



Vanderbilt University Conflict of Interest and Commitment Policy

Article I: Policy Statement

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

The University's core values include a commitment to the following goals: educating students; protecting academic freedom; advancing and communicating knowledge about the world; protecting the safety of patients and of research participants; protecting the integrity and objectivity of research and instruction; supporting the ideals of goodwill, fair play, and transparency; and encouraging public service.

Accordingly, all individuals in the University community have a clear obligation to make decisions and conduct the affairs of the University based upon the desire to promote the best interests of the University in a manner consistent with those goals. Trustees and members of senior administration are fiduciaries and owe special duties of care and loyalty to the University as a whole and must keep the University's interests paramount to all others.

The relationships between Vanderbilt University, the individual members of the University community, private industry, federal and state governments, and the non-profit sector have grown increasingly complex. As a result, there are opportunities for professional interactions and development that may benefit the University 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 University community. The purpose of the Vanderbilt University 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 the University 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 University 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 the University'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 interferes with his/her primary obligation and commitment to the University. Individuals in the University community should evaluate and arrange their external interests in order to avoid compromising their ability to carry out their primary obligations to the University, 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 University 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 schools or 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 the University, (iii) remedy Conflicts of Interest or Commitment or comply with any management or monitoring plan

prescribed by the University, (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 respective schools and departments in furtherance of and in accordance with this policy.

Article II: Conflict of Interest Guidelines

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

A. University Administration

The internal administration of the University can present the potential for conflicts of interest. Members of the University community with administrative responsibilities must take particular care to avoid relationships in which Financial Interests or other personal interests intersect with the University's interests and have the potential for inappropriate factors to be considered in administrative decisions, including hiring decisions. In particular, individuals who have University 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 the University; 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 the University 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 University 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 the University. If the enterprise does business with the University, or proposes to do business with the University, 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 the University with respect to the Business in which the individual or Family member has an interest. Members of the University community may not review, approve, or administratively control contracts or business relationships when the contract or business relationship is between the University 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 the

University. This section is not intended to apply to the adoption of textbooks, software, or other teaching aids written by faculty members or their Family Members for use in their own course of instruction, although such use must have prior approval from the faculty member's department chair or dean, must be related to the faculty member's or such faculty member's Family Member's general area of study or scholarship, and must comply with all other applicable rules and regulations of the University.

C. Gifts and Contributions

No gifts or accommodations of any nature, including unrestricted grants, may be accepted by the **University** or **individual members** of the University 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 the University, or reflect adversely on their integrity or that of the University. All gifts given in support of an institutional mission must be directed through the Development offices.

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 Vanderbilt, a list of which is provided at [this link](#).¹ 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 unit's 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 are normally tax exempt, and as such may only be accepted through the VUMC Development Office.

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.

¹ To determine whether a vendor qualifies as a Health Care Industry Supplier contact coi@vanderbilt.edu.

Types of activities viewed as gifts include:

- **Food** - Except meals offered at national meetings linked to educational, scientific, or consultative events.
- **Travel** - Except travel expenses related to necessary education or training regarding equipment, products, or other medical devices purchased previously by Vanderbilt. 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 Vanderbilt personnel accept offers from the Health Care Industry to pay for travel, meals, or other expenses which are related to procurement activities by Vanderbilt personnel.
- **Tickets** to entertainment events
- **Ghost-writing services**
- **Promotional items** which incorporate or display Health Care Industry supplier or product logos. Exceptions are:
 1. Items purchased by Vanderbilt.
 2. Materials which have been reviewed and approved by leadership in a clinical practice area for use in education.
 3. 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.
 4. Materials presented at approved vendor fairs which allow University personnel to compare and contrast products/services from more than one vendor.
 5. 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.
 6. Logos from non-profit and/or professional organizations which promote missions consistent with the missions of the University.

