Subject: Investigating Any Non-Compliance, Serious, or Continuing Non-Compliance

Definitions:
1. Non-compliance: Failure to follow the determinations or requirements of the IRB.
3. Finding of Non-Compliance: A proven or obvious incident of non-compliance.
4. Serious Non-compliance: An action or omission taken by an Investigator that any other reasonable investigator would have reasonably and clearly seen as compromising the rights and welfare of a participant.
5. Continuing Non-compliance: A pattern of repeated actions or omissions taken by an Investigator that indicates a deficiency in the ability or willingness of an Investigator to comply with federal regulations, HRPP Policy, or determinations or requirements of the IRB.
6. Research Misconduct: Any fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Policy:
It is the policy of the HRPP to uphold its role in assuring prompt reporting of any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB.

I. All reports of alleged non-compliance or inappropriate involvement of humans in research are investigated. Such reports may come from any source such as an IRB Committee Member, an Investigator, a participant or their family members, institutional personnel, other institutional Committees, VUMC Patient Affairs, the Research Subject Advocate, the VU or VUMC Compliance Office, the media, anonymous sources, or the public. Goals of the IRB, in general, in investigating and managing issues of potential noncompliance include:
   A. Assuring the safety of human participants;
   B. Developing action plans to prevent reoccurrence, and promote future compliance;
   C. Educating research staff to assure the understanding of FDA and OHRP guidelines and regulations, and HRPP Policy;
   D. Reporting serious or continuing noncompliance.

II. Instances meeting the definition of research misconduct will be reported to the Dean of the Investigator’s School (See VU Faculty Manual) by the HRPP Director.
   A. Attempts to unduly influence an IRB Committee Member or IRB staff are considered research misconduct.
   B. IRB members or staff who believe that they have been subject to undue influence must report this to the HRPP Director.
   C. The HRPP Director will report all attempts of undue influence of the IRB process to the Dean of the Investigator’s School.

References:
45 CFR 46
21 CFR 50 & 56
VU Faculty Manual, Part IV