

VANDERBILT  UNIVERSITY
MEDICAL CENTER

Policy: Conflict of Interest and Commitment

Category	Compliance
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Applicable to VUMC Areas (and associated workforce members):

- Compliance Finance Hospitals and Clinics Human Resources
 Information Technology Research

Approval Committee(s)

- Compliance and Corporate Integrity Committee VUMC Board of Directors

Content Expert(s)

Director, Conflict of Interest and Protection of Minors

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I. Policy:

All individual Members of the Vanderbilt University Medical Center (VUMC) Community (including Board of Directors, VUMC Officials, and all full-time, part-time, temporary, or adjunct faculty and staff of VUMC) must fulfill the education, research, patient care, and public service missions to which VUMC is dedicated.

VUMC’s core values include a commitment to deliver exemplary health care, improving the lives of individuals and communities regionally, nationally and internationally. Through the exceptional capabilities and caring spirit of its people, Vanderbilt will lead in improving the healthcare of individuals and communities regionally, nationally and internationally. We will combine our transformative learning programs, compelling scientific discoveries, and distinctive personalized care to foster the health of all people.

Accordingly, all individuals in the VUMC Community have a clear obligation to make decisions and conduct the affairs of VUMC based upon the desire to promote the best interests of VUMC in a manner consistent with those goals. The Board of Directors and members of Senior Administration are fiduciaries and owe special duties of care and loyalty to VUMC as a whole and must keep VUMC’s interests paramount to all others.

The relationships between VUMC, the individual Members of the VUMC Community, private industry, federal and state governments, and the nonprofit sector are complex. As a result, there are opportunities for professional interactions and development that may benefit the VUMC Community and its individual members, but which may also present the potential for or the appearance of conflicting loyalties and responsibilities for the individuals within

the VUMC Community. The purpose of VUMC Conflict of Interest and Commitment Policy is to set forth a policy statement regarding Conflicts of Interest and Commitment and to provide guidelines to protect VUMC and its mission.

A **Conflict of Interest** refers to a situation in which an individual's financial, professional, or other personal considerations may directly or indirectly affect, or have the appearance of affecting, an individual's professional judgment in exercising any VUMC duty or responsibility, including the conduct or reporting of research. Typically, a Conflict of Interest may arise when an individual has the opportunity or appears to have the opportunity to influence VUMC's business, administrative, academic, patient care, research, or other decisions in ways that could lead to financial, professional, or personal gain or advantage of any kind, whether or not the value is readily ascertainable.

A **Conflict of Commitment** refers to a situation where an individual engages in external activities, either paid or unpaid, that interfere with his/her primary obligation and commitment to VUMC. Individuals in the VUMC Community should evaluate and arrange their external interests in order to avoid compromising their ability to carry out their primary obligations to VUMC, and most Conflicts of Interest or Commitment should generally be avoided or resolved through the exercise of personal judgment or discretion.

All individual Members of the VUMC Community are expected to (i) abide by the Conflict of Interest and Commitment Policy and standards set forth in this policy (including any specific procedures adopted by specific departments pursuant to or in furtherance of this policy), (ii) fully and continually disclose professional and relevant personal activities and relationships that create a Conflict of Interest or Commitment or have the appearance of creating a Conflict of Interest or Commitment as required by VUMC, (iii) remedy Conflicts of Interest or Commitment or comply with any management or monitoring plan prescribed by VUMC, (iv) remain aware of the potential for Conflicts of Interest and Commitment, and (v) take initiative to manage, disclose, or resolve Conflicts of Interest or Commitment as appropriate. All senior administrators have the responsibility to understand and implement this policy, including, as necessary, the adoption of specific procedures for their departments in furtherance of and in accordance with this policy.

II. Definitions:

- A. **Business:** Any company or corporation, any partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, trust (business, real estate, estate planning, or otherwise), enterprise, or any legal entity whether organized for profit or not-for-profit, including any entity controlled by,

controlling, or under common control with any such entity, but excluding the VUMC.

- B. Family or Family Member: Spouse, child, stepchild, parent, sibling, or domestic partner (individual not related by blood or marriage, but currently in a committed relationship and residing in a common household sharing joint responsibility for the household) of a Member of the VUMC Community. For purposes of the employment of Family Members at VUMC, grandparent, grandchild, father-in-law, and mother-in-law are also included.
- C. FDA: The Food and Drug Administration. The FDA evaluates clinical studies submitted in marketing applications, required by law, for new human drugs and biological products and marketing applications and reclassification petitions for medical devices. The FDA policy on Conflicts of Interest can be found at:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=54&showFR=1>
- D. Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

Examples of Financial Interests:

Salary or other payments for services (including fees, honoraria, “gifts,” or other “in kind” compensation whether for consulting, membership on a board of directors or advisory board, or any other purpose such as partial, interim, or milestone payments).

Intellectual Property rights (including patents, copyrights, and royalty income or the right to receive future royalties under a patent or other Intellectual Property rights, whether pursuant to a license or otherwise).

Ownership and equity interests or entitlement to such interests in a publicly or non-publicly traded Business (including stock, stock options, partnership interests, and convertible debt but excluding interests in publicly traded diversified mutual funds where the individual investor has no control over the selection of holdings).

- E. Institutional Responsibilities: For purposes of the disclosure and assessment of potential Conflicts of Interest and Conflicts of Commitment, the definition of Institutional Responsibilities shall be defined as a Member of the VUMC Community’s activities and duties on behalf of VUMC or which fall within the scope of employment by VUMC (e.g., research, consultation related to the scope of VUMC employment, teaching, professional practice, institutional committee memberships, and service on panels at VUMC or as assigned by VUMC).

