



TOURO UNIVERSITY

C A L I F O R N I A

CONFLICTS OF INTEREST POLICY

Policy 5.3,

Volume 5, Research

Chapter 003, Conflicts of Interest Policy

Responsible Executive, Office of Sponsored Programs, Review Committee, Provost

Executive Council Approval Date, August 13, 2012

Originally Issued, August 1, 2012

Updates and Complements, Touro College and Touro University Conflicts of Interest Policy,
November 17, 2010

Revised,

WHO SHOULD READ THIS POLICY

- Dean, Associate and Assistant Deans
- University Research and OSP Director
- Fiscal Officers
- Program Directors, Department Chairs, Faculty

REASON FOR POLICY

I. General Principles

Touro University California ("University") is an educational and research institution dedicated to the pursuit of knowledge and to the principle of free, open and objective inquiry into the conduct of its teaching, research and service missions. The faculty and employees at the University share its commitment to these goals.

The University has been given special privileges and exemptions by society in relation to the activities it performs and teaches others to perform. It is the responsibility of the University and its employees, in consideration of this public trust, to carry out these purposes and objectives with integrity. It is essential that all members of the University community deal with all others humanely, with consideration, fairness and honesty. It is further incumbent upon all faculty and employees neither to engage in any improper conduct nor to create the perception of improper conduct that could adversely affect the University's reputation, welfare and morale.

POLICY STATEMENT:

II. Purpose

To establish guidelines and set standards for faculty and employees to share with the University in its commitment to achieve the highest level of ethical conduct in its teaching, research and service missions. To ensure that the University meets its academic and research obligations with integrity and that all members of the University community deal with all others humanely, with consideration, fairness and honesty. It is further incumbent upon all faculty and employees neither to engage in any improper conduct nor to create the perception of improper conduct that could adversely affect the University's reputation, welfare and morale.

This policy is more general than other policies and procedures prescribed by the University for specific subjects and circumstances, such as those set out in policies covering sponsored programs and all research programs, intellectual property and patent rights, in published academic standards, or in regulations issued by federal and state agencies relating to government sponsored grants and contracts. This policy does not displace or supersede these more specific policies and procedures, but extends and complements them. It is the obligation of each employee or faculty member to be aware of those policies pertinent to his/her function and responsibilities.

III. Applicability

This Code of Conduct applies to all University employees, faculty, students and any individual engaged in research at the University.

IV. Definitions

"Affected Entity" means an entity other than Touro University California 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 faculty member's Outside Activities compromise or may compromise his/her ability to meet the faculty member's obligations at the University.

"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 University and the interests of the

University. 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 University, 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 University Research and Other Sponsored Projects.

"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-University related activity. Such Outside Activities must be in compliance with all University 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 University.

"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 University in

accordance with the University's intellectual property policies, including its Statement of Policy on Patents.

"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 or 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 University:

1. With regard to any publicly traded entity, a Significant Financial Interest exists if (i) 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
2. 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
3. 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:

- a. Salary, royalties, or other remuneration paid by the University while the recipient is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
- b. 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;
- c. 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

- d. 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.

V. Conflicts of Commitment

Faculty must not allow Outside Activities to detract from their obligations to the University. A Conflict of Commitment occurs when a faculty member's Outside Activities compromise or may compromise his/her ability to meet the faculty member's obligations at the University.

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 University policies.

A. Full-Time Faculty

Full-time faculty members at the University owe their primary professional allegiance to the University, and their primary commitment of time and intellectual activities should be to the University's teaching, research, and clinical programs. Appointment as a full-time faculty member is inconsistent with engaging in significant Outside Activities. Regardless of the guidelines below, Outside Activities must not interfere with the faculty member's primary responsibilities to the University. Thus, full-time faculty members must comply with the following regarding all Outside Activities prior to engaging in such activities:

1. Timely disclose in writing all Outside Activities to the appropriate Department Chair, with copies to the appropriate School Dean and the Provost;
2. Obtain the prior written approval of the 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 work day).

Exceptions to the aforementioned limitation and prohibition are rare and may be made only with the prior written approval of the School Dean.

B. Part-Time Faculty

Part-time 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 University.

VI. 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 University and the interests of the University. 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 University employee, whether faculty or staff, or anyone else in a position of trust at the University, to gain a financial benefit at the University's expense, beyond normal compensation or as otherwise permitted by express University policy. Financial benefits are gained at the University's expense when an individual diverts or misuses the University's resources or privileges afforded by association with the University 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 University away from the University or to some restricted University purpose when the restriction is not necessary.

