Subject: Procedure for Reporting to the Appropriate Institutional Officials, and the Department or Agency Head(s)

Procedure:

I. IRB Responsibilities.
   A. The IRB Chair will report to the HRPP Director:
      1. Any problem determined by the IRB to represent any unanticipated problem involving risk to participants or others;
      2. Any non-compliance determined by the IRB to be serious or continuing non-compliance; and
      3. Any action of the organization to suspend or terminate IRB approval.

II. HRPP Administration Responsibilities.
   A. The HRPP Director in conjunction with the leadership team prepare a letter that outlines:
      1. The nature of the event;
      2. The findings of the organization and IRB;
      3. Actions taken by the organization or IRB;
      4. Reasons for the organization’s or IRB’s actions; and
      5. Plans for continued investigation or action.
   B. The letter is sent to the following people for review and approval:
      1. The Associate Vice Chancellor for Research and/or the Vice Provost for Research; and
      2. The IRB Chair of the Committee that made the determination.
   C. The letter is signed by the Institutional Official of VU or VUMC.
   D. The HRPP Director send a copy of the letter to:
      1. The IRB Members of the applicable Committee (as an information item in the agenda packet);
      2. The Associate Vice Chancellor for Research for all determinations involving faculty, staff, or students whose primary affiliation is with the Vanderbilt University Medical Center;
      3. The Vice Provost for Research for all determinations involving faculty, staff, or students whose primary affiliation is with Vanderbilt University;
      4. The Dean of the appropriate School;
      5. OHRP, if federally funded;
      6. FDA, if the research is FDA regulated;
      7. Study sponsor, if the research was sponsored (this includes NIH, DoD, NSF, and Industry sponsors);
      8. Any common rule agency that is conducting or supporting research or otherwise has regulatory oversight;
      9. VUMC Investigational Drug Service, if the research involves investigational drugs;
      10. The Office of Contracts Management, if the research involves a contract for all determinations involving Vanderbilt University Medical Center faculty, staff, or students;
      11. The Division of Sponsored Research if the research involves a grant;
12. The Department Chair, Supervisor, and/or Faculty Advisor of the Principal Investigator, if applicable;
13. Institutional Officials at external sites where the research is conducted and VUMC serves as their IRB of Record;
14. Legal Counsel, if appropriate; and
15. Risk Management, if appropriate.

III. Investigator Responsibilities.
A. The Investigator will notify the HRPP within 24 hours of receiving notification of an impending FDA or other federal agency visit/inspection. When applicable, the HRPP will be involved in the visit/inspection.
B. All formal communications in response to any compliance concerns brought forth by the FDA or other federal agency are sent to the HRPP Director for review prior to sending.
C. The Investigator will assure that all communication(s) are sent within the timelines mandated by the FDA or other federal agency.