SYRACUSE UNIVERSITY
HUMAN RESEARCH PROTECTION PROGRAM
STANDARD OPERATING PROCEDURES

TITLE: PROTOCOL DEVIATION/VIOLATION REPORTING		DOCUMENT NUMBER: 026
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Title: PROTOCOL DEVIATION/VIOLATION REPORTING

1.0 Purpose:
The purpose of this Standard Operating Procedure (SOP) is to provide guidance in the reporting requirements and responsibilities of the Investigator and the Syracuse University (SU) Institutional Review Board (IRB) regarding protocol deviations or violations.

2.0 Policy:
It is the policy of the SU IRB to be notified of any protocol deviations, and violations that result in an increase in risk or a decrease in benefit to participants.

    2.1   Deviations.

        2.1.1   It is the responsibility of the Investigator not to deviate from the protocol approved by the IRB, except to avoid an immediate hazard to the participant. The Investigator must submit an amendment request to the IRB and receive written approval prior to implementation of any change to the protocol.

        2.1.2   Deviations need to be reported to the IRB as a potential unanticipated problem involving risks to participants or others (see *SOP 027*) when they:

            2.1.2.1 Increase risk or decrease benefit, affect the participant's rights, safety, welfare, or affects the integrity of the resultant data;

            2.1.2.2 Have the potential to recur; or

            2.1.2.3 Were undertaken to eliminate an apparent immediate hazard to a research participant.

        2.1.3   When a sponsor requests that the IRB be notified of a deviation, the IRB will perform an expedited review of the "IRB Amendment" Form submitted by the Investigator.

        2.1.4   Repetitive deviations may be ruled by the SU IRB to constitute a violation.

    2.2   Violations.

        2.2.1   Violations as defined by the SU IRB must be reported to the IRB. Because such violations increase risk or decrease benefit, affect the participant's rights, safety, welfare, or the integrity of the resultant data, they are reported as an unexpected harm or unanticipated problem to the participant or others (See *SOP 027*).

        2.2.2   When a sponsor requests that the IRB be notified of a violation but it does not increase risk or decrease benefit, affect the participant's rights, safety, welfare or the integrity of the resultant data, the IRB will review the "IRB Amendment" Form submitted by the Investigator.

        2.2.3   Protocol deviations and violations are to be reported to the Board.

        2.2.4   The Investigator must submit reports to the IRB as soon as possible upon receipt, but no later than 10 working days after the Investigator first learns of the report.

3.0 References and Reference Documents:
SOP 014, Amendments to Previously Approved Applications or Claims for Exemption
SOP 027, Reporting Unanticipated Problems Involving Risk to Participants or Others
SOP 028, Investigating and Managing Potential Issues of Non-compliance

4.0 Procedure:

4.1 Investigator Responsibilities.

    4.1.1 The Investigator submits any changes in the protocol prior to implementation to the IRB for review and approval as required by the Federal regulations using the "IRB Amendment" Form.

    4.1.2 The Investigator monitors research activities for adherence to the protocol and determines whether protocol deviations or violations have occurred.

    4.1.3 If deviations or violations have occurred, the Investigator evaluates the deviation or violation to determine if it meets the definition of an unanticipated problem involving risk to participants or others.

        4.1.3.1 Deviations or violations that meet the definition are reported to the IRB utilizing the "Report of Unanticipated Problem Involving Risks to Participants or Others" Form.

        4.1.3.2 Deviations that do not meet the definition must be reported to the IRB using the IRB Amendment form.

        4.1.3.3 When the sponsor requires reporting of deviations that do not affect the risk/benefit ratio or the participant's or other's rights, safety or welfare or on the integrity of the resultant data, the Investigator uses the "IRB Amendment" Form.

    4.1.4 All safety monitoring reports are submitted to the IRB as soon as possible upon receipt, but no later than 10 working days after the Investigator first learns of the report.

4.2 IRB Responsibilities.

    4.2.1 The IRB will review deviations and violations reported under this policy according to *SOP 027*.

    4.2.2 The IRB will decide whether each reported protocol deviation or violation involves non-compliance according to *SOP 028*.

4.3 ORIP/IRB Responsibilities.

    4.3.1 The ORIP Director will verify whether deviations submitted by the Investigator qualify as a deviation per IRB definition and, if so, whether the deviation affected the risk/benefit ratio, the participant's or other's rights, safety or welfare or on the integrity of the resultant data.

        4.3.1.1 The ORIP Director will stamp the original document as received and send to the IRB Chair or his/her designee for an administrative acknowledgement.

        4.3.1.2 A copy of the document will be placed in the IRB file and the original returned to the Investigator.

    4.3.2 If the ORIP Director determines the deviation or violation may have affected the risk/benefit ratio, the participant's or other's rights, safety or welfare, or the integrity of the resultant data, they will request the deviation be reported to the IRB utilizing the "Report of Unanticipated Problem Involving Risks to Participants or Others" Form.

    4.3.3 At any time, the ORIP Director may consult with the IRB Chair or his/her designee for guidance.

Approved by: _BR Ware_ _____   _7-20-08_ _____
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