

# UNIFORM CONFLICT OF INTEREST POLICY

**TOURO COLLEGE  
TOURO UNIVERSITY  
TOURO UNIVERSITY NEVADA  
TOURO UNIVERSITY WORLDWIDE  
NEW YORK MEDICAL COLLEGE  
YESHIVAS OHR HACHAIM  
HEBREW THEOLOGICAL COLLEGE**

Date: December 22, 2020

Supersedes: *Code of Conduct and Policy on Conflicts of Interest 12/15/08; NYMC Code of Conduct and Policy on Conflicts of Interest and Conflict of Commitment 5/31/2012; Touro College Conflict of Interest Policy.*

Effective Date: December 22, 2020

## **1.0 PURPOSE**

The purpose of this Conflict of Interest Policy (“Policy”) is to continue to protect and enhance Touro College and University System’s (“the College”) reputation by ensuring that all trustees, officers, faculty and employees of Touro College and its affiliates, everywhere, understand how the College seeks to avoid even the appearance of impropriety. Protecting our ethical standing is not only the right thing to do -- it's good university practice. Students, the public and educational partners judge us by our conduct, as well as our courses and offerings. Potential employers of our students as well as donors want to be associated only with an institution that meets high standards for honesty, integrity, and public responsibility. Our Conflict of Interest Policy reflects the evolution of the College, as well as changes in applicable laws and regulations.

## **2.0 SCOPE**

This policy applies to all members of the College Community, including but not limited to trustees, officers and administrators, employed faculty, voluntary faculty and other full-time and part-time employees of the College (“College Community”).

## **3.0 DEFINITIONS**

“Affected Entity” means an entity other than the College that would reasonably appear to be affected by, or might in turn affect, the institutional responsibilities, including teaching, research, clinical, or service, of the faculty member or Investigator. It also includes entities that control, are controlled by or are under common control with the Affected Entity. In the context of Research and Other Sponsored Projects, an Affected Entity is an entity, such as the research sponsor, that would reasonably appear to be affected by, or might in turn affect, the Research and Other Sponsored Projects.

“Conflict of Commitment” occurs when a member of the College community’s Outside Activities compromise or may compromise his/her ability to meet the member’s obligations at the College.

"Conflict of Interest" means any circumstance in which the personal, professional, financial or other interests of an individual (including the Immediate Family of the individual) may potentially or actually diverge from, or may be reasonably perceived as potentially or actually diverging from, his or her professional obligations to the College and the interests of the College. A Conflict of Interest may exist whenever an independent observer might reasonably question whether the individual's professional actions or decisions, including the ethical and objective conduct of scholarship, research or clinical care, are determined by considerations of personal gain, financial or otherwise.

"Immediate Family" means an individual's spouse (or other significant relationship), children, parents, siblings and, for purposes of this policy, all persons dependent upon the individual or resident in the same household.

"Investigator" is defined for Research and Other Sponsored Projects as the principal investigator or program director, co-investigator, sub-investigator, and any other person who applies for or receives funds for Research and Other Sponsored Projects at the College, or who is responsible for the design, conduct or reporting of Research and Other Sponsored Projects, or who is directly involved in treatment or evaluation of research subjects, or who is responsible for making decisions related to eligibility of research subjects or for obtaining the informed consent of research subjects. Investigator also includes persons who do any of the foregoing for subgrantees, contractors, collaborators, or consultants of College Research and Other Sponsored Projects.

"Office of Research Administration" means each campus' respective Office of Research Administration or Office of Sponsored Programs.

"Outside Activities" include external professional and academic endeavors (such as public service, activities or membership in professional societies or organizations, or lecturing as a guest speaker) or any other non-College related activity. Such Outside Activities must be in compliance with all College policies, including Conflicts of Interest as set forth in this Policy and the Policy on Interactions with the Pharmaceutical, Biotechnology, Medical Device, Hospital and Research Equipment and Supplies Industries. Additional disclosures shall be required pursuant to such policies.

"Ownership Interest" means holding a financial or ownership interest in a business or entity, including stock, stock option, partnership or LLP interest, or other ownership interest. The words "property" or "benefit" mean anything of value, tangible or intangible, that may be transferred or sold or assigned for money or other consideration, including, but not limited to, cash, stock, stock options or warrants, leases, licenses, real or personal property or property rights, contract rights, rebates, vendor credits or reimbursement of personal expenses, gifts or gratuities.

"Research and Other Sponsored Projects" means any internally or externally funded research, training or professional service project conducted at or under the auspices of the College.

