

Procedure Category:	Clinical Management
Procedure CLM-01-09:	Reviewing Adverse Events and Reporting Serious Adverse Events

Procedure Overview

To define the standard procedures for reviewing adverse events and reporting serious adverse events (SAEs).

Responsible Individuals

Qualified MICHHR personnel (including, but not limited to, Project Manager and Clinical Study Monitor); Contracted Clinical Research Associates; Director, MICHHR

Procedure

The following procedures are performed during the review and reporting of adverse events:

- Ensure that all adverse events occurring during the study are recorded on CRFs. The following are reviewed for documentation of adverse events:
 - ◇ Clinic and nurses notes
 - ◇ Patient diaries
 - ◇ Available medical records
 - ◇ Concurrent medications
 - ◇ Laboratory data:
 - Laboratory abnormalities confirmed by repeat testing
 - Laboratory abnormalities suggestive of a disease and/or organ toxicity
 - Laboratory abnormalities of a severity requiring active management (discontinuation/reduction of dose, diagnostic evaluation, additional medication)
- Ensure all recorded adverse events are either new events, unexpected events or treatment-emergent events

NOTE: Unless documented in the protocol or by other information provided by the sponsor, events which were present at baseline (prior to receiving study medication, undergoing a study-related procedure, or utilization of a test device) and did not become more intense and/or more frequent than at baseline do not have to be recorded as adverse events.

- Ensure all adverse events are defined by diagnosis when possible. If a diagnosis is not available then signs/symptoms are reported.

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- Review all adverse events for those meeting the "serious" criteria as defined in the protocol. Unless otherwise specified, 21 CFR 312.32 will be utilized.
 - ◊ A serious adverse drug experience is any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. (21 CFR 312.32)
 - ◊ Hospitalizations for elective or diagnostic surgeries for pre-existing conditions are not considered serious adverse events
 - ◊ Efficacy outcomes (lack of efficacy), as defined in the protocol, are not recorded as SAEs
- Ensure all serious adverse events have been appropriately reported to the sponsor:
 - ◊ Assist study site personnel in reporting the SAE to the sponsor
 - ◊ Assist study site personnel in obtaining appropriate documentation
 - ◊ Any SAE discovered by or reported to UM MICHHR is reported to the sponsor within 24 hours of detection or notification using the Serious Adverse Event Reporting Forms developed by either the sponsor or by UM MICHHR/PMM (upon request of sponsor).
- Follow-up on any unresolved SAEs and collect any outstanding documentation.
- Ensure that documentation of any FDA 7-calendar day or 15-calendar day reportable SAEs (7-calendar day: unexpected, related to study medication, and fatal or immediately life-threatening; 15-calendar day: unexpected and related to study medication, or study device) has been forwarded from the sponsor to the investigator and HSRC/IRB/EC, and is stored in the UM MICHHR files.

Documentation

The following serve as documentation for this procedure:

- Monitor report

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- Telephone contact report (completed if the SAE is reported to UM MICHHR by phone or other telecommunication mode and/or if UM MICHHR informs the sponsor by phone or other telecommunication mode)
- Sponsor's serious adverse event reporting form (if applicable)
- Adverse event case report forms
- Correspondence between sponsor and study site personnel

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

CRA - Clinical Research Associate
 AE - Adverse Event
 SAE - Serious Adverse Event
 HSRC - Human Subjects Review Committee
 IRB - Institutional Review Board
 EC - Ethics Committee
 PMM - Project Management & Monitoring

Procedure Author

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