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

A. Financial Interests

No individual who is an employee or faculty member in a position to influence the outcome of a transaction affecting the University 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 University'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 University on the basis of whether or not the judgment or discretion of the individual in matters affecting the University is or may be influenced by consideration of personal gain or financial benefit.

B. University's Name and University Association

The name of Touro University California and the privilege of association with the University 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 University'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 Provost and Senior Provost.

In situations in which association of a faculty or staff member with the University 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 University, unless that person is speaking in his capacity as a faculty member or employee and such statements are consistent with the position of the University.

The University 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 University, even though the same faculty might be engaged independently in billing for professional clinical services individually or through their employment by other organizations. 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 University or any University department or component. This policy does not preclude a faculty member from identifying oneself with the University 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. University Property and Resources

All University 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 University in carrying out its mission and purposes. University property and resources may not be used for personal use, including in Outside Activities, and may not be diverted away from the University to the benefit of any other organization or individual. University property includes information that would not normally be available for public disclosure without approval of the Provost.

D. Confidential Information

The University's confidential information includes information that would not normally be available for public disclosure without approval of Provost, or other appropriate administrative or academic officer. Obtaining, using or disclosing University confidential information for direct or indirect personal interest, profit or advantage or, for a purpose that may be detrimental to the University creates a Conflict of Interest. Use of University confidential information for a purpose that is not authorized by the University or disclosure of University confidential information to a person who or entity that is not authorized by the University 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 employee or faculty member 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 University.

F. Political Contributions and Lobbying

By law, no contributions may be made by TUC (whether directly or through reimbursement), by anyone acting on behalf of TUC, or with any funds of TUC 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 University may be used for lobbying public officials except as lawfully permitted and with written approval of the Provost.

G. Outside Activities

Faculty must not allow Outside Activities or other personal activities to detract from their primary obligations to the University, 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 University 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 University may create a similar conflict. These interests and activities should be disclosed according to the procedures described in this policy.

VII. Conflicts of Interest in Research and Other Sponsored Projects

A. Principles

The University 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 University 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 University community who engages in or seeks to engage in University Research and Other Sponsored Projects has the responsibility to disclose to the University 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 University 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 University 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.

The University'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,

limits 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 University for which extramural support is sought, Investigators shall be required to complete training on the University'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 University revises its policy or procedures on conflict of interest;
 - b. An Investigator is new to the University; or
 - c. The University 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 of this policy on the University'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 University under the University'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); (iii) 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.

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 University 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 University and any review and/or action taken with respect to such Conflicts of Interests. Such time periods must meet the University's disclosure and reporting requirements.

VIII. Procedures: Disclosures and Review

The University 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 University has established a procedure according to

which individuals may disclose their interests and activities so that the University may evaluate whether such interests and activities present an actual or potential Conflict of Commitment or Conflict of Interest.

A. Annual Notice

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

B. 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 TUC website) will be distributed that is intended to solicit information so that the University 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 University 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 Provost should be sought when an individual is in doubt about whether an interest or activity creates a Conflict of Commitment or Conflict of Interest.

Such Annual Disclosure Form requires, among other things:

1. Certification of compliance with this policy and related policies of the University and applicable school;
2. Disclosure of information about the faculty member'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 VI and VII 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 V of this policy; and
4. All of the following interests held by the faculty member 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 (either in print or, when available, electronically) within the time prescribed. 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 University. A summary report of the disclosures received shall be provided to the Office of Sponsored Programs, and the Provost.

C. Update Disclosure Form

Faculty members, employees and Investigators shall 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, 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. Such disclosures shall be made by submitting the Update Disclosure Form to the Office of the Provost.

D. Review Procedures for Annual and Update Disclosure Forms

Annual and Update Disclosure Forms will be reviewed by Office of the Provost. For disclosures related to Research and Other Sponsored Projects, the Office of Institutional Compliance shall refer such disclosures to the Office of Sponsored Programs, which shall review the disclosures in accordance with the procedures in section VIII. E below. For all other disclosures, Office of the Provost shall review, determine whether there are any actual or potential Conflicts of Interest or Conflicts of Commitment, and resolve such conflicts in a timely manner. In making its determinations, the Provost may consult with appropriate School Deans, Department Chairs, and the Committee for Review of Conflicts of Interest (the "Review Committee") (see section VIII.F below).

