

	Standard Operating Procedures
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Procedure Category:	Study Activities
Procedure CLN-04-03:	Serious Adverse Event Reporting

Procedure Overview

This procedure describes the activities necessary to identify, report, and track serious adverse events on behalf of the study sponsor or CRO and the IRB.

Responsible Individuals

Investigators; Qualified MICHHR personnel (including, but not limited to, Study Coordinator and Research Assistant); Director, MICHHR

Procedure


1. A serious adverse event (SAE) is any untoward medical occurrence that:
 - Results in death
 - Is life-threatening
 - Requires inpatient hospitalization or prolongation of existing hospitalization
 - Results in persistent or significant disability/incapacity
 - Is a congenital anomaly/birth defect
 - Occurrence of malignancy
 - Suggests significant hazard, contraindication, side effect or precaution
 These conditions define a serious adverse event whether or not the event is considered to be related to the investigational material.
2. MICHHR personnel or investigator reviews the SAE reporting procedure as defined by the study sponsor or CRO.
3. When a serious adverse event occurs involving a patient enrolled at the University of Michigan, MICHHR personnel or investigator reports the event by telephone to the study sponsor or CRO designee and the IRB within 24 hours. Information regarding the study sponsor or CRO contact is usually specified in the protocol. The following information is typically required when providing initial notification:
 - Protocol number, patient initials, age and sex
 - Adverse event
 - Date adverse event occurred
 - Date investigational material was administered
 - The investigator's opinion regarding the relationship of event to the investigational material

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Approval Signature, Date:	

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4. Within two business days of the adverse event, MICHHR personnel complete and submit a written report to the study sponsor or CRO designee and the IRB. The following information is typically required in the written report:
 - Protocol number, patient initials, age and sex
 - Adverse event reported, all relevant test results and laboratory data, and the status of the event to date
 - Dates of investigational material administration, from first exposure to onset of the adverse event
 - Whether or not the investigational material was discontinued and, if so, whether the event ceased
 - Whether or not investigational material administration was resumed and, if so, whether the event reappeared
 - Whether or not the investigator believes the experience was related to the investigational material
 - Any other facts the investigator considers to be relevant (e.g. concomitant medication, medical history, diagnosis)
5. Qualified MICHHR personnel or the investigator are responsible for:
 - Documenting the SAE on the study specific SAE log sheet.
 - Entering all SAE events into the MICHHR database for tracking.
 - Medically managing any abnormal laboratory values, clinical findings, or adverse events until resolution.
 - Providing the study sponsor or CRO and the IRB with weekly updates until the SAE has resolved. Refer to specific requirements as defined by the study sponsor or CRO and the IRB.
 - Sending the study sponsor or CRO final SAE documents for review and approval.
 - Once approved by IRB, send copy of SAE acknowledgment to the study sponsor or CRO designee as required.
6. When a serious adverse event occurs involving a subject from another site (in multiple site studies, not at the University of Michigan), the sponsor will send an adverse event report. The report will have a SAE report number and indicate the subject identification number, type of event, and the event relationship to the investigational material. Upon receipt of the report, qualified MICHHR personnel are responsible for:
 - Documentation of receipt of the report in the SAE log sheet, located in the study- specific SAE notebook and in the MICHHR database.

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- Reporting of the SAE to the IRB in a Request for Review of a Previously Approved Project Application.
 - Upon receipt of the IRB Notice of Outcome, documentation of the date of SAE acknowledgement in the SAE log sheet, located in the study-specific SAE notebook and in the RSC database.
7. The study coordinator and appropriate MICHHR personnel are responsible for assuring that all SAE reports from other investigational sites are sent to the IRB for acknowledgement.

Documentation

Documentation for this procedure includes the study-specific SAE notebook and all other SAE documentation including all documents required by the study sponsor or CRO and the IRB.

Deviation Approval

The Director, MICHHR or designee, must approve deviation from this procedure. The Director, MICHHR or designee, must store documentation of the deviation approval.

Relevant Definitions

SAE – Serious Adverse Event

Appendices

Appendix 1 Serious Adverse Event Log Sheet

Procedure Author

Manager, Research Support Core

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