

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:

