

University of Chicago Pritzker School of Medicine
2016 AMSA Scorecard Policy Submission Documents
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THE UNIVERSITY OF CHICAGO

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

August 24, 2012

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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.¹ “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 (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 Significant Financial Interests of their spouse or University-registered domestic or civic union partner and dependent children. Significant

¹ 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.

Financial Interests do not include income from seminars, lectures, or teaching engagements sponsored by governmental or nonprofit entities, and income from service on advisory committees or review panels for governmental or nonprofit 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 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).

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.² 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 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.

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

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 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 federal, state, or local government agency, an institution of higher education (as defined at 20 U.S.C. 1001(a)), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education, and income from service on advisory committees or review panels for such 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 related to their Institutional Responsibilities unless the travel was sponsored or reimbursed by the University. Disclosure does not need to include the monetary value of the travel, but it 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 federal, state, or local government agency, an institution of higher education (as defined in 20 U.S.C. 1001(a)), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education does not need to be disclosed.

B. Training. As required by PHS regulations, the University will develop 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 or civic union 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.³

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

³ 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.

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 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 agreements to assure that applicable 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:
http://researchadmin.uchicago.edu/docs/policies_compliance/conflict_interest/ICOI%20Revised%2005_13_10.pdf
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://facultyhandbook.uchicago.edu/sites/facultyhandbook.uchicago.edu/files/uploads/nepotism_policy_academic_employees.pdf
4. University of Chicago Nepotism Policy for Staff Employee:
<http://hrservices.uchicago.edu/fpg/policies/200/p206.shtml>
5. Business Conduct at the University of Chicago:
http://finadmin.uchicago.edu/business_conduct.shtml
6. UCMC Officer, Employee and Influential Medical Staff Member Conflict and Vendor Relationship Policy:
http://frontline.mcis.uchicago.edu/admin/hsp_pp.nsf/110c44d662f7a775862565ad005de7b7/4ddc16e89f02e4ab862568eb006f1116?OpenDocument&Highlight=0,00-12
7. UCMC Conflict of Interest Policy - Officers, Trustees and Certain Committee Members:
http://frontline.mcis.uchicago.edu/admin/hsp_pp.nsf/110c44d662f7a775862565ad005de7b7/2c8f33ae563a4d478625720c006ac1c5?OpenDocument&Highlight=0,Conflict
8. UCMC Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies & Services Industries: https://adm-roscoe-secure.bsd.uchicago.edu/compliance/secure/Documents/Conflict_of_Interest_uch_019649.pdf.

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.⁴ 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

⁴ 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.

retrospective review⁵, 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.

⁵ 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 in Appendix VI (and on line as http://researchadmin.uchicago.edu/policies_compliance/conflict_interest)

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, covered persons are required to report in 30 days, any travel undertaken that has been externally funded.

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 administrative guidance. 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

http://researchadmin.uchicago.edu/policies_compliance/conflict_interest

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 the 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.

THE UNIVERSITY OF CHICAGO

**OUTSIDE PROFESSIONAL AND COMMERCIAL
INTERESTS OF FACULTY
/ CONFLICT OF INTEREST**

Approved by the Council of the University Senate,
March 12, 1996

Amended to incorporate Recommendations of the Report of the Ad hoc Faculty Committee
on Conflict of Interest, January 16, 2004

Edited by Keith Moffat, Deputy Provost for Research; approved by the Faculty Committee
on Individual Conflict of Interest on June 18, 2007 and by Thomas Rosenbaum, Provost, on
July 27, 2007

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Appendix I: Flow Charts

I. What is a Conflict of Interest?

This policy addresses situations in which there might be a potential financial or personal conflict between a particular outside interest of a faculty member and the obligation that the faculty member owes to the University. In such situations a faculty member's profit or advantage may come, or may reasonably appear to come, at the expense of the well-being of the University. An individual conflict of interest is thereby generated.

Involvement with, or financial interest in, professional or commercial activities outside of the University should not compromise the fulfillment of a faculty member's obligations to the University. Such outside activities conflict with obligations to the University when they involve excessive commitments of time; that is, they generate a conflict of commitment. University policy permits faculty members who are full-time University employees to devote no more than 11 days/quarter, with the approval of their Chair/Dean, to outside professional and commercial activities.

These activities also conflict with obligations to the University when they bias the nature and direction of scholarly research, or when they influence a faculty member's decision or behavior with respect to teaching and student affairs, appointments and promotions of faculty, or other matters of interest to the University. Sensitivity to these potential conflicts of interest is especially important when a faculty member has a substantial involvement in commercial enterprises related to that faculty member's research or when the faculty member is engaged in prolonged and intensive consultancies.

II. Why Does the University Have a Conflict of Interest Policy?

The history of the University Conflict of Interest policy is summarized in Section X.

Faculty participation in outside professional and commercial activities makes important direct and indirect contributions to the strength and vitality of the University. Through participation in such activities, faculty add to 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 faculty members and to the larger society of which the University is a part, the University recognizes that limited participation of its faculty in outside professional and commercial activities is fully appropriate.

However, it is essential to have a policy in place, to guard against the dangers of inappropriate or excessive participation. This policy also serves to protect the interests of individual faculty through advancing a very positive goal: defense of the integrity and objectivity of the research and scholarship carried out by the University's faculty.

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.”

Faculty involvement in outside professional and commercial activities has become increasingly complex, which makes it impossible to set out detailed guidelines in advance for resolving conflicts in all situations. Sound administrative discretion is an integral part of the University's procedures for dealing with conflicts of interest. While disclosure alone of a potential conflict of interest 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 faculty members when disclosed in advance. Second, failure by any faculty member 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 faculty members 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 faculty member 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 faculty member 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.

III. To Whom Does the Policy Apply?

The University's Conflict of Interest policy applies to all faculty and other academic personnel (as described in University Statute 11) of the University of Chicago. It also applies to 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, and to other academic personnel or staff employees serving as "Investigators" or “Key personnel” on research and other sponsored projects.

The term "Investigator" designates those individuals who carry out particular activities in sponsored research and educational programs administered by the University. "Investigator" means the Principal Investigator (PI) or investigators, co-Principal Investigators, and any other person who is responsible for the design, conduct, or reporting of research or educational activities or for proposals for funding. "Investigator" as defined for these purposes may not be limited to those individuals titled or budgeted as "investigators" on a particular proposal. 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."

For disclosures of Financial Interests, "Faculty member" or "Investigator" includes the individual faculty member or Investigator, his or her spouse and dependent children.

The term "Key personnel" denotes 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 identified by name on NIH and NSF grant applications.

Although this policy is directed toward faculty and other academic personnel, the University does have a separate Conflict of Interest policy for staff employees. Staff employees who engage in business or professional 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 which may come, nor reasonably appear to come, at the expense or well-being of the University or its reputation [see <http://hr.uchicago.edu/policy/p600.html>]. 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.

IV. What Must Be Disclosed?

Consistent with U. S. Public Health Service (PHS) regulations, faculty members or Investigators are responsible for disclosing: (1) those Financial Interests (defined below) that would reasonably appear to be affected by or to affect their research or educational activities; and (2) any Financial Interests in entities whose financial interests would reasonably appear to be affected by or to affect the person's performance of his or her University duties. Put another way, this means that if a faculty member or Investigator has a Financial Interest, then disclosure is necessary if (1) there is a chance that this interest could reasonably appear to affect his or her research, teaching or other University activities; or (2) if there is a chance that his or her research, teaching or other University activities could reasonably appear to affect the interests of the external entity in which the faculty member has a Financial Interest.

"Financial Interest" means anything of monetary value, including but 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 (e.g. stocks, stock options or other ownership interests) and intellectual property rights (e.g. patents, copyrights, licenses and royalties from

such rights). Excluded from “Financial Interest” and hence from this disclosure requirement are income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; and income from service on advisory committees or review panels for public or nonprofit entities.

(The term “Financial Interest” used throughout this University policy is similar but not identical to the longer phrase “Significant Financial Interest” used in the PHS regulations. The University requires that royalties received from the University of Chicago be disclosed; and the University has established a zero threshold for disclosure reporting both in dollar value and in % of equity holding. See also below.)

In the absence of known valuation of stock options or equity holdings, disclosure to the University of the existence of the options or holdings is still required. Potential equity value should be considered in those instances where the faculty member has an equity interest in a privately-held company and the potential exists for bias in design, conduct, or reporting of research based on future financial benefit. The true value of that interest may not be known until a later time (e.g. when the firm goes public) but the faculty member should make a reasonable assessment of the future market value of the equity.

The disclosure must include all “Financial Interests” described above. In the course of the review of such information, the University may deem certain outside interests as *de minimis* that require no or minimal management, and others as “Significant Financial Interests” that require explicit Management Plans.

It is the responsibility of the University, not the faculty or investigator, to determine if the disclosed interests could directly and significantly affect the performance of University responsibilities and to require the management, reduction or elimination of the conflict. The designated University office for determination of faculty financial conflict of interest matters is the Office of the Provost.

Faculty and investigators are encouraged to disclose any other financial or related interest that could present an actual conflict of interest, or might be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of inappropriate behavior. Faculty and investigators are encouraged 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.

A conflict of interest exists when the designated official reasonably determines that a Financial Interest could directly and significantly affect the performance of University duties. The Office of the Provost reviews all financial disclosures, determines whether a conflict of interest exists and if so, determines what actions should be taken by the University to manage, reduce or eliminate such conflict of interest.

V. Areas in Which Conflicts of Interest May Arise

A conflict of interest may arise when a faculty member holds an equity or financially beneficial interest in a commercial enterprise. Possible examples are 1) if a faculty member is developing a product for a firm (including a company supported by or developed through UChicagoTech) in which he or she has a 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 faculty member is asked to serve on a University (including University of Chicago Medical Center) committee that evaluates a firm or product in which the faculty member has a financial interest; 4) when a faculty member receives personal compensation for services which may, or could be perceived to, conflict with University duties. For example, a faculty member might initiate or participate in business activities which compete with, or may be perceived as competing with, the business or educational interests of the University; or a faculty member might participate in a Speakers' Bureau whose object is to promote a company's products.