- F. Intellectual Property: Patents, copyrights, trademarks, trade secrets, technology (whether or not reduced to practice), databases, software, and any other tangible or intangible intellectual property.
- G. Investigator: The project director, Principal Investigator and any other person regardless of title or position who is responsible for the design, conduct or reporting of Research including sponsored Research or proposed sponsored Research.
- H. Member of the VUMC Community: Board of Directors, VUMC Officials, full-time, part-time, temporary faculty and staff.
- I. NSF: The National Science Foundation. The National Science Foundation (NSF) is an independent Federal agency created by the National Science Foundation Act of 1950, as amended (42 USC 1861-75). The NSF policy on Conflicts of Interest can be found at <https://www.nsf.gov/policies/conflicts.jsp>.
- J. PHS: The Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated. The PHS regulation on Conflicts of Interest can be found at <http://grants.nih.gov/grants/policy/coi/index.htm>.
- K. PHS Awarding Component: The organizational unit of the PHS that funds a specific Research project.
- L. Research: A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied Research and product development.
- M. Significant Financial Interest: a Financial Interest consisting of one or more of the following interests of the Member of the VUMC Community (and those of the Member of the VUMC Community's Family):
 - 1. With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any payments or any remuneration received from the publicly traded entity received in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceed \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary, received from the publicly traded entity (e.g. consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined

through reference to public prices or other reasonable measures of market value.

2. With regard to any non-publicly traded entities, a Significant Financial Interest exists if the value of any payments or any remuneration received from the non-publicly traded entity in the twelve (12) months preceding the disclosure, when aggregated, exceed \$5,000 or when the Member of the VUMC Community (or the Member of the VUMC Community's Family) holds any amount of equity interest (e.g., stock, stock option, or other ownership interest). For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary received from the non-publicly traded entity (e.g., consulting fees, honoraria, paid authorship).
3. Intellectual property rights and interests not paid by Vanderbilt University or VUMC (e.g., patents, copyrights, royalties), upon receipt of income royalties related to such rights and interests.

All other definitions not set forth in this section shall be as defined in the body of the policy.

III. Conflict of Interest Guidelines:

Conflicts of Interest can arise under many situations. These guidelines set forth principles for members of the VUMC community to follow. Disclosure and approval are required before engaging in activities that are inconsistent with these guidelines.

A. VUMC Administration

The internal administration of VUMC can present the potential for Conflicts of Interest. Members of the VUMC Community with administrative responsibilities must take particular care to avoid relationships in which Financial Interests or other personal interests intersect with VUMC's interests and have the potential for inappropriate factors to be considered in administrative decisions, including hiring decisions. In particular, individuals who have VUMC duties involving the procurement, exchange, receipt of gifts, or sale of goods, services, or other assets; the negotiation or formation of contracts or other commitments affecting the assets or interests of VUMC; the handling of confidential or privileged information; the provision of patient care; the conduct of sponsored research and the handling of any research results or resulting transfer of technology; or the rendition of professional advice to VUMC must be particularly conscious of potential Conflicts of Interest or the appearance of Conflicts of Interest.

B. Business Relationships.

In general, when individual Members of the VUMC Community or their Family Members have Financial Interests in a Business or are involved in a Business as an owner, operator, or as an executive officer, they must be alert to the possibility that a Conflict of Interest may arise, if the Business has a relationship with VUMC. If the enterprise does business with VUMC, or proposes to do business with VUMC, the individual is expected to disclose that fact. Generally, there will be no Conflict of Interest if the individual is not in a position to influence VUMC with respect to the Business in which the individual or Family member has an interest. Members of the VUMC community may not review, approve, or administratively control contracts or business relationships when the contract or business relationship is between VUMC and a Business in which the individual or a Family Member has a Financial Interest or when the individual or a Family Member is an employee of the Business and is directly involved with activities pertaining to VUMC.

C. Gifts and Contributions

No gifts or accommodations of any nature, including unrestricted grants, may be accepted by VUMC or individual members of the VUMC community when to do so would place them in a prejudicial or compromising position, interfere in any way with the impartial discharge of their duties to VUMC, or reflect adversely on their integrity or that of VUMC. All gifts given in support of an institutional mission must be directed through the VUMC Development Office.

NO GIFTS, of any amount, may be accepted by individuals from suppliers of pharmaceuticals, medical equipment and devices, or medical service vendors (hereafter referred to as the Health Care Industry) or their agents. This includes, but is not limited to, companies currently engaged in or proposing to do business with VUMC, a list of which is provided at this [link](#) (to determine whether a vendor qualifies as a Health Care Industry Supplier contact coi.vumc@vanderbilt.edu). One exception to this is funds from Health Care Industry sources given as unrestricted gifts towards meals and refreshments at on-campus, regularly scheduled meetings, which further the operational VUMC missions, and which are elected to be used by department chairs, division chiefs, center directors, institute directors, and CEOs (or their designees) for this purpose. These gifts may only be accepted through VUMC Development Office.

In addition, to avoid the appearance of impropriety, VUMC personnel will not offer or provide gifts to Health Care Industry representatives.

This includes, but is not limited to, companies currently engaged in or proposing to do business with VUMC.

VUMC personnel may not accept gifts or compensation for listening to a sales talk by a Health Care Industry representative, using/prescribing a particular product or service, or for prescribing medications or changing a patient's prescription.

VUMC personnel may not accept meals or other hospitality funded directly by the Health Care Industry, whether on campus or off campus. Meals offered at national meetings (or at associated satellite symposia approved by meeting organizers) may be accepted so long as the activity linked to the meal is educational, scientific, or consultative, and not marketing.

VUMC personnel may not accept compensation from the Health Care Industry, including the defraying of costs, for simply attending a CME or other activity (i.e., if the individual is not speaking or otherwise actively participating at the event).

Consulting arrangements that pay VUMC personnel a guaranteed amount without any associated duties (e.g., scientific advisory boards that do not meet regularly and provide scientific advice) shall be considered gifts and are consequently prohibited.

Individuals may, however, accept gifts, meals, entertainment, and other normal social amenities no greater in value than \$300 per year from a single source, whether an individual or a Business, provided that the source is not a Health Care Industry entity or its agent as noted above and such amenities are not otherwise extravagant under the circumstances.

Types of activities viewed as gifts include:

1. Food - Except meals offered at national meetings linked to educational, scientific, or consultative events.
2. Travel - Except travel expenses related to necessary education or training regarding equipment, products, or other medical devices purchased previously by VUMC. If this travel is necessary, specific language should be included in the vendor contract, noting the party responsible for incurring these travel and training expenses.

Note: Under no circumstance, may VUMC personnel accept offers from the Health Care Industry to pay for travel, meals, or other expenses which are related to procurement activities by VUMC personnel.

3. Tickets to entertainment events.
4. Ghost-writing services.
5. Promotional items which incorporate or display Health Care Industry supplier or product logos. **Exceptions are:**
 - a. Items purchased by VUMC.
 - b. Materials which have been reviewed and approved by leadership in a clinical practice area for use in education.
 - c. Branded educational manuals which are intended to promote safe and appropriate use of a medication or medical device are permissible so long as there has already been a clinical judgment that the particular product or device is best for the care of an individual patient.
 - d. Materials presented at approved vendor fairs which allow VUMC personnel to compare and contrast products/services from more than one vendor.
 - e. Logos appearing on products in public areas which have been approved for on-site sale to the public or for special pre-approved charitable or philanthropic events.
 - f. Logos from nonprofit and/or professional organizations which promote missions consistent with the missions of VUMC.

D. Use and Appropriation of VUMC Assets

VUMC possesses both tangible and intangible assets. These assets include buildings, personnel, equipment, patents, copyrights, technology, and work products, as well as VUMC's reputation and prestige. As custodian of these assets, members of the VUMC community owe a fiduciary duty to VUMC to act in accordance with applicable VUMC procedures regarding the proper expenditure of VUMC funds, as well as the use and control of VUMC assets, including confidential and privileged information. Where specific procedures regarding the disposition and control of VUMC assets do not exist, individuals are expected to protect the best interests of VUMC in its tangible and intangible assets. Conduct constituting the misappropriation or unauthorized use of VUMC assets in connection with any external activity is prohibited (including implying sponsorship or

endorsement by VUMC or otherwise trading on the reputation or goodwill of VUMC). Mere identification of VUMC as one's employer and of one's position at VUMC is permitted, provided that such identification is not used to imply VUMC sponsorship or endorsement.

E. Research Activities

1. General:

All VUMC research must comply with this subsection E.1, regardless of any funding source, in addition to the requirements of any funding source or sponsor. For purposes of research funded or proposed for funding by PHS, subsection E.2 shall also apply.

Conflicts of Interest in research involve situations in which financial, professional, or other personal considerations may compromise, or have the appearance of compromising an individual's judgment in the design, conduct, or reporting of research. The bias which may result from such Conflicts of Interest may impact not only the collection, analysis, and interpretation of data, but also the hiring of staff, procurement of materials, subcontracting, clinical referrals, sharing of results, choice of protocol, the use of statistical methods, the use of human participants, or otherwise influence the course of a research project.

Individual members of the VUMC community may not review, approve, or administratively control contracts, grants, clinical trials, or other research collaborations when such contract, grant, clinical trial, or other collaboration pertains to a research project involving VUMC and a business or intellectual property in which the individual or a family member has a Significant Financial Interest (SFI) or when the individual or a family member is an employee of the business and directly involved with activities pertaining to the research project. In particular, absent compelling circumstances, individuals may not participate in research involving human research subjects if they have a Significant Financial Interest in the sponsor of the research or any technology that could be affected by the outcome of the research. This presumption against human subjects' research by financially interested individuals may be rebutted by compelling circumstances that are reviewed in advance by appropriate VUMC officials. No research with human subjects that involves a Conflict of Interest may receive final approval from the Institutional Review Board until the Conflict of Interest is addressed under this policy. Every individual participating or

involved in VUMC research is responsible for learning and complying with all other applicable policies and procedures.

In addition, all individual members of the VUMC community are expected to comply with any applicable federal requirements pertaining to Conflict of Interest in their research activities. Additional policies and procedures related specifically to Conflicts of Interest in sponsored research and projects are required by the National Science Foundation (NSF) and the Public Health Service (PHS). The complete PHS Conflict of Interest Regulations are available at 42 CFR Part 50 and 45 CFR Part 94.

For research regulated by the Food and Drug Administration (FDA²), there are Conflict of Interest requirements that apply to both the sponsor of the study, as well as the investigators. The individual members of the VUMC community are expected to comply with all applicable FDA requirements pertaining to Conflict of Interest whether the individual is the investigator or the sponsor or both.

2. Additional Requirements Applicable Only to PHS-Funded Research:

While the conditions of section E.1. apply to all research, the Public Health Service (PHS) also requires for research it funds that VUMC obtain disclosures, from all Investigators, of any Significant Financial Interests and determine whether each Investigator's Significant Financial Interest could be affected by the Investigator's PHS-funded Research, and if so, whether the Significant Financial Interest constitutes a Financial Conflict of Interest in Research. All Investigators who receive or apply for funding from PHS must comply with the requirements of this subsection E.2.

