Procedure
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: VII.C.1
Section: Committee Roles and Responsibilities
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: March 19, 2004
Revision Dates: August 30, 2004; December 14, 2004; July 1, 2015

Subject: Procedure for IRB Committee Member, Consultant, and Regulatory Compliance Analyst Conflicting Interest

Procedure:
This procedure outlines the IRB Committee member, consultant, and Regulatory Compliance Analyst responsibilities regarding required disclosure of conflicts of interest when reviewing human subjects research.

I. Conflict Responsibilities
   A. Each Committee Member must review this Procedure and corresponding Policy and sign a “Conflict of Interest Declaration” initially and annually at IRB Committee Member training.
   B. Each consultant must read this Procedure and corresponding Policy and sign an affirmation statement before reviewing a research protocol and disclose any conflicting interest.
   C. Each Regulatory Compliance Analyst must review this Procedure and corresponding Policy and sign a “Conflict of Interest Declaration” initially and annually at IRB Committee Member training.
   D. At the initiation of the IRB Committee meeting, the Chairperson or a designated Committee Member will call upon IRB members or others in attendance of the meeting to declare any conflicting interests with items on the agenda.
   E. IRB Committee Members, consultants, Regulatory Compliance Analysts with a conflicting interest may not participate in any portion of the review of research activities except to provide information requested by the IRB and must absent themselves from the meeting during the IRB’s deliberative discussion and vote on the affected research.
   F. IRB Committee Members, consultants, and Regulatory Compliance Analysts may absent themselves from the discussion and vote for any reason, if they feel it is necessary to avoid any appearance of a conflicting interest.
   G. IRB Committee Members, consultants, and Regulatory Compliance Analysts may absent themselves from the discussion and vote for any reason, if they feel any member of the research team or others has exerted undue influence. Such situations must be reported to the Dean of the Investigator’s school according to the VU Faculty Manual.

II. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
   A. The RCA assists with identification and disclosure of any conflicting interest during Committee meetings.
   B. The RCA records in the minutes and database each time a member is excused from the Committee discussion and vote due to a conflicting interest.