D. Use and Appropriation of University Assets

The University possesses both tangible and intangible assets. These assets include buildings, personnel,

equipment, patents, copyrights, technology, and work products, as well as the University's reputation and prestige. As custodian of these assets, members of the University community owe a fiduciary duty to the University to act in accordance with applicable University procedures regarding the proper expenditure of the University's funds, as well as the use and control of University assets, including confidential and privileged information. Where specific procedures regarding the disposition and control of University assets do not exist, individuals are expected to protect the best interests of the University in its tangible and intangible assets. Conduct constituting the misappropriation or unauthorized use of University assets in connection with any external activity is prohibited (including implying sponsorship or endorsement by the University or otherwise trading on the reputation or goodwill of the University). Mere identification of the University as one's employer and of one's position at the University is permitted, provided that such identification is not used to imply University sponsorship or endorsement.

E. Research Activities

1. General

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 University 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 the University and a business or intellectual property in which the individual or a family member has a Significant Financial Interest 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 University 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 University research is responsible for learning and complying with all other applicable policies and procedures.

All individual members of the Vanderbilt University 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. All university 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 university research funded or proposed for funding by PHS, the following subsection E.2 shall also apply.

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 University 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 the University 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 the University, 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 University officials and must have completed required University 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, the University 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, the University determines that a subsequent Financial Conflict of Interest in Research develops or exists, a report of the University's management plan for that Financial Conflict of Interest in Research will be submitted to the PHS Awarding Component within sixty days of the identification of the new Financial Conflict of Interest in Research.

In situations where the University conducts PHS funded Research with or through other entities such as subgrantees, subcontractors or collaborators (collectively, "Subrecipients"), the University will take reasonable steps to ensure that Investigators working for Subrecipients comply with the PHS Conflict of Interest Regulations. Subrecipients of University Research that are funded by PHS shall be required to report identified financial conflicts of interest to the University in accordance with the PHS Conflict of Interest Regulations. In turn, the University will report to PHS the existence of any financial conflicts of interest reported to the University by any Subrecipients 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 days of any subsequently identified conflict of interest.

In the event of a failure by an Investigator to comply with this University policy or an applicable management plan, the University 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

² The complete FDA regulation on Conflict of Interest can be found at: <http://www.fda.gov/oc/advisory/waiver/coiguidedft.html>

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. The University 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 University Community, and which is not funded through the University 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, a medical center, or a research institute that is affiliated with an institution of higher education is excluded from this requirement. 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 Vanderbilt travel policies for travel expenses paid by Vanderbilt.

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. The University will ensure that all Members of the University Community who require training under the PHS-funded regulations complete such training upon employment and every four years thereafter.

- For purposes of this Section E.2, Financial Conflicts of Interest in Research shall include instances in which:
 - (a) research or research contract, grant, clinical trial, or other research project or collaboration (“Research Project”) pertains to any research involving the University and a Business or Intellectual Property in which the Member of the University Community has a Significant Financial Interest, OR
 - (b) the outcomes of such research or Research Project could reasonably be expected to affect

the Significant Financial Interest held by the Member of the University Community or to affect a Business or Intellectual Property in which the Member of the University Community has a Significant Financial Interest, OR

- (c) the Member of the University 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 University officials reasonably determine that the Investigator’s Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the research.

- For purpose of this Section E.2, Key Personnel shall be defined as: any Member of the University Community named as the Principal Investigator, project director, or otherwise identified as senior/key personnel by the University in a grant application, progress report, or any other report submitted to the PHS by the University.
- 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:
 - (a) 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 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;
- (b) 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 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
 - (c) Intellectual property rights and interests not paid by Vanderbilt (*e.g.*, patents, copyrights), upon receipt of income related to such rights and interests.

F. Healthcare Industry Sponsored Activities

Conflicts of interest in Healthcare 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.

Personnel may not receive compensation or consulting payments of a guaranteed amount:

- I.** 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 only 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

- c. Health Care Industry or event planners contracted by the Health Care industry, 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.

