

THE UNIVERSITY OF CHICAGO

**CONFLICT OF INTEREST AND CONFLICT OF COMMITMENT POLICY  
FOR FACULTY AND OTHER ACADEMIC APPOINTEES**

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## I. Defined Terms

“Assurance” means the written declaration of a Covered Person assuring their compliance with this policy, submitted in accordance with Appendix A.

“Conflict of commitment” (CoC) means a situation in which a Covered Person’s outside professional or commercial activities, whether paid or unpaid, interfere or have the potential to interfere with his or her Institutional Responsibilities

“Conflict of interest” (COI) means a situation in which a Covered Person’s Significant Financial Interests or other personal interests *directly and significantly* affect the performance of Institutional Responsibilities, or could reasonably be perceived to do so, as determined by the University.

“Covered Persons” means (i) all faculty and other academic appointees (as defined in University Statute 11) of the University, (ii) all individuals who are permitted by virtue of their appointment at the University or by approval of the Provost’s office to serve as Principal Investigator, (iii) all "Investigators" or "Key personnel," and (iv) all other appointees and title holders designated by the Provost or by agreement as covered by this policy.

“Significant Financial Interest” means anything of monetary value that does or could reasonably be perceived to *directly and significantly* affect the design, conduct or reporting of funded research, or the performance of other Institutional Responsibilities, whether or not the value is readily ascertainable.<sup>1</sup> “Significant Financial Interests” can include, but are not limited to, salary or other payments for services (e.g., appointment or employment at another institution, consulting fees or honoraria), royalties from the University of Chicago or other organizations, equity interests (e.g., stocks, stock options or other ownership interests) and intellectual property rights (e.g., patents, patent applications, copyrights, licenses and royalties from such rights). For purposes of disclosure of Significant Financial Interests, Covered Persons must disclose their own Significant Financial Interests, as well as

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<sup>1</sup> Please note that the word “Significant” in “Significant Financial Interest” (a term used to track the terminology in the Public Health Service conflict of interest regulations) refers to the potential that the financial interest could affect the design, conduct or reporting of research, not to the dollar value of the financial interest. The University has established a zero threshold for disclosure reporting both in dollar value and in percentage (%) of equity holding, meaning that if the financial interest could reasonably be perceived to directly and significantly affect the design, conduct or reporting of research, it must be reported even if its dollar value or percentage is de minimus.

Significant Financial Interests of their spouse or University-registered domestic partner and dependent children. Although Significant Financial Interests do not include income from seminars, lectures, or teaching engagements sponsored by US-Governmental or -Academic Entities, and income from service on advisory committees or review panels for US-Governmental or -Academic Entities, income that is sponsored or sourced from third parties other than US-Governmental or -Academic Entities (e.g., universities and research institutes located outside of the United States) is included. In addition, the performance of these activities (whether in connection with a US-Governmental or -Academic Entity or otherwise) may require disclosure to and approval by the chair and dean for conflict of commitment purposes (e.g., when the activities are conducted during a period of residence as defined in the Statutes) or require disclosure to funding agencies in accordance with applicable regulations or agency requirements. Investments such as mutual funds and retirement accounts do not need to be disclosed as long as the investment decisions in underlying assets are not made by the Covered Person.

“Institutional Responsibilities” means the professional responsibilities and obligations of a Covered Person to and on behalf of the University, as defined in any agreement or document governing the Covered Person’s relationship to the University, the University’s Statutes, and policies of the University, including, as applicable, responsibilities for (i) designing, conducting, collaborating on, and reporting research, (ii) teaching and mentoring of students, (iii) professional practice (e.g., clinical practice), (iv) service on boards and committees in any of the units that comprise the University or its affiliates, (v) administrative affairs at any level within the University (including appointments, promotions, and dealings with student affairs), and (vi) other activities that promote the activities and mission of the University.

“Investigator” means the project director, Principal Investigator (PI), co-Principal Investigators, co-Investigators or any other person, regardless of title, who has the ability to make independent decisions related to the design, conduct, or reporting of research or educational activities or for proposals for funding. “Investigator” as defined for these purposes is not limited to those individuals titled or budgeted as “investigators” on a particular proposal, but does not include individuals who perform only incidental or isolated tasks. Typically students would not be considered “Investigators” although there may be circumstances where, in the PI’s judgment, a student is working relatively autonomously and should be considered an “Investigator.”

“Key personnel” means Investigators who, although not the PI on a project, have independent responsibility for their contributions to the design, conduct and reporting of research. Key personnel are normally recorded as such in the grant application, progress report, or any other report submitted to the research sponsor by the University. Key personnel must disclose their Significant Financial Interests to the University.

“PHS-Funded Investigator” means any Investigator who is engaged in any research project funded by the Public Health Service (PHS) of the U.S. Department of Health and Human

Services, including any component of the PHS (e.g., the National Institutes of Health).

“US-Governmental or -Academic Entity” means a (i) federal, state, or local government agency in the United States, (ii) an institution of higher education in the United States as defined in 20 U.S.C. 1001(a), or (iii) an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education described in (ii). For clarity, a US-based foundation or other not for profit entity that is not affiliated with an institution of higher education in the United States as defined in 20 U.S.C. 1001(a) is not a “US-Governmental or -Academic Entity” for purposes of this Policy.

## **II. To whom does this Policy apply?**

This policy applies to all Covered Persons at the University of Chicago.

The University has a separate Conflict of Interest policy for staff employees.<sup>2</sup> Staff employees who engage in professional or commercial activities outside the University should ensure that these activities do not interfere with their obligations to the University. Staff employees should neither profit nor gain any advantage from any endeavor that may come, or reasonably appear to come, at the expense or well-being of the University or its reputation. If the outside interest of the staff employee is directly related to the research or University activity in which he or she is engaged, the staff employee must disclose the outside interest in accordance with the staff policy. If a staff employee meets the definition of a "Covered Person," that staff employee must separately comply with this Policy in addition to the Conflict of Interest policy for staff employees.

## **III. What is a Conflict of Interest?**

This policy addresses situations in which there is or might reasonably be perceived to be a potential conflict between a particular personal interest or Significant Financial Interest of a Covered Person and that Covered Person’s Institutional Responsibilities. In such situations a Covered Person’s profit or advantage may come, or may reasonably appear to come, at the expense of the University’s interests. An individual conflict of interest is thereby generated.

Outside professional or commercial activities or Significant Financial Interests conflict with Institutional Responsibilities when they bias or could appear to bias the nature, direction or reporting of scholarly research, or when they influence a Covered Person’s decision or behavior with respect to teaching and student affairs, appointments and promotions, service on University committees and boards, or other matters of professional responsibility to the University. Sensitivity to these potential conflicts of interest is especially important when a Covered Person has substantial involvement in a commercial enterprise related to that

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<sup>2</sup> The University’s conflict of interest policy for staff is located at <http://hr.uchicago.edu/policy/p600.html>.

