

Unanticipated Problem Involving Risk Form

Study # / SLHN #	Patient Initials/ Subject #	Name of Site
Date of Occurrence	Date PI Became Aware	Person Completing Form

Title of Protocol: _____

PI Name: _____ Department/Division: _____

UAP Category (check one):

***Refer to instructions on Page 2*

- Protocol Deviation/Violation** (e.g. informed consent, eligibility, missed procedures, change in protocol without prior IRB approval, etc.)
- New data or information increasing risk** (e.g. journal article, change in FDA approval, study suspension for risk, etc.)
- Pharmacy Issue** (e.g. incorrect amount of IP dispensed, missed doses, etc.)
- Other**

Specific Details of Incident:

Site Plan of Action (future prevention efforts to avoid reoccurrence):

PI or Co-I
Signature

Date

Person Completing Report
Signature

Date

INSTRUCTIONS

Consider each of the following criteria in order to determine whether an event is an unanticipated problem involving risks to subjects or others:

- Is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Is related or possibly related to participation in the research (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
- 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.

HELPFUL TIPS

The Unanticipated Problem Form (UPR) should be submitted in a timely fashion related to the seriousness of the Unanticipated Problem. Unanticipated problems that are serious adverse events should be reported to the IRB within 10 working days of the investigator becoming aware of the event. Any other unanticipated problem should be reported to the IRB within 15 working days of the investigator becoming aware of the problem. See the IRB Investigators Manual for definitions and reporting requirements for Adverse Events (AEs) and Serious Adverse Events (SAEs).

Some events do not qualify as AEs, SAEs or Unanticipated Problems posing risks to subjects or others. Most of these are events or circumstances encountered in the usual course of receiving medical attention. Examples of these are pain or minimal bleeding at the time of venipuncture, drowsiness after sedation, boredom while waiting for the scheduled visit or procedure, or other similar scenarios.

Unanticipated Problems posing risks to subjects or others are unforeseen and indicate that participants or others are at increased risk of harm. Examples include but are not limited to the following:

- An interim analysis of the data suggesting or indicating additional risk associated with a study procedure or test article.
- A report (journal article or abstract, etc.) that shows that the risks or potential benefits of the research might now be different from those initially presented to the IRB.
- A breach of confidentiality.
- Change in FDA labeling or withdrawal from marketing of a drug, device, or biological used in a research protocol.
- Change made to the research without prior IRB review to eliminate an apparent immediate hazard to a subject.
- Incarceration of a subject in a protocol not approved to enroll prisoners.
- An event that requires prompt reporting to the sponsor.
- Sponsor imposed suspension for risk.
- Complaint of a subject when the complaint indicates unexpected risks or cannot be resolved by the research team.
- A change to a protocol or procedure that is not pre-approved by the IRB.
- Protocol violation (an accidental or unintentional change to the IRB-approved protocol) that may harm subjects or others or that indicates that subjects or others may be at increased risk of harm.
- Other unanticipated information that indicates participants or others might be at increased risk of harm.

Medical judgment may be involved in making decisions regarding whether an event represents an Unanticipated Problem (UAP). If you have questions, please call the Human Research Protections Office/IRB at (610) 776-4832 or (610) 776-4856.