reporting criteria: Is this event an unanticipated problem involving risk to participants or others? Please check all that apply:	
1.12	Reason for report:	
1.13	If other, please describe:	
1.14	Was the event related to the study product?	
1.15	Action taken:	
1.16	Concomitant medication or products (if applicable):	
1.17	Does the PI recommend the study be stopped?	
1.18	Does the PI recommend a change to the protocol?	
1.19	Does the PI recommend a change to the site consent form?	
1.20	Does the PI recommend a change to the study-wide consent form?	
1.21	If a change to the consent form(s) is recommended, do you plan to re-consent current participants?	
1.22	Please provide description:	

2. Local Serious Adverse Event ONLY

#	Question	Answer
2.1	Please describe the event including pertinent health history, severity of SAE, and assessment of causality:	
2.2	Concomitant medication or products:	
2.3	Does the PI consider this SAE as an increase in risk for the participant?	