"Royalty Income" means any royalty income, licensing income or other proceeds (e.g., payments linked to product sales or other usage and milestone payments), or the written contractual right to receive future royalties, licensing income or other proceeds, directly or indirectly, under a pending or issued patent, license, copyright or other property right, and includes, for purpose of this policy,

all income received by the person from the College in accordance with the College's intellectual property policies.

"Remuneration" includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, travel reimbursement).

"Significant Financial Interest" means any financial interest consisting of one of more of the following interests of an individual (which also includes those of an individual's Immediate Family Members) that reasonably appears to be related to the individual's institutional responsibilities with the College:

- A.** With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any Remuneration from Outside Activities received from the entity in the twelve months preceding the disclosure (or expected to be received from the entity in the twelve months following the disclosure) and the value of any Ownership Interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000, or (ii) the Ownership Interest as of the date of disclosure exceeds five percent (5%) in any class of the entity's securities; or
- B.** With regard to any non-publicly traded entity, a Significant Financial Interest exists if (i) the value of Remuneration from Outside Activities received from the entity in the twelve months preceding the disclosure (or expected to be received from the entity in the twelve months following the disclosure), when aggregated, exceeds \$5,000, or (ii) there is any Ownership Interest in the entity; or
- C.** Intellectual property rights (e.g., patent or copyrights), royalties from such rights, and agreements to share in royalties related to such rights.

Significant Financial Interests do not include the following types of financial interests:

1. Salary, royalties, or other Remuneration paid by the College while the recipient is currently employed or otherwise appointed by the College, including intellectual property rights assigned to the College and agreements to share in royalties related to such rights;
2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the individual does not directly control the investment decisions made in these vehicles;
3. Income from seminars, lectures, or teaching engagements sponsored by: (i) a federal, state, or local government agency; (ii) an institution of higher education as defined at 20 U.S.C. 1001(a); (iii) an academic teaching hospital; (iv) a medical center; or (v) a research institute that is affiliated with an institution of higher education; or

4. Income from service on advisory committees or review panels for: (i) a federal, state, or local government agency; (ii) an institution of higher education as defined at 20 U.S.C. 1001(a); (iii) an academic teaching hospital; (iv) a medical center; or (v) a research institute that is affiliated with an institution of higher education.

“User” means any member of the College community completing the Conflict of Interest survey.

#### **4.0 CONFLICTS OF COMMITMENT**

Members of the College community must not allow Outside Activities to detract from their obligations to the College. A Conflict of Commitment occurs when an individual’s Outside Activities compromise or may compromise his/her ability to meet his/her obligations at the College.

Outside Activities that do not constitute a Conflict of Commitment are permissible only if they also do not result in a Conflict of Interest (as discussed below) and are in accordance with all College policies, including this policy and the Policy on Interactions with the Pharmaceutical, Biotechnology, Medical Device, Hospital and Research Equipment and Supplies Industries.

##### **A. Full-Time Employees and Full-Time Faculty**

Full-time employees and full-time faculty members at the College owe their primary professional allegiance and their primary commitment of time and intellectual activities to the College. Regardless of the guidelines below, Outside Activities must not interfere with the employee’s and faculty member’s primary responsibilities to the College. Thus, full-time employees and full-time faculty must comply with the following regarding all Outside Activities prior to engaging in such activities:

1. Timely disclose in writing all Outside Activities to their supervisor or the appropriate Department Chair, with copies to the appropriate School Dean, if applicable, and the Office of Institutional Compliance.
2. Obtain the prior written approval of their supervisor or their respective Department Chair for any Outside Activities that either singularly or in the aggregate exceeds an average of one-half day (or the equivalent of 4 hours) per week.
3. All consulting relating to medical negligence or serving as an expert witness in litigation require the prior written approval of the School Dean.
4. All Outside Activities, when aggregated, must not exceed an average of one day per seven-day week (or the equivalent of an eight-hour workday).

Exceptions to the aforementioned limitation and prohibition are rare and may be made only with the prior written approval of the Office of Institutional Compliance.

## **B. Part-Time Employees and Part-Time Faculty**

Part-time employees and faculty members may accept outside employment as long as it does not result in a Conflict of Interest (see below) or otherwise interfere with any of their obligations at the College.

### **5.0 CONFLICT OF INTEREST - GENERALLY**

A Conflict of Interest means any circumstance in which the personal, professional, financial or other interests of an individual (including the Immediate Family of the individual) may potentially or actually diverge from, or may be reasonably perceived as potentially or actually diverging from, his/her professional obligations to the College and the interests of the College. A Conflict of Interest may exist whenever an independent observer might reasonably question whether the individual's professional actions or decisions, including the ethical and objective conduct of scholarship, research or clinical care, are determined by considerations of personal gain, financial or otherwise.

