Policy
Department: HUMAN RESEARCH PROTECTIOS PROGRAM
Policy Number: VI.C
Section: Investigator Responsibilities
Review Responsibility: HRPP Policy and Procedure Committee
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Subject: Investigator and Key Study Personnel Conflicts of Interest

Definitions:
1. Individual Conflict of Interest: A circumstance such that any action or decision in which an individual is substantially involved with the research may have direct or predictable effect on a financial interest of the individual’s spouse, minor child, or organization in which the individual serves as an officer, trustee, partner or employee.
2. Key Research Personnel: The Principal Investigator and all individuals responsible for the design or conduct of the study.
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.
5. Compensation whose value could be affected by the study outcome.
6. 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.
7. 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.
8. Any equity interest in the sponsor (e.g., stock, stock options, founders’ share) if a non-publicly traded company.

Policy:
It is the policy of the Human Research Protections Program that all conflicts of interest be reported to the IRB for review to assure protection of the rights and welfare of participants in human subjects research.

References:
HRPP Procedure VI.C.1
VU and VUMC Policy “Conflicts of Interest”
VU Faculty Manual, Part III, Section 3