SECTION: Research and Compliance				NUMBER: CLN-36.00
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 5/12/2009	REV. B: 8/30/2010	REV. C:
TITLE: Adverse Event Reporting			Page 1 of 2	

1. PURPOSE

To establish the requirements and procedures for reporting routine adverse events (AEs)/experiences at the clinical site.

2. SCOPE

Applies to Principal Investigator (PI) and, when delegated by the PI, additional Investigators, Study Coordinators (SCs), and other designated site personnel.

3. RESPONSIBILITIES

The PI is responsible for assessing the relationship between the study drug, device, or procedure(s) and an AE, and for following the applicable documentation and reporting requirements.

4. BACKGROUND

Routine AE reports include any undesirable change in or worsening from a study participant's (SP's) baseline condition, regardless of causality or severity. Routine AEs also include reports of unwanted effects, such as symptoms or physical findings. SPs should be routinely instructed to notify research personnel of any change in their baseline condition.

5. PROCEDURE

5.1. The PI is responsible for reporting all AEs to research sponsors, if applicable. The PI may delegate to the SC(s) the role of reviewing subject medical records for potential adverse experiences, as well as entering adverse experience information on the Case Report Forms (CRFs) or data collection sheet. The responsibility for diagnosis and evaluation of AEs, however, remains with the PI.

5.2. SPs should be questioned regarding changes in their current or previous health status during study visits and other planned/unplanned study-related contacts (e.g., telephone and/or mailed correspondence).

5.3. AE information in the source document should include:

- 5.3.1. Date of onset
- 5.3.2. Description of signs and symptoms
- 5.3.3. Severity of the adverse experience
- 5.3.4. Relationship to study drug, device, and/or procedure
- 5.3.5. Action taken
  - 5.3.5.1. Laboratory tests performed and results (if applicable)
  - 5.3.5.2. Treatment(s)/medication(s)

5.3.6. Final diagnosis (if known)
5.3.7. Outcome
5.3.8. Date of resolution (if applicable)
5.3.9. Yes/No classification as serious

5.4. The PI should make the judgment as to the relationship between the study drug, device, and/or procedure and the AE.

5.5. The PI and designees should refer to the study protocol for adverse experience definitions, severity scoring systems, reporting timelines, and other reporting requirements as specified by the sponsor.

5.6. The PI or designee will forward AE reports to the sponsor as required by the protocol.

5.7. The PI will follow AEs until they are resolved or etiology determined, and/or appropriate follow-up is arranged. Any changes will be reported to the sponsor, as required by the protocol.

6. TERMS & ABBREVIATIONS

AE Adverse Event
PI Principal Investigator
SC Study Coordinator
SP Study Participant

7. REFERENCES

7.1. 21 CFR 312.32 - IND Safety Reports
7.2. 21 CFR 312.64 - Investigator Reports
7.3. 21 CFR 314.80 - Post-marketing Reporting of Adverse Drug Experiences
7.4. 21 CFR 812.3 - Investigational Device Exemptions – Definitions
7.5. 21 CFR 812.140 - Investigational Device Exemptions – Records
7.6. 21 CFR 812.150 - Investigational Device Exemptions – Reports
7.7. ICH GCP Consolidated Guideline - Part 4.11 Safety Reporting

8. ATTACHMENTS

None