Covered Person's research, or when the Covered Person is engaged in prolonged and intensive consultancies.

It is ultimately the responsibility of University officials, not the Covered Person, to assess the effects of any particular Significant Financial Interest, including the relatedness of the Significant Financial Interest to Institutional Responsibilities and whether the Significant Financial Interest creates a Conflict of Interest, and to determine the proper management, reduction or elimination of a conflict of interest. The designated University office for determination of faculty financial conflict of interest matters is the Office of the Provost.

Covered Persons who are PHS-Funded Investigators are as a matter of federal regulation subject to additional conflict of interest requirements as described in the section VI. below.

In addition, applicable federal regulations and agency requirements (e.g., issued by National Institutes of Health, National Science Foundation, Department of Energy, Department of Defense, etc.) often also require that Covered Persons report financial or other relationships with outside entities to funding agencies.<sup>3</sup> Covered Persons are responsible for understanding and complying with these additional disclosure and reporting requirements. *Disclosure to the University under this Policy is not sufficient to satisfy all disclosure and reporting obligations to funding agencies.* Covered Persons should consult with University Research Administration to ensure they are aware of, and complying with, agency-specific disclosure obligations that are not covered by this Policy.

#### **IV. What is a Conflict of Commitment?**

A conflict of commitment occurs when a Covered Person's outside professional or commercial commitments, whether paid or unpaid, interfere or have the potential to interfere with his or her Institutional Responsibilities. In general, an individual appointed to full-time service under University Statute 11 owes the University all of his or her professional effort during quarters in residence, regardless of when that effort is expended (e.g., nights and weekends), and may not have an academic appointment at another institution, except for visiting appointments during an approved leave of absence or when out of residence, or brief transitional appointments as approved by the Provost. To sustain the contribution that is consistent with these obligations to the University, the time committed by full-time employees to outside professional or commercial activities must not exceed 11 days per academic quarter.

*A member of the Faculty or an academic appointee under Statute 11.2 during the Quarters of residence may not engage in consultation, teaching at other universities, regular*

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<sup>3</sup> These disclosures are sometimes referred to by federal agencies as "other support", "current and pending support" or "active and pending support."

*compensated lecturing, compensated editorial activities, or other substantial outside employment, unless such activity is consistent with the faculty member's or academic appointee's obligations to the University, is not inimical to the fullest development of scholarly activities, and meets with the approval of the faculty member's or academic appointee's Chair and Dean. [University Statute 14]*

Traditional academic responsibilities such as preparing papers, speeches, evaluations, articles, scripts, musical scores, books and graphic works for publication, performance, oral presentation, peer review, or for display, for which royalties, honoraria, or the like are received, are considered a part of a Covered Person's Institutional Responsibilities and are not considered outside professional activities.

## **V. Why does the University have a Conflict of Interest/Conflict of Commitment Policy?**

Participation in outside professional or commercial activities makes important direct and indirect contributions to the strength and vitality of the University. Through participation in such activities, Covered Persons add to the knowledge and understanding that is relevant and useful to teaching and research, develop sources of funding and support for their activities and establish relationships valuable to the University. Because of its value to the University, to individual Covered Persons, and to the larger society of which the University is a part, the University recognizes that limited participation of Covered Persons in outside professional or commercial activities is fully appropriate.

It is essential, however, to have a policy in place to guard against the dangers of inappropriate or excessive outside interests or participation. This policy also serves to protect the interests of Covered Persons through advancing a very positive goal: defense of the integrity and objectivity of the research and scholarship carried out at the University.

The basic elements of this policy are articulated in "University Statute 14: Residence Requirements for Members of the Faculty," which states in relevant part: "A member of the Faculty during the Quarters of residence may not engage in consultation, teaching at other universities, regular compensated lecturing, compensated editorial activities, or other substantial outside employment, unless such activity is consistent with the faculty member's obligations to the University, is not inimical to the fullest development of scholarly activities, and meets with the approval of the faculty member's Chairman and Dean." The minutes of the Council of the University Senate for March 10, 1987 describe the Senate's discussion and approval of the "University Policy on Outside and Commercial Activities of Faculty."

Involvement in outside professional or commercial activities has become increasingly complex, which makes it impossible to set out detailed guidelines in advance for resolving all situations. Sound administrative discretion is an integral part of the University's procedures for dealing with conflicts of interest and conflicts of commitment. While disclosure alone does not resolve these conflicts, disclosure is necessary to initiate the

process for dealing with them and routes information to the appropriate administrators.

Within this framework, review of a potential conflict of interest is undertaken in light of five general propositions.

First, conflicts of interest *per se* are inevitable, and do not represent any impropriety by Covered Persons when disclosed in advance. Second, failure by any Covered Person to disclose a conflict of interest for administrative review and response would be a violation of University policy. Third, there is a presumption in favor of allowing Covered Persons to act in dual roles once the conflict of interest has been disclosed. Fourth, conflicts of interest may be so profound under some (limited) circumstances that it would be best for all concerned if the Covered Persons did not participate in a particular transaction. Fifth, the Provost's Office will draw up a Management Plan that describes a set of required actions to eliminate, reduce, mitigate or diminish the impact of conflicts of interest. The goal of the Management Plan is to assure the objectivity of research conducted at the University and maintain integrity in the conduct of University duties. The terms of the Management Plan will be implemented by the Covered Persons in concert with his/her department Chair and others. In this way, the conflict of interest is rendered manageable.

While this policy describes a formal procedure for the assurance of compliance with the University's policy regarding financial conflict of interest, it is not intended to substitute for or replace the traditional communication and informal discussions between faculty members and their department Chairs, Directors and Deans regarding outside activities. Such communication or consultation does not supplant compliance with this policy.

The history of the University Conflict of Interest policy is summarized in Appendix B.

## **VI. What must be disclosed?**

The processes for disclosure of Significant Financial Interests and outside professional or commercial activities are described in detail in [Appendix A](#).

### **A. Conflict of Interest Disclosures**

Covered Persons are responsible for disclosing to the University, using the processes described in this policy, their Significant Financial Interests (and those of their family members) that could reasonably appear to affect the design, conduct or reporting of their research or their performance of other Institutional Responsibilities. Put another way, if a Covered Person has a Significant Financial Interest that does or could reasonably appear to affect his or her research, teaching or other University activities or duties, then disclosure is required. Covered Persons may have difficulty in determining whether a financial interest could reasonably appear to effect his or her research and therefore constitute a Significant Financial Interest. Accordingly, Covered Persons should always err on the side of reporting.