At the time of submitting a proposal for PHS funding to VUMC, each Investigator participating in the design, conduct or reporting of the Research in the proposal is required to certify that he or she has disclosed any Significant Financial Interests to the appropriate VUMC officials and must have completed required VUMC training. Updated disclosures must be provided at least annually and within thirty (30) days of the creation of a new Significant Financial Interest.

Before the expenditure of any funds from a PHS grant award for which a Financial Conflict of Interest in Research exists, VUMC will either eliminate the Financial Conflict of Interest in Research

or report to the PHS Awarding Component the existence of the Financial Conflict of Interest in Research. The report will include required information about the management plan for that Financial Conflict of Interest in Research. If, after review, VUMC determines that a subsequent Financial Conflict of Interest in Research develops or exists, a report of VUMC's management plan for that Financial Conflict of Interest in Research will be submitted to the PHS Awarding Component within sixty (60) days of the identification of the new Financial Conflict of Interest in Research.

In situations where VUMC conducts PHS-funded Research with or through other entities such as sub-grantees, subcontractors or collaborators (collectively, "Sub-recipients"), VUMC will take reasonable steps to ensure that Investigators working for Sub-recipients comply with the PHS Conflict of Interest Regulations. Sub-recipients of University Research that are funded by PHS shall be required to report identified Financial Conflicts of Interest to VUMC in accordance with the PHS Conflict of Interest Regulations. In turn, VUMC will report to PHS the existence of any Financial Conflicts of Interest reported to VUMC by any Sub-recipients and obtain necessary information for purposes of such report, as well as assurances that the Conflict of Interest has been managed prior to the expenditure of funds and within sixty (60) days of any subsequently identified Conflict of Interest.

In the event of a failure by an Investigator to comply with this policy or an applicable management plan, VUMC will promptly complete a retrospective review of the Investigator's activities and the PHS-funded Research project to determine whether any portion of the PHS-funded Research was biased in the design, conduct or reporting of such Research and notify the PHS Awarding Component of the corrective action taken or to be taken, including but not limited to the submission of a mitigation report when bias is found. VUMC will also submit required reports on an annual basis to the PHS Awarding Component regarding the status of all Financial Conflicts of Interest in Research related to PHS funding and any changes to the management plan, for the duration of the related PHS-funded Research.

For purposes of this Subsection E.2, PHS-funded Investigators must disclose reimbursed or sponsored travel paid on behalf of or by reimbursement to the Member of the VUMC Community, and which is not funded through VUMC when related to Institutional Responsibilities. Exempted from such disclosure is travel reimbursed or sponsored by a federal, state, or local government

agency, an institution of higher education as defined at 20 USC 1001(a), an academic teaching hospital, VUMC, or a research institute that is affiliated with an institution of higher education. Any disclosure of reimbursed or sponsored travel must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration and a statement from the traveler indicating whether or not the travel and accommodations provided were reasonable, customary, and similar to what would be acceptable under VUMC travel policies for travel expenses paid by VUMC.

Disclosure to the public of Financial Conflicts of Interest in Research shall be required upon request for all Financial Conflicts of Interest in Research that are related to PHS-funded Research if they are held by Key Personnel. VUMC will ensure that all Members of the VUMC Community who require training under the PHS-funded regulations complete such training upon employment and every four (4) years thereafter.

- a. For purposes of this Section E.2, Financial Conflicts of Interest in Research shall include instances in which:
 - i. research or research contract, grant, clinical trial, or other research project or collaboration (“Research Project”) pertains to any research involving VUMC and a Business or Intellectual Property in which the Member of The VUMC Community has a Significant Financial Interest, OR
 - ii. the outcomes of such research or Research Project could reasonably be expected to affect the Significant Financial Interest held by the Member of the VUMC Community or to affect a Business or Intellectual Property in which the Member of the VUMC Community has a Significant Financial Interest, OR
 - iii. the Member of the VUMC Community or a Family Member is, whether or not compensated, an (i) officer or director of a Business involved in the research or Research Project, or an (ii) employee, consultant, faculty member (or similar appointment), or advisor for the Business or otherwise affiliated with the Business and directly involved with activities pertaining to the research or Research Project, if a Significant Financial Interest is discovered,

AND the appropriate VUMC officials reasonably determine that the Investigator's Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the research.

- b. For purpose of this Section E.2, Key Personnel shall be defined as: any Member of the VUMC Community named as the Principal Investigator, project director, or otherwise identified as senior/key personnel by VUMC in a grant application, progress report, or any other report submitted to the PHS by VUMC.
- c. For purposes of this Section E.2, Significant Financial Interest shall be defined as: A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's family members) that reasonably appears to be related to the Investigator's Institutional Responsibilities:
 - i. With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - ii. With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's family members) holds any equity interest (e.g., stock, stock option, or other ownership interest). For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary received from the non- publicly traded entity (e.g. consulting fees, honoraria, paid authorship); or

F. Health Care Industry-Sponsored Activities

Conflicts of Interest in Health Care Industry-Sponsored Activities involve situations in which financial, professional, or other personal considerations may compromise, or have the appearance of compromising an individual's judgment in the provision of patient care, procurement, or other professional activities. The bias which may result from such Conflicts of Interest may impact not only the collection, analysis, and interpretation of data, but also the hiring of staff, procurement of materials, clinical referrals, sharing of results, choice of treatment, or otherwise influence the provision of patient care or the execution of one's professional duties.

