Institutional Review Board (IRB)
Lewis University
FORM G

REPORT OF

Serious Adverse Event, Unanticipated Problem, or Protocol Deviation

(P)dition Examples participation in research increases risk of harm to subjects, administrative hold of study, Examples of protocol deviations: noncompliance with protocol as approved by LRB/IRB.

Submit this form to the LRB Chairperson/Committee for review and possible University IRB review. Please provide all the information requested in order to comply. Please use one report for each event

TITLE OF STUDY:

FACULTY SPONSOR:

PRINCIPAL INVESTIGATOR:

1) Check one: ☐ **Local Event(s)** **(i.e., Lewis University subjects) (complete table below) (See #3)**
☐ **Problem – unanticipated**
☐ **Protocol deviation**

ID (Initials or Study number only)	*Brief summary of event NOTE: ONE EVENT PER REPORT	Initial or Follow-up	Age / Gender				Event

2) What is the current status of the study:
☐ **Active to enrollment**
☐ **Closed to enrollment, participants being followed**
☐ **Data analysis only**

3) If event was *unanticipated,* did it increase risk to the participant and/or others? If yes, describe actions taken to reduce immediate harm to subject or others.

4) If unanticipated problem, describe action plan to prevent future occurrences:

5) Additional information or Comments:

6) NUMBER OF CURRENT (Active) PARTICIPANTS: