Policy

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

Definitions:
1. Individual Conflict of Interest: A circumstance such that any action or decision in which an individual is substantially involved may have a direct or predictable effect on a financial interest of the individual, spouse, minor child, or organization in which the individual serves as an officer, trustee, Board or executive member, partner or employee.
2. IRB Committee Member: An individual serving as an IRB Committee Member including Chairs, the IRB Pharmacy reviewers, alternates or expert consultants regardless of voting privileges.
3. Immediate Family Member: Spouse, domestic partner, or child.
4. Significant Financial Interest: Any of the following financial interests of any key research personnel, or his or her immediate family, in aggregate. (The thresholds described below apply to the aggregate ownership of a key research personnel and his or her immediate family. For example, if an Investigator, his/her spouse, domestic partner and dependent children). The thresholds do not apply to the combined ownership of all Investigators:
   a. Compensation whose value could be affected by the study outcome
   b. A proprietary interest in the tested product included but not limited to a patent, trademark, copyright or licensing agreement, or the right to receive royalties from product commercialization.
   c. Annual income (e.g., consulting fees, honoraria, paid authorship) and/or equity interest (e.g., stock, stock options) in the sponsor or product valued in excess of $5,000.
   d. Any equity interest in the sponsor (e.g., stock, stock options, founders' share) if a non-publicly traded company.
5. Conflicting Interest: IRB Committee Members, consultants and Regulatory Compliance Analysts are considered to have a conflicting interest if they or his or her immediate family member have any:
   a. Financial interest;
   b. Role in the conduct of or participation in the research; or
   c. Other individual conflict of interest.

Policy:
It is the policy of the Human Research Protections Program (HRPP) that all conflicting interests of an IRB Committee Member, consultant, and Regulatory Compliance Analyst be declared before review of any research under HRPP jurisdiction. IRB Committee Members, consultants, and 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. This also pertains to IRB Committee Members, consultants, and Regulatory Compliance Analysts whose immediate family member has any conflicting interest.

References:
HRPP Policy VI.B
VUMC Policy, OP 30-06
VU Faculty Manual, Part III, Chapter 3