A conflict of interest may arise out of a single transaction and should therefore 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 faculty member's involvement with, or interest in, outside commercial or professional applications of research should not bias judgment concerning the faculty member's own scholarly research or that of other faculty, research staff 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, faculty members 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 some 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 faculty member's interest in outside commercial and professional activities. When a faculty member 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 postdoctorals who may be supported in whole or in part by that company.

D. Appointments and Promotions. Dedicated participation of faculty in recommendations and decisions concerning faculty appointments and promotions is vital to the continued strength of

the University. A faculty member's recommendations and decisions on matters of appointment and promotion should never be used to advance an actual or prospective relationship in outside commercial or professional activities (either cooperative or competitive) with candidates for appointment or promotion.

E. University Contribution. A faculty member's contribution to the University derives not only from scholarly research and formal classroom teaching, but also from less formal interactions with colleagues and students, and from participation in the affairs of the faculty member's department and of the University. To sustain the contribution consistent with a faculty member's obligation to the University, time committed to outside professional and commercial activities should not exceed the accepted standard for such activities. Section 14.2 of Statute 14 makes special provisions for faculty holding Four-Quarter appointments in the School of Medicine. The fees referred to in this 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.

F. Clinical Trials. Faculty 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 faculty members, whether such development took place at the University of Chicago or elsewhere; and where such trials may lead to commercial development either through UChicagoTech, the faculty member's own company, or by license to a company in which the faculty member has a financial interest. Similar concerns arise when a faculty member consults for the company whose product is being studied.

When both the University and the inventing faculty member 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 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 clinical investigators be permitted to continue developing their discoveries/inventions for “new use”, or for improvements in existing uses? The intention is to encourage clinical investigators to pursue inquiry consistent with traditional academic practice while recognizing that the faculty member 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 faculty member, 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 financial interest by the faculty member, or taking of a leave of absence.

G. 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 approval by the IRB for any clinical study.

H. Office/Laboratory Space and Other Resources. A faculty member 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; the University should be reimbursed for additional costs. University facilities such as laboratories, scientific equipment, University personnel or students should not be used for activities outside the scope of a faculty member's academic responsibilities if those activities are conducted primarily for the financial benefit of the faculty member or for the benefit of a company or enterprise with which the faculty member is associated. A faculty member 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.

I. Hiring Family Members for University Business. The hiring of family members on University business is generally to be discouraged and should be done, if at all, only with the approval of the appropriate department chair or dean. It is a long-standing University policy that faculty and staff members may not be in the position of supervising, directing, or setting the pay for spouses, children, or other close relatives.

J. Service on Committees. Faculty members 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 faculty members will report in writing to the committee chair any potential conflict of interest that arises before acceptance or after the work has begun. Faculty members 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 faculty member 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 faculty member to continue service on the committee, but some conflicts may be so severe that they are resolvable only if the faculty member resigns from the committee.

K. Consulting. Consulting relationships with companies in the private sector are a normal, traditional and recognized part of the outside activities of faculty. However, consulting relationships also have the potential to create situations in which the terms of the consulting agreement conflict with the obligations of a faculty member 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.

VI. Guidelines for Faculty Members

When a faculty member's involvement in outside professional or commercial activities substantially impairs fulfillment of obligations to the University, the most appropriate method for managing the conflict of interest may be for the faculty member to take a leave of absence from the University. Except in extraordinary circumstances a leave of absence should not exceed two years, and the frequency and duration of leaves of absence should not be such as to impair a faculty member'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 and commercial activities be postponed, reduced or terminated.

When involvement is not of an extent or nature that substantially impairs fulfillment of obligations to the University, but when the time committed to outside professional or commercial activities exceeds the accepted standard for such activities, a faculty member should determine, in consultation with the chairman and dean, an appropriate reduction in University responsibilities and compensation. To protect the University from the undesirable consequences of part time faculty, arrangements for part time status to accommodate outside professional and commercial activities should normally be of limited duration. Requests for such arrangements may sometimes be denied in order to protect the University's vital interests.

To maintain the effectiveness and the integrity of the process for considering faculty appointments and promotions, faculty members 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 faculty member 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 faculty member should normally avoid situations where a student's degree-related research becomes entangled with the faculty member'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 faculty member 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 faculty member 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.

Faculty members 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 faculty member's own office, assuming it does not interfere with University obligations and operations. Whenever possible, faculty members should arrange direct payment to third party vendors, for example by billing express mail packages to third parties.

When a faculty member 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 subaward 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 is not 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.

Faculty members 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 faculty member 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 faculty member shall disclose any Financial Interest he or she has in an entity which 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 faculty member holds an equity or intellectual property interest in the organization sponsoring or benefiting from the research outcome.

In accord with the recommendation of the "2004 Faculty Report" and consistent with AAU recommendations, the University has adopted a "zero threshold" for faculty and other academic personnel to disclose all Financial Interests. Royalties from all sources are to be disclosed, including those from the University of Chicago. For further clarification of the requirements of disclosure, see Section IV above.

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

As employees of the University, all inventions and discoveries by faculty, other academic personnel, staff 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 employee 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.

The University reserves the right to examine individual consulting agreements to assure that applicable 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. 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 which involves a conflict should proceed.

VII. Additional Responsibilities of Principal Investigators

The PI is responsible for determining who meets the definition of "Investigator" described above in Section III, for each sponsored activity. Each such investigator at the University is required to disclose to the PI all 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 such investigator is in compliance with the sponsoring agencies' Financial Conflict of Interest requirements, preferably prior to submitting the proposal to the sponsoring agency. The PI should identify these investigator(s) 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" must complete an Assurance of Compliance (COIForm1 - http://researchadmin.uchicago.edu/regulations/coi.shtml#assurance_form) and disclose all Financial Interests using the Disclosure of Information form (COIForm2 - http://researchadmin.uchicago.edu/regulations/coi.shtml#disclosure_form) to the appropriate department chair, dean, and if applicable, to the Institutional Review Board (IRB) prior to the submission of a proposal to an outside agency.

Collaborators at other institutions must either comply with the policies of the University of Chicago or certify to the PI at the University of Chicago that they have reviewed their portion of the project according to the policies of their own institution on conflicts of interest. Administratively, the University has implemented this requirement by having consultants or subawardees assure that any Significant Financial Interest (see Section IV) 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 collaborators are not formally associated with the project through a consulting agreement or subcontract should confirm that these collaborators meet the requirements of the conflict of interest policies of the sponsoring agencies.

Under current PHS regulations, when the University of Chicago is the prime grantee from PHS, any Significant Financial Interests of investigators on subawards must be disclosed by the subaward institution to the University of Chicago. The University of Chicago must then report this Disclosure to PHS. University Research Administration will provide a form to meet this need, upon request.

Investigators are required to update disclosures of Financial Interests annually or as such interests change during the period of the sponsored project.

VIII. Responsibilities of University Administrators

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 faculty members 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.

IX. Procedures for Resolving Violations of Policy or Failure to Comply

Faculty members, other academic personnel and staff employees of the University can be subject to the ordinary disciplinary process of the University if they fail to fully and truthfully disclose conflict of interest situations or fail to comply with any stipulated plan for managing the disclosed conflict. They may be additionally subject to criminal sanctions or civil liability under federal or state law.

X. 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 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 subsequently 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.

XI. 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 retains central responsibility for the policy and its implementation and assures that one standard applies to all faculty, while each case is considered on its own merits.

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

Provost's Office

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

The Provost or his designee should report periodically to the Standing Committee on the status of faculty compliance with the conflict of interest policy, and on major issues concerning the outside professional and commercial interests of faculty. The report should include 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.

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 designed to eliminate, reduce or otherwise manage the financial conflict, 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 in reviewing 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, postdoctorals, and other research staff with financial conflicts are identified and such situations managed; and assures that appropriate education programs inform all faculty, other academic personnel and staff employees of their personal responsibility to disclose financial conflicts 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 implementation and documentation of compliance.

Standing 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 Standing Committee replaces a previous *ad hoc* committee for evaluating the risks and benefits associated with disclosures from individual faculty. This Standing 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.

Divisional and Unit Responsibilities

1. Assurance and Disclosure

Departments and Schools are responsible for informing new faculty members and other academic personnel 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 should be paid to faculty members and other academic personnel who will be engaged in sponsored research, and those who must comply with Public Health Service and National Science Foundation requirements.

The individual's Disclosure of Information is submitted to the Associate Vice President for Research (AVPR). The AVPR 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 requested to review the Disclosure for comment/recommendations.

2. Local Implementation of the Management Plan

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

Written procedures and processes at the divisional or dean's level should be developed and available for review by central University officials. The procedures should clearly state how the division or unit would oversee the Management Plan to assure compliance. These procedures should be distributed to chairs through Dean's meetings or other appropriate opportunities for raising the general knowledge of the divisional responsibility for assuring compliance with management plans for disclosed conflicts.

B. Procedures for Disclosure of Conflicts of Interest

Flow charts for BSD, non-BSD and University-wide situations that present the disclosure process and all subsequent steps taken both to evaluate that disclosure and to develop the management plan are in Appendix I (and on line as http://researchadmin.uchicago.edu/regulations/Individual_CofI_Final_Flow_Charts.pdf.) [

1. Faculty members, including Other Academic Personnel, and investigators assure compliance with the University policy by completing an "Assurance of Compliance" form. This "Assurance of Compliance" (COIForm1) is available on line from University Research

Administration (URA) at

http://researchadmin.uchicago.edu/regulations/coi.shtml#assurance_form.

The electronic filing is stored in URA. A web-based assurance system is under development and will replace paper forms in the near future. At this time a paper copy of the form may also be completed and returned to URA.

2. Based on the information provided on the Assurance form, a more detailed Disclosure of Information (COIForm2 -

http://researchadmin.uchicago.edu/regulations/coi.shtml#disclosure_form) may be required.

If so, the URA office will send the Disclosure of Information form to the faculty member or investigator, identifying the appropriate questions that need additional information.

3. The faculty member or investigator must make all financial disclosures required, in accordance with the definition of "Financial Interests," on the Disclosure of Information form (COIForm2 - http://researchadmin.uchicago.edu/regulations/coi.shtml#disclosure_form) and forward the completed form to the administrative official designated to manage the Financial Conflict of Interest compliance on behalf of the Office of the Provost. This official is currently the Associate Vice President for Research (AVPR). The official assures that the Disclosure is properly logged into the compliance process and notifies the appropriate department chair or Dean that a disclosure has been received.

