

# St. Luke's University Health Network

SOP 305: Adverse Events and Unanticipated Problems

Version # 3.0

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## **PURPOSE:**

This standard operating procedure (SOP) describes the responsibilities and steps of the research team for reporting and documenting adverse events (AEs) and Unanticipated Problems Involving Risk (UAP) from the time an AE and/or UAP is identified until all follow-up activities associated with its resolution have been completed.

## **DEFINITIONS/ABBREVIATIONS:**

- **Adverse Event (AE):** Any untoward medical occurrence encountered by an individual during the course of a clinical trial which may or may not be associated with the study drug, procedure, or device. An AE can include previously undetected symptoms, or the exacerbation of a pre-existing condition. When an AE has been determined to be related to the investigational drug, it is considered an Adverse Drug Reaction.
- **AE Reports:** Investigator reports of all serious and adverse events, injury, and deaths given to the sponsor, the IRB and the FDA or appropriate regulatory body.
- **Case Report Form (CRF):** A Case Report Form can be either paper (CRF) or electronic (eCRF). These forms are used to collect data that is then submitted to the sponsor of the clinical trial. The CRF is constructed to collect pertinent information to the clinical trial from the patient's records.
- **Clinical Research Nurse/Coordinator (CRC):** Clinical Trials staff responsible for oversight and coordination of assigned protocols.
- **Clinical Trials Office (CTO):** Centralized clinical trials staff, responsible for the conduct and support of SLUHN clinical trial functions
- **Common Terminology Criteria for Adverse Events (CTCAE):** A National Cancer Institute document which can be used for adverse event reporting.
- **Data Doctor Office Technology Systems (DDOTS):** A software program system utilized by the CTO staff to integrate comprehensive functionalities needed throughout the clinical trial process into a single, open web platform.
- **Electronic Medical Record (EMR):** A digital/electronic version of a paper chart and documents that contain all of the patient's medical history.
- **Electronic Signature:** A computer data compilation of any characters executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.
- **Institutional Review Board (IRB):** Independent ethics committee formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects.
- **Principal Investigator (PI):** Lead investigator, responsible for the sound conduct of the project in accordance with the protocol and regulations.
- **Serious Adverse Event (SAE):** Any untoward medical occurrence that: results in death, is life-threatening, requires inpatient hospitalization or prolongation of

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- existing hospitalization, results in persistent or significant disability/incapacity, and or congenital anomaly/birth defect.
- **Source Documents:** Original documents and records including, but not limited to, hospital records, clinical and office charts, laboratory notes, subject's diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, magnetic media, x-ray, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in a clinical trial.
  - **St. Luke's University Health Network (SLUHN)**
  - **Standard Operating Procedures (SOPs):** Detailed, written instructions to achieve uniformity of the performance of a specific function.
  - **Unanticipated Problems Involving Risk (UAP):** Unanticipated Problems posing risks to subjects or others that are unforeseen and indicate that participants or others are at increased risk of harm.
  - **UAP Reports:** Investigator reports of all Unanticipated Problems posing risks to subjects or others given to the sponsor, the IRB and the FDA or appropriate regulatory body.

## **SCOPE:**

This SOP applies to all clinical research site personnel involved in the conduct of clinical research.

This policy describes the process:

- Starting from the time the research team becomes aware of the adverse event.
- Ending when the AE/SAE or UAP has resolved.

This policy is applicable to:

- All clinical trials at SLUHN conducted by the CTO, which may include Industry or Government Sponsored trials, Cooperative Group trials and Investigator Initiated Trials

## **PERSONNEL RESPONSIBLE:**

This SOP applies to members of the clinical trials research team involved in the management of a subject's participation in a clinical trial. This includes the following:

- Principal Investigator
- Research Nurse/Coordinator
- Institutional Review Board
- Regulatory Coordinator

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## ROLES:

The following information describes which areas and associated roles that shall adhere to this policy:

**Principal Investigator (PI):** The Principal Investigator or designee shall be responsible for clinical trials conduct and overall oversight at SLUHN. S/he will ensure that any AE, SAE and/or UAP is reported and followed until resolution.

**Research Nurse/Coordinator (CRC):** The Research Nurse/Coordinator shall be responsible for reporting SAEs, AEs and/or UAPs in accordance with defined timelines to the sponsor and Regulatory Coordinator (RC). CRC will send the SAE or UAP report to the RC for uploading into DDOTS for IRB notification.

**Regulatory Coordinator (RC):** The Regulatory Coordinator shall be responsible for the IRB submission of ongoing AE and UAP Logs to the IRB at the time of Periodic Review, as well as the filing of all AE and UAP Logs in the regulatory binder as part of the IRB submission. The RC shall also be responsible for reporting SAEs and UAPs via DDOTS in line with IRB reporting requirements, and filing the IRB acknowledgement in the Regulatory Binder.

**Institutional Review Board (IRB):** The IRB shall review all SAE and UAP reports to reevaluate the risks and benefits of the research, need for changes, etc in accordance with IRB policies and procedures.

## PROCEDURES:

### ADVERSE EVENT REPORTING

- The PI or CRC becomes aware of the adverse event.
- The PI or CRC shall gather information from the patient or source documents of the AE.
- The PI shall determine the severity and/or grade of the adverse event using the AE scale provided by the study.
- The PI shall determine relationship of the AE and whether its association with the study drug, device or research-related procedure is definitely, probably, or possibly related, or unknown.
- The CRC shall record the adverse event on the adverse event tracking log (*see Attachment B*) with the PI initials at the time of the event and resolution, and place the log on patient shadow chart.
- The PI will sign the bottom of AE Log at the time of the periodic review and a copy of the signed AE Log shall be submitted to the IRB.

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## SAE REPORTING

- The PI or CRC becomes aware of the SAE.
- The PI or CRC shall report all serious adverse events to the sponsor within 24 hours of becoming aware of the SAE (or as defined per protocol) by completing an eCRF or faxing the paper CRF as specified by the protocol, and will indicate the category of SAE as follows:
  - fatal
  - life threatening
  - requires hospitalization
  - resulted in a disability (temporary or permanent)
  - resulted in a congenital anomaly or birth defect.
- The PI shall determine the relationship of the SAE and whether its association with the study drug, device or research-related procedure is definitely, probably, possibly related, or unknown.
- The PI shall note a brief description of the SAE and describe the action taken toward resolution.
- Both PI and CRC shall review the patient's EMR, manage the patient as medically necessary until the SAE is resolved, and shall submit a follow-up SAE case report form to the sponsor if necessary.
- Once the Sponsor has been notified of the SAE, the SAE information as required by the SLUHN IRB shall be noted on a SLUHN Adverse Event Reporting Form (**Attachment A**) and reported to the IRB within 10 days of becoming aware of the event.
- The CRC maintains a log of adverse events (see above procedure for AE Reporting), and shall note the SAE on the AE tracking log (**see Attachment B**). The adverse event will also be graded by the PI according to the clinical significance/severity using the AE scale specified by the clinical trial protocol. The log is also signed and dated by the PI (**see Attachment B**) at the time of the event and at resolution.
- If the SAE involved death of the subject enrolled by the St. Luke's Investigator, the PI shall report immediately (within 72 hours) to SLUHN IRB.
- If the SAE is death from natural causes or underlying disease that occurs 30 days following completion of the study treatment, the AE does not need to be reported to the IRB.
- The CRC shall submit the Adverse Event Reporting Form (**Attachment A**) signed by the PI to the Regulatory Coordinator, and file a copy of the SAE in the patient's shadow chart and regulatory binder.
- The RC shall submit the SAE to the IRB via DDOTS, and notify all pertinent staff (e.g. IRB, CRC, CRA, and Financial Research Analyst)
- The RC shall receive the DDOTS e-mail acknowledgement of the AE report.
- Regulatory Coordinator prints the DDOT's AE report form (**Attachment A**), attaches the acknowledgement and files it in regulatory binder.

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### UNANTICIPATED PROBLEM REPORTING

- The PI or CRC becomes aware of the UAP.
- The CRC shall update the UAP Tracking Log (*Attachment C*) with this information
- If the UAP involves risk to the subject, the PI or CRC shall complete the UAP Report (*see Attachment C*) with details of the incident and note the site action plan preventing the reoccurrence. This form shall be signed and dated by the PI.
- The PI or CRC shall provide the RC with the signed UAP Report for IRB submission, and shall maintain a copy in the patient's research shadow chart.
- The RC shall submit the completed and signed UAP Form via DDOTS for IRB review within 7 days of the PI or CRC becoming aware of the event
- The PI or CRC shall inform the SLUHN IRB of any unanticipated problems that result in social or psychological harm rather than physical harm to subjects within 30 days via DDOTS.
- The RC shall print the DDOT's UAP report form, along with the IRB acknowledgement, and attach the IRB acknowledgement to the UAP report and file in regulatory binder.
- A copy of the UAP Log shall be submitted to the IRB at the time of periodic review.

### Reporting of AEs

Role	Step	Activity
Principal Investigator	1.0	Review all adverse events from the beginning to the resolution of the AE.
Principal Investigator or designee	1.1	Determine the severity and/or grade of the AE using the AE scale provided by study, if applicable.
Principal Investigator	1.2	Determine relationship of the AE and whether its association is definitely, probably, or possibly related, or unknown.  <b>NOTE:</b> Report all unanticipated, non-serious AE's that are probably or possibly related to the study drug/device within 30 days of becoming aware of the event (see Steps 2.3 through 2.6).
Research Nurse/Coordinator or designee	1.3	Complete the AE Log with the required information.
Principal Investigator	1.4	Sign and date the AE Log at time of periodic review.
Research Nurse/Coordinator or designee	1.5	Retain copies of the adverse event log in the patient shadow charts with the PI signature.

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Regulatory Coordinator	1.6	Obtain a copy of the AE Log from the assigned CRC, and submit to the IRB at the time of Periodic Review.
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### Reporting for SAE

Role	Step	Activity
Principal Investigator/CRC	2.0	Become aware of the SAE.
Research Nurse/Coordinator or designee	2.1	Review EMR and gather source documents to review with the PI for completion of the sponsor eCRF/CRF and SLUHN Adverse Event Reporting Form ( <b>Attachment A</b> ).
Principal Investigator/CRC	2.2	Inform the sponsor of the SAE by completing the eCRF or faxing the CRF specified by the clinical trial within 24 hours of notification of the SAE, or as outlined in the protocol.
Principal Investigator/CRC	2.3	Send the completed and signed Adverse Event Reporting Form ( <b>Attachment A</b> ) to the RC within 7 days.  <b>NOTE:</b> If the SAE is death, this form must be completed and provided to the RC within 48 hours of becoming aware of the event.
Research Nurse/Coordinator or designee	2.4	Retain copies of the SAE in research shadow chart and enter SAE in the adverse event log ( <b>Attachment B</b> ).
Regulatory Coordinator	2.5	Notify the IRB via DDOTS of the SAE within 10 calendar days of the date the PI and/or CRC became aware of the event, obtain a copy of the SAE IRB Acknowledgement via DDOTS and print a copy for the Regulatory Binder.  <b>NOTE:</b> Deaths must be reported within 72 hours of becoming aware of the event unless the death is from "natural causes" or underlying disease that occur more than 30 days following completion of the study interventions (i.e., events not temporally associated) which need not be reported.
Regulatory Coordinator	2.6	File a copy of the IRB Acknowledgement and signed AE Report Form in the Regulatory Binder.

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### Reporting of UAP's

Role	Step	Activity
Principal Investigator/CRC	3.0	Becomes aware of the UAP.
Research Nurse/Coordinator or designee	3.1	Review EMR and gather source documents to review with the PI for completion of the UAP ( <i>Attachment C</i> ) Form.
Principal Investigator/CRC	3.2	Inform the Sponsor of the UAP according to protocol.
Principal Investigator/CRC	3.3	Notify the RC of any unanticipated events posing risks to patients by providing a completed UAP form ( <i>Attachment C</i> ) inclusive of an action plan to prevent reoccurrence of same event within 8 calendar days of becoming aware of the event.
Research Nurse/Coordinator or designee	3.4	Retain copies of the UAP and also update the UAP Tracking Log ( <i>Attachment D</i> ).
Regulatory Coordinator	3.5	Report the UAP via DDOTS to the IRB within 10 days of the date the PI and/or CRC became aware of the event, obtain a copy of the UAP IRB Acknowledgement via DDOTS email, and print a copy for the Regulatory Binder.
Regulatory Coordinator	3.6	File a copy of the IRB Acknowledgement and signed/dated UAP Report Form ( <i>Attachment C</i> ) in the Regulatory Binder.
Regulatory Coordinator	3.7	Obtain a copy of the UAP Log ( <i>Attachment D</i> ) from the assigned CRC, and submit to the IRB at the time of Periodic Review.

### **RESOURCES:**

St. Luke's University Health Network Institutional Review Board Information

Federal Drug Administration (FDA) 21 CFR 312.32

Federal Drug Administration (FDA) 21 CFR 312.64

**Endorsed by:** SOP Committee (5/12/14; 2/20/15; 4/8/16)

**Approved by:** Tracy Butryn, Director of Clinical Trials and Research (5/28/14; 7/29/14; 2/20/15; 7/12/16)

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## ATTACHMENT A (PAGE 1 of 2)

Institutional Review Board

801 Ostrum Street, Bethlehem, PA 18015 - Phone: 484-526-4944  
<http://medafairs.slhn.org>

### Adverse Event Reporting Form

<b>Research Protocol Title:</b> <b>IRB Number:</b> _____ <b>Patient Number:</b> _____
<b>Principal Investigator:</b> Address: _____ Phone: _____ Email: _____
<b>Research Coordinator:</b> Address: _____ Phone: _____ Email: _____

**ADVERSE EVENT:** *Any unfavorable and unintended sign (including abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure, that is not listed as a risk on the consent form, regardless of whether it is considered related to the treatment or procedure; also an "unanticipated problem" of any nature (e.g., psychological or social harm)*

**Date of Adverse Event:** \_\_\_\_\_ **Date PI Became Aware:** \_\_\_\_\_ **Date IRB Notified:** \_\_\_\_\_

**1. The site where research was performed:**

- SLH - Allentown       SLH - Miners       SLW - Warren  
 SLH - Bethlehem       Private Office (Specify location(s): \_\_\_\_\_  
 SLH - Quakertown       Other (Specify): \_\_\_\_\_

**2. The research involves:**

- Drug(s) Name of drug(s): \_\_\_\_\_  
 Device(s) Name of device(s): \_\_\_\_\_  
 Research -related procedures Name or description of procedures: \_\_\_\_\_

**3. The adverse event... (check all that apply)**

- Was fatal (resulted in death)  
 Was life threatening (immediate risk of death), but not fatal  
 Resulted in a disability (temporary or permanent)  
 Resulted in hospitalization or prolonged hospitalization  
 Resulted in congenital anomaly or birth defect

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4. The Adverse Event was:  Expected  Unexpected

5. The relationship of the adverse event to the study is...

- Definitely related *(The event has a timely relationship to the administration of the investigational drug/study procedure and follows a known pattern of response for which no alternative cause is present)*
- Probably related *(The event has a timely relationship to the administration of the investigational drug/study procedure and follows a known pattern of response, but for which a potential alternative cause may be present)*
- Possibly related *(The event has a timely relationship to the administration of the investigational drug/study procedure, follows no known pattern of response, but a potential alternative cause does not exist)*
- Unrelated *(There is evidence that the event is definitely related to a cause other than the investigational drug/study procedure; in general, no timely relationship to the administration of the drug/procedure exists, or if so, the event does not follow a pattern of response and an alternative cause is present)*
- Unknown

6. Please provide the Grade of the Adverse Event (Oncology Only): \_\_\_\_\_

7. Please provide the Severity of the event by checking the appropriate box below:

- Mild  Moderate  Severe  Other: \_\_\_\_\_

8. Brief Description of the Adverse Event:

\_\_\_\_\_

9. Briefly describe the action taken:

\_\_\_\_\_

10. Will the protocol be changed as a result of the adverse event?

- Yes (Please include necessary documents and amendment form)
- No

11. Will the currently or previously enrolled subjects be notified of the adverse event?

- Yes (Please include copies of the information to be conveyed to subjects)
- No Rationale: Not related to study drug

Principal Investigator's Signature: \_\_\_\_\_

Date: \_\_\_\_\_

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**ATTACHMENT B**

**Adverse Event Log**

Patient Initials: _____			Patient ID: _____										
Protocol: _____			Study Agents: _____										
Adverse Event	Grade	<input checked="" type="checkbox"/> if started prior to tx	Start Date	End Date	Continuing?	Relationship to Study Drug/Device	SAE? Yes or No	Date Reported to IRB (if SAE)	Action(s) Taken	Comments	PI Initials and Date (Start)	PI Initials and Date (End)	
<b>Reviewed and Approved</b>													
PI Signature: _____													
Date: _____													

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ATTACHMENT C (PAGE 1 OF 3)



Unanticipated Problem Involving Risk Form

Table with 2 rows and 3 columns: Study # / SLHN #, Patient Initials, Name of Site; Date of Occurrence, Subject #, 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:

Three horizontal lines for text entry.

Table with 2 columns: Effective Date(s) (6/28/14) and Revision Date(s) (7/29/14; 2/20/15; 4/8/16)

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

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\_\_\_\_\_  
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 HINTS**

The Unanticipated Problem Form (UPR) should be submitted in a timely fashion related to the seriousness of the Unanticipated Problem. If the event poses increased risk to a research subject or a person not involved in the research, not more than 10 working days should elapse between the event or knowledge of the event and submission of the UPR.

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.

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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.

It is clear that medical judgment may be involved in making decisions regarding whether an event represents an Unanticipated Problem. You should call the Vice Chairman (484-526-4669) or (484-526-4944) with any questions.

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**ATTACHMENT D**



**Study Related Protocol Deviations, Violations and Unanticipated Problems**

**Study Title:** \_\_\_\_\_ **IRB Number:** \_\_\_\_\_

<b>Patient #</b>	<b>Patient Initials</b>	<b>Description of the event</b>	<b>Increased Risk?? Yes or No</b>	<b>Date Reported to IRB (UAP Form)</b>	<b>Action taken if any</b>

**PI Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

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