E. Review Procedures for Disclosures Related to Research and Other Sponsored Projects

1. **Initial Review** Disclosures related to Research and Other Sponsored Projects shall be reviewed by the Office of Sponsored Programs. 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 Sponsored Programs 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 Sponsored Programs 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 Sponsored Programs 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. **Review by the Review Committee-** Any actual or potential Conflicts of Interest not resolved by the Office of Sponsored Programs shall be referred to the Review Committee (see section VIII.F below), which shall develop and implement a management plan (see subsection E.3 below) to resolve or manage such financial Conflict of Interest.

Upon timely review and deliberation on a Conflict of Commitment or Conflict of Interest case, the Review Committee shall make its recommendation to the Office of Sponsored Programs and the appropriate School Dean. The School Dean will decide on the propriety of each Conflict of Interest involving external support of faculty research within the School Dean's authority. It is anticipated that the School Dean will follow the Review Committee's recommendations closely.

3. **Management Plan-** The Office of Sponsored programs and/or the Review Committee may request that the Investigator 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 Investigator 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;
 - c. 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;
 - d. Change of research personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - e. 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;
 - f. 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;
 - g. Notification, in a timely fashion, to the Committee for the Protection of Human Subjects of the potential Conflict of Interest and of the Review Committee's recommendation. This notification is necessary only when the proposal is for the support of a clinical trial or other research involving human subjects;
 - h. Recommendation that the University not accept external support for the Research and Other Sponsored Project.
4. **Retrospective Review**-Where a financial Conflict of Interest is present but was not disclosed or reviewed in a timely manner, the Office of Sponsored Programs and/or the Review Committee 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, 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.

5. **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 and the Review Committee 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.
6. **Reporting to Funding Agencies**- The Office of Sponsored Programs 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.
7. The disclosures made to Office of Sponsored Programs and Review Committee and their deliberations are to be treated as highly confidential matters. Notification of actual or potential Conflicts of Interest or Conflicts of Commitment and the Review Committee's recommendations and the School Dean's decision regarding each case shall be given only to the following as applicable and necessary:
 - a. The School Dean, as a recommendation for his or her executive judgment;
 - b. The Committee for the Protection of Human Subjects and the Institutional Review Board, when the proposal is for research involving human subjects. In order to expedite the complete review of such proposals, the Committee for the Protection of Human Subjects will be informed of both the Review Committee's initial recommendation and the School Dean's final ruling;
 - c. The Office of Sponsored Programs in cases involving Research and Other Sponsored Projects;
 - d. The applicable funding agency (ies), when this is required. Ordinarily, the Office of Sponsored Programs will be responsible for notifying external agencies regarding Conflicts of Interest;
 - e. The principal investigator and to the Investigator(s) with the identified conflict (if different), each of whom will need to agree to the plan(s) before the Research and Other Sponsored Projects may proceed;

- f. The Investigator's Department Chairperson, who will be informed of the final decision;
 - g. The Provost, in any case in which a significant Conflict of Interest or Conflict of Commitment would be one in which the Investigator is bound by some constraint beyond simple disclosure of a relationship with the sponsor in publications. The Provost need not be informed if an application is withdrawn in response to the recommendation of the Review Committee or to the School Dean's ruling;
 - h. **Public Access**-If required by the applicable external funding agency (e.g., regulations of the Department of Health and Human Services for any PHS-funded research), the Review Committee shall determine the method and content of any public disclosure of a financial Conflict of Interest, such as posting (by the Office of Sponsored Programs) on a publicly accessible Web site, or by written response to any requestor within five business days of a request for information, and shall update such information in accordance with such requirements.
8. **Enforcement**- The Office of Sponsored Programs and the Review Committee shall establish adequate enforcement mechanisms to ensure compliance as appropriate.
9. **Records** --The University 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 School Dean's office and/or the Office of Sponsored Programs.

