1 PURPOSE

1.1 To define the AMITA Health Institutional Review Board (IRB) requirements for investigators reporting protocol deviations, violations or exceptions.

Federal regulations specifically require the IRB of record to review proposed changes in a research activity and to ensure that such changes in approved research are not initiated without prospective IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subject. Investigator deviations from or non-adherence to the protocol in order to eliminate apparent immediate hazards to a subject are not subject to this policy. [See related AMITA Health SOP, “Unanticipated Problems in Human subjects Research” (PP-213) for applicable reporting requirements].

During the course of the study, changes to the protocol may be proposed or unintentional changes in the conduct of the study may be discovered. Changes to the IRB-approved research activity (see 1.1 below), planned or otherwise, must be reviewed by the IRB. NOTE: Any permanent or planned change to the research activity constitutes an amendment that must be submitted for IRB approval prior to initiation and not reported as a protocol deviation.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 See SOP: “Definitions” (PP-001) for complete definition descriptions

3.2 It is the responsibility of the principal investigator to determine whether a deviation or violation is major or minor and to ensure proper reporting to the IRB. Reports of protocol deviations, violations and exceptions should be submitted to the sponsor as outlined in the sponsor’s protocol.

3.3 All protocol exceptions should be submitted to the IRB for review and approval prior to subject enrollment using the AMITA Health “Protocol Deviation / Violation / Exception” (HRPP-220) form.

3.4 All major deviations should be submitted to the IRB for review and approval within five (5) working days of when it is known that a deviation from the protocol is anticipated using the AMITA Health “Protocol Deviation / Violation / Exception” (HRPP-220) form so that the IRB has time to review and take action.

3.5 Minor deviations need not be submitted to the IRB for prospective review. Rather, they should be tabulated and submitted to the IRB at the time of continuing review along with administrative resolutions. NOTE: More than 3 minor deviations of the same type are considered a major violation.

3.6 All protocol exceptions and deviations not submitted for prior IRB review are considered protocol violations. Major violations must be reported within 10 working days of discovery using the AMITA Health “Protocol Deviation / Violation / Exception” (HRPP-220) form. Major violations occurring in order to eliminate an apparent immediate hazard to the subject must be reported as unanticipated problems in accordance with AMITA Health IRB policy, “Unanticipated Problems in Human Research (PP-213).” Minor violations are to be tabulated and submitted to the IRB at the time of continuing review along with administrative resolutions.

4 RESPONSIBILITIES

4.1 Principal Investigator / Treating Physician & IRB

5 PROCEDURE
5.1 Principal investigators are responsible for obtaining prior IRB review and approval before making any changes to the approved research procedures using the AMITA Health “Protocol Deviation / Violation / Exception” (HRPP-220) form. Reports may be accepted by other means such as e-mail or phone provided all of the required information is related to the IRB and followed up with a completed form.

5.2 Protocol violations classified as major by the principal investigators must be reported within 10 working days of discovery.

5.3 All major and minor deviations, violations, and exceptions occurring during the period of approval, whether or not reported separately, must be tabulated and submitted to the IRB at the time of continuing review.

5.4 Investigators should report protocol deviations, violations and exceptions to the sponsor as outlined in the sponsor’s protocol.

6 MATERIALS
6.1 Protocol Deviation Report - FORM (HRPP-220 )

7 OTHER RELATED POLICY/PROCEDURES
7.1 Unanticipated Problems in Human Research (PP-213)

8 REFERENCES
8.1 45 CFR 46.103(b)(5)
8.2 21 CFR 56.108(b)(2)