As defined in this Policy, “Significant Financial Interests” can include, but are not limited to, salary or other payments for services (e.g., consulting fees or honoraria), royalties from the University of Chicago or other organizations, equity interests in companies (e.g., stock, stock options or other ownership interests), and intellectual property rights (e.g., patents, patent applications, copyrights, licenses and royalties from such rights).

In the absence of known valuation of stock options or equity holdings, disclosure to the University of the existence of options or holdings is still required. The true value of that interest may not be known until a later time (e.g., when the firm goes public) but the Covered Person should if possible make a reasonable assessment of the future market value of the options or equity.

“Significant Financial Interests” do not include income from seminars, lectures, or teaching engagements sponsored by a U.S.-Governmental or -Academic Entity, and income from service on advisory committees or review panels for such U.S.-Governmental or -Academic Entities. However, the performance of these activities may require disclosure to and approval by the chair and dean for conflict of commitment purposes, e.g., when the activities are conducted during a period of residence as defined in the Statutes. Investments such as mutual funds and retirement annuities do not need to be disclosed as long as the investment decisions in underlying assets held by the mutual fund or annuity are not made by the Covered Person.

## **B. Conflict of Commitment Disclosures**

Concerning conflicts of commitment, Covered Persons are also required (i) to disclose to and receive prior approval from their chair and dean for all outside professional or commercial activities of any length of time, and (ii) to disclose to the University annually as part of the assurance and disclosure processes described in Appendix A any outside professional or commercial commitments, whether paid or unpaid and whether or not approved in accordance with this policy, that interfere or have the potential to interfere with obligations and commitments to the University. In the context of outside consulting activities, this obligation of disclosure requires that Covered Persons disclose such arrangements to their chair and dean in advance to assure that the arrangement does not interfere with the Covered Person's Institutional Responsibilities. Outside consulting is defined as the performance of services for which remuneration in any form is received by the Covered Person from a person, firm or corporation other than the University of Chicago (or the University of Chicago Medical Center).

## **C. Assessment and Updating of Disclosures**

It is ultimately the responsibility of the University, not the Covered Person, to assess the effects of any particular Significant Financial Interest or outside professional or commercial commitments, and whether a Significant Financial Interest creates a Conflict of Interest, and

to determine the proper management, reduction or elimination of a conflict of interest or conflict of commitment. The designated University office for determination of faculty financial conflict of interest and conflict of commitment matters is the Office of the Provost.

Covered Persons are also required to update disclosures of Significant Financial Interests and other outside professional or commercial commitments within thirty (30) days of any change in their Significant Financial Interests or outside professional or commercial commitments that could reasonably give rise to a conflict of interest or conflict of commitment.

*Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of inappropriate behavior. Covered Persons are encouraged to err on the side of disclosure and to seek guidance from their department Chair, Dean or the Provost's Office even if their situation is not directly covered by the disclosure procedures in this policy.*

#### **D. Confidentiality**

The University will hold information concerning Significant Financial Interests disclosed under this policy in confidence to the greatest extent practicable. This means that the University will share the information internally only with individuals who have a specific need to know the information under this policy, other University policies, or applicable law. This also means that the University will share the information with third parties only as required by applicable law or to satisfy the University's contractual obligations to sponsors of research. The University's commitment to maintaining the confidentiality of disclosures shall not restrict the University's ability to require disclosure of Significant Financial Interests in managing a particular conflict of interest, including public disclosure on University or external websites.

### **VII. Additional Responsibilities for PHS-Funded Investigators**

The following additional requirements apply only to PHS-Funded Investigators:

A. Travel. As required by PHS regulations, PHS-Funded Investigators must disclose the occurrence of any reimbursed or sponsored travel that they or the Investigator's spouse or University-registered domestic partner and dependent children undertake when such travel reasonably appears to be related to the Investigator's Institutional Responsibilities unless the travel was sponsored or reimbursed by the University. Disclosure should be made within 30 days of each occurrence and include a reasonable estimate of the monetary value of the travel, and must include (1) the purpose of the trip; (2) the identity of the sponsor/organizer; (3) the destination; and (4) the duration. The University may investigate

the monetary value in order to determine whether the travel constituted a conflict of interest with the PHS funded research. Travel sponsored or reimbursed by a US-Governmental or -Academic Entity does not need to be disclosed. Travel sponsored or sourced from third parties other than US-Governmental or -Academic Entities, for example travel sponsored by a university or research institute located overseas must be disclosed.

B. Training. As required by PHS regulations, the University has developed a mandatory training program that specifically addresses conflict of interest compliance issues related to PHS funded research. All PHS-Funded Investigators must complete the University's training program before starting their PHS-sponsored research project and at least once every four years thereafter. The University also will provide training to PHS-Funded Investigators immediately under these circumstances: (1) when the University has changed its financial conflict of interest policy in such a way that it affects disclosure requirements; (2) when a PHS-Funded Investigator is new to the University; or (3) when the University determines that a PHS-Funded Investigator is non-compliant with this policy or an applicable management plan.

C. Public Disclosure. As required by PHS regulations, before the University expends funds for a research project sponsored by PHS, the University will provide public access to information concerning a Significant Financial Interest of a PHS-Funded Investigator if (1) the Significant Financial Interest has been disclosed to the University and is still held by the PHS-Funded Investigator; (2) the University has determined that the Significant Financial Interest is related to the PHS sponsored research; and (3) the University has determined that the Significant Financial Interest is a conflict of interest.

When these circumstances occur, the University is obligated to disclose the conflict of interest in writing within five calendar days of a written request. The disclosed information will include (1) the PHS-Funded Investigator's name; (2) the PHS-Funded Investigator's title and role with respect to the PHS research project; (3) the name of the entity in which the Significant Financial Interest is held (if applicable); (4) the nature of the Significant Financial Interest; and (5) the approximate dollar amount (dollar ranges may be used) of the Significant Financial Interest, or a statement that the value of the interest cannot be readily determined by reference to public prices or other measures of fair market value. This information will remain available to the public for at least three years after the date on which the information was last updated.

### **VIII. Areas in which Conflicts of Interest may arise**

A conflict of interest may arise when a Covered Person holds a Significant Financial Interest in a commercial enterprise. Possible examples are (1) if a Covered Person is developing a product for a firm (including a company supported by or developed through UChicagoTech) in which he or she has a Significant Financial Interest; (2) when a clinical

investigator has an interest in a product that is being studied or tested on human subjects; (3) when a Covered Person is asked to serve on a University (including University of Chicago Medical Center) committee that evaluates a firm or product in which the Covered Person has a Significant Financial Interest; or (4) when a Covered Person receives personal compensation for services which may or could be perceived to conflict with University duties. For example, a Covered Person might initiate or participate in business activities that compete with, or may be perceived as competing with, the business or educational interests of the University; or a Covered Person might participate in a Speakers' Bureau whose object is to promote a company's products.

