SOUTHERN ILLINOIS UNIVERSITY EDWARDSVILLE

ADVERSE EVENT/UNANTICIPATED PROBLEM REPORT

Researchers must report to the Southern Illinois University (SIUE) Institutional Review Board (IRB) all incidents of adverse events and/or unanticipated problems that happen during research conducted with human subjects. A written report should be submitted to the SIUE IRB within 48 hours of the researchers' knowledge of the event.

The U.S. Department of Health & Human Services (DHHS), Office of Human Research Protections (OHRP) defines *adverse event*s and *unanticipated problems* as follows:

> Any adverse event occurring in one or more subjects participating in a research protocol, the nature, severity, or frequency of which is **not** consistent with either:
>
> 1. the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
>
> 2. the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.
>
> Any unanticipated problems involving risks to subjects or others is found but not defined in the HHS regulations at 45 CFR part 46. OHRP considers *unanticipated problems*, in general, to include any incident, experience, or outcome that meets **all** of the following criteria:
>
> 1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
>
> 2. related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
>
> 3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

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Complete this form and submit it to
The Office of Research and Project (ORP), Campus Box 1046

FORM

Primary Investigator/Researcher_____

Advisor's name (if student):_____

Department: _____

Phone:_____

Date: __/ __/ __

Title of Research Proposal:_____

_____

1. Describe in detail the nature and severity of the adverse event/unanticipated problem:
2. Describe in detail what steps have been taken to address the situation:
3. How many participants have been affected by the adverse event/unanticipated problem:
4. Was the adverse event/unanticipated problem listed in the current consent form?
5. Describe what changes you plan to make to the current consent form to better inform participants of these adverse events/unanticipated problems (please attach the revised consent form for approval by the IRB).
6. If participants are children, have you notified the parents/guardians of the event/problem?

_____

Principal Investigator's/Researcher's signature Date

_____

IRB Chair Signature Date