4. If the proposed research involves human subjects, a copy of the Disclosure of Information (COIForm2 - http://researchadmin.uchicago.edu/regulations/coi.shtml#disclosure_form) must also be provided by the PI on the protocol submitted to the Institutional Review Board. Note that that PI is responsible for reporting to the IRB the Financial Interests of **all** investigators named on the protocol, not just his/her own Financial Interests.

5. The faculty member or investigator is responsible for updating his/her disclosure if they acquire new, reportable Financial Interests related to University duties. In accordance with the policies of external sponsoring agencies, the faculty member or investigator may be required to update their Assurance of Compliance annually.

Compliance with the University of Chicago Conflict of Interest Policy is established by the University reporting requirements and definitions described in this policy and the accompanying administrative guidance. 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.

6. Although the Assurance and Disclosure processes center on financial conflicts of interest in research, scholarly and education activities, other matters are included in the University policy such as conflicts of commitment and outside professional activities which may conflict with University obligations. Any activities that compete with, or may appear to compete with, the business interests of the University should also be disclosed under this policy.

C. Procedures for University Review and Management of Disclosures

See the flow charts in Appendix I

(http://researchadmin.uchicago.edu/regulations/Individual_Cofl_Final_Flow_Charts.pdf).

- 1.** The Disclosure of Information form is submitted directly to the AVPR and logged in to the conflict of interest management system. The AVPR may contact the faculty or investigator to seek additional information or clarification, to ensure that the Disclosure is complete and accurate. The AVPR then routes the Disclosure to the appropriate divisional or Dean's level for review. If the review confirms that the Financial Interest gives rise to a conflict, the Dean makes recommendations to manage, reduce or eliminate the conflict that could be developed as components of a Management Plan and forwards these to the AVPR. The AVPR 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.
- 2.** 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 is "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 on Individual Conflict of Interest. 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 returns a signed copy to the AVPR where it is filed.
- 3.** 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.
- 4.** 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 related 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 financial interest as well as the potential impact of outside financial interests is factored into the assessment of human research risks.
- 5.** 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.

6. Upon request by Federal agencies that sponsor research at the University, the University is required 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.

7. For each conflict of interest, the University maintains records of financial disclosures and all actions taken by the University for a reasonable period of time. 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.

8. Prior to executing a license agreement for technology arising from University research, UChicagoTech will seek confirmation from the AVPR 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.

9. In drawing up the Management Plan to address conflicts of interest, the University should evaluate such 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 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

10. The letter describing the Management Plan developed to address a conflict of interest typically has several clauses. Although each case is treated individually, features are often common to many cases and over time, a set of standard clauses has been drawn up. A subset of these clauses forms part of most Plans, supplemented where appropriate by clauses that specifically address unusual features in a particular case.

Examples of standard clauses

1. CONSULTING TIME

You are reminded of the University policy regarding external activities and that any time commitments over eleven days per quarter require prior approval by both your department chair and the Dean.

2. DISCLOSURE - INTERNAL

Your financial relationship with (INSERT NAME OF COMPANY/IES) must be disclosed to all research staff in your laboratory, and to other University collaborators, on a regular basis. If an issue or conflict related to your company relationship arises, the research staff including students, fellows, technicians or residents should be instructed to freely discuss these issues with the Associate Dean for Clinical Research [Dean in divisions other than the BSD] or the Associate Vice President for Research.

3. DISCLOSURE - EXTERNAL

Your financial relationship with [INSERT NAME OF COMPANY/IES] must be disclosed in any and all publications or oral/written presentations reporting on research whose results are related to the commercial interests of the company, or could be perceived to impact the commercial interests of the company. Such disclosure will include (if applicable) consultancies, advisory board memberships, lecture fees paid by a commercial sponsor, service as an expert witness on behalf of a commercial sponsor, industry-sponsored grants or contracts, patents received or pending, royalties received or anticipated, and stock ownership or options.

This requirement to disclose holds both when you are the communicating author and when you are a junior author. In the latter case, you must disclose your interests to the communicating author and ensure that he/she discloses those interests in the publication or oral/written presentation.

Human subjects research

The University pays particularly close attention to oversight and management of research involving human subjects where there are financial conflicts of interest. In such cases, clauses may implement a requirement that the investigator who has the conflict of interest may not serve as the PI on a clinical study. He or she may be replaced by another investigator who is a neutral party, who can take the lead in the recruitment of subjects, recording, tabulating, analysis and reporting of clinical data. Other clauses may call for the establishment of an independent data and safety monitoring board; the implementation of special subject selection, recruitment or informed consent processes; and the oversight of study design, IRB protocol development, data analysis by a data monitoring board.

Examples of standard clauses in clinical research

4. DISCLOSURE TO IRB

You are obliged to disclose to the IRB your financial relationship with any company related to the clinical research that is the subject of the IRB protocol. If you are not the PI on a proposed study, you must ensure that the proposed PI is aware of your financial relationship with any company related to the study. You must adhere to the IRB's guidance with respect to disclosure to subjects of such financial interests in informed consent documents.

5. PI CLINICAL RESEARCH LIMITATION

You may not serve as Principal Investigator on clinical research study at the University of Chicago sponsored by [INSERT NAME OF COMPANY] or studying [INSERT NAME OF DRUG/DEVICE WHICH HE/SHE INVENTED/DISCOVERED]. You may participate as co-Investigator in clinical trials performed at the University sponsored by [INSERT NAME OF COMPANY] or studying [INSERT NAME OF DRUG/DEVICE WHICH HE/SHE INVENTED/DISCOVERED].

D. Audit of Policy Compliance and Oversight

The 2004 Faculty Report noted that the AAU recommends a regular system of audits to determine whether disclosures are completed and processed appropriately, and whether they are shared with other offices or functions as necessary. The University should continue the practice of asking Internal Audit to examine compliance with University policy for assurance/disclosure of financial conflicts of interest.

APPENDIX I: Flow Charts

http://researchadmin.uchicago.edu/regulations/Individual_CofI_Final_Flow_Charts.pdf

Flow Charts of the Disclosure, Development of the Management Plan and Oversight Processes

- 1) Individual Financial Conflict of Interest Process**
- 2) IRB Conflict of Interest Process**
- 3) Other Transactions that Trigger the Individual Conflict of Interest Process**



December 17, 2008

Dear Colleagues:

Attached is the final “Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device and Research Equipment and Supplies and Services Industries” effective Wednesday, December 17, 2008. Also attached is the accompanying “Frequently Asked Questions” document. The development of this policy is an important milestone for Chicago BioMedicine, and has been reached in no small part due to your engagement and input into this process. I thank you, the faculty, for your input throughout. I would also like to take this opportunity to thank Ted Stamatakos, Kerry DeMott, Patricia Shymanski, and Carolyn Wilson for their efforts in bringing the policy to this point.

Implementation will now begin under the guidance of Kerry DeMott in the Office of Medical Center Compliance and is expected to be completed within the next twelve months. We will establish a number of committees to centralize management of pharmaceutical samples, develop standards for production of patient educational materials, and to review conflict of interest disclosures.

Given the heightened sense of scrutiny in the public arena, this policy comes at an opportune time. It is our intention through this policy to manage conflict of interest as a matter of professionalism that is critical to maintain the public trust.

In the meantime, please keep in mind the spirit of the policy – to safeguard the public trust and the reputation of Chicago BioMedicine by reserving your interactions with Industry solely for the highest level of medical and scientific collaboration.

Sincerely,

James L. Madara, M.D.

Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies & Services Industries

PROLOGUE

1. This policy aspires to establish management of conflict of interest as a matter of professionalism that is critical to maintain the public trust.¹
2. This policy aspires to impart the notion that 1) interaction with industry should be reserved for the highest level of medical and scientific collaboration; and 2) these highest level interactions must not be tarnished by low level interactions such as attendance at sales, marketing, or entertainment events, involvement with ghost writing, or acceptance of personal gifts.
3. We aspire only to manage conflict of interest and do not aspire to a state that is absent thereof.
4. This policy does not prohibit collaboration with industry for research or continuing medical education so long as these relationships are managed appropriately as described in this policy.
5. This policy does prohibit interaction with industry for purposes of entertainment, sales, marketing, and the like.

APPLICABILITY AND RELATIONSHIP TO OTHER POLICIES

The University of Chicago has comprehensive policies on faculty and staff conflicts of interest and commitment.¹ The University Academic Policy governs faculty, academic personnel, and postdoctoral researcher conflicts of interest and commitment. Likewise, University staff are obligated to comply with the University Staff Policy on Conflicts of Interest (U600).²

This policy supplants *neither* the University Staff Policy nor the primacy of University Academic Policy and the responsibility that faculty, academic personnel, and postdoctoral researchers have to comply with that Policy, including but not limited to the responsibility for timely disclosure and compliance with conflict of interest management

¹ Recent AAMC documents reflecting the importance of this issue within academic medicine nationally include *Industry Funding of Medical Education*, Report of an AAMC Task Force, June 2008); *Protecting Patients, Preserving Integrity Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research*, A Report of the AAMC/AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research, February 2008; and *The Scientific Basis of Influence and Reciprocity: A Symposium*, June 12, 2007.

¹ See *Outside Professional and Commercial Activities of Faculty and Conflict of Interest*, prepared by the Council on Research and approved by the Council of the University Senate on July 27, 2007; and *The Report of the Standing Committee on Conflict of Interest*, dated January 16, 2004 and setting forth recommendations to clarify, streamline, and strengthen the University Policy.

² UCMC Staff, Officers, and Influential Medical Staff Members are also obligated to comply with the UCMC Conflict of Interest Policy (A00-12) and the UCMC Vendor Relations Policy (A05-08).

plans. Rather, this policy serves to supplement the University Academic and Staff Policies in areas that are specific to BSD clinical activities and associated relationships with Industry, provide guidelines for certain activities when more restrictive than the University's Policies, and to provide guidance for Medical Center Enterprise staff and trainees. Faculty, academic personnel, and postdoctoral researchers must take affirmative steps to periodically reacquaint themselves with the disclosure and other requirements of the University policy. University staff employees likewise must regularly acquaint themselves with the University Staff Policy.

