



Unanticipated Problem/Adverse Event Report

This form must be completed and submitted to the ETBU IRB for each unanticipated problem/adverse event that occurs on an approved research project. **This form must be received by the ETBU 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 advisor (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 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.

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

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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)

Signatures:

Principal Investigator

Date

Research Advisor

Date

Submit this form to Dr. LaShondra Manning at lmanning@etbu.edu