CASE WESTERN RESERVE UNIVERSITY

CWRU UNANTICIPATED PROBLEM WORKSHEET

Instructions: Answer all three questions below and follow the guidance at the completion of worksheet.

Does the event, incident, experience, or outcome meet the following criteria?		
1. Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the population being studied.	☐ YES	☐ NO
2. Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).	☐ YES	☐ NO
3. Suggests that the research places participants or others (which may include research staff, family members, or other individuals not directly participating in the research) at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or expected.	☐ YES	☐ NO

If all 3 statements above are "YES"

This is an Unanticipated Problem (UP). Report within 3 days if the study involves (a) drugs, biologics, or devices *or* (b) if study participants experienced an immediately life-threatening or severely debilitating event. Report within 5 days if neither (a) nor (b) apply. In either reporting circumstance, document on the study's Unanticipated Problem tracking log.

If any 1 statement above is "NO"

This is not an Unanticipated Problem (UP). Cross reference the Adverse Event and Protocol Deviation worksheets to determine if the event matches one or both of those categories. Document accordingly on the study's Adverse Event and/or Protocol Deviation tracking log(s).

ALL unanticipated problems, regardless of reporting requirement(s) must be documented in the study's unanticipated problems tracking log.