In addition, as Medical Center employees, medical residents and fellows are subject to the UCH Officer, Employee and Influential Medical Staff Member Conflict and Vendor Relationship Policy (A00-12) as well as the University of Chicago Medical Center Vendor Relations Policy (05-08). While this policy does not supplant the Medical Center policies, it forms the basis of expected behavior of the residents and fellows as members of the treatment team and representatives of the Medical Center Enterprise.

PURPOSE

This Policy is designed to establish principles and guidelines for the interactions between representatives of the Pharmaceutical, Biotechnology, and Medical Device and Research Equipment and Supplies & Purchased Services Industries (collectively, "Industry") with the faculty, other academic appointees, postdoctoral researchers, medical students, residents, fellows, executives, managers, and staff (collectively, "Individuals") of Chicago BioMedicine (the Enterprise) to the extent they are engaged in clinical activities.

This Policy and its guidelines seek to preserve the objectivity—and the appearance of objectivity—of physician decision-making; to foster patient and public trust in the principle that physicians' advice is fashioned solely for the patients' benefit and is not compromised by physician self-interest; and to comply with government regulations applicable to healthcare providers and tax-exempt organizations.

OVERVIEW

Interactions with Industry occur in a variety of contexts, including marketing of new pharmaceutical products, medical devices, and research equipment and supplies; on-site training of newly purchased devices; the development of new devices; educational support of medical students, residents and fellows; and continuing medical education. Individuals also participate in interactions with Industry off campus and in scholarly publications. Many aspects of these interactions promote the Enterprise's educational, clinical, and research missions. Indeed, the Enterprise generally encourages appropriate interactions with Industry that may benefit not only the participants, but also the Enterprise and the public at large.

All parties engaged in these activities concur that their interactions will be ethical and avoid actual or perceived conflicts of interest, recognizing that conflicts could endanger

patient safety, and data integrity; the integrity of our education, research, and educational programs; and the reputation of Individuals or the Enterprise.

POLICY PRINCIPLES AND SUMMARY

By way of overview, this Policy establishes standards in specific areas listed below and offers examples of interactions that commonly arise in matters of business conduct.

These examples cannot, however, contemplate every possible dilemma that an individual might face when interacting with Industry. Please keep the spirit of this policy in mind--to preserve the public trust by avoiding even the appearance of impropriety--when interacting with Industry.

- Individuals may not solicit or accept personal gifts and payments as described in Section I(A).
- Individuals may accept pharmaceutical and device samples in accordance with Section III below.
- Industry sales and marketing personnel may visit the Medical Center Enterprise site subject to both Section III and the University of Chicago Medical Center Vendor Relations Policy (A05-08).
- The Medical Center Enterprise may accept industry-funded scholarships and other educational funds for students, residents and fellows in accordance with Section IV.
- Educational and other professional activities are encouraged. However, Industry payment of fees and expenses associated with these activities are subject to Section V.
- Individuals may not receive payment for passive attendance at Industry-sponsored meetings, but may receive compensation for active participation in such a meeting under certain circumstances set forth in Section V.
- Individuals may not attend Industry events such as lunches, dinners, and panel discussions where the primary intent of the event is entertainment, sales, or marketing. Attendance raises both an actual and an appearance of impropriety, and the potential for misuse of the reputation of both the caregiver, and the Medical Center Enterprise.
- Individuals who have a role in making a Medical Center Enterprise decision or direct recommendation to procure or support medical supplies, equipment, services and pharmaceuticals must disclose Industry relationships.

I. Gifts and Payments

- A. Individuals may not receive or solicit personal items or gifts, gifts for the Medical Center Enterprise, “business courtesies,” discounts, benefits, favors, or other items of value from a representative of Industry regardless of site or circumstance. For the purposes of this Policy, a “Gift” does not have a value

threshold—an item of any value constitutes a gift. By way of example only, but not limitation, this includes:

- 1) Gifts, payments, meals or entertainment provided to listen to a sales talk, presentation, or educational session by an Industry representative.
- 2) Gifts or payments that infer or result in formulary decisions or recommendations or change in the volume of or change in prescription writing practices.
- 3) Gifts or payments for attending a CME, presentation, meeting, conference or other activity if not speaking or otherwise actively participating or presenting at the event (as set forth more fully below in Section V).
- 4) Gifts of anatomical models, textbooks, patient education brochures and displays, or equipment.
- 5) Payment for or provision of meals and entertainment, including, for example, food brought in to a clinic by a sales or marketing representative, dinner, night club or golf outings, and tickets to sporting events, concerts, or plays.
- 6) Cash or cash equivalent, including gift certificates and gift cards.
- 7) Stock, stock options, or other financial interests.
- 8) Access to an item or service that imputes a favor, such as providing sold out tickets to an athletic event at the tickets face value, providing access to a country club or closed nightclub.
- 9) Industry payment for travel to a vendor site or the site of another hospital or clinic to evaluate a product.

B. Individuals must consciously and actively divorce clinical care decisions from any perceived or actual benefits expected from or offered by Industry. However, this limitation is not intended to affect faculty participation in clinical trials or other Sponsored research.

C. Individual sponsored research and payments for services are governed by University Conflict of Interest Policy and residents/fellows governed by UCMC Conflict of Interest policy.

II. Pharmaceutical and Device Samples

Individuals must be aware that the law prohibits them from certain activities associated with the offering and/or receipt of items of value in exchange for referrals of items or services.

- A. The DCAM retail pharmacy will centrally manage pharmaceutical sample distribution of drugs on UCMC formulary utilizing a voucher system administered with

manufacturers. Exceptions to central distribution must be pre-approved by the Chief Pharmacy Officer and the Chair of the Pharmacy and Therapeutics Committee.

- B. The law prohibits the sale or billing for drug samples. Individuals must never sell or bill for drug samples.
- C. The policies above also have the benefit of preventing an Individual's personal use of samples or the use of samples by their family or friends.

III. Physician and Site Access by Industry Sales and Marketing Representatives

The following guidelines are in addition to the requirements set forth in The University of Chicago Medical Center Vendor Relations Policy (A05-08).

- A. Industry sales and marketing personnel, e.g. drug and device representatives, are permitted in non-patient care areas by appointment only. Appointments may be made for purposes such as:
 - 1. In-service training of Individuals for research or clinical equipment or devices already purchased.
 - 2. Evaluation of new purchases of equipment, devices, or related items.
- B. In the specific instance of devices and equipment, industry sales and marketing personnel are permitted in patient care areas (a) by appointment, **and** (b) only when requested by the attending physician, unit/clinic director or vice president, or department chair or division chief, **and** (c) only when the patient care area access is required to provide in-service training, technical support (including, without limitation, evaluating new purchases of equipment, devices, or related items), and maintenance of devices and other equipment.
- C. Appointments to obtain information about drugs will be issued pursuant to policies established by the Pharmacy and Therapeutics subcommittee. This Policy is not intended to restrict the practice of vendors providing valuable information about drugs

to individuals. However, these practices must conform to this Policy and the UCMC Vendor Relations Policy.

- D. Appointments may be made on a per visit basis or as a standing appointment for a specified period of time, at the discretion or request of an attending physician, or his or her section or department chief.
- E. Students, residents and fellows who are to be involved in meetings with industry sales and marketing personnel, e.g. drug and device representatives, may do so only for educational purposes and must do so only under the supervision and with the presence of an attending physician, and subject to Section V below.

IV. Industry-Sourced Student, Resident, and Fellow Scholarships and Other Educational Funds

- A. Industry support of students, residents, and fellows must be free of any actual or perceived conflict of interest, must explicitly serve an educational purpose, and must comply with all of the following provisions. These provisions apply to on-site and off-site educational programs.
 - 1. The sponsorship, funds, program, or conference are not solicited outside of CME protocol.
 - 2. The Chief of the Biological Sciences Division department, program, or section determines that the CME approved conference or program has the educational merit necessary for the purpose and selects the students or trainees to attend.
 - 3. The funds are provided to a central administrative department identified by the Dean of the Biological Sciences Division of the University of Chicago, and not to a department, program, section, physician, student, or trainee.
 - 4. The recipient is not subject to any implicit or explicit expectation of providing something in return for the support (e.g., “quid pro quo”).

- B. This section may not apply to national or regional merit-based awards, which are considered on a case-by-case basis.

V. Industry Support for Educational and Other Professional Activities

Presentations on the use of all healthcare products, regardless of their source, must ordinarily occur in a structured learning environment (e.g. forum or seminar) that is supervised by faculty. Examples of inappropriate learning environments include a vendor talk at a restaurant, a lecture at a vacation resort or country club, and a conversation at a sporting event. In addition, the educational offerings must be science based, supporting the free exchange of information with knowledgeable parties presenting and participating. The following support this general policy and are irrespective of location (e.g. off-site versus on-campus).

- A. General. ACCME *Standards for Commercial Support* (the “Standards”) must be followed for all Industry support for educational activities. These activities must be coordinated with The University of Chicago Clinical Medical Education (“CME”) office regardless of whether the educational session is provided for CME credit. The *Standards* provide guidelines for evaluating all forms of Industry interaction, both on and off campus and including both Enterprise-sponsored and other events. The *Standards* may be found at <http://www.accme.org>. This Section is not intended to prohibit Industry from providing financial support for departments, section, and programs of the Enterprise when such support is provided in a manner that is consistent with this Policy (including Section IV) and the *Standards*. Such financial support must be unrestricted and the department, section, or program is free to utilize such support in the manner it sees fit, subject to the limitations noted in section V(C) below.

- B. Medical Center Enterprise Sponsored Education. Industry financial support may be provided to the Medical Center Enterprise on behalf of any department, section, or program within the Enterprise. The funds are provided to a central administrative department identified by the Dean of the Biological Sciences Division of the University of Chicago, and not to a department, program, section, or physician. Leadership within the department, section, or program may request the distribution of monies from the fund, which the designee of the Dean will grant or deny in its sole discretion and consistent with all applicable Medical Center Enterprise and University policies. Industry personnel must not restrict but may request, how such monies are

spent within the Medical Center Enterprise, department, section, or program.
However,
Industry financial support provided for educational purposes must be used solely to support educational purposes. To ensure compliance with the *Standards*, among other things the CME office will independently examine proposed programs and periodically audit the content and quality of offerings that have taken place.