This definition includes any situation or relationship that permits a College employee, whether faculty or staff, or anyone else in a position of trust at the College, to gain a financial benefit at the College's expense, beyond normal compensation or as otherwise permitted by express College policy. Financial benefits are gained at the College's expense when an individual diverts or misuses the College's resources or privileges afforded by association with the College for personal gain or for the private gain of other individuals or organizations inside or outside the institution. Such benefits are also gained by diverting opportunities that should belong to the College away from the College or to some restricted College purpose when the restriction is not necessary.

The College has broad power to require disclosures of Conflicts of Interest to determine whether a Conflict of Interest exists, to manage or eliminate Conflicts of Interest, to impose appropriate sanctions on faculty and Investigators who violate this policy, to release information about Conflicts of Interest and to require faculty and Investigators to take Conflict of Interest training. Faculty or Investigators who are unclear as to whether a matter must be disclosed should err on the side of disclosure.

It is the policy of the College for faculty and employees to follow the principles outlined in this policy in relation to an actual or potential Conflict of Interest at the College:

#### **A. Financial Interests**

No individual who is an employee or faculty member in a position to influence the outcome of a transaction affecting the College should be a party to such transaction when it is with another person or organization in which the individual and/or his/her Immediate Family holds an ownership or other financial interest or holds a fiduciary position such as employee, director, officer, shareholder or consultant. For purposes of this policy, a possible Conflict of Interest includes but may not be limited to:

1. An agreement to obtain or receive an ownership or creditor's interest in another entity;

2. An agreement for compensation or consulting payments, dividends, fees, property or other thing of value from another individual or entity;
3. Any equity or other ownership or controlling interest in another entity; or
4. An interest under a royalty or similar agreement with another organization held by an individual and/or his/her Immediate Family except as permitted under the College's Intellectual Property Policy.

In determining items which require disclosure, faculty and employees should refer to existing guidelines, such as those specified in the financial disclosure requirements for sponsored research programs. In general, the materiality of a financial interest or Conflict of Interest will be judged by the College on the basis of whether or not the judgment or discretion of the individual in matters affecting the College is or may be influenced by consideration of personal gain or financial benefit.

#### **B. College's Name and College Association**

The name of the College and the privilege of association with the College as evidenced by a faculty, administrative or other title are valuable assets and attributes. They are to be used only for legitimate purposes that enhance the College's academic activities and its reputation for fair dealing in the public interest. No one may use the institution's name or one's professional title or association with the institution for advertising purposes, to identify the institution with an outside entity or to endorse the entity's product without special written approval from the Chief Compliance Officer or his/her designee.

In situations in which association of a faculty or staff member with the College is apparent from written or oral statements or from the context in which the statement(s) is made, the individual must emphasize that his comments or opinions are not to be construed as those of the College, unless that person is speaking in his capacity as a faculty member or employee and such statements are consistent with the position of the College.

The College may and does employ members of the clinical faculty and does afford them compensation in return for teaching, supervision, administration and research that are performed for the College, even though the same faculty might be engaged independently in billing for professional clinical services individually or through their employment by other organizations. The College is not a vehicle, agent or employer of its clinical faculty in their capacities as providers of clinical services billed to patients or third-party payers, except as may be the case, any University Faculty Practice Corporation under New York, California, Nevada or Illinois State law that the College may form in the future. Clinical faculty members and their practice entities are not authorized to provide clinical services under the name of any College entity, nor under the name of any College department or component forming part of the College, including divisions, centers or institutes. Clinical faculty members and their practice entities are also precluded from billing or collecting fees or corresponding as part of providing clinical services in such a context using the name of the College or any

College department or component. This policy does not preclude a faculty member from identifying oneself with the College in his academic capacity.

Clinical faculty members have a responsibility to the medical profession and to the public to become and remain informed about laws, rules and regulations applicable to third party billing for professional services, especially those relating to the Medicare and Medicaid programs.

### **C. College Property and Resources**

All College property and resources (including correspondence, records, documents, data, information (in any format), funds, personnel, intellectual property and property rights, equipment, supplies and institutional opportunities for financial gain) are to be conserved and used exclusively for the benefit and development of the College in carrying out its mission and purposes. College property and resources may not be used for personal use, including in Outside Activities, and may not be diverted away from the College to the benefit of any other organization or individual. College property includes information that would not normally be available for public disclosure without approval of the Chief Compliance Officer or his/her designee.