- II.** For Health Care Industry sponsored promotions or lectures on the use of drugs or devices for unapproved indications (off-label), not approved by the FDA, and sold by the same Healthcare Industry vendor.
- III.** For grants or contracts to conduct Health Care Industry sponsored Research on unapproved indications (off-label) of drugs or devices while receiving payments for lecturing and/or consulting from the same Healthcare Industry company.
- IV.** For listening to sales talks or simply attending a CME or other activity.
- V.** For prescribing medications or changing a patient's prescription.
- VI.** Without associated duties. All consulting or service activities must follow University 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.

G. Activities Related to Students

An individual Member of the University Community may not assign students, postdoctoral fellows, or other trainees to University 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 University 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 University official 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, post-doctoral 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 University 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 the University or otherwise review or participate in reviewing a Family Member's work as an employee of the University.

Article III: Conflict of Commitment Guidelines

One type of Conflict of Interest is Conflict of Commitment. A Conflict of Commitment relates to an individual's distribution of effort between University employment or faculty appointment 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 the university, 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.

A Conflict of Commitment can arise when the external activities burden or interfere with the University member's primary obligations and commitments to the University. It is the policy of the University that all full-time faculty and staff members are expected to devote their primary professional loyalty, time, and energy to their position at Vanderbilt.

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 University 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.

Faculty-specific guidelines

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 the 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 course obligations or become unavailable to students and colleagues. External activities must be of such nature and conducted in such manner as will not bring discredit to the University and must not compromise any Intellectual Property owned by the University.

Accordingly, the maximum expenditure of time spend on external activities by a full-time faculty

member appointed on a nine-month basis should not exceed forty days during the academic year, including holidays. For those full-time faculty members appointed on a twelve-month basis, time spent on external activities should not exceed fifty days per year, including holidays. For those academic year faculty receiving external funding during the summer months (currently May 16 through August 15), the policy for full-time faculty appointed on a twelve-month basis will apply – i.e., no more than fifty 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 schools and 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. The Provost or Vice Chancellor for Health Affairs may grant exceptions in extraordinary cases upon recommendation of the appropriate Dean.

Staff-specific guidelines

Employment outside Vanderbilt 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.

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 the University and must not compromise any Intellectual Property owned by the University.

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 Vice Chancellors may grant exceptions to this policy in extraordinary cases upon recommendation of the University Conflicts Committee.

Article IV: Disclosure

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

In order to identify and review Conflicts of Interest or Commitment, and the appearance of Conflicts of Interest or Commitment, Members of the University Community must disclose in advance all Significant Financial Interests and outside activities and Financial Interests that create or have the appearance of creating Conflicts of Interest to the appropriate University officials as follows: the initial disclosure is reviewed by supervisors, deans, and/or department chairs with a secondary review performed by the School of Medicine Office of Faculty Affairs and/or the Office of Conflict of Interest and Commitment Management. These University officials will review the disclosures to determine whether a Conflict of Interest exists and what conditions or restrictions, if any, should be imposed in order to manage, reduce or eliminate the Conflict of Interest.

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 University Community has an obligation to cooperate fully in the review of the pertinent facts and circumstances. Individual schools and departments may implement more specific procedures and require additional information in furtherance of this policy.

Certain University activities will involve more specific procedures with respect to conflicts of interest either because of governmental requirements or corporate fiduciary duty. Trustees and General Officers, as well as anyone involved with sponsored Research or the development and licensing of Intellectual Property under the auspices of the University, is responsible for complying with all applicable procedures.

Disclosure required by any governmental, accreditation, or other self-regulatory agency, such as the PHS, FDA, or NSF or the Joint Commission on Accreditation of Healthcare Organizations regulations, should be made to the appropriate University official, on the required forms before grant application submission. Additionally, disclosure should be made to publications and journal editors when Research manuscripts are submitted and to the audience during any oral presentation of Research if the presenter has a Conflict of Interest.

The Office of Conflict of Interest and Commitment Management is available as a resource for questions involving University 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 University 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.