VUMC personnel may not participate in or receive compensation or consulting pay of any amount:

1. For talks supported directly by suppliers of pharmaceuticals, medical equipment and devices, or medical service vendors (hereafter referred to as the Health Care Industry) or their agents, a list of which is provided at <http://vanderbilt.edu/compliance/vendors.php> if:
 - a. The selection of speaker, topic, and/or audience is determined by an entity which provides speakers for events supported or sponsored by the Health Care Industry;
 - b. The content of the lectures given is subject to any form of prior review or approval by either representatives of the Health Care Industry or event planners contracted by the Health Care industry;
 - c. The content of the presentation is not based on a balanced review of the best available scientific evidence; or
 - d. The discussant refers predominantly to or promotes a specific drug, device, or service which is manufactured and/or marketed by the sponsor of the talk or its affiliate. In essence, the lecturer is expected to determine the lecture's content, including slides and written material, and to provide a balanced assessment of therapeutic options.
2. For listening to sales talks or simply attending a continuing medical education (CME) or other activity where the vendor is paying participants to attend the event.
3. For prescribing medications or changing a patient's prescription.

4. Without associated duties. All consulting or service activities must follow VUMC guidelines relating to consulting and may accept only fair market compensation for specific, legitimate services provided to industry with payment commensurate with time and effort.

These guidelines are not meant to discourage constructive scholarly interchange between VUMC personnel and the Health Care Industry research and development efforts. However, while pursuing such activities, VUMC personnel must follow VUMC guidelines relating to consulting and may accept only fair market compensation for specific, legitimate services provided to industry with payment commensurate with time and effort.

1. The terms of the arrangements, services provided, and compensation must be set forth in writing.
2. If one consulting relationship will pay the individual in excess of \$10,000 in consulting fees over any continuous 12 month period, prior review and written approval must be received from the department chair (for faculty and academic departmental staff), appropriate Associate Dean (for students, residents, fellows, or post-doctoral fellows), or the appropriate CEO/CEO's designee (for medical center staff).
3. Each consulting relationships with entities which have any other type of relationship with VUMC (e.g., vendor, research sponsor, source of gifts, etc.) must be reported by faculty and staff using the appropriate annual COI disclosure tool.
4. In some instances, it may be mutually desirable for VUMC personnel to provide consulting services to a company in the Health Care Industry as a component of their VUMC duties. An example of this might be a collaborative project using VUMC space, resources, and/or personnel for research or for development of innovative technologies, devices, or treatments. Such services may be provided only under a contract which specifies the terms for such services and that payment will be made to VUMC rather than to the individuals. Advice should be sought early in developing any such proposal from the Office of Research, Office of Grants and Contracts Management, the IRB, and the Office of Legal Affairs/Conflict of Interest, as appropriate.
5. When VUMC personnel are involved in providing education to Health Care Industry personnel (or to other persons identified or

sponsored by the Health Care Industry) and such activity will utilize any VUMC facilities, space, resources, equipment, and/or subordinate VUMC personnel, such activities will occur only under a services agreement contract between the sponsor and VUMC which defines the scope of the intended activities and the compensation for the same.

G. Projects Sponsored by Business

An individual Member of the VUMC Community may not assign students, postdoctoral fellows, or other trainees to VUMC projects sponsored by any Business if the individual or a Family Member has a Financial Interest in the Business. An individual also may not assign students or permit students to participate in any consulting relationship in which the individual or a Family Member has a Financial Interest.

Deans and department chairs have the responsibility for protecting the interests of students, fellows, and trainees who may be directly or indirectly involved in a Conflict of Interest situation related to a Member of the VUMC Community or a Family Member of the VUMC Community or a Family Member with a Financial Interest in the situation. Students and trainees should not be permitted to participate in consulting activities if the terms and conditions of those activities would prevent the students or trainees from meeting applicable University degree or training requirements. Students, postdoctoral fellows, and trainees involved in any Conflict of Interest situation should be informed that the Conflict of Interest situation exists; and that their concerns, if any, can be discussed with the appropriate VUMC and University officials, or, if applicable, the monitor or monitoring panel.

Additionally, deans or their designees and department chairs must meet regularly (at least annually) with any students, postdoctoral fellows, or trainees involved in a Conflict of Interest situation. Deans and department chairs may also consider assigning an observer to the Research advisory committee/theses or dissertation committee of any student involved in a Conflict of Interest situation.

H. Activities Related to Family Members

Members of the VUMC Community may not participate in the hiring process or any employment-related decisions pertaining to their Family Members. Likewise, they may not be in a position to supervise a Family Member as an employee of VUMC or otherwise review or participate in reviewing a Family Member's work as an employee of VUMC.

I. Expert Witnesses

When agreeing to become an expert witness, please be advised of the following:

Unless requested to do so by VUMC, in agreeing to serve as an expert witness or expert consultant in a legal proceeding or in providing expert testimony to legislative/deliberative bodies, a VUMC faculty or Staff member is acting outside the usual scope of his/her employment, and thus is not representing VUMC. Faculty and Staff members are advised to consider all potential facets of the matter in dispute, and must at all times present his/her opinions (whether oral or written) as individual opinions, not to be construed as representing those of VUMC. In every instance, the faculty and staff member must provide a disclaimer to this effect which will become part of the permanent record in the matter. In addition to notifying his/her Department Chair (or Chair's designee) or Department Head of any invitation to provide expert opinion, if the subject matter involves allegations of medical malpractice, the faculty or staff member must contact the VUMC Office of Risk and Insurance Management at 615-936-0660 before accepting the offer to serve as an expert. This will permit a review to ensure that there is no present or foreseeable overlap/Conflict of Interest with any matter in which VUMC is (or may become) an interested party. A faculty or staff member who provides expert witness/consultation services is advised to keep in force a personal liability policy to protect himself/herself against claims related to this activity. Medical malpractice indemnification through VUMC provides no coverage for such private consulting activities. Absent a stipulation in the faculty or staff member's written consulting agreement by which the external entity retaining the faculty or staff member agrees to be responsible for any costs incurred by VUMC as result of the faculty or staff member's services, the faculty or staff member may be held responsible for these.

