SECTION: Research and Compliance				NUMBER: CLN-32.00
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 5/12/2009	REV. B: 8/30/2010	REV. C:
TITLE: Breaking Study Blind			Page 1 of 2	

1. PURPOSE

To standardize the procedure for breaking the code that lists the treatment assignment of a given Study Participant (SP) in a clinical research study with a double-blind design.

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 maintaining the 'blind' of all studies and for making the decision to request the breaking of the 'blind' for SP safety reasons.

4. BACKGROUND

All efforts should be made to maintain the blind of a clinical research study, but under certain conditions it may become necessary to reveal the treatment assignment of a given SP for clinical or ethical reasons. This standard operating procedure (SOP) lists situations under which this may occur and the procedures that will be followed to arrive at the decision to request a break in the blinded code.

5. PROCEDURE

5.1. All adverse events (AEs) occurring during the course of a clinical drug trial are brought to the attention of the PI. For significant AEs and serious adverse events (SAEs), the PI and/or the sponsor will decide on an appropriate intervention. Most AEs should not normally lead to the breaking of the treatment assignment code. However, if the AE is so severe that it significantly compromises the well-being of the SP, the PI and/or sponsor may decide to break the blindness code and withdraw the SP from the study.

5.1.1. A "Reporting Form for Reportable New Information" must be completed and submitted to the Institutional Review Board (IRB).

5.2. In the case of AEs of intermediate severity, as when a certain laboratory parameter or clinical sign or symptom gradually deviates from normality, the PI may find it difficult to decide at which point the treatment assignment code (i.e., placebo or active drug) should be broken. In such situations, he/she must consult with the study sponsor available for all clinical research trials, if applicable. The sponsor will be aware of the treatment assignment of the patient in question and thus will have more information on which to base their decision. They will advise the PI to continue to observe the abnormal laboratory parameter or other abnormality or to break the code immediately.

5.3. If an SP chooses to withdraw from the study and requests information about his/her treatment assignment (i.e., placebo or active drug), the PI will discuss the situation with the SP. Based on this discussion, the decision may be made to withdraw the SP from the study, but the blind may not be broken until all SPs have completed the study at all sites and the study data is locked by the study sponsor.

5.4. Under some circumstances, a certain investigational drug will produce side effects on such a high SP percentage that it becomes evident who is receiving the active study drug and who is receiving the study placebo. Study personnel must maintain silence about the randomization of the subject unless the sponsor decides to break the blind.

6. TERMS & ABBREVIATIONS

AE Adverse Event
IRB Institutional Review Board
PI Principal Investigator
SAE Serious Adverse Event
SC Study Coordinator
SOP Standard Operating Procedure
SP Study Participant

7. REFERENCES

7.1. ICH GCP Consolidated Guideline - Parts 4.7

8. ATTACHMENTS

None