### **D. Confidential Information**

The College's confidential information includes information that would not normally be available for public disclosure without approval of the Chief Compliance Officer or his/her designee, a School Dean, the Chief Financial Officer, or other appropriate administrative or academic officer. Obtaining, using or disclosing College confidential information for direct or indirect personal interest, profit or advantage or, for a purpose that may be detrimental to the College creates a Conflict of Interest. Use of College confidential information for a purpose that is not authorized by the College or disclosure of College confidential information to a person who or entity that is not authorized by the College to receive it creates a Conflict of Interest. Confidential information includes, but is not limited to, medical, personnel, security, academic, background check, conflict of interest or identifiable biometric records and other information of individuals; computer system passwords and security codes, proprietary knowledge about anticipated material requirements or price actions; proprietary knowledge of information about forthcoming programs or selection of contractors or subcontractors in advance of official announcements; unpublished grant proposals, research data, or manuscripts and correspondence; non-public financial, procurement, health-safety, audit, insurance and claims information; and internal investigation, pre-litigation and non-public litigation and administrative agency charge, audit and inquiry information.

### **E. Gratuities**

No member of the College Community shall accept or permit any member of his/her Immediate Family to accept any gift (including entertainment), a loan (other than an arm's length loan made in the ordinary course of business from a banking or other

financial institution), a favor or gratuity of more than nominal value from any person or entity with a business relationship or seeking to have a business relationship with the College.

#### **F. Political Contributions and Lobbying**

By law, no contributions may be made by the College (whether directly or through reimbursement), by anyone acting on behalf of the College, or with any funds of the College from any source to, or for the benefit of, any political campaign or in support of the election of any individual for public office. No funds of the College may be used for lobbying public officials except as lawfully permitted and with written approval of the College's President.

#### **G. Outside Activities**

Employees must not allow Outside Activities or other personal activities to detract from their primary obligations to the College, as discussed in Article V above relating to Conflict of Commitment. Memberships on boards of directors, committees, advisory groups of governmental, for-profit or not-for-profit entities) distinct from the College may create potential Conflicts of Interest or the perception of a conflict. An ownership interest by the employee or by a member of the employee's family in any property or entity related to business transactions with the College may create a similar conflict. These interests and activities should be disclosed according to the procedures described in this policy and the Policy on Interactions with the Pharmaceutical, Biotechnology, Medical Device, Hospital and Research Equipment and Supplies Industries.

### **6.0 CONFLICTS OF INTEREST IN RESEARCH AND OTHER SPONSORED PROJECTS**

#### **A. Principles**

The College is committed to the principle of academic freedom and the enhancement of knowledge and health through the conduct of objective research. Investigators participating in research at the College have a primary obligation to conduct the research free of Conflicts of Interest so as to avoid the tainting or the perception of tainting of the research. Each member of the College community who engages in or seeks to engage in College Research and Other Sponsored Projects has the responsibility to disclose to the College all outside interests, as defined in this policy, which may represent a real or apparent Conflict of Interest. Based upon its review of such disclosures, the College may decide that such outside interests be severed or modified in order to remove, reduce, manage or eliminate a Conflict of Interest as a condition of accepting external research support. Alternatively, the College may structure a mechanism so that the design, conduct and reporting of research by researchers are not likely to be biased nor be perceived to be biased by any conflicting financial interests of those researchers. This policy applies to all sponsored awards, both those issued to the institution and those issued to individuals, except for Phase I SBIR/STTR applicants and recipients.



The College's primary responsibility towards its students is to educate and train them for the professions appropriate to their degree programs. In general, students' research efforts should be devoted towards projects that will enhance their training, education and ability to pursue their own next career step. For example, participation of students in projects that, because of proprietary or other justified considerations, limit the freedom of the student to discuss the results in public forums in a timely fashion may not be in the student's best interests. The participation of students in projects and contracts supported by industrial or commercial sponsors, therefore, should be carefully evaluated as to its suitability for the students' welfare.

## **B. Policy**

1. Training – Prior to engaging in research or any other academic activity at the College for which extramural support is sought, Investigators shall be required to complete training on the College's policy on conflict of interest and his/her responsibilities regarding disclosure of Significant Financial Interests and at least every four years, and immediately when any of the following apply:
  - a. The College revises its policy or procedures on conflict of interest;
  - b. An Investigator is new to the College; or
  - c. The College finds that an Investigator is not in compliance with this policy
  
2. Disclosure – Each time a faculty member or other Investigator is planning to participate in proposed Research and Other Sponsored Projects, the faculty member and each other Investigator involved with the proposed Research and Other Sponsored Project must have completed and submitted the Annual Disclosure Form and an Update Disclosure Form and/or any other form then in effect, which forms will refer the faculty member or other Investigator to this policy (including the availability and public accessibility of this policy on the College's website). Such forms require, among other matters, disclosure of the faculty member's or other Investigator's and his/her Immediate Family's:
  - a. Significant Financial Interests (specifying if any such Significant Financial Interest is in an Affected Entity relative to the Research and Other Sponsored Projects);
  - b. Employment/management roles held in any Affected Entity relative to the Research and Other Sponsored Projects;
  - c. Any rights held in intellectual property covering products or processes being used in the Research and Other Sponsored Projects (including any right to Royalty Income from intellectual property assigned to the College under the College's intellectual property policies); and