- C. Identification of the Sponsor. Industry contributors must be recognized in an appropriate manner as outlined in the *ACCME Guidelines*.
- D. Food. Industry must not directly fund meals or other types of beverage and/or food offerings at Medical Center Enterprise meetings, luncheons, case conferences, etc.
- E. Attendance. Because of the high potential for a perceived or real conflict of interest, individuals—especially faculty and other academic personnel—must carefully assess their own participation in meetings and conferences that are fully or partially sponsored or run by Industry.
- F. Active Participation. Individuals who actively participate in meetings and conferences supported in part or in whole by Industry (e.g., by giving a lecture, organizing the meeting) whether on-site or off-site must follow these guidelines:
 - 1. The meeting sponsor must fully disclose the financial support by industry.
 - 2. The meeting or lecture content and materials must be determined and created by the speaker and not the Industry sponsor.
 - 3. The Individual must provide a fair and balanced assessment of therapeutic options to promote objective scientific and educational activities and discourse.
 - 4. An industry sponsor must not require the Individual to accept advice or services concerning speakers, content, etc., as a condition of the sponsor's contribution

of funds or services.

5. The Individual must make clear that content reflects individual views and not the views of any institution within the Medical Center Enterprise.
6. The use of the “The University of Chicago” or “The University of Chicago Medical Center” name and logo in non-University of Chicago events is limited to the identification of the individual by his or her title and affiliation.

NOTE: This Section does not apply to meetings of professional societies that may receive partial Industry support or meetings governed by the *Standards*.

G. **Off-Site Activities.** Individuals must not attend sales or marketing sessions. A sales or marketing session is any non-CME event that is sponsored by industry whether or not the topic is focused directly or indirectly on the sponsor’s product. For example, a breakfast, lunch, or dinner talk at a restaurant that is given by a physician thought leader hired by the sponsor for the event is a marketing session. This is true even if the agenda or topic for discussion is advertised as a topic of general medical or scientific interest. Individuals must comply with the *ACCME Standards* in the same manner as if the education was organized by the Medical Center Enterprise. Additionally, as stated above, individuals must not accept personal gifts or payments from industry regardless of site or circumstance. Individuals may only accept items of value as permitted in this policy.

H. **Speakers’ Bureaus, Consulting Arrangements, and Other Services**

1. Individual participation in speakers’ bureaus poses special concerns, including damage to the Individual’s credibility and the real potential for misuse of the Enterprise’s reputation as a consequence of the individual’s academic affiliation. Be wary of invitations to any event, including panel discussions, to which you are invited to participate with payment in cash or in kind and for which the sponsor provides you with talking points or other materials to discuss or present.
2. Participation in speakers’ bureaus or other consulting engagements is subject to timely disclosure under and in compliance with the University’s Staff Policy on Conflicts of Interest.

I. Individuals may receive compensation from Industry if the compensation is for services rendered. Both the services rendered and compensation must be set forth in a written agreement signed by both parties and the compensation is fair market

value. Such compensation agreement must be disclosed by the individual according to Faculty and Staff Policies.

- J. Procurement: Individuals may evaluate products or services offsite as part of purchasing decision only when UCMC pays for site visit.

VI. Disclosure of Relationships with and Interests in Industry

- A. An individual must not publish an article solely or primarily under his or her own name if the article was in fact written in whole or material part by an Industry employee or employees without attribution. Individuals must retain the discretion to review or edit published material.
- B. In scholarly publications, Individuals must disclose their related financial interests in accordance with the requirements of the journal or publication.
- C. Individuals who have a role in Enterprise decisions or recommendations related to supply, equipment, services, or drug procurement or the hospital's formulary decisions must disclose to the purchasing unit or committee—prior to making any discussion on the matter—any interest (financial or otherwise) they or their immediate family have in entities that might benefit from the decision or recommendation. Such interests include but are not limited to equity ownership, options, compensated or uncompensated positions on advisory boards, a paid consultancy, fiduciary roles, or other forms of remunerated relationship. This disclosure obligation excludes indirect ownership such as stock held through mutual funds. Individuals must also disclose any research or educational interest they or their department or section has that might substantially benefit from the decision. The purchasing unit or committee chair will decide whether the Individual must recuse him/herself from the purchasing decision.
- D. The reporting outlined in this Section does not modify the disclosure requirements set forth in the University Faculty and Staff Policies or The University of Chicago Medical Center Conflict of Interest Policy (A00-12). Each entity within the Medical Center Enterprise will share conflict and other germane information to facilitate compliance with applicable law, reporting obligations, and institutional policies.
- E. For disclosure requirements related to educational activities, see the *Standards*.

VII. Training of Students, Residents, Fellows, and Faculty Regarding Potential Conflict of Interest in Interactions with Industry

Individuals must receive information and training regarding this Policy and potential conflicts of interest associated with interactions with Industry.

VIII. Enforcement and Questions

Questions regarding this policy must be directed to the Medical Center Compliance Office or the Office of Legal Affairs of the University or Medical Center.

This policy will be enforced by the Office of the Dean for the Biological Sciences Division.

IX. References

- A. Accrediting Council for Continuing Medical Education (ACCME) Standards for Commercial Support (<http://www.accme.org/>)
- B. *University of Chicago Medical Center Conflict of Interest Policy* (A00-12) (http://frontline.mcis.uchicago.edu/admin/hsp_pp.nsf/110c44d662f7a775862565ad005de7b7/4ddc16e89f02e4ab862568eb006f1116?OpenDocument)
- C. *University of Chicago Medical Center Vendor Relations Policy* (A05-08) ([http://frontline.mcis.uchicago.edu/admin/hsp_pp.nsf/110c44d662f7a775862565ad005de77/57a725fe832c0340862568ef00577d0a/\\$FILE/A05-08%20Vendor%20Relations%20Policy\(10.2007\).doc](http://frontline.mcis.uchicago.edu/admin/hsp_pp.nsf/110c44d662f7a775862565ad005de77/57a725fe832c0340862568ef00577d0a/$FILE/A05-08%20Vendor%20Relations%20Policy(10.2007).doc))
- D. *University Staff Policy on Conflicts of Interest* (U600) (<http://hr.uchicago.edu/policy/p600.html>)
- E. *Outside Professional and Commercial Activities of Faculty and Conflict of Interest*
(prepared by the Council on Research and approved by the Council of the University Senate on July 27, 2007)
(<http://researchadmin.uchicago.edu/regulations/coi.shtml>)
- F. *The Report of the Standing Committee on Conflict of Interest* (dated January 16, 2004 and setting forth recommendations to clarify, streamline, and strengthen the University Policy) (<http://researchadmin.uchicago.edu/regulations/coi.shtml>)
- G. *Industry Funding of Medical Education Report*, AAMC Task Force, June 2008 (https://services.aamc.org/Publications/showfile.cfm?file=version114.pdf&prd_id=232&prv_id=281&pdf_id=114).

- H. *Protecting Patients, Preserving Integrity Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research*, A Report of the AAMC/AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research, February 2008
(https://services.aamc.org/Publications/showfile.cfm?file=version107.pdf&prd_id=220&prv_id=268&pdf_id=107).
- I. *The Scientific Basis of Influence and Reciprocity: A Symposium*, June 12, 2007
(https://services.aamc.org/Publications/showfile.cfm?file=version106.pdf&prd_id=215&prv_id=262&pdf_id=106)

Frequently Asked Questions

Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies & Services Industries

1. Conferences – Attendance at conferences and related receptions that are sponsored by industry.

Situation: I am attending a conference that is hosted by a professional association. I/my department or section am/is paying a registration fee to the professional association to cover attendance at the meeting. I/my department or section am/is paying for airfare, hotel, and meals.

I noticed while reading the meeting brochure that industry is sponsoring some portion of the conference and in particular the evening reception that occurs at the end of each day of meetings.

Q: Is it a violation of the Medical Center's conflict of interest policy to attend the conference?

A. It is not a violation of the Medical Center's conflict of interest policy for a member of the faculty or a resident to attend a professional association meeting that is sponsored in part by industry so long as you or your department or section pays for the registration fee. In addition, a department may accept scholarship money to allow residents or fellows to attend. This (applying for a grant to attend a conference) is something that would be handled in a centralized manner and absolutely not on a personal level. Do not personally accept "comp" offers from the meeting planners or industry to attend any meeting free of charge.

Q. Is it a violation of the Medical Center's conflict of interest policy to attend the evening reception?

- A.** a. It is not a violation of the Medical Center's conflict of interest policy for a member of the faculty or a resident to attend a post-conference reception that is sponsored by industry so long as the reception is open to all conference participants and covered under the basic registration fee.
- b. It is a violation of the Medical Center's conflict of interest policy to attend at the sponsor's expense a private reception or dinner whether on the conference premises or at a nearby location. These are generally invitation only events through which you are notified

in writing, via e-mail or text-page, by a phone call, or in-person invitation. If you wish to attend, you must pay your own way. Sponsors understand that most invitees will be subject to a conflict of interest policy that require the attendee to pay and will be prepared to quote you a price when you call to inquire.

2. Conferences – Scholarships for residents and fellows to attend professional association meetings.

Q: Does the conflict of interest policy prohibit us from accepting scholarship funds from industry that would permit us to send a resident or fellow to a professional conference.

A: The conflict of interest policy does not prohibit a department or section from accepting scholarship funds from industry for the purpose of sending a resident or fellow to a professional conference so long as these funds are secured in accordance with CME protocol. Section IV of the Medical Center's conflict of interest policy addresses this issue and sets forth the requirements for managing these scholarships.

3. Breakfast, Brunch, Lunch, and Dinner

Q: I occasionally have dinner with sales (drug or device) representatives and/or scientists of industry. Is it permissible under the conflict of interest policy to allow the industry representative to pay for my meal?

A: It is never acceptable under the policy to allow an industry representative to pay for your meal. Please pay for your own meal whether it is breakfast, brunch, lunch, or dinner. See Section I and V of the policy for more information.

4. Educational Materials for Patients

Q: Several pharmaceutical and device companies provide written materials and other education tools that we distribute to patients. The company logo is printed on each document. Are we permitted under the conflict of interest policy to continue to accept these materials and give them to our patients?

A: We are not permitted to accept these educational materials from industry whether or not the materials are branded with the company logo. Industry is welcome to contribute to a central fund that is managed by your department. The department may then distribute funds to be used to produce educational materials for patients. The Medical Center recognizes that it may take certain departments and sections time to transition away from educational materials that display Industry logos and will allow six to twelve months for implementation.

