



Procedure Name: Reporting of Protocol Violations and Deviations
Effective Date: February 26, 2010
Revision: 02
Initiating Department: Office of Clinical Trials
Procedure Number: CR-010 Rev 2
Application: Principal Investigators and all Key Personnel
Page: Page 1 of 2

OBJECTIVE:

The objective of this procedure is to describe the process of reporting protocol violations and deviations (as applicable) both to the Institutional Review Board (IRB) and to the sponsor.

REFERENCES:

OPHS-IRB Manual, Section 17.6	Reporting Protocol Violations: Protocol Violations, Deviations and Reporting of Errors that Occur During the Informed Consent Process
--	---

BACKGROUND:

Protocol violations are considered to be any change in or departure from the study design of a research protocol that affects the subject’s rights, safety or well-being; changes the risk/benefit ratio of the study; and/or compromises the integrity (completeness, accuracy and/or reliability) of the study data.

Examples of serious protocol violations include but are not limited to the following:

1. Dispensing incorrect study medication or dosing;
2. Enrolling subjects outside the inclusion/exclusion criteria (does not apply to screen failures);
3. Losing study data, however inadvertently, (e.g. through the loss or theft of laptop or such) resulting in a potential breach of subject confidentiality;
4. Changing the protocol without IRB approval;
5. Performing study procedures that do not correspond to those in the approved version of the protocol;
6. Performing study procedures prior to obtaining a signed informed consent form;
7. Consenting vulnerable subjects without a legally authorized representative’s/guardian’s signature;
8. Employing inadequate /improper informed consent procedures;
9. Using an unapproved or expired informed consent document;
10. Committing other consenting errors that the study sponsor requires to be reported to the IRB.

CONTROLLED COPY, Do Not Duplicate

CONFIDENTIAL and PROPRIETARY
VERIFY THAT THIS IS THE CORRECT VERSION BEFORE USE

UNT-HSC OFFICE OF CLINICAL TRIALS
Reporting of Protocol Violations and Deviations

CRO-010, Rev. 2

Page 2 of 2

Protocol deviations are considered to be the changes or alterations in the conduct of the study which do **not** have an impact on the subject's rights, safety, or well-being; change the risk/benefit ratio of the study and/or compromise the completeness, accuracy or reliability of the study data.

Examples of protocol deviations include the following:

1. Laboratory tests or study visit not being conducted within the acceptable time frame(s) as defined by the sponsor.
2. Collection of study data (e.g., temperature readings) performed incorrectly by subject or subject's parent/guardian.

SCOPE:

This procedure applies to all sponsor-initiated clinical trial protocols.

RESPONSIBILITY:

The Principal Investigator (PI) and all Key Personnel associated with each protocol are responsible for following this policy.

PROCEDURE:

Protocol violations must be reported both to the IRB and to the sponsor within ten business days of discovery. The PI must submit a signed letter with the following information:

1. IRB project number;
2. Description of the violation and how the event deviated from the protocol;
3. Date the study sponsor was notified of the incident;
4. Investigator's assessment regarding the violation's affect on the subject's risk;
5. Description of the implemented corrective and preventative action plan to prevent recurrence.

Protocol deviations are not required to be reported to the Institutional Review Board (IRB). However, if the study sponsor requires that the deviation be reported to the IRB, the PI will submit the report of protocol deviation to the IRB. The IRB will provide acknowledgement of the receipt and review of the protocol deviation. File this acknowledgement in the IRB section of the Regulatory Binder.

Office of Clinical Trials staff will review reports of protocol deviations to determine if they represent a pattern that warrants a corrective and preventative action plan by the PI.

REVISION HISTORY

Rev	DCO	Description of Change	Approved by
2	BCE-01	Edited for clarity and style; combined with CR-011 and CR-012	Michael V.W. Bergamini

CONTROLLED COPY, Do Not Duplicate

CONFIDENTIAL and PROPRIETARY
VERIFY THAT THIS IS THE CORRECT VERSION BEFORE USE