Article V: University Conflicts Committee

A. Composition

There shall be established a University Conflicts Committee which shall be a University resource on Conflict of Interest matters and Conflict of Commitment matters. The Committee shall have representatives from relevant areas across the University, appointed by the Chancellor, including faculty, audit, Research, legal, administrative, and compliance. At least one representative on the Committee shall be a person from outside the University community. The University's General Counsel shall serve as the chair of the Committee, and the representatives on the Committee shall serve for a renewable three-year term.

B. Duties and Responsibilities

1. The Committee's primary responsibility is to serve as a resource to the University on Conflict of Interest and Conflict of Commitment matters in which the University's mission, philosophy, and overall purpose could be compromised by the University's relationships with the individual members of its community.

2. The Committee is responsible for reviewing all Conflict of Interest cases involving the University as a party or when an institutional Conflict of Interest exists. The Committee will also review all cases where human subjects 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 University 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 Conflict of Interest and Commitment Management 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, the University 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 years from the date of submission of the final expenditures report or until the resolution of any governmental or University 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 assuring consistency with the terms of this policy. It shall carry on whatever dialogue is necessary with college deans and directors or administrative officers 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 Office of Conflict of Interest and Commitment Management, the Office of Compliance, and the Office of General Counsel, 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 Board of Trust on matters within its scope of responsibility. At the discretion of the chair of the Committee, conflicts of interest or commitment involving the Chancellor or other General Officers of the University may be referred to

the Audit Committee of the Board of Trust for review and approval.

C. Procedures

The Committee shall establish procedures to implement this policy, in cooperation with the University's schools and other 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, supersede the provisions of this policy. In that event, applicable reporting procedures and other substantive and procedural requirements will be followed.

Article VI: Oversight

The Office of Conflict of Interest and Commitment Management is responsible for overseeing the implementation of this policy. They 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; and (c) failure to comply with a prescribed management or monitoring plan. Such cases may be forwarded to the University Conflicts Committee for review and recommendations by the Office of Conflict of Interest and Commitment Management.

Penalties for deliberate violations of this policy will be adjudicated in accordance with applicable disciplinary policies and procedures of the Human Resources Staff Guidelines or the Faculty Manual, as applicable. Possible penalties include reimbursement to the University for misused resources; formal admonition; inclusion in a staff member's file of a letter from their dean or 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 University Community may report a situation involving a Conflict of Interest or commitment or a violation of this policy to an appropriate University official, the Office of Compliance anonymous helpline at 322-1033, the Medical Center Compliance Office anonymous helpline at 343-0135, or the Office of Conflict of Interest and Commitment Management at 322-2401. The University 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 the Office of Conflict of Interest and Commitment Management at 322-2401.

Definitions

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 University.

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 University Community. For purposes of the employment of Family Members at Vanderbilt University, grandparent, grandchild, father-in-law, and mother-in-law are also included.

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/cfcfr/CFRSearch.cfm?CFRPart=54&showFR=1>

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).

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 University Community’s activities and duties on behalf of the University or which fall within the scope of employment by the University: (e.g., such as research, consultation related to the scope of Vanderbilt employment, teaching, professional practice, institutional committee memberships, and service on panels at Vanderbilt or as assigned by Vanderbilt.).

Intellectual Property: Patents, copyrights, trademarks, trade secrets, technology (whether or not reduced to practice), databases, software, and any other tangible or intangible intellectual property.

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.

Member of the University Community: Trustees, University officials, full-time, part-time, temporary, or adjunct faculty and staff.

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 (http://www.nsf.gov/publications/pub_summ.jsp?ods_key=manual15)

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://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=42:1.0.1.4.23&idno=42#42:1.0.1.4.23.6> (“PHS Conflict of Interest Regulations”).

PHS Awarding Component: The organizational unit of the PHS that funds a specific Research project.

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.

Significant Financial Interest: a Financial Interest consisting of one or more of the following interests of the Member of the University Community (and those of the Member of the University 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 twelve 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 months preceding the disclosure, when aggregated, exceed \$5,000 or when the Member of the University Community (or the Member of the University 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 (e.g., patents, copyrights), upon receipt of income 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.

See Frequently Asked Questions at: <http://www.vanderbilt.edu/compliance/>