

SOUTHEASTERN UNIVERSITY INSTITUTIONAL REVIEW BOARD

Unanticipated Problem/Adverse Event Report

This form must be completed and submitted to the SEU IRB for each unanticipated problem/adverse event that occurs on an approved research project. **This form must be received by the SEU IRB within 5 days of initial notification of the investigator about the event.**

IRB NUMBER:

DATE SUBMITTED:

PRINCIPAL INVESTIGATOR:

PROJECT TITLE:

DATE OF EVENT:

1. TYPE OF EVENT:

- Event which in the opinion of the Principal Investigator (1) was unexpected and (2) was related to the research procedures;
- Event that requires prompt reporting according to the research sponsor (if any);
- Accidental or unintentional change to the IRB approved protocol that involves risks or has the potential to recur;
- Deviation from the protocol without prior IRB approval to eliminate any apparent immediate hazard to a research participant;
- Publication in the literature, safety monitoring report, interim result or other finding that indicates an unexpected change to the risk/benefit ratio of the research;
- Breach in privacy/confidentiality/data security/loss of study data that may involve risk to participant(s);
- Complaint of a participant that indicates an unanticipated risk or which cannot be resolved by the research staff.

(NOTE: EVENTS THAT DO NOT FIT INTO THE ABOVE CATEGORIES DO NOT REQUIRE REPORTING TO THE IRB UNTIL THE CONTINUATION-RENEWAL FORM IS FILED. HOWEVER, THE EVENT MAY REQUIRE REPORTING BY THE PI TO THE SPONSOR OR DATA MONITORING PLAN.)

2. Briefly describe the unanticipated problem or adverse event. (Use additional pages as necessary)

3. If a participant was involved, will he/she continue with the study?

- Yes No – Date Stopped: _____

4. Will the research project itself continue?

- Yes No – Date Stopped: _____

5. What actions have been taken? What will be done to minimize reoccurrence? (Use additional pages as necessary)

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Signatures:

Principal Investigator

Date

Student PI (if applicable)

Date

Submit one original copy of this form to:

IRB@seu.edu