CASE WESTERN RESERVE UNIVERSITY

CWRU PROTOCOL DEVIATION WORKSHEET

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

1. Was any study component altered or modified, whether intentionally or inadvertently, prior to IRB approval? ***If NO, this is not a protocol deviation. Check the Unanticipated Problem and Adverse Event worksheets.***	☐ YES	☐ NO
2. Did the deviation impact, or potentially impact, the participant's (or other's such as research staff, family members) rights, safety, or well-being? ***If YES, cross reference the event with the Unanticipated Problem and Adverse Event worksheets.***	☐ YES	☐ NO
3. Did the deviation impact, or potentially impact, the completeness, accuracy, or reliability of study data? ***If YES, cross reference the event with the Unanticipated Problem worksheet.***	☐ YES	☐ NO

Report to the IRB within five (5) days of discovery if:
Questions 2* and 3 are YES

Report the event during the study's annual continuing review or annual check-in if:
Question 1 is YES but questions 2 and 3 are NO

**If the Adverse Event Worksheet question 2a is YES, the event must be reported with three (3) days of discovery.*

ALL protocol deviations, regardless of reporting requirement(s) must be documented in the study's protocol deviation tracking log.