- d. The occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to his/her institutional responsibilities (provided that this requirement does not apply to travel that is reimbursed or sponsored by: (i) a federal, state, or local government agency; (ii) an institution of higher education as defined at 20 U.S.C. 1001(a);
      - e. an academic teaching hospital; (iv) a medical center; or (v) a research institute that is affiliated with an institution of higher education). The disclosure shall include, at a minimum, the following information: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Additional information may be requested to determine whether the travel constitutes a Conflict of Interest.
3. Disclosures must be made prior to the submission of an application for the Research and Other Sponsored Projects to the sponsor, updated annually for the duration of the Research and Other Sponsored Projects, and updated within thirty days of acquiring any such new activity or interest (e.g., through gift, marriage or inheritance). The Investigator's disclosure forms must be submitted even if there is no interest, position or rights to disclose.
4. Disclosures shall be required of all individuals who are significant participants in the project, i.e., those who will be decision makers or is responsible for the design, conduct and/or reporting of the funded research, including the principal investigator, co-investigators, sub-investigators, collaborators, and consultants.
5. When a grant or contract proposal involves a subgrantee or subcontractor arrangement with investigator(s) at another institution, the written agreement with the subgrantee or subcontractor shall incorporate terms that establish whether the conflict of interest policy of the College or that of the subgrantee or subcontractor will apply to the subgrantee's or subcontractor's investigators. If it is the latter, the above referenced agreement must contain a written certification from the subgrantee or subcontractor that its policies are in full compliance with all applicable laws and the regulations of the funding agency. In addition, the above-referenced written agreement must specify time period(s) for the subgrantee or subcontractor to report all identified Conflicts of Interest to the College and any review and/or action taken with respect to such Conflicts of Interests. Such time periods must meet the College's disclosure and reporting requirements.

## **7.0 PROCEDURES: DISCLOSURES AND REVIEW**

The College is committed to ensuring an ethical and equitable environment in which to conduct teaching, in limited circumstances patient care and research while avoiding Conflicts of Commitment and Conflicts of Interest and even the appearance of such conflicts. Given the

complexity and diversity of personal and professional relationships and the fact that the perception of a Conflict of Commitment or Conflict of Interest may vary from individual to individual, the College has established a procedure according to which individuals may disclose their interests and activities so that the College may evaluate whether such interests and activities present an actual or potential Conflict of Commitment or Conflict of Interest.

**A. New Employees:**

New employees must review a copy of this policy and complete the Annual Disclosure Form prior to their first day of employment. The Annual Disclosure Form shall be distributed by and submitted to the Human Resources Department and reviewed in compliance with Section E below.

**B. Annual Notice:**

A copy of this policy shall be distributed annually to members of the College Community.

**C. Annual Disclosure Form**

With the annual distribution of a copy of this policy, an Annual Disclosure Form (which will refer to this policy, including the availability of this policy on the College's website or TouroOne portal) will be distributed. The Annual Disclosure Form is intended to solicit information so that the College can determine whether an individual has been or is currently involved in situations of conflict or potential Conflict of Commitment or Conflict of Interest with the College and its interests. Each individual to whom such a disclosure form is distributed will be expected to review his/her activities and relationships thoughtfully and thoroughly, complete and return the disclosure form each year. Consultation with one's Department, the School Dean, and/or the Office of Institutional Compliance should be sought when an individual is in doubt about whether an interest or activity creates a Conflict of Commitment or Conflict of Interest.

The Annual Disclosure Form requires, among other things:

1. Certification of compliance with this policy and related policies of the College and applicable school;
2. Disclosure of information about the employee's (and his or her Immediate Family Members) Outside Activities and other personal, professional, financial or other interests that may reasonably be perceived as giving rise to a Conflict of Interest as described in Articles 6 and 7 of this policy;
3. Disclosure of information about his or her Outside Activities as pertinent to a potential Conflict of Commitment as described in Article 5 of this policy; and
4. All of the following interests held by the employee and his or her Immediate Family in the aggregate in any Affected Entity:

- a. Each Employment/Management Role;
- b. All Ownership Interests (other than an interest in a publicly-traded corporation that does not exceed either (A) \$5,000 or (B) a five percent interest in any class of the corporation's securities);
- c. All Remuneration from an Outside Activity greater than \$5,000 in the past 12 months or expected to be greater than \$5,000 in the upcoming 12 months; and
- d. All Royalty Income greater than \$5,000 in the past 12 months or expected to be greater than \$5,000 in the upcoming 12 months.