A conflict of interest may arise from a single transaction and should be addressed, whenever possible, before that transaction is undertaken.

Among the specific issues and problems requiring particular sensitivity and attention are the following:

**A. Research.** Decisions concerning the nature and direction of scholarly research at the University should be governed by judgments of scholarly merit and intellectual importance. A Covered Person's involvement with, or interest in, outside professional or commercial applications of research should not bias judgment concerning the Covered Person's own scholarly research or that of other Covered Persons or students.

**B. Publication.** Free communication of the results of scholarly research is an important and long-standing policy of the University. Involvement in outside professional or commercial activities should not delay or inhibit the publication of scholarly research or the sharing of information derived from such research. Where appropriate, such as in situations involving clinical trials, Covered Persons are expected to disclose (as described below) relevant outside consulting arrangements or affiliations in their published scholarly works. This obligation is now routinely imposed by many journals.

**C. Education of Students.** Students rely on faculty advice and guidance concerning educational matters within the University, such as the nature and direction of research, and temporary and career employment opportunities outside the University. Such advice and guidance should always be governed by a student's best interest and should not be made to serve a Covered Person's interest in outside professional or commercial activities. When a Covered Person holds equity in a company that sponsors research at the University, special attention should be focused on protecting the academic interests of students, research staff or post-doctorals who may be supported in whole or in part by that company.

**D. Appointments and Promotions.** Dedicated participation of Covered Persons in recommendations and decisions concerning faculty appointments and promotions is vital to the continued strength of the University. A Covered Person's recommendations and decisions on matters of appointment and promotion should never be used to advance an actual or prospective relationship in outside professional or commercial activities (either

cooperative or competitive) with candidates for appointment or promotion.

**E. Clinical Trials.** Covered Persons who assume responsibility for the design, conduct or reporting of clinical trials have a special obligation to avoid bias, or the appearance of bias, in the conduct of these studies. Careful scrutiny is required for clinical trials at the University or the University Medical Center that involve materials, devices or procedures invented or discovered by Covered Persons, whether such development took place at the University of Chicago or elsewhere; where such trials may lead to commercial development either through UChicagoTech, the Covered Person's own company; or by license to a company in which the Covered Person or the University has a Significant Financial Interest. Similar concerns arise when a Covered Person consults for the company whose product is being studied.

When both the University and the inventing Covered Person hold equity interests in the development of a clinical drug or device, additional considerations govern any continuing institutional involvement in the commercialization of the IP. These interests are particularly important if human subjects are involved in the testing of the drug/device because of the real and/or perceived prospect of conflicts of interest. Financial benefits to the involved parties may influence selection of subjects, may lead to failure to fully disclose risks, may overemphasize benefits, and may lead to biased reporting of clinical outcomes or other inappropriate management.

In the presence of such conflicts, under what circumstances and with what oversight might Covered Persons be permitted to continue developing their discoveries/inventions for "new use," or for improvements in existing uses? The intention is to encourage Covered Persons to pursue inquiry consistent with traditional academic practice while recognizing that the Covered Person and the University will be held to a higher standard of scrutiny. By disclosure and the subsequent development of a Management Plan, the financial conflicts may be rendered manageable. In some circumstances, the situation may be so complicated that in the interests of the Covered Person, the institution and the public, the research is best continued outside the University of Chicago. An extreme strategy for managing a major conflict of interest may be divestiture of the outside Significant Financial Interest by the Covered Person, or the taking of a leave of absence.

**F. Human Subjects/Institutional Review Board.** Any possible conflict of interest relating to human subjects must be routinely disclosed to the Institutional Review Board (IRB) as part of the normal obligation for submission to the IRB of any clinical study.

**G. Office/Laboratory Space and Other Resources.** A Covered Person may make reasonable use of his/her office and office equipment for all activities permitted within the scope of their University employment. Incidental modest expenses associated with the use of office or office equipment for consulting conducted within the permissible consulting periods is acceptable; however, the University should be reimbursed for these costs. University facilities such as laboratories, scientific equipment, University personnel or students should not be used for activities outside the scope of a Covered Person's academic

responsibilities if those activities are conducted primarily for the financial benefit of the Covered Person or for the benefit of a company or enterprise with which the Covered Person is associated. A Covered Person who wishes to use University laboratory space for a commercial project must receive prior approval from the appropriate department Chair and Dean.

All research carried out for the benefit of an outside entity that uses University facilities or other resources must be conducted under a grant or contract administered by the University.

**H. Hiring Family Members for University Employment.** Under the University's nepotism policies, faculty, other academic appointees, and staff are prohibited from making, participating in, or attempting to influence employment decisions regarding relatives. It is a long-standing University policy that faculty, other academic appointees, and staff members may not be in the position of supervising, directing, or setting the pay for spouses, University-registered domestic partners, children, or other close relatives.

**I. Service on Committees.** Covered Person are often asked to serve on committees or other groups to assist the University or Medical Center in its relationships with outside vendors, suppliers and contractors. It is expected that Covered Persons will report in writing to the committee chair any potential conflict of interest that arises before acceptance or after the work has begun. Covered Persons are not automatically disqualified from serving on University committees when potential conflicts appear. Early disclosure of outside interests is critical. The focused nature of this service makes it unnecessary for a Covered Person to disclose to the committee chair outside activities that are unrelated to the task at hand. In most circumstances, it should be possible for the Covered Person to continue service on the committee, but some conflicts may be so severe that they are resolvable only if the Covered Person resigns from the committee.

**J. Consulting.** Consulting relationships with companies in the private sector are a normal, traditional and recognized part of the outside activities of Covered Persons. However, consulting relationships also have the potential to create situations in which the terms of the consulting agreement conflict with the obligations of a Covered Person to the University. These may arise for example in such areas as academic freedom, ownership of IP, creation of conflicts of commitment, and the integrity of the design, conduct and reporting of research.

**H. Clinical Care.** Covered Persons in the Biological Sciences Division may be involved in the delivery of clinical care to patients. When the Significant Financial Interests of such a Covered Person could be perceived to be in conflict with decisions made regarding the treatment of patients, such conflict may be addressed in the Covered Person's management plan.

## **IX. Guidelines for Covered Persons**

### **A. Conflict of Commitment**

One's contribution to the University derives not only from scholarly research and formal classroom training, but also from less formal interactions with colleagues and students and from participation in the affairs of one's department and of the University.