F. Committee for Review of Conflicts of Interest

- 1. The Provost in consultation with the Executive Committee of the Faculty Senate shall appoint a Committee for Review of Conflicts of Interest (the "Review Committee"). The membership of this Review Committee shall include no fewer than three full-time, senior faculty members (associate and full professors). Appropriate representatives of the Administration, such as from the Offices of Sponsored Programs, shall also be included as ex-officio members. The Review Committee's membership should include sufficient breadth of expertise so as to be able to evaluate the nature of proposals that come before the Review Committee, i.e., the membership should include both clinicians and basic scientists. It would also be valuable

towards achieving a balanced committee if some of the members have had previous professional contact with industry, e.g., as consultants or recipients of grants or contracts. Members of the Review Committee shall be appointed to serve 3-year terms. Terms shall be staggered so that there is significant year-to-year continuity in membership. If a case comes before the Review Committee that involves a company or other external agency in which a member of the Review Committee has significant managerial or financial interests, that committee member shall excuse himself or herself from the Review Committee's deliberations with regard to that particular case.

2. It is within the scope of this policy for the Review Committee, with the approval of the appropriate administrative officials, to delegate part of the review and action process implemented under this policy to a designated administrative official or office. The Review Committee, however, shall retain its responsibility and authority to ensure a fair and uniform interpretation and implementation of this policy.
3. It is anticipated that the Review Committee will devise its own explicit or de facto guidelines for judgment, based upon its evolving experience, consistent with applicable laws and regulations. In order that the process of evaluating Conflicts of Interest be itself evaluated by the University community, the Chairman of the Review Committee shall be required to submit an annual report to the Provost, the Provost, and the School Deans of the respective Schools summarizing both the number and types of cases and decisions it considered during the year and also describing the principles it used in reaching those decisions. The Review Committee is encouraged to recommend changes in procedure or other aspects of this policy as it sees fit. This annual report shall also be forwarded to the Executive Committee of the Faculty Senate. Moreover, the Chairman of the Review Committee shall be required to meet with the Executive Committee at least once every 2 years to discuss conflict of interest policy and the operation of the Review Committee.
4. The Review Committee may also be used as a forum for evaluating potential Conflicts of Interest that may arise independently of some specific application for research support. For example, an outside company may wish to donate a substantial piece of equipment to the University in exchange for some consideration. Many other possibilities might also serve as examples. The Provost, the School Deans or other relevant official may submit the idea to the Review Committee, whose input to the overall decision making process would be valuable. The role of the Review Committee in this case is to offer its opinion as to the propriety of the arrangement. This opinion would be viewed as valued input because of the Review Committee's familiarity with the ethical

issues that might be involved in such an arrangement. Such out of the ordinary ventures, however, should also be discussed thoroughly within the administrative leadership, among the faculty, as represented by the Faculty Senate, and within the Board of Trustees, as would be appropriate for the specific case.

IX. 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 University, the following considerations, among others, will be taken into account. The guidelines in this Article IX 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 Articles of this policy, will provide both for sufficient flexibility and sufficient consistency so that conflicts that may impede the University's mission are avoided, while at the same time, useful cooperation between the University 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 University'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 University 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 University employee or person in position of trust for the University (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 University's reputation, divert important opportunities from the University, or excessively benefit a University employee or person in a position of trust at the University, has serious consideration been given to the actual and potential negative effects on the University and its interests if, in the aggregate, multiple situations involving similar effects on the University 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 University that

may, however, be outweighed by actual or potential long-term harm to the University, the morale of University faculty or staff and/or the University's reputation?

- F. Should agreements or arrangements with other third-party entities be more beneficial to the University than the agreement or arrangement proposed by a University employee, faculty member or other person in a position of trust at the University be explored or solicited to ensure that the University 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 University, might even just the apparent incentive for personal gain on the part of the University employee or other person in a position of trust at the University and the consequent challenge to his/her objectivity be sufficiently strong or questionable the results of the University 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 Review Committee 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 University 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 University itself. There may be cases in which the University 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 University, 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 University in exchange for access to specialized laboratories or professional expertise in the University. These arrangements may present valuable opportunities for the University and a chance for fruitful collaboration between the University and industry. The University 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 University 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 Review Committee shall be guided by relevant regulations established by funding agencies, particularly those of the Public Health Service ("PHS") of the 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.

X. Requests for Inquiry

It is the University's expectation and requirement that all persons subject to this Code of Conduct and 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 University 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 University's Provost.

Thereafter, the Provost or shall conduct the appropriate inquiry into the facts and process any matters coming within this policy as provided by its terms.

XI. Interpretations

The Provost of Touro University California shall have the authority when he or she deems it necessary 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.