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

Study ID:

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

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

Reviewer:

Review Date (MM/DD/YYYY):

Additional information. *If, after review of the medical records, the reviewer determines that s/he needs additional information, please record what specific additional information is needed and submit form to CC.*

Reviewer's Comments:

Reviewer's Assessment of SAE / UAP:

Serious Adverse Event [SAE]? ☐ No ☐ Yes
Unanticipated Problem [UAP]? ☐ No ☐ Yes

☐ No action by SOS is required. SAE can be reviewed at the next SOS meeting.
☐ Action may be required. SOS should be convened as soon as possible to discuss event.

Signature of Reviewer:
(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