Q: May we accept a grant from a pharmaceutical company to create and film an educational video for patients?

A: Yes -- so long as your section and department follow the pharmaceutical company's formal award process, meaning that an application is completed and sales representatives or other company representatives are not solicited for funds.

Q: May we accept a grant from a pharmaceutical company to cover the costs of creating and printing educational brochures for patients?

A: Yes -- so long as your section and department follow the pharmaceutical company's formal award process, meaning that an application is completed and sales representatives or other company representatives are not solicited for funds.

5. Industry Support - General

Q: I have heard that it is against policy to request funds from industry to sponsor educational events or to support conference scholarships for residents or educational materials for patients. Yet at the same time the policy talks about managing funds centrally. Please clarify.

A: Industry has a mechanism for contributing support that should be followed carefully. Do not request or solicit funding from individual sales or other company representatives. Instead, ask for the contact information of the person or department in the company that accepts applications for support. Most pharmaceutical and device companies have this information posted on their websites. Follow this transparent application process. If funds are awarded, then they should be managed centrally in the department or section. Funds should not be delivered to an individual faculty member, fellow, resident, or staff.

6. Evaluating Equipment and Services

Q: Does the policy prohibit the practice of allowing industry to pay for travel to off-site locations to evaluate equipment or other services?

A: Unless provision has been made for payment through the request for proposal process, it is not permissible to allow industry to pay for travel and other expenses associated with a trip to evaluate equipment or services.

7. Collaboration with Industry on Scientific Papers

Q: Does the policy prohibit me from collaborating with a colleague in industry on a paper for publication in a scientific or medical journal?

A: No. The policy does not prohibit legitimate collaboration that occurs in accordance with established professional authorship standards. What the policy

does absolutely prohibit is ghost writing, or the practice of allowing industry to write a paper that a faculty member would then publish under his or her name.

8. Consulting Arrangements

Q: Does the policy prohibit a legitimate consulting arrangement, which is an arrangement that is set forth in writing for which compensation is commensurate with work performed?

A: The policy does not prohibit legitimate consulting arrangements. You should consider carefully, however, the number of such arrangements in which you participate and be certain that such commitments do not violate that time granted to you by the University (11 days per quarter) for participation in such activities. Keep in mind that any arrangement, consulting or otherwise, that you have with a pharmaceutical or device manufacturing company will be published by these companies on their websites. In most cases this is, at present, voluntary. Soon it will be required by law.

9. Speaker's Bureaus

Q. Does the policy prohibit participation in speaker's bureaus?

A. While the policy does not expressly prohibit participation in speaker's bureaus or discussion panels, approach this activity with caution. Never participate in branded speaker's bureaus activities. This would include events for which the sponsor proposes that you speak about the sponsor's drug or device. This also includes events that are unbranded but for which the sponsor wishes to provide the speaker with a script of statements to be made during the course of the talk. It is a good idea to protect yourself by negotiating a clause in your contract with the sponsor that clearly states that you are under no obligation to mention or advocate for the sponsor's products.

In order to avoid putting themselves at risk, residents and faculty should carefully evaluate activities that Industry sponsors propose to avoid becoming unwittingly involved in something that is intended, designed, or likely to be perceived as a marketing event.

10. Off-site CME Events

Q: Our residents and faculty are often invited to attend citywide evening educational lectures accompanied by a dinner. These are often but not always ACCME-approved events. There is typically not a registration fee at an event like this. The educational presentations are given by academic local, regional, or national faculty. May our residents and faculty continue to attend such events?

A: Residents and faculty may attend these events so long as 1) the event is unbranded and 2) the resident or faculty pays for his food and drink. If these two conditions are met, residents and faculty may attend, whether or not the event is CME. Keep your receipts. Consider carefully the appearance of impropriety factor and the likelihood that your name will be listed on the sponsor's records. Federal investigations of sponsors (drug and device companies) are occurring at increasing frequency. Information gathered through these investigations is being used to identify physicians who are frequent attendees at these events. These physicians may themselves become the subject of an investigation.

Q: Sometimes a member of the faculty gives a presentation at the kind of events described in above. If the faculty is compensated for participation through a legitimate consulting or speaker's bureau arrangement (both of which would need to be fully disclosed to UC, UCMC, and at the speaking site) may our faculty continue to participate in this kind of activity?

A: Yes, so long as the talk is not a branded talk meaning that neither the written content nor spoken comments are scripted by the sponsor. See our cautions above about attendance at these events and the appearance of impropriety.

11. Conferences – Investigator Meeting prior to the conduct of an Industry Sponsored Clinical Trial

Q: Does the conflict of interest policy prohibit us from attending the Industry sponsored “Investigator Meetings” held prior to the initiation of a clinical trial?

A: Attendance at the national study initiation meetings (“Investigator Meetings”) when the clinical trial agreement with the University is either pending or finalized and for which attendance is an expectation of participation, is acceptable. The conflict of interest policy does not prohibit faculty or staff from attending these national study initiation meetings and it is acceptable for the Industry sponsor to pay for the associated costs, if it is contractually that the principal investigator attends the meeting. Participation in an Industry sponsored Clinical Trial is governed formally by the clinical trial agreement between Industry and the University.

12. Patient Holiday Parties

Q: Is it okay for Industry to sponsor our annual Christmas party?

A: No. Industry sponsorship of patient holiday parties is not permitted.

13. Employee Holiday Parties

Q: Is it okay for Industry to sponsor holiday parties for faculty, staff, or residents?

A: No. Industry sponsorship of faculty, staff, or resident holiday parties is not permitted.

14. International Activities

Q: Do these rules apply to my interactions with Industry that occur outside of the United States? Do these rules apply to interactions that occur in the United States with an Industry company that is headquartered outside of the United States?

A: In both cases the answer is yes. These rules apply to all of your activities, whether on campus or off, in the United States or abroad, regardless of where the Industry entity is headquartered.

The University of Chicago Human Resource Services

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Forms, Policies, & Guides

600 - Conflict of Interest Policy

Subject: Conflict of Interest Policy

Section: U600

Date: May 24, 2010

Prior Version Date(s): May 17, 2004; October 15, 1986; October 31, 1985

PURPOSE:

The purpose of this policy is to establish guidelines for conflicts of interest or commitment that might arise in the course of staff employees' duties and external activities. This policy does not seek to unreasonably limit external activities, but instead seeks to emphasize the need to disclose conflicts and potential conflicts of interest and commitment, to manage such conflicts and to ensure that the University's interests are not compromised.

As a basic condition of employment, all University staff employees have a duty to act in the University's best interest in connection with matters arising from or related to their employment and other University activities. In essence, this duty means that staff employees must not engage in external activities that interfere with their obligations to the University, damage the University's reputation, compete with the University's interests, or compromise the independence of the University's research and business activities, or can reasonably be seen as doing so. Staff employees likewise must not profit or otherwise gain advantage from any external activity at the University's expense or engage in external activities under circumstances that appear to be at the University's expense.

POLICY:

Staff employees must disclose and avoid actual and perceived conflicts of interest or commitment between their University responsibilities and their external activities. Depending on the circumstances, employee participation in activities in which a conflict or perceived conflict of interest exists may be prohibited or may be permitted but affirmatively managed.

DEFINITIONS:

Staff employee: All part-time and full-time University staff employees, including officers who are not primarily academic employees within the meaning of the University's Statutes or policies.

External activity: outside financial, business, political, professional, public service and academic activities.

Business activity: the full spectrum of University commercial activities, including but not limited to purchasing, selling, hiring, contracting, investing, licensing, and leasing.

Financial interest: anything of monetary value, including but not limited to, compensation, payments for service (e.g. consulting fees or honoraria), royalties, equity or ownership interests (with the exception of owning not more than 1% of any publicly traded class of shares of any company), and intellectual property rights.

Conflicts of commitment: when a staff employee's external activities (e.g., consultation arrangements, service on boards, leadership positions in external organizations) involve a dedication of time or other obligations that interfere with the staff employee's fulfillment of University responsibilities or when a staff employee uses University resources for external activities without appropriate authorization.

Relative: the spouse, domestic partner, and, whether by blood, adoption, marriage or domestic partnership, the child, parent, grandparent, sibling, grandchild, aunt or uncle, niece or nephew, or any person residing in the immediate household (or the household of the spouse or domestic partner of any of these relatives) of the University employee, or his or her spouse or domestic partner.

GUIDELINES:

1. A staff employee must fully disclose any external activity or financial interest of the staff employee or relative that would reasonably appear to be affected by or to affect the staff employee's decisions, actions or participation in University business activities. Put another way, if a staff employee or staff employee's relative is engaged in an external activity or has a financial interest then full disclosure is necessary if: (i) there is a chance that the interest or activity could reasonably appear to affect the staff employee's decisions, actions or participation in University business activities; (ii) or there is a chance that the staff employee's job duties or participation in other University activities could reasonably appear to affect the external activity or the interests of the external entity in which the staff employee or relative has a financial interest.
2. A staff employee must also disclose when they provide non-University related services to another entity, including a corporation, business, association, government agency or nonprofit organization as an officer, director, owner, agent, consultant, or employee when the services may involve the commitment of time during business hours or otherwise conflict in any way with the University's interests or their responsibilities to the University.
3. All disclosures required by this policy must be in writing to the department/unit head or to the appropriate University vice president as soon as a staff employee becomes involved in covered external activities, aware of an actual or potential conflict of interest or involved in a sexual, romantic, or external business relationship as provided in paragraph 12. Disclosures should provide details such as the nature of the external activity or financial interest, expected or actual role in the external activity, and whether there is compensation or other financial remuneration associated with the external activity. The department/unit head or appropriate University vice president shall respond in writing to acknowledge the disclosure and identify whether a written management plan is necessary. Depending on the nature of the conflict, a written management plan should be devised by, as appropriate, the unit's lead, senior human

resources representative of Human Resource Services, and must be approved by the head of the organizational unit (e.g., Dean, Director, Chairperson) with a copy maintained by the unit. At a minimum, management plans must: (i) address the external activity, interest, or commitment in a way that will ensure that it will not interfere with the interests of the University, (ii) ensure the staff employee is not participating in making decisions on the University's behalf, which the external activity, interest, or commitment will cast doubt on the fairness or integrity of the University's business dealings and (iii) establish a review and approval process as appropriate. To ensure continuity and appropriateness, review and, as needed, revision of the approved management plan should occur at least annually and also whenever there is a germane change in reporting relationships. If the at-issue relationship involves the leader of an organizational unit, the management plan must be reviewed and approved by the organizational leader to whom the at-issue unit leader is accountable.