However, involvement with, or Significant Financial Interests in, professional or commercial activities outside the University should not compromise the fulfillment of one's obligations to the University. A conflict of commitment occurs when a Covered Person's outside professional or commercial activities, whether paid or unpaid, interfere or have the potential to interfere with his or her obligations and commitments to the University.

To sustain the contribution that is consistent with the Covered Person's obligations to the University, the time committed by full-time employees to outside professional or commercial activities shall not exceed 11 days/quarter.<sup>4</sup>

In every case, all outside professional or commercial activities of any length of time must be disclosed to and receive prior approval from the Covered Person's Chair and Dean. In addition, all outside professional or commercial activities must be disclosed to University Research Administration annually as part of the assurance and disclosure processes described in Appendix A.

When involvement in outside professional or commercial activities **does not** substantially impair fulfillment of obligations to the University, yet the time committed to outside professional or commercial activities exceeds 11 days/quarter, a Covered Person should discuss, in consultation with his or her Chair and Dean, an appropriate reduction in University responsibilities and compensation. The Dean may recommend to the Provost a reduction of effort. To protect the University from the undesirable consequences of part-time faculty, arrangements for part-time status to accommodate outside professional or commercial activities should normally be of limited duration. Requests for such arrangements may sometimes be denied by the Provost in order to protect the University's vital interests.

When a Covered Person's involvement in outside professional or commercial activities **does** substantially impair fulfillment of obligations to the University, the most appropriate method for managing this conflict may be for the Covered Person to request a leave of absence from the University. Except in extraordinary circumstances, a leave of absence should not exceed

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<sup>4</sup> Statute 14.2, makes special provisions for faculty holding Four-Quarter appointments in the School of Medicine. The fees referred to in that section include fees from those activities related to patient care, consultations on patients, procedures on patients and preparations of reports on the faculty members' patients whether within the University hospital or any other location, including patient care rendered at another hospital or medical school.

two years, and the frequency and duration of leaves of absence should not be such as to impair a Covered Person's contribution to the University. To protect the University from the adverse consequences of leaves of absence, it may be appropriate to deny some requests for leave or to require that some involvements in outside professional or commercial activities be postponed, reduced or terminated.

## **B. Institutional Conflicts of Interest**

Chairs of departments and committees, Deans of divisions and schools, the Provost, the President, and other senior academic officials play a special role in administering the affairs of the University. It is especially important that Covered Persons serving in these administrative positions minimize (or if possible avoid) personal involvement in outside professional or commercial activities that pose potential conflicts of interest with fulfillment of their responsibilities to the University. Their necessary involvement in the appointment and promotion process, in decisions concerning students, and in the supervision of other faculty requires that they be especially sensitive to potential conflicts of interest and that they uphold a particularly rigorous standard for avoiding such conflicts.

If these conflicts exist, then an Institutional Conflict of Interest is present. A separate policy dealing with Institutional Conflicts of Interest is in place and must be consulted by a University administrator who believes that he or she may have such a conflict.

## **C. Other Conflicts of Interest**

To maintain the effectiveness and the integrity of the process for considering faculty appointments and promotions, Covered Persons should avoid, to the greatest extent possible, involvements in outside professional or commercial activities that might give rise to conflicts of interest in recommendations and decisions concerning faculty appointments and promotions. When conflicts arise with a particular appointment or promotion, the Covered Person with a conflict should disclose the interest and avoid participation in the consideration of that case.

It is necessary to ensure that the nature and direction of degree-related research conducted by students is governed by considerations of scholarly merit and intellectual importance. The efforts of students in such research must always serve the student's best interest. A Covered Person should normally avoid situations where a student's degree-related research becomes entangled with the Covered Person's outside professional or commercial activities. This guideline does not preclude the temporary or part time employment of a student in outside research or consulting activities with which a Covered Person is associated, provided that such employment serves the best interest of the student, does not substantially impede the student's progress toward a degree, and does not restrict the student's communication with other students or researchers, or the right of the student to publish his or her work. A Covered Person should be prepared to describe procedures that

are in place to insure that workplace disagreements do not influence the student's academic performance, evaluation or placement.

Covered Persons should reimburse the University for any administrative costs (e.g., secretarial assistance, phones, postage, or computer services) that outside consulting activities impose. This obligation does not extend to situations where outside work is done in the Covered Person's own office, assuming it does not interfere with University obligations and operations. Whenever possible, Covered Persons should arrange direct payment to third party vendors, for example by billing express mail packages to third parties.

When a Covered Person seeks to market or test an invention or process using University facilities or personnel, he or she must first receive the University's approval through the disclosure process. This approval is necessary whether the invention or process is developed within or outside the service of the University, or formally through a sub-award on an SBIR or STTR, or informally as a consultant on a business development application. The University's approval process is separate from any business decision made by UChicagoTech or other outside partner.

Approval is likely to be granted only in those extraordinary circumstances where the project is of substantial benefit to the University, where the University is fully compensated for the use of its facilities, where all relevant parties are aware of the source of funding for the outside activities, and where researchers are allowed freely to publish the findings and results of this research (except for delays strictly necessary to allow patent applications to be filed). It should not be expected that these arrangements will be frequently approved, nor should they be, since commercial or industrial facilities are normally able to undertake these activities on their own premises.

Covered Persons should not hire staff to work in University buildings in the service of their outside professional or commercial activities.

Other cases are likely to arise, where for example a Covered Person on an occasional basis wishes to use unusual resources or equipment such as databases or measuring devices ordinarily not available for outside activities. Approval to do so can be granted by the department Chair, provided the outside activities do not interfere with the ordinary academic and research work of the University, and the University receives adequate reimbursement for the use of its resources or equipment.

A Covered Person shall disclose any Significant Financial Interest he or she has in an entity that provides him or her support through a grant or contract administered by the University. This is of particular concern in, but not limited to, those areas involving consulting relationships with organizations sponsoring clinical studies, and in research directed to commercial development where the Covered Person holds an equity or intellectual property

interest in the organization sponsoring or benefiting from the research outcome.

Participation in the activities of an outside commercial enterprise, including a Covered Person-owned or -managed company, and disclosure of conflicts of interest pursuant to this policy, does not excuse a Covered Person from the normal IP requirements and procedures for disclosing discoveries and inventions that occur at the University. [See Statute 18. Patent Policy]

All inventions and discoveries by Covered Persons and students must be disclosed to the University (through UChicagoTech) in accordance with University policy so that IP can be appropriately assessed and protected.

Any Covered Person who personally patents University IP without its prior disclosure to UChicagoTech and its release is not in compliance with University policy. While such action does not pose a financial conflict of interest *per se*, circumventing the University's requirement for disclosure of inventions is clearly a conflict of commitment of effort, and may lead to inappropriate personal financial benefit, as well as disciplinary action.