IV. Support for Educational and Other Professional Activities:

A. Educational Activities:

All educational events sponsored by VUMC and its affiliates must be compliant with ACCME Standards for Commercial Support whether or not CME credit is awarded. Use of CME certifying entities other than the Vanderbilt Division of Continuing Medical Education is prohibited if doing so would result in being out of compliance with these guidelines.

1. Educational grants that are compliant with the ACCME Standards may be received from the Health Care Industry, but must be administered by departments, centers, institutes, or divisions and not by individuals.

2. The Division of Continuing Medical Education should be informed at the time of submission of requests for grants to support educational events. Agreements governing grants supporting educational events must receive prior approval by the Division of Continuing Medical Education.
3. VUMC departments must maintain records of compliance with ACCME Standards in a manner consistent with the guidelines of the Division of Continuing Medical Education.

B. Educational activities Funded by Health Care Industry Sources:

Provision of funds from Health Care Industry sources to support activities by VUMC personnel (i.e., scholarships, reimbursement of travel expenses, or other non-research funding in support of scholarship or training) must be free of any actual or perceived Conflict of Interest, whether the funds are provided directly to VUMC or indirectly through industry grants to professional organizations.

1. Industry may not earmark contributions to fund specific recipients or to support specific expenses.
2. Funds must be provided to the VUMC department or the sponsoring professional organization rather than directly to the trainee.
3. The VUMC personnel must be selected according to clear criteria.
4. The VUMC department must determine that the conference or training has educational merit.
5. The recipient of the funds must not be subject to any implicit or explicit *quid pro quo*.

C. Gifts for Non-CME Activity:

Department chairs, division chiefs, center directors, institute directors and senior leadership figures overseeing faculty and staff activities must report all unrestricted gifts, except those supporting certified CME activities as referenced above, to the VUMC Development Office with indication of the amount and the accounts into which the funds have been deposited.

1. Any such funds are to be received as gifts. Any stipulation as to use must be generic, (e.g., house staff library, and there is to be no explicit or implied *quid pro quo* regarding the purpose to which such gift funds will be applied.

2. There will be an annual reporting of any such funds accepted together with an itemized record detailing how such funds were spent.

V. Display of Industry-Provided Promotional Items:

A. Promotional Items:

Promotional items which incorporate or display a product or company logo of a Health Care Industry entity must not be used or displayed on the VUMC campus. This prohibition shall include exhibitions by industry representatives at, or adjacent to, certified CME activities. This prohibition does not include:

1. Materials and equipment purchased by VUMC where awareness of the displayed company or branding logo is helpful in identification and/or safe use of the product.
2. Materials presented at VUMC approved vendor fairs which allow VUMC personnel to compare and contrast products/services from more than one vendor.
3. Products in public areas which have been approved by VUMC for on-site sale to the public.

B. Patient Education Materials:

It is desirable that materials used or provided by VUMC personnel for patient education be devoid of Health Care Industry logos, branding, and marketing content. When it is not practical to remove or conceal logos or branding information, or when doing so would fundamentally compromise the quality of the patient/family education, such materials may be utilized subject to the following requirements:

1. The materials to be used have been reviewed and approved by leadership in the practice area for use in education.
2. Educational materials linked to coupons or discounts for drugs, medical devices, or other goods or services to be purchased by the patient are prohibited.
3. Educational materials linked to referral to a non-VUMC vendor or supplier of health care goods or services are prohibited.
4. Branded educational materials/manuals which are intended to promote safe and appropriate use of a medication or medical device are permissible so long as there has already been a clinical

judgment that the product or device is best for the care of the individual patient.

C. VUMC Personnel:

While on the VUMC campus and while off-campus during activities when representing VUMC, VUMC personnel will not wear or otherwise display upon their persons any visible article of clothing, uniform, badge, pin, sign, or other item which displays the name of a non-VUMC health care service, health care product, or company logo. This restriction may be waived for special charitable or philanthropic events with the expressed consent of the Chief of Clinical Staff for VUMC with respect to faculty, and the Chief of Human Resources for all other staff. Specifically excluded from this restriction are:

1. Photo identification badges from other health care facilities.
2. Logos from non-profit and/or professional organizations which promote health in general or promoted research, prevention, treatment and/or education in a specific disease or health area.

VI. Conflict of Commitment Guidelines:

A. General Information:

1. One type of Conflict of Interest is Conflict of Commitment. A Conflict of Commitment relates to an individual's distribution of effort between VUMC employment and commitment to external business activities or employment, external professional activities, or personal activities. It is possible to have a Conflict of Commitment even if the individual does not receive compensation for the external activity. External activities may include employment outside VUMC, involvement with professional societies, participation related to review panels, education meetings, community service, conferences, consulting, other professional activities, and business activities related to outside entities, including start-up companies.
2. A Conflict of Commitment can arise when the external activities burden or interfere with VUMC member's primary obligations and commitments to VUMC. It is the policy of VUMC that all full-time faculty members are expected to devote their primary professional loyalty, time, and energy to their positions at VUMC and Vanderbilt University. Similarly, VUMC staff are expected to devote their primary professional loyalty, time, and energy to their position at VUMC.

