CASE WESTERN RESERVE UNIVERSITY

CWRU ADVERSE EVENT WORKSHEET

Instructions: Answer all five questions below unless question 1 is answered "No." Follow the reporting guidance at the completion of worksheet.

1. Did the participant(s) experience unintended, negative physical, psychological, or other harm associated with the study materials or procedures? ***If NO, this is not an adverse event. Check the Unanticipated Problem and Protocol Deviation worksheets.***	☐ YES	☐ NO
2. Did the event result in death, a life-threatening experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect? ***If YES, proceed to question 2a. If NO, proceed to question 3.***	☐ YES	☐ NO
2a. If question 2 is YES, does this study involve the use of drugs, biologics, or devices?	☐ YES	☐ NO
3. Is the event unexpected in nature, severity, or frequency? ***If YES, cross reference the event with the Unanticipated Problem worksheet.***	☐ YES	☐ NO
4. Is the event related or possibly related to participation in the research? ***If YES, cross reference the event with the Unanticipated Problem worksheet.***	☐ YES	☐ NO
5. Does the event suggest that the research places participants or others at a greater risk of physical, psychological, or other harm than was previously known or recognized? **NOTE: if the adverse event is SERIOUS, the answer is always YES.** ***If YES, cross reference the event with the Unanticipated Problem worksheet.***	☐ YES	☐ NO

Report to the IRB within three (3) days of discovery if:
Question 2a is YES

Report to the IRB within five (5) days of discovery if:
Question 2, 3, 4, or 5 are YES but 2a is NO or not applicable

Report during the study's annual continuing review or annual check-in if:
Question 1 is YES but questions 2-5 are all NO

ALL adverse events, regardless of reporting requirement(s) must be documented in the study's adverse event tracking log.