The University reserves the right to examine individual consulting and other agreements to confirm that applicable regulations and University policies are not breached, and that the consulting services do not impinge on the integrity of the design, conduct or reporting of the research performed at the University. Covered Persons are encouraged to refer to the University's written guidance concerning commercial consulting agreements, available on the University Research Administration and UChicagoTech websites, and to incorporate the University's consulting agreement addendum into commercial consulting agreements before entering into them. Knowledge of the specifics of the consulting relationship may be necessary to define an appropriate Management Plan. For example, the conflict of interest posed by a clinical investigator who is compensated by a company as a member of an advisory board to improve marketing of an approved drug might be treated differently from that in which the consulting activities include the design of and/or data analysis from a trial carried out at the University of Chicago.

Some federal funding agencies permit research to proceed despite the presence of disclosed conflicts, if the review determines that imposing restrictions or conditions would be either ineffective or inequitable, or if the potential negative impacts that may arise from a Significant Financial Interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare. However, the University is ultimately responsible for the determination of whether a research or educational project that involves a conflict should proceed.

#### **D. Related Policies**

In addition to this policy, the University and the University of Chicago Medical Center have established the following policies that are pertinent to conflicts of interest and conflicts of commitment:

1. University of Chicago Institutional Conflicts of Interest Policy:  
<https://uchicago.app.box.com/s/kgzw5u2ex3dl9f8obcoz769m3b2q0pxs>
2. University of Chicago Conflict of Interest Policy for Staff Employees:  
<http://hrservices.uchicago.edu/fpg/policies/600/p600.shtml>
3. University of Chicago Nepotism Policy for Faculty and Other Academic Appointees: <https://provost.uchicago.edu/handbook/clause/nepotism-policy-faculty-and-other-academic-appointees>
4. University of Chicago Nepotism Policy for Staff Employee:  
<https://humanresources.uchicago.edu/fpg/policies/200/p206.shtml>
5. Business Conduct at the University of Chicago:  
[http://finadmin.uchicago.edu/business\\_conduct.shtml](http://finadmin.uchicago.edu/business_conduct.shtml)

These policies may be amended from time to time, and additional related policies may be created, at the University's or Medical Center's discretion.

#### **X. Additional Responsibilities of Principal Investigators**

The PI is responsible for determining who meets the definition of "Investigator" or "Key personnel," described above in Section III, for each sponsored activity. Each such Investigator or Key personnel is required to disclose to the PI all Significant Financial Interests as defined above in Section IV that give rise to, or might be perceived to give rise to, a conflict of interest.

The PI then must take reasonable steps to assure that each Investigator and Key personnel is in compliance with the University's financial conflict of interest requirements, preferably before submitting the proposal to the sponsoring agency. The PI should identify those Investigator(s) and Key personnel to the Office of University Research Administration, which will provide them with information describing how to assure their compliance with the University's policies on conflict of interest.

All Investigators and Key personnel must complete the University's assurance and disclosure processes as outlined in Appendix A.

#### **XI. Sub-recipients**

The University will take reasonable steps to ensure that sub-recipients (e.g., sub-contractors, collaborators or consortium members) at other institutions will comply with the conflict of interest policies of the University of Chicago. Sub-recipients may certify that they will comply with their own institution's conflict of interest policy, as long as that policy conforms

to the University's policy.<sup>5</sup> If the sub-recipient cannot provide this certification, the sub-recipient will be subject to the University's conflict of interest policy and will be required to disclose Significant Financial Interests that are directly related to the sub-recipient's work for the University.

Administratively, the University implements this requirement by having sub-recipients certify that any Significant Financial Interest which could directly affect the design, conduct or reporting of the work will be disclosed directly to the University of Chicago's PI. It is the responsibility of the University's PI to determine if the disclosed interest requires further institutional consideration for management, reduction or elimination of the conflict. PIs whose sub-recipients are not formally associated with the project through a consulting agreement or sub-contract should confirm that the sub-recipients meet the requirements of the University's conflict of interest policy.

## **XII. Compliance**

Covered Persons can be subject to the ordinary disciplinary process of the University if they fail to fully and truthfully disclose conflict of interest or conflict of commitment situations or fail to comply with any stipulated plan for managing the disclosed conflict. Additionally, they may be subject to criminal sanctions, civil liability, or both, under federal or state law.

If the University determines that a Covered Person did not comply with the University's financial conflict of interest/conflict of commitment policy or Management Plan, or if the University discovers that a Covered Person had a Significant Financial Interest that was not disclosed in a timely manner pursuant to this Policy, the University will conduct a retrospective review<sup>6</sup>, and if, upon conclusion of the review, the University finds that a conflict of interest existed that could have affected the design, conduct or reporting of the research, the University will take appropriate steps in accordance with this Policy to manage or eliminate the conflict and report its finding to the funding agency, if required by law. The University's report will address the conflict's impact on the research project, and the actions that the University took or will take to eliminate or mitigate the harm. The University has broad discretion in determining which measure(s) it may take in order to eliminate or mitigate the effect of a conflict of interest or conflict of commitment.

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<sup>5</sup> Pursuant to PHS regulations, when the University of Chicago is the prime grantee from PHS, sub-recipients must disclose their Financial Interests to the University even when they comply with their own institution's conflict of interest policy. The University of Chicago will then report the disclosed information to PHS. University Research Administration will provide a form to meet this need, upon request.

<sup>6</sup> For PHS-supported research, the retrospective review should be completed and documented within 120 days of the University's determination of noncompliance in accordance with PHS regulations.



## APPENDIX A Administrative Processes and Roles

### **I. Procedures for Disclosure of Conflicts of Interest and Conflicts of Commitment**

The disclosure process and all subsequent steps taken to evaluate that disclosure and to develop the management plan are described in charts online at <https://ura.uchicago.edu/page/coi-coc-processing>).

Covered Persons are to follow the following processes:

A. Covered Persons assure compliance with the University policy by completing a Disclosure of Information Form online, in AURA-COI (<http://aura.uchicago.edu>).

B. Covered Persons are responsible for updating their disclosure if they acquire new Significant Financial Interests related to Institutional Responsibilities, or if they undertake new outside professional or commercial commitments. Updated disclosures must be made at least annually and within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest or taking on a new outside professional or commercial commitment. Additionally, certain federal agencies require Covered Persons to report in 30 days, any reimbursed or sponsored travel, subject to certain exclusions for US-Governmental and -Academic Entities.

Compliance with the University of Chicago's Conflict of Interest/ Conflict of Commitment Policy is established by the University's reporting requirements and definitions described in the policy, and the accompanying agency-specific requirements. Disclosures required by and filed with other entities or governmental groups such as FDA, pharmaceutical companies, oncology cooperative groups, professional societies, etc., do not constitute compliance with the University's Disclosure requirement.

