Serious Adverse Event or Unanticipated Problem
Safety and Outcomes Subcommittee – Review Form

Study ID:

☐ **SAE** ☐ **UAP (according to description provided by the site)**

SAE / UAP Onset Date (MM/DD/YYYY):

Reviewers present:

Review Date (MM/DD/YYYY):

SOS Comments [summarized by Chair]:

SOS Assessment of SAE / UAP:

Recommendation by SOS for status of research activities (check all that apply)

☐ No further action is required

☐ Study-wide hold in research activities *

☐ All research activities for all participants.

☐ Specific research activities for all participants

Specify:

☐ Specific research activities for sub-group of participants

Specify:

☐ New participant enrollment

☐ Site-specific hold or stop in research activities

☐ All research activities for all participants

☐ Some (or all) research activities for a specific participant

Specify:

Specific research activities for sub-group of participants

Specify:

☐ Specific research activities for all participants

Specify:

☐ New participant enrollment

** Any recommendation for action that affects the study at all sites will be communicated to the Steering Committee and Executive Committee for further discussion and subsequently to the DSMB for approval and implementation. A safety report with recommendation will be sent to all sites.*

Recommendation by SOS for study-wide changes in protocol and informed consent forms (check all that apply)

☐ No change in study protocol or informed consent forms

☐ Changes in study protocol

Specify:

☐ Changes in informed consent forms

Specify:

If changes in informed consent form(s) are required, is it recommended that currently enrolled participants require notification and/or re-consenting as a result of the event?

☐ Yes ☐ No

Signature of SOS Chair (or designee):
(e-signature accepted)

Final steps to submission:
Save a copy of this form to your computer.
Click on the "Submit" button and follow the directions to submit electronically. Alternatively, you may attach the file manually to an email and send to: D2d@TuftsMedicalCenter.org.

Submit