The Annual Disclosure Form shall be submitted electronically within the time prescribed by the Human Resources Department, Office of Institutional Compliance or upon request. Failure to complete such a questionnaire responsibly and accurately or to return it as required shall be grounds for disciplinary action, which may include termination of employment or faculty appointment, or other dismissal from the College.

#### **D. Update Disclosure Form**

All members of the College Community have a continuing obligation to disclose on a timely basis current, proposed or pending situations that may raise questions of Conflict of Commitment or Conflict of Interest. Such disclosures must be made in advance of the conflict arising if possible, and otherwise within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) such situations. It is the duty of all members of the College Community to make such disclosures by submitting the Updated Disclosure Form to the Human Resources Department or Office of Research Administration. Failure to report a conflict shall be grounds for disciplinary action, which may include termination of employment or faculty appointment, or other dismissal from the College.

#### **E. Review Procedures for Annual Disclosure Forms**

Each January, the Human Resources Department of each campus will distribute the Annual and Updated Disclosure Forms to all members of their respective College Community. The Human Resources Department will collect and review all responses. Any disclosures with any actual or potential Conflicts of Interest or Conflicts of Commitment shall be sent to the Office of Institutional Compliance or, if research related, to the Office of Research Administration which shall resolve such conflicts in a timely manner. In making its determinations, the Institutional Compliance Office and/or the Office of Research Administration may consult with appropriate Department Heads, Deans, or Department Chairs. For disclosures related to Research and Other Sponsored Projects, the Office of Research Administration shall review the disclosures in accordance with the procedures in section 8. E below.

Disclosures related to all issues other than Research and Other Sponsored Projects shall be reviewed by the Office of Institutional Compliance. The Office of Institutional Compliance shall review each disclosures and evaluate any disclosed Significant Financial Interest or an actual or potential Conflict of Interest on a case by case basis, following the guidelines delineated in this policy as closely as possible. The Office of Institutional Compliance shall determine whether the Significant Financial Interest relates to the proposed research, and if so, whether a financial Conflict of Interest exists. A Significant Financial Interest is related to the User's compliance with the policy when the significant financial interest could be affected by the Outside Activity or is in an Affected Entity. A financial Conflict of Interest exists when the Significant Financial Interest could directly and significantly affect the User's obligations to the College. If the Office of Institutional Compliance reasonably determines that a financial Conflict of Interest exists, it shall develop and implement a management plan (see subsection F.3 below) to resolve or manage such financial Conflict of Interest.

## **F. Review Procedures for Disclosures Related to Research and Other Sponsored Projects**

### **1. Initial Review**

- a. Disclosures related to Research and Other Sponsored Projects shall be reviewed by the Office of Research Administration. Prior to commencement of a Research and Other Sponsored Project (including any enrollment of research subjects) or any expenditure of research funds, and consistent with the regulations of the applicable funding agency, the Office of Research Administration shall review each Investigator's disclosures and evaluate any disclosed Significant Financial Interest or an actual or potential Conflict of Interest on a case by case basis, following the guidelines delineated in this policy as closely as possible. The Office of Research Administration shall determine whether the Significant Financial Interest relates to the proposed research, and if so, whether a financial Conflict of Interest exists. A Significant Financial Interest is related to the proposed research when the significant financial interest could be affected by the proposed Research and Other Sponsored Project or is in an Affected Entity. A financial Conflict of Interest exists when the Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the proposed research. If the Office of Research Administration reasonably determines that a financial Conflict of Interest exists, it shall develop and implement a management plan (see subsection E.3 below) to resolve or manage such financial Conflict of Interest.

In the case of an ongoing Research and Other Sponsored Project, when a new Investigator discloses a Significant Financial Interest or an existing Investigator discloses a new Significant Financial Interest, the disclosure will be renewed in accordance with the procedures set forth herein, with the review and evaluation completed within sixty days, including implementation on an at least an interim basis of any necessary or appropriate management and/or mitigation plan, and with timely compliance with reporting required by the sponsor or funding agency.

