Institutional Review Board (IRB)
Lewis University
FORM G

REPORT OF
Serious Adverse Event, Unanticipated Problem, or Protocol Deviation

Local serious adverse events (SAEs) and Unanticipated problems must be reported <u>within 48 hours</u> to the LRB and/or IRB.

*This form should be completed for each **SAE**, **unanticipated problem, or protocol deviation** involving risks to subjects or others associated with research at Lewis University.*
Examples of SAEs: death, life-threatening injury, hospitalization, disability
Examples of unanticipated problems: incarceration of a subject in a protocol not approved to enroll prisoners, when participation in research increases risk of harm to subjects, administrative hold of study, study suspension by sponsor
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**	**Is the Event Study Related?**	**Is Event** anticipated Y/N (See #3)	**Date Enrolled**	**Date of 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:

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7) NUMBER OF PAST PARTICIPANTS:

8) AS A RESULT OF THE ADVERSE EVENT OR PROBLEM, ARE CHANGES NECESSARY TO THE INFORMED CONSENT?

☐**YES**.....☐**NO**

If yes, attach copy with the revisions highlighted. Current participants must be notified and new consent obtained. It is the expectation of the IRB that additional risks and willingness for continuing participation is discussed with the participant. Additionally, an assessment must be made if past participants should be contacted

9) SHOULD PAST PARTICIPANTS BE NOTIFIED OF THIS EVENT?

☐**YES**.....☐**NO**

For local events and problems, the IRB may determine if this is necessary

_____
Principal Investigator's Signature and Date

FOR IRB REVIEWER USE ONLY:

Considerations to be made by IRB Member -Reviewer

1. IS THIS EVENT//PROBLEM: ☐ **Serious** ☐ **Not Serious**

2. Is this Event/Problem: ☐ **Anticipated** ☐ **Not anticipated**

3. Is this Event/Problem: ☐ **Related** ☐ **Possibly Related** ☐ **Unrelated to the Research**

4. Does this event/Problem require immediate action to Prevent Harm PRIOR to convened IRB

☐ **YES** ☐ **No**

Suggested action:

5. Does this event/Problem require review by convened IRB for discussion of action plan (IMMEDIATE action not required**)**

☐ **YES** ☐ **No (Immediate action IS required)**

6. Does this event/Problem require change in the Informed consent document?

☐ **YES** ☐ **No**

if yes – convened IRB must determine and document:

- Previously enrolled subject need to be notified
- When and how documented

_____ _____
Reviewer Signature Date