3. Although a specific work-week is not defined for faculty, senior administration and full-time exempt staff, it is expected that such positions constitute a full-time obligation and that, with the exceptions explicitly permitted by VUMC policies on external activities, they will not engage in other employment. Accordingly, external activities must be arranged so as not to interfere with the primary commitments.

B. Faculty-Specific Guidelines:

1. External activities conducted by a faculty member should be of such nature as to improve effectiveness as a teacher or contribute to scholarly attainments, or should in some manner serve the interests of VUMC, Vanderbilt University, or of the community. External activities must not distract significantly from primary responsibilities and must not require such extensive absence as to cause the faculty member to neglect primary responsibilities or become unavailable to trainees and colleagues. External activities must be of such nature and conducted in such manner as will not bring discredit to VUMC or to Vanderbilt University and must not compromise any Intellectual Property owned by VUMC or by Vanderbilt University.
2. Accordingly, the maximum expenditure of time on external activities by a full-time faculty member should not exceed fifty (50) days per year, including holidays. It is expected that half-days will be accumulated into full days and that time traveling to and from activities or engagements and preparing for them also will be accumulated and counted in the total. Individual departments may implement more specific procedures and require additional information in furtherance of this policy. Faculty members should periodically re-examine the nature and extent of their external activities and conscientiously avoid engaging in activities that constitute Conflicts of Commitment

C. Staff-Specific Guidelines:

1. Employment outside of VUMC or other activities that could create a Conflict of Commitment, or the appearance of a Conflict of Commitment, should be disclosed as outlined in this policy and discussed with the staff member's supervisor to ensure it will not create a Conflict of Commitment. Hourly paid staff, or part-time exempt staff, should also disclose and discuss with their supervisors external obligations so that a Conflict of Commitment does not arise.

2. Accordingly, external activities must be arranged so as not to interfere with a staff member's primary commitments. External activities must be of such a nature and conducted in such a manner as will not bring discredit to VUMC and must not compromise any Intellectual Property owned by VUMC.
3. Staff members should periodically re-examine the nature and extent of their external activities and conscientiously avoid engaging in activities that constitute Conflicts of Commitment. The Chief Executive Officer of VUMC (or designee) may grant exceptions to this policy in extraordinary cases upon recommendation of the VUMC Conflicts Committee.

VII. Disclosure:

A. Duty to Disclose:

(Other than specifically outlined under PHS-Funded Research Section E.2 above.)

1. In order to identify and review Conflicts of Interest or Commitment, and the appearance of Conflicts of Interest or Commitment, Members of the VUMC Community must disclose in advance all Significant Financial Interests (SFI) and outside activities and Financial Interests that create or have the appearance of creating Conflicts of Interest and Commitment to the appropriate VUMC officials as follows: The initial disclosure is reviewed by supervisors (for staff) or department chairs (for faculty) with a secondary review performed by the Director of Conflict of Interest Office in the Office of Legal Affairs (for staff) or the School of Medicine Office of Faculty Affairs (for faculty). These officials will review the disclosures to determine whether a Conflict of Interest and Commitment exists and what conditions or restrictions, if any, should be imposed in order to manage, reduce or eliminate the Conflict of Interest and Commitment.
2. Such disclosures shall be sufficiently detailed and timely as to allow accurate and objective evaluation prior to making commitments or initiating activities that create Conflicts of Interest or commitment. The information must be accurate and not false, erroneous, misleading, or incomplete. Each Member of the VUMC Community has an obligation to cooperate fully in the review of the pertinent facts and circumstances. Individual departments may implement more specific procedures and require additional information in furtherance of this policy.

3. Certain VUMC activities will involve more specific procedures with respect to Conflicts of Interest either because of governmental requirements or corporate fiduciary duty. The Board of Directors and VUMC Officers, as well as anyone involved with sponsored Research or the development and licensing of Intellectual Property under the auspices of VUMC, are responsible for complying with all applicable procedures.
4. Disclosure required by any governmental, accreditation, or other self-regulatory agency, such as the PHS, FDA, or NSF or The Joint Commission regulations, should be made to the appropriate VUMC official, on the required forms before grant application submission. Additionally, disclosure should be made to publications and journal editors when scholarly manuscripts are submitted and to the audience during any oral presentation of scholarship if the presenter has a Conflict of Interest.
5. The VUMC Office of Legal Affairs is available as a resource for questions involving VUMC policies and procedures and for guidance on any issues related to the disclosure process

B. Annual Disclosure Process:

In addition to the duty of advance disclosure discussed above, all Members of the VUMC Community are required to provide a disclosure of all Significant Financial Interest or situations or relationships that create or have the appearance of creating a Conflict of Interest or Commitment upon initial employment and annually thereafter. Updated disclosures must also be provided throughout the year if changes in circumstances that arise that either (a) create a new Conflict of Interest or Commitment or (b) change or eliminate a Conflict of Interest or Commitment previously disclosed. All disclosure statements and management plans are official records and will be maintained according to an appropriate retention schedule. The disclosure statements contain information that may have a direct bearing on an individual's employment. The disclosure statements will be considered confidential, however, the information may be released in accordance with and as required by federal, state, or local law or court order.