2. Management Plan – In the event of an actual or perceived conflict, the Office of Research Administration and/or the Office of Institutional Compliance may request that the User provide, either in writing or via a meeting, more specific information before developing a management plan. A management plan to resolve the conflict may include, without limitation, one or more of the following mechanisms:
  - a. Stipulation that the User will publicly disclose the financial Conflict of Interest (e.g., when presenting or publishing the research);
  - b. Recommendation that the support for the Research and Other Sponsored Project be accepted only if the relationship between the Investigator and the sponsor, or the financial interest of the Investigator in the product, be modified or terminated in some specified way. The Investigator may choose to continue the relationship while withdrawing the request for financial support or approval to conduct the research; Stipulation that the support for the Research and Other Sponsored Project be accepted only if the proposal is modified in some specified way – e.g., to allow for continuous or regular, independent, external review of the project and its results, or to clarify or modify the participation of students in the project;
  - c. Change of research personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  - d. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial Conflict of Interest;
  - e. Recommendation that the funding agency be notified formally that a potential Conflict of Interest exists. This recommendation will depend largely upon the requirements of funding agencies, notably the federal and state agencies, for such disclosure;
  - f. Notification, in a timely fashion, to the Committee for the Protection of Human Subjects of the potential Conflict of Interest . This notification is necessary only when the proposal is for the support of a clinical trial or other research involving human subjects;
  - g. Recommendation that the College not accept external support for the Research and Other Sponsored Project.
  - h. Recommendation to reduce or eliminate the financial interest (e.g., sale of an equity interest.
  - i. Recommendation to sever a relationship that creates financial conflict.

3. Retrospective Review – Where a financial Conflict of Interest is present but was not disclosed or reviewed in a timely manner, the Office of Research Administration or the Office of Institutional Compliance will implement, on at least an interim basis, a conflicts mitigation plan that will include a retrospective review and determination as to whether the Research and Other Sponsored Projects, or any portion thereof, or the Outside Activity conducted prior to the identification and management of the Conflict of Interest was biased in the design, conduct, or reporting of such Research and Other Sponsored Projects or Outside Activity.
4. Compliance with Regulations – In developing, implementing and reporting any management plan, mitigation plan or retrospective review relating to Research and Other Sponsored Projects, the Office of Research Administration shall comply with all requirements of the applicable funding agency (notably, the regulations of the Department of Health and Human Services for any Public Health Service (PHS) funded research), including any and all time restrictions, due date requirements and reporting requirements.
5. Reporting to Funding Agencies – The Office of Research Administration will be responsible for submitting any notifications, periodic reports, updates, mitigation reports and/or retrospective reviews to the applicable funding agency as required by and in accordance with such agency’s regulations.
6. The disclosures made to the Office of Research Administration and the Office of Institutional Compliance and their deliberations are to be treated as highly confidential matters.
7. Enforcement – The Office of Research Administration and the Office of Institutional Compliance shall establish adequate enforcement mechanisms to ensure compliance as appropriate.
8. Records --The College shall maintain records of all financial and managerial disclosures and all actions taken with respect to each Conflict of Interest for three years beyond the date of submission of the final expenditures report to the applicable funding agency. Under special circumstances, or if required explicitly by the funding agency, records may be kept for a longer period. These records shall be maintained by the appropriate Office of Institutional Compliance and/or the Office of Research Administration.

## **8.0 STANDARDS FOR RESOLUTION OF CONFLICTS OR POTENTIAL CONFLICTS OF INTEREST**

In determining whether a relationship or situation involving a conflict or potential Conflict of Interest should or may be prohibited, modified, or managed by the College, the following considerations, among others, will be taken into account. The guidelines in this section are not meant to be either rigid or inclusive. Certain potential Conflicts of Interest, as outlined herein, may be acceptable in practice in particular cases. By the same token, one can imagine situations not

explicitly covered here that would not be appropriate or acceptable. It is our intent and hope that the mechanism set up for evaluating potential Conflicts of Interest, as outlined in other sections of this policy, will provide both for sufficient flexibility and sufficient consistency so that conflicts that may impede the College's mission are avoided, while at the same time, useful cooperation between the College and the community is fostered.

- A.** Will a requested or proposed resolution of a conflict or potential Conflict of Interest enhance, not meaningfully affect, or detract from the College's reputation, responsibility or obligation for the objective pursuit of truth in science and the education of students, or a favorable public perception of the College in the manner in which it carries out its mission, goals and objectives?
- B.** Is it possible, practically and realistically, to modify or manage a Conflict of Interest or potential Conflict of Interest so as to ensure objectivity in the work to be performed and in the results to be reported?
- C.** Have all proposed and preexisting relationships, interests and agreements, express or implied, involving the College employee or person in position of trust for the College (and members of his/her Immediate Family) and third parties involved in the Conflict of Interest been fully and adequately disclosed and inquired into?
- D.** Even if the particular conflict or potential Conflict of Interest under review is not individually likely to compromise the College's reputation, divert important opportunities from the College, or excessively benefit a College employee or person in a position of trust at the College, has serious consideration been given to the actual and potential negative effects on the College and its interests if, in the aggregate, multiple situations involving similar effects on the College were to be given approval?
- E.** Will a conflict or potential Conflict of Interest, if permitted as first presented or as subsequently modified, result in short-term benefits to the College that may, however, be outweighed by actual or potential long-term harm to the College, the morale of College faculty or staff and/or the College's reputation?
- F.** Should agreements or arrangements with other third-party entities be more beneficial to the College than the agreement or arrangement proposed by a College employee, faculty member or other person in a position of trust at the College be explored or solicited to ensure that the College will receive the benefits of the agreement or arrangement objectively most favorable to the institution as a whole?
- G.** Despite possible measures to modify or manage a Conflict of Interest at the College, might even just the apparent incentive for personal gain on the part of the College employee or other person in a position of trust at the College and the consequent challenge to his/her objectivity be sufficiently strong or questionable that the results of