C. Any activities that compete with, or may appear to compete with, the business interests of the University should also be disclosed under this policy.

### **II. Procedures for University Review and Management of Disclosures**

The process for administrative review of disclosures and the creation of management plans is described in charts online at: <https://ura.uchicago.edu/page/conflict-interest-conflict-commitment-coi-coc>.

A. The Disclosure of Information form is completed on-line, in AURA-COI, and then reviewed by URA (University Research Administration), under the direction of the AVPR

(Associate Vice President for Research). URA may contact the Covered Person to seek additional information or clarification in order to ensure that the Disclosure is complete and accurate. URA then routes the Disclosure to the appropriate divisional or Dean's level for review. If the review confirms that the Significant Financial Interest gives rise to a conflict of interest, or that an outside professional or commercial activity gives rise to a conflict of commitment, the Dean will make recommendations to manage, reduce or eliminate the conflict that could be developed as components of a Management Plan and forwards these recommendations to URA. URA works with the Deputy Provost to develop a Management Plan that addresses the conflict presented in the Disclosure. The Deputy Provost may seek the advice of the Standing Committee on Individual Conflicts of Interest in particular cases.

B. A letter describing the Management Plan is sent by the Deputy Provost to the individual making the Disclosure. The Plan includes a signature requirement in which the discloser assures in writing that the Plan has been "read and understood." If the discloser does not agree to the Plan, he or she may appeal to the Deputy Provost. (The appeal should be in the form of a letter of response from the individual to the Deputy Provost who may consult the Standing Committee. The Standing Committee would review the particulars under appeal and offer recommendations for the modification of the Plan, if appropriate.) When the Plan is agreed on, the discloser must return a signed copy to the AVPR.

C. When the Management Plan delegates monitoring and oversight responsibilities to a division, the divisional contact will be openly copied on the Plan. If the Plan calls for a third party to be a neutral resource for students, fellows, investigators and others, that party will receive a copy of the Plan. All others named in the Plan will be copied. All Management Plans will be monitored in order to assure compliance until completion of the funded research project.

D. In all cases in which human subjects are involved, the Management Plan will be shared with the IRB chair and copied to the appropriate IRB administrator. This practice assures that all aspects of the Plan potentially subject to IRB oversight are available to the IRB for its consideration. It is the responsibility of the IRB Chair to share full information with the IRB members during the discussion of the protocol so that adequate consideration of the nature of the outside Significant Financial Interest as well as the potential impact of outside Significant Financial Interests is factored into the assessment of human research risks.

E. Prior to the expenditure of any funds awarded under a sponsored project, terms imposed by the sponsor and accepted by the University, such as the requirement to report the existence of a conflict, must be satisfied.

F. Certain Federal agencies that sponsor research at the University require the University to supply information regarding all identified conflicts of interest, and to

describe how those interests have been managed, reduced or eliminated to protect the research from bias. For PHS-supported research, the University is also legally obligated to provide certain information to members of the public who make a written request for such information, as described in Section VII of the Policy.

G. For each conflict of interest, the University maintains records of financial disclosures (even if the disclosure did not result in the University's determination of a financial conflict of interest) and all actions taken by the University for at least three years from the date the final expenditures report was submitted to the sponsor. For sponsored research activities, records will be retained for at least three years from the date of submission of the final expenditure report, or from other dates specified by the sponsoring agency.

H. Prior to executing a license agreement for technology arising from University research, UChicagoTech will seek confirmation from URA that a disclosure has been filed and a management plan is in place. A copy of the full Management Plan is not generally shared with UChicagoTech, but components of it that may be pertinent to UChicagoTech commercialization and licensing oversight may be supplied to UChicagoTech upon request.

I. In drawing up a Management Plan to address a conflict of interest or conflict of commitment, the University will evaluate conflicts in light of their potential to harm or compromise the academic values and the integrity of individuals and the University. When the conflict of interest or conflict of commitment may have a harmful effect on academic values, create risks to human subjects in research or negatively affect University interests, the University will take steps to eliminate, mitigate, or manage the conflict. Sometimes the risks inherent in the conflict may outweigh the benefits of the outside relationship. Risk assessment is already a factor in the conduct and management of many aspects of research.

In evaluating whether real or potential risks are manageable, certain sensitivities and priorities merit careful scrutiny:

- Absence or delegation of oversight of appropriate controls in the conduct of science such that research subjects could be harmed
- Exploitation of students for private gain
- Compromise affecting objectivity in the conduct of research
- Adverse effect by those in leadership roles on the professional or academic advancement of colleagues, staff, or students
- Undue personal gain from public funds
- Unfair access by a company to information or technology
- Use of University resources for private gain
- Compromise of University priorities due to financial considerations

- Distraction from central University mission to the benefit of outside commitments or personal interests

### **III. Administrative Oversight**

#### **A. Governance**

Clear designation of the roles and responsibilities of individuals and academic administrative offices assures effective implementation of the conflict of interest policy. The Office of the Provost is the administrative office charged with assuring that individuals comply with the policy. The Provost has delegated oversight of the policy to the Deputy Provost for Research. This delegation retains central responsibility for the policy and its implementation and assures that one standard applies to all Covered Persons, while each case is considered on its own merits.

Areas of responsibility of particular individuals and offices are more specifically described below.

##### **1. Provost's Office**

The Provost appoints the members of the Committee on Individual Conflicts of Interest and designates the Deputy Provost for Research as its chair.

The Provost or his or her designee reports periodically to the Faculty Committee on the status of Covered Person compliance with the conflict of interest policy, and on major issues concerning the outside professional or commercial interests of Covered Persons. The Provost's report includes how the risks identified above have been addressed through Management Plans or other practices intended to provide for the reduction, elimination or management of financial conflicts of interest or conflicts of commitment.

The Deputy Provost seeks assessment of the risks and recommendations for responsible management from department Chairs and Deans and others such as the Director of University Research Administration and the Office of Legal Counsel. He/she determines a Management Plan to eliminate, reduce or manage the financial conflict or conflict of commitment, and communicates a summary of the disclosed conflict and the complete Management Plan to the individual, the department Chair, the Dean or Director of the unit, and any others named in the plan.

The Deputy Provost implements the Individual Conflict of Interest policy; reviews divisional recommendations for disclosures; determines Management Plans for individual disclosures; and educates Chairs/Deans in their roles and responsibilities to assure

compliance with this policy.

The Deputy Provost uses the Standing Committee for guidance to assess whether the Conflict of Interest Policy is accomplishing its objectives, and to assist him or her in reviewing cases and making recommendations for the management of complex and nuanced disclosures.