VIII. VUMC Conflicts Committee:

A. Composition:

There shall be established a VUMC Conflicts Committee which shall be a VUMC resource on Conflict of Interest matters and Conflict of Commitment matters. The Committee shall have representatives from relevant areas across VUMC, appointed by VUMC's Chief Executive

Officer including faculty, audit, research, legal, administrative, and compliance. The General Counsel/Secretary for VUMC in the Office of Legal Affairs shall serve as the chair of the Committee, and the representatives on the Committee shall serve for a renewable 3-year term.

B. Duties and Responsibilities:

1. The Committee's primary responsibility is to serve as a resource to VUMC on Conflict of Interest and Commitment in matters in which VUMC's mission, philosophy, and overall purpose could be compromised by VUMC's relationships with the individual members of its Community.
2. The Committee is responsible for reviewing all Conflict of Interest cases involving VUMC as a party or in which VUMC as an institution is subject to a Conflict of Interest. The Committee will also review all cases where human subject's research is being proposed and the principal investigator has a Significant Financial Interest related to the proposed research, as well as cases where the initial review committee cannot reach a decision. The Committee may also review appeals from adverse decisions and cases that may be referred to it. The Committee will conduct a thorough review of each case and will either approve or deny the proposed activity, management plan, and/or monitoring plan.
3. In the event of an appeal, the Committee shall be provided with a copy of any disclosure statement which reveals a real or apparent Conflict of Interest, together with a recommendation from the appropriate VUMC official. The Committee must provide individuals the opportunity to appear before the Committee and/or submit written comments regarding the recommendation. The response of the individual will become an official part of the Conflict of Interest review record.
4. The Committee shall maintain oversight of the annual and periodic disclosures from all faculty and staff that address Conflicts of Interest. The Office of Legal Affairs shall provide the Committee with such summaries, reports, or disclosure statements as it may require.
5. With respect to Research and activities supported by PHS or NSF funding, VUMC Office of Legal Affairs shall maintain records of all financial disclosures and all actions taken by the Institution with respect to each Conflict of Interest disclosed pursuant to this policy for at least three (3) years from the date of submission of the final expenditures report or until the resolution of any governmental or

VUMC action involving those records unless other dates are specified by applicable law.

6. The Committee shall maintain an ongoing awareness of procedures, practices, and standards with regard to Conflicts of Interest with a view to assuming consistency with the terms of this policy. It shall carry on whatever dialogue is necessary with VUMC Officers and Directors to insure that its knowledge is sufficiently current and complete. It shall also insure that a proper balance is maintained between confidentiality and its operations and standards.
7. The Committee shall maintain an awareness of externally imposed Conflict of Interest requirements.
8. The Committee shall review this policy periodically and may make amendments to the policy, in consultation with the VUMC Office of Legal Affairs, and the VUMC Office of Health Care Compliance, by a majority vote of all current Committee members.
9. Upon request, the Committee shall make recommendations relating to the enforcement of this policy and any disciplinary action.
10. The Committee shall perform such additional functions as may be assigned from time to time by the Chair of the Committee.
11. The Committee will report semiannually to the Audit Committee of the VUMC Board of Directors on matters within its scope of responsibility. At the discretion of the chair of the Committee, Conflicts of Interest or Commitment involving the Chief Executive Officer or other VUMC Officers may be referred to the Audit Committee of the VUMC Board for review and approval.

C. Procedures:

The Committee shall establish procedures to implement this policy, in cooperation with VUMC's departments, and may make use of subcommittees to carry out its various functions. The Committee shall maintain confidential minutes of its deliberations. In the case of Research or other activities subject to applicable governmental regulations on Conflicts of Interest, the requirements of such governmental regulations shall apply and supplement and/or, to the extent inconsistent with this policy, superseded the provisions of this policy. In that event, applicable reporting procedures and other substantive and procedural requirements will be followed.

IX. Oversight:

The Office of Legal Affairs is responsible for overseeing the implementation of this policy for VUMC staff. The Office of Faculty Affairs is responsible for overseeing the implementation of this policy for faculty members. The relevant group will review all violations of this policy, including: (a) failure to comply with the disclosure process (by refusal to respond, by deliberately responding with incomplete, inaccurate, or misleading information, or otherwise); (b) failure to remedy Conflicts of Interest or Commitment; and (c) failure to comply with a prescribed management or monitoring plan. Such cases may be forwarded to the VUMC Conflicts Committee for review and recommendations by the Office of Legal Affairs. When appropriate in the setting of mutual interests, the VUMC Conflicts Committee will consult and collaborate with the Vanderbilt University Conflicts Committee.

X. Consequences of Non-Compliance:

Penalties for deliberate violations of this policy will be adjudicated in accordance with applicable disciplinary policies and procedures of the VUMC Human Resources Department Staff Guidelines or the Faculty Manual, as applicable. Possible penalties include reimbursement to VUMC for misused resources; formal admonition; inclusion in a staff member's file of a letter from their supervisor indicating that the individual's good standing has been called into question; ineligibility to participate in grant applications, Institutional Review Board approval, or working with graduate students; performance improvement counseling, up to and including dismissal from employment consistent with the Staff Guidelines.

Any Member of the VUMC Community may report a situation involving a Conflict of Interest or Commitment or a violation of this policy to an appropriate VUMC official, the VUMC Office of Health Care Compliance, or the Office of Legal Affairs. VUMC will make every effort to protect anyone who reports a violation from reprisal.

General questions about the policy or disclosure requirements should be directed to coi.vumc@vanderbilt.edu.

XI. Endorsement:

VUMC Board of Directors

September 2017

XII. Approval:

Wright Pinson, MD
CEO of Vanderbilt Health System
Deputy CEO of Vanderbilt University Medical Center
Chair, Compliance and Corporate Integrity Committee

9/13/17