the College individual's work will probably be subject to suspicion or criticism by others?

#### **H. In Cases of Research and Other Sponsored Projects**

1. Research sponsored by a company or agency in which the Investigator has a financial or managerial interest presents a Conflict of Interest. The Office of Research Administration, together with the Office of Institutional Compliance should evaluate whether the Investigator's influence within the company or agency might cause the normal review of the application for support to be short-circuited, thus bypassing an important component of science's system of checks and balances. Another issue to consider is whether the Investigator might be using the College and its resources (space, equipment, students, etc.) to support and further his or her external interests.
2. Although reasonable consultation fees, honoraria or paid travel are normally acceptable, a potential conflict may arise when an Investigator seeks research support from a company or agency from which the Investigator has accepted significant amounts of gratuities or special favors. Thus, any payment for services not otherwise identified as salary – e.g., consulting fees, honoraria, paid authorship, reimbursed travel or sponsored travel related to institutional responsibilities – must be disclosed and evaluated by the Review Committee.
3. Promises of future considerations (consultancies, ownership, royalties, etc.) in connection with or contingent upon the results of the proposed research are also problematic.
4. Research evaluating a product in which the Investigator holds a financial interest is particularly problematic. The severity of the problem increases with the magnitude of the financial interest. Early developmental research on a product by its inventor is undeniably justifiable, whatever the inventor's financial stake. However, an Investigator's financial interest in a product (e.g., through ownership in equity or intellectual property rights, such as patents or copyrights) may be significant as to constitute a financial Conflict of Interest. Thus, as a general rule, it is inappropriate for an Investigator who has a Significant Financial Interest in a product to conduct research that evaluates the suitability of that product for public consumption, particularly in the case of new drugs or other biomedical products.
5. The principle outlined in the previous guideline may be applied as well to the College itself. There may be cases in which the College has patent or licensing rights, or an equity interest in a product that is to be evaluated for efficacy or safety as a prelude to public availability. Careful consideration must be given to the propriety of such evaluative research being done by any individual associated with the College, even if the individual has no personal financial interest in the product.
6. Situations may arise in which a company offers to donate money, equipment or other resources to the College in exchange for access to specialized laboratories or professional expertise in the College. These arrangements may present valuable

opportunities for the College and a chance for fruitful collaboration between the College and industry. The College should be careful, however, that such arrangements do not clash with its primary academic, educational and service missions.

7. In all of the instances outlined above, reference to the financial or managerial interests in an external company or agency of any individual faculty member, administrator or other employee of the College is intended to include the financial and managerial interests of that individual's Immediate Family. Major financial interests of the Investigator's parents or by the parents of the Investigator's spouse may also be considered in evaluating potential Conflicts of Interest.
8. The Office of Research Administration, together with the Office of Institutional Compliance shall be guided by relevant regulations established by funding agencies, particularly those of the Public Health Service ("PHS") of the
9. U.S. Department of Health and Human Services, 42 C.F.R. §601 et seq., with regard to thresholds for external reporting of Conflicts of Interest to funding agencies.

## **9.0 REQUESTS FOR INQUIRY**

It is the College's expectation and requirement that all persons subject to this Conflicts of Interest and Conflicts of Commitment policy will endeavor faithfully to comply with its terms and requirements. In the event, however, that any person shall have reason in good faith to believe that a member(s) of the College community subject to this policy is not in compliance with the policy through ignorance, inadvertence or otherwise, that person is requested to report his/her concern in a timely manner, on an identified or an anonymous basis, in writing or by telephone, to the College's Compliance Officer or the Chief Compliance Officer. Thereafter, the Compliance Officer or Chief Compliance Officer shall conduct the appropriate inquiry into the facts and process any matters coming within this policy as provided by its terms.

## **10.0 INTERPRETATIONS**

The Chief Compliance Officer of the College or his/her designee shall have the authority to issue interpretations of the terms and provisions of this policy which shall be binding on the participants subject to review by the Board of Trustees or its Audit Committee.