4. Staff employees who knowingly have or reasonably should know that they have (i) a financial interest in, (ii) a familial relationship with, or (iii) a relative who has a financial interest in, an individual or entity with whom the University is engaged or is actively considering engaging in a business activity, must disclose the interest or relationship and must not act on behalf of the University or otherwise participate in, or seek to directly or indirectly influence, any University decision or transaction regarding or related to that individual or entity. The following are examples of financial interests and relationships that must be disclosed:

- The landscaping business owned by the father of a staff employee in the Facilities Department seeks to bid on a University landscaping contract.
- A consulting firm bids on a contract to provide statistical analysis, and a staff employee is a partner in the firm.
- A staff employee recommends using an office supply company with an excellent reputation and owned by the staff employee's brother.

5. The University encourages staff employees' participation in professional, charitable, community, government, and other public service organizations, which can be beneficial to the staff employee and the University. However, staff employees must not allow external activities to interfere with fulfilling their responsibilities to the University. To avoid conflicts of commitment all external activities involving a significant time commitment during business hours or other obligations that may impact fulfilling responsibilities to the University must be disclosed to the department/unit head or the appropriate vice president of the University, who may approve (with or without modification and/or a management plan) the external activity if it advances or otherwise serves the University's interests. The following are examples of external activities that must be disclosed:

- Serving as an officer of an organization when the commitment will require substantial travel and work during University business hours;
- Providing expert witness services in any civil or criminal case;
- Serving on the board of a nonprofit organization;
- Working as an editor or reviewer for a professional or academic journal; or

- Serving on a panel or committee for a professional organization.

6. Staff employees must refrain from external activities involving personal gain or financial benefit for themselves or relatives (e.g., the purchase or sale of securities, real property, or other goods or services) in which they use, appear to use or likely have the opportunity to use, confidential information or special knowledge gained as a result of their employment by the University and/or participation in other University activities.

7. Staff employees must use confidential information consistent with **U601 Confidential Information Policy** and must refrain from unauthorized disclosure of non-public information concerning the University's business activities, including but not limited to its investments, property development, sale or acquisition, and purchasing and contracting activities.

8. Staff employees must not engage in the unauthorized use of University resources for his/her personal benefit or for the benefit of any other person or external organization. The following are examples of prohibited conduct:

- Using University property such as photocopiers or printers for an employee's cosmetic business;
- Purchasing personal items with a University credit card or account;
- Spending considerable time on a telephone call for the staff employee's consulting business during University business hours; or
- Donating old computers to a nonprofit organization without appropriate authorization.

9. Staff employees must exercise good judgment in giving or receiving gifts or entertainment. It is sound practice to discourage personal gifts and favors from entities and individuals with whom the University engages in business activities or is considering engaging in business activities. Personal gifts of more than nominal value should be declined or returned to avoid any appearance or suggestion of improper influence. Entertainment or travel with a more than nominal value paid for by an external individual or entity must first be disclosed to and approved by the department head or an appropriate vice president of the University. Staff employees may only take vacations with individuals or other entities with which the staff employee directly engages in University business activities, regardless of who pays for the vacation, if the vacation is first disclosed to and approved by the department head or appropriate vice president of the University. The following are examples of prohibited conduct:

- An employee travels and speaks at a conference at a vendor's expense without prior approval from the department head;
- An employee receives a \$100 gift card from a vendor and uses it for personal use; or
- A department attends a dinner paid for by a potential vendor without prior approval by the appropriate vice president.

10. Staff employees involved in awarding or administering contracts using federal or other government funds are prohibited by law from soliciting or accepting gratuities, favors or anything of monetary value from contractors or potential contractors.

11. Staff employees must not make, participate in or attempt to influence other University employees' decisions in University business activities involving a relative. Staff employees should refer to **U206 Nepotism Policy** for additional guidelines. The following are examples of prohibited conduct:

- A staff employee's nephew applies for a Research Assistant position, and the staff employee pressures the hiring manager to hire the nephew;
- A vice president's son wants a schedule change, and the vice president calls the son's supervisor and encourages the schedule change; or
- A staff employee learns of his/her spouse's possible termination of employment and encourages the supervisor to issue a warning instead of termination.

12. Staff employees must avoid favoritism or the appearance of favoritism that may be associated with making employment or business decisions related to a person with whom the staff employee has a romantic, sexual or external business relationship. A staff employee must disclose a personal, romantic, sexual, or external business relationship if it appears to create a conflict of interest or casts doubt on the fairness or integrity of the University's employment or business decisions. Additionally, a staff employee may not make, participate in, or attempt to influence employment or other business decisions involving a person with whom the staff employee has a sexual or romantic relationship. Sexual and romantic relationships also may be proscribed by the University's Policy on **Unlawful Discrimination and Harassment**. The following are examples of relationships that must be disclosed:

- Pat, a staff employee has been dating another staff employee, Chris, and Chris applies for a position indirectly reporting to Pat.
- An employee at a business owned, in part, by a staff employee applies for a position in the department at the University in which the staff employee works, and the applicant may report, directly or indirectly, to the staff employee if hired.
- An employee's neighbor and longtime friend applies for a position reporting directly to the employee.

13. Staff employees are strongly encouraged to disclose any other financial interest or external activity that could present an actual conflict of interest or commitment, or might reasonably be perceived to create a conflict of interest or commitment. Disclosure is a key factor in protecting one's reputation and career from embarrassing or harmful allegations of inappropriate conduct. Staff employees are encouraged to seek guidance from their supervisor or HRS even if their situation is not directly covered by the disclosure obligations in this policy.

14. Failure to disclose an actual or potential conflict of interest or commitment or comply with an applicable management plan, is a violation of this policy and may result in corrective action up to and including termination of employment.

Employees represented by a bargaining unit may be governed by the appropriate bargaining unit agreement.

Last updated on 9/21/10

Human Resource Services

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773-702-8900



**The University of Chicago Medical Center
Policy and Procedure Manual
VENDOR RELATIONS POLICY**

Date Effective: July 1, 2007

Date Revised: March 2011

I. PURPOSE

The detailing of products and services at University of Chicago Medical Center (UCMC) by company representatives is a granted privilege, not a right. Because of the high level of activity related to this function, the following guidelines are necessary to provide fair and equal opportunity for company representatives to conduct business with UCMC, while permitting UCMC to carry out its missions of patient care, research, and education. Sales representatives as guests of UCMC are expected to be aware of their role and conduct themselves accordingly. This policy applies to clinical and non-clinical work areas.

II. POLICY

Initial Registration/Certification

Companies must be certified with the Purchasing Department prior to engaging in any promotion or information activities – hereafter called “Certification” – involving their company’s products and services at UCMC. All Company. Purchasing will utilize an outside organization called **Vendormate** for purposes of Certification. Registration cannot be completed until **Vendormate** has certified the company.

Note: New representatives of Certified Companies must go through registration.

Arrival and Identification Badge

Upon arriving at the Medical Center ALL vendors are required to either park at a city meter or park using valet parking. Self parking in the Medical Center garages is strictly prohibited and will result in immediate loss of visitation privileges. This parking is restricted to patient, patient family and limited staff parking ONLY.

The University of Chicago Medical Center recognizes that our vendors are an essential part of our delivery of the best patient care, and we value that relationship. In October 2007 we implemented the Vendormate program. The program helps us maintain consistent and professional relationships with our vendors. We require that vendors use the University of Chicago Medical Center vendor program to register and set appointments with our staff before visiting. ***All representatives who visit the Medical Center will be required to have an appointment in the UCMC Outlook calendar in order to sign in electronically and print a badge. With a valid appointment and current credentials, a representative will be able to print out a single-use identification badge that is to be worn throughout his or her visit to any location. Appointments will not be permitted without a current, compliant registration.***

III. APPOINTMENTS

Company representatives are not permitted to enter any areas without a scheduled appointment. However, the

UCMC staff member does have the authority to schedule appointments at a location of their choice. If in a patient care area, necessary steps to assure patient confidentiality and privacy will be requested. Representatives may also be required to adhere to the same hospital policies governing employees, faculty, and students regarding immunizations and other health requirements when in patient areas, e.g. rubella immunization, TB skin test.

Loitering in UCMC corridors, cafeterias, and Lobbies in an attempt to facilitate a nonscheduled meeting or to conduct Business with an UCMC staff member is prohibited.

Active Clinical Staff, Residents, Fellows and Medical Students

Clinical staff physicians and Medical Students in all clinical departments are to be contacted by appointment **only**. The representative **must have a prior appointment** with the clinical staff before proceeding to the department. Representatives may not go to the department area to make an appointment. Clinical staff should be contacted for appointments by mail, email, or telephone. An appointment with one clinical staff member does not grant permission to meet with other clinical staff/medical students in that department. Medical students, at the request of Clinical Staff may be included in appointments with vendor representatives. Company representatives must leave the area immediately upon completion of an appointment.

Nursing Staff

Nursing Department staff is to be contacted by appointment only. The company representative **must have a prior appointment** with the staff nurse before proceeding to the department. Company representatives may not go to a departmental area to make an appointment. Nursing staff should be contacted by mail, email or telephone. An appointment with a particular staff nurse does not grant permission to meet with other nurses in that department. The company representative must leave the area immediately upon completion of an appointment.

Perioperative Services Staff

Perioperative Services Department staff is to be contacted by appointment only. The company representative **must have a prior appointment** with a member of the Perioperative staff before proceeding to the department. Company representatives shall make appointments via Perioperative Department Secretaries. An appointment with a particular staff member does not grant permission to meet with other staff members in the Perioperative Services department. The company representative must leave the area immediately upon completion of an appointment.

REGULATIONS FOR PHARMACEUTICAL REPRESENTATIVES

POLICY

Pharmaceutical representatives will be permitted to demonstrate their products to members of the medical, nursing and pharmacy staffs on a regular basis (Tuesdays and Thursdays 8AM – 5PM). The Department of Pharmaceutical Services must approve deviations from these approved days. It is the responsibility of the pharmaceutical representative to contact the Department of Pharmaceutical Services (773-702-6242) prior to this date to provide this information.