The Deputy Provost assures that the University is compliant with the regulations and requirements of federal and other sponsors; assures that student, post-doctorals, and other research staff with financial conflicts are identified and in such situations managed; and assures that appropriate education programs inform all Covered Persons of their personal responsibility to disclose financial conflicts and conflicts of commitment and to conduct their research, educational and outside professional activities in compliance with University-approved Management Plans.

The Deputy Provost assures that sufficient resources are available to support the implementation and documentation of compliance.

## **2. Faculty Committee on Individual Conflicts of Interest**

To assure that faculty would be regularly involved in the implementation and practice of the individual conflict of interest policy, the 2004 Faculty Report recommended, and the Provost accepted, that a Standing Committee on Individual Conflicts of Interest be formed. The Committee replaced an *ad hoc* committee that evaluated the risks and benefits associated with disclosures from individual faculty. This Committee is advisory to the Deputy Provost, or to whomever the Provost designates as responsible for overseeing individual conflict of interest matters.

The Committee serves as a resource for policy interpretation and implementation, and provides continuity in consideration of management practices. The Standing Committee may recommend specific oversight or management practices, and identify cases in which the conflict appears to present either unmanageable complexity or unacceptable risks.

The Committee also advises the Deputy Provost on particular cases and on conflict of interest policies; reviews general practices for management of disclosed financial conflicts; reviews Assurance and Disclosure forms and practices; advises on appropriate education programs and materials; and participates in regularly scheduled meetings with the Deputy Provost to discuss management of individual conflicts of interest.

The Committee should be comprised of a sufficient number of individuals to handle both the anticipated number and diversity of disclosures. Typically, clinical and basic science faculty from the BSD, faculty from the PSD and faculty from non-science areas of the university will be members, supplemented by *ex officio* membership of the Associate

Vice President for Research. The Committee may consult as appropriate with representatives of UChicagoTech and the Office of Legal Counsel. Terms run for 2 or 3 years and are staggered to maintain continuity and consistency. All activities of the Committee are conducted in strict confidence.

### **3. Assurance and Disclosure Process**

#### **a. Divisional and Unit Responsibilities**

Oversight at the Divisional level is the best mechanism to assist Covered Persons with implementing the Management Plan developed by the Deputy Provost. The strength of the institution's overall compliance ultimately depends on assuring that this is done and done well.

Written procedures and processes at the Divisional or Dean's level are available for review by central University officials. These procedures state how the division or unit oversees Management Plans in order to assure compliance. These procedures are distributed to department Chairs through Dean's meetings or other appropriate opportunities to promote the general knowledge of the divisional responsibility for assuring compliance with management plans for disclosed conflicts.

#### **b. Local Implementation of the Management Plan**

Departments and Schools are responsible for informing new Covered Persons of their obligation to comply with the University's Conflict of Interest Policy and in particular, for ensuring that they file an Assurance of Compliance. Generally this should be done as part of the "new hire" process. Particular attention must be paid to Covered Persons who will be engaged in sponsored research, and those who must comply with federal requirements, such as Public Health Service and National Science Foundation requirements.

The individual's Disclosure of Information is submitted to URA. URA provides a copy of the Disclosure to the relevant Dean/Director for review and recommendation of potential management practices. At the discretion of the Dean/Director, the department Chair may be asked to review the Disclosure for comment/recommendations.

## **APPENDIX B**

### **Historical Background**

On March 10, 1987, the Council of the University Senate adopted a Policy on Outside Professional and Commercial Activities of Faculty. In the spring of 1991, a Committee examining policies concerning outside activities of faculty members submitted to the Council a report calling for a more detailed Policy on Conflict of Interest applicable to all faculty members in all divisions and schools of the University. The report and a revised Conflict of Interest Policy were adopted by the Council on April 30, 1991.

The Public Health Service (PHS) at the Department of Health and Human Services (DHHS) published (July 11, 1995 as 60 FR 35810) its final regulations governing financial conflicts of interest. At around the same time, the National Science Foundation (NSF) published technical changes to its final guidelines (June 28, 1994, as 59 FR 33308, clarified July 11, 1995, as 60 FR 35820) to make them more consistent with the final DHHS rule (60 FR 35810). A revised policy, titled "Outside Professional and Commercial Interests/Conflict of Interest," was approved by the Council of the University Senate on March 12, 1996. This revision integrated the 1987 and 1991 University policies into a uniform statement that was consistent with the new Federal regulations and guidelines and superseded the earlier University policies.

Since that time, a significant increase in entrepreneurial and technology transfer opportunities has occurred at research universities. Particular concerns have been raised nationally about clinical studies in which an investigator may benefit financially if his/her study demonstrates therapeutic promise. Indeed, the climate for tolerance of financial relationships in clinical research has changed dramatically since 2000, following the death of a young subject in a gene therapy trial at a major academic medical center.

In 2002, the VP for Research suggested that, in the light of experience by our faculty and administrators, a careful review of both the Conflict of Interest policy and procedural mechanisms to assure compliance with that policy would be beneficial. He appointed an Ad Hoc Faculty Committee on Conflict of Interest to conduct this review. In its report in 2004 the Committee affirmed that the policy adopted in 1996 is philosophically sound in principle and that it would not benefit significantly from major reconstruction. The policy recognizes that conflicts of interest are inherent in faculty activities. The routine disclosure of real or perceived financial conflicts is not a negative judgment, but rather initiates a process of identification and management of relationships designed to assure the protection of academic integrity and values.

The Committee made recommendations to better harmonize policy and practice; to make the policy more accessible to faculty and thus to assure greater accountability; to

strengthen the oversight of outside Significant Financial Interests related to human subjects research; to clarify the roles and responsibilities of those involved; and thus to streamline and strengthen implementation of the policy. These recommendations were accepted by the Provost.

Since the document setting forth the policy had acquired additions, duplications and inconsistencies over the years, it was edited for clarity in 2006-07 by Keith Moffat, the Deputy Provost for Research. His version was checked for consistency with the policy by the standing Faculty Committee on Individual Conflict of Interest and by Russell Herron from the Office of Legal Counsel, and approved by them and by the Provost, Thomas Rosenbaum.

The Policy was further amended in 2011-2012 to comply with revised federal regulations governing Public Health Service-funded research and to make the Policy's core requirements easier to understand. These revisions were reviewed and approved by the Faculty Committee on Individual Conflicts of Interest and by the Provost, Thomas Rosenbaum.

In 2020, the Policy was amended to include clarifications regarding Covered Persons disclosure obligation to federal agencies. These revisions were reviewed and approved by the Faculty Committee on Individual Conflicts of Interest and by the Provost, Ka Yee Lee.