**ADVERSE EVENT / UNANTICIPATED PROBLEM REPORT**

**PLEASE NOTE: If this is a deviation from the approved IRB protocol please complete the** [**Deviation Report**](https://research.umd.edu/research-resources/research-compliance/institutional-review-board-irb/irb-forms)**.**

**Principal Investigator:** Click here to enter text.

**Protocol Number (IRBNet):** Click here to enter text.

**Project Title:** Click here to enter text.

**Question 1: Please describe the event and/or problem.**

Click here to enter text.

**Question 2: Was the event/problem related to study participation?**

Click here to enter text.

**Question 3: Is the possibility of this event/problem described in the consent/assent? If NO, does the**

**consent/assent need to be revised?**

Click here to enter text.

**Question 4: What was the result? Did any follow-up occur? If so, please describe.**

Click here to enter text.

**Question 5: Is this event a Serious Adverse Event (SAE)? If YES, has a report been filed with the**

**IRB, and sponsor (if applicable)?**

Click here to enter text.

**NOTE: Please have both the staff member completing this report and the Principal Investigator for this protocol electronically sign the IRBNet package prior to submitting this report in IRBNet.**