REGISTRATION

All pharmaceutical representatives must be registered with the Department of Pharmaceutical Services in room TE026 (Sub-basement of Mitchell Hospital). All pharmaceutical representatives must complete the Pharmaceutical Representative Form (attached). In addition, pharmaceutical representatives will receive a copy of this policy and will sign a statement that they are aware of, and agree to abide by, all policies and procedures included in this document.

Pharmacy stores and/or Drug Information Service will see representatives on Tuesdays and Thursdays by appointment. Other pharmacy staff may also be seen by appointment. Representatives are not allowed in other areas of pharmacy without a supervisor being present.

Requests for appointments with the medical staff may originate from the medical staff itself, through the pharmacy or by the representative prior to the date of the appointment, and such meetings should be conducted in private offices or non-patient care areas. *Representatives are not permitted in patient care areas. Deviation from this*

access restriction must be approved by Pharmacy management for the specific visit prior to the time of visit. Additionally, representatives must be escorted at all times by their host. All floors of Mitchell/Comer Hospitals, including the Emergency Departments, are considered patient care areas. In the Duchossois Center for Advanced Medicine (DCAM), representatives are only allowed behind the reception desk of the clinics with the permission of the medical staff or charge nurse. A staff member must accompany representatives and their presence limited to one area, which is secluded from patients and not disruptive to the medical or nursing staffs. Drug samples must be dispensed in compliance with the Hospitals' Drug Sample Usage and Record Policy.

Pharmaceutical representatives are required to wear at all times company-provided identification, which includes name of the representative and company. Additionally, pharmaceutical representatives must sign-in at the Hospitals' or Duchossois Center for Advanced Medicine's entrances with the Public Safety Officer and receive a UCH vendor badge. This, too, must be worn at all times with the medical center.

PRODUCT INFORMATION

Marketed Products: The Drug Information Service of the Pharmacy is the source of information for healthcare professionals. The medical staff may be informed of these additions or changes in previously marketed products. The Drug Information pharmacist should be advised of all new products, changes in product literature, and changes in previously marketed products.

Investigation Drugs: Pertinent detailed information on all investigational drugs must be forwarded to the department for filing and reference purposes. This includes information on studies that are not being operated through the department

Drug Displays: At specific intervals, medical representatives will be allowed to set-up displays to which medical faculty and house-staff will be invited. At these times there will be opportunities for representatives to discuss their products with the house-staff.

STOCKING OF NEW PRODUCTS

New drug products will be stocked in the pharmacy in accordance with procedures established by the Subcommittee on Pharmacy and Therapeutics. The Department of Pharmaceutical Services is the sole source of supply for all medications and intravenous solutions used in the University of Chicago Medical Center.

PHARMACY INVENTORY

Pharmaceutical representatives are permitted in the office area of the pharmacy. Representatives are not permitted to check stock levels of their company's products or to access records of purchases.

PHARMACEUTICAL REPRESENTATIVE REGISTRY FORM

It is the responsibility of each representative to update the Registry Form as the occasion arises. This information is essential to the pharmacy, but is only of value if the information is current. When changes are necessary in the Registry Form, the pharmacy department's front-desk person is to be advised of this information.

POLICY ADHERENCE

It is the expectation that Pharmaceutical Representatives will comply with the policy. The Director of Pharmaceutical Services will oversee this policy and its compliance. Disciplinary measures will be taken to ensure compliance with this policy. For the first offense, the representative will lose the use of his ID badge for 1 week; for the second offense - 1 month; and for the third offense - 1 year. The fourth offense will result in permanent revocation of privileges.

Hospital personnel should contact the Director of Pharmaceutical Services at 773-702-6242 if representatives are seen violating these policies.

Purchasing Department Staff

The Purchasing staff is available to meet with company ³representatives during the hours of 8:30 am to 5:00 pm by

appointment only.

IV. VENDOR RULES

Note: Access to patient care areas is strictly prohibited unless requested by clinical staff for educational purposes. These areas include: All Adult and Pediatric Nursing Units, Emergency Departments, Outpatient Sites, General Operating Rooms, DCAM Operating Rooms, Comer Operating Rooms, Radiology and all other inpatient/outpatient areas.

Vendor representatives are to be in the General Operating Room, the DCAM Operating Room, Adult Cardiac Catheterization Lab, Pediatrics Cardiac Catheterization Lab, Electrophysiology Lab and all Center for Advanced Medicine (DCAM) procedure areas only when invited by a Surgeon, Physician, Anesthesiologist, or Management Team member, for sanctioned purpose only:

- In-service new product or device including pharmaceuticals
- Technical consultation sanctioned by surgeon, physician or management team member
- Department of Surgery, Nursing Department, Management Team member or Materials Management Department sanctioned product needs assessment and/or educational in-services

This includes only:

- New procedure with current product or device
- New instruments
- Complex procedure requiring technical consultation
- Product and equipment trials
- Research and field tests of unreleased products or devices
- Current product review
- Other by approval

Representatives are permitted to offer technical advice to the surgical/procedure team regarding their equipment or devices while in use on a patient. **Representatives are NOT permitted to operate any equipment or devices.**

Educational or research programs may necessitate representatives to have access to confidential patient information. Under no circumstance are representatives to have access to confidential patient information unless a signed HIPAA agreement is on file in the Purchasing Department and/or Hospital Compliance Office. Representatives must also comply with hospital patient and/or medical staff consent policies.

- Representatives are not permitted to operate any UCMC equipment.
- Representatives are not to touch patients at any time.
- Representatives may not scrub on any procedure.

If the new product is an implantable, the OR Supply Chain Team (ORSCT) must approve it. If the device is investigational, pre-approval must be obtained by the Investigational Review Board (IRB) and the Vice President of Perioperative Services. All non-implantable supplies and devices must have pre-approval from the ORSCT. Each company must receive a UCMC no-charge PO prior to use of any demo equipment and/or supplies. The Medical Center will not pay for any device that is not used or implanted during the specific procedure. No “extras” may be left in the department for “inventory” purposes. Leaving excess devices behind will constitute a gift to the Medical Center.

All new medical equipment and demo equipment must be reviewed and approved for use by the UCMC Clinical Engineering Department prior to its use.

The Vendor Representative must provide nursing staff involved in the procedure with an in-service on new

devices or pieces of equipment prior to the beginning of the surgical procedure. This must be coordinated with the Office of Nursing Education and Professional Development for all Nursing units and the Perioperative Education department.

Instruments or supplies needing sterile processing must be received at least 24 hours prior to surgery.

Attendance at Hospital Meetings

Attendance at Grand Rounds and departmental meetings is by invitation only.

Product Evaluation for Stock and Non-Stock Products

Company representatives are aware of the costs associated to UCMC for in-use evaluation of their products. Therefore, these products and/or pharmaceuticals must be provided at no cost to UCMC. Products that are to be evaluated in an actual clinical setting are to be delivered in properly sealed cartons, paying particular attention to packaging that assures the integrity of sterile products until the point of use.

Representatives may not accept any order (verbal, phone, electronic, fax or written) for products or pharmaceuticals unless an official purchase order is authorized and assigned by Purchasing or Pharmacy, respectively.

All pharmaceuticals must be coordinated through the Pharmacy Department. With exception of selected outpatient clinical trial medications, all drugs must be delivered directly to Pharmacy. Drug samples may only be utilized in outpatient settings when requested by Attending faculty members; however they must be registered with the Pharmacy prior to delivery to the requesting physician.

Addition of New Products

New products/pharmaceuticals are considered for addition only after review by the appropriate Supply Chain Team or the Pharmacy and Therapeutics Committee who have the authority to approve new products for use at UCMC.

Educational In-services

Educational in-services must be requested and coordinated by authorized persons and shall not be promotional in nature.

Non-Formulary medications may not be in-serviced without permission of and attendance by a Pharmacy manager.

Note: ***Rooms must be left clean and orderly at the conclusion of the in-service program.***

Violation of Policies

These policies and regulations for company representatives are to be followed rigidly. All UCMC staff will assist in monitoring the level of compliance. In the event that a member of the UCMC staff observes a vendor in an UCMC work area without an UCMC approved Vendor Badge, the staff member should do the following:

- Ask the vendor if they are aware of the Vendor Visitation Policy (If not, they should be directed to the Office of the Director of Purchasing, located in the AMB Room M100, phone number 773/702-0919)
- Ask the vendor for his/her name and company and request that they leave the area immediately
- Notify the Department of Purchasing (773/702-9400) with the vendor information

Gifts and Compensation

Personal gifts from Vendor companies including Food/Meals are prohibited and may not be accepted by any UCMC employee.

Violation of Patient Privacy (HIPAA)

Violation of any patient privacy will result in IMMEDIATE loss of visitation privileges.

Failure to comply with all other sections this policy can result in the following actions:

- a. **First infraction** – Loss of visitation privileges for one month
- b. **Second infraction** – A letter of reprimand with a copy being sent to the company representative's immediate supervisor, and loss of visitation privileges for three months
- c. **Third infraction** – A letter of reprimand with a copy being sent to the company representative's immediate supervisor with a request of change of vendor representative. Failure to do so will result in loss of certification for the Company and will no longer be able to do business with UCMC.

PERSONS RESPONSIBLE

Director, Purchasing

Director, OR Management

Director, Pharmacy

PERSONS RESPONSIBLE FOR REVIEW OF POLICY

Vice President Support Services

Vice President, Perioperative Services

Chief Pharmacy Officer

Director, Purchasing

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The University of Chicago Medical Center
Policy and Procedure Manual

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**UCMC Officer, Employee and Influential Medical Staff Member Conflict and Vendor
Relationship Policy**

Issued: August 1992 Page 1 of 7

Revised: September 2010 Administrative Policy 00-12

Reviewed: September 2010 UCMC Officer, Employee and Influential Medical Staff
Member Conflict and Vendor Relationship Policy

Purpose

The University of Chicago Hospitals strives to maintain a business environment that is in the best interest of the hospital. One aspect of an appropriate business environment is taking particular care in employees' relationships with those who do business or want to do business with the hospital, avoiding not only actual improprieties but also the appearance of impropriety. Because