Subject: Procedure for Reporting Noncompliance with the Protocol

Procedure:
This procedure provides guidance in the reporting requirements and responsibilities of the Investigator and the HRPP regarding noncompliance with the protocol.

I. Investigator Responsibilities.
   A. The Investigator submits any changes in the protocol prior to implementation to the IRB for review and approval as required by the federal regulations.
   B. The Investigator monitors research activities for adherence to the protocol and determine if noncompliance have occurred.
   C. All noncompliance is reported to the Data and Safety Monitor or Board or IRB as outlined in the IRB approved data and safety plan.
   D. 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.

II. IRB Committee Responsibilities.
   A. The IRB will review the noncompliance with the protocol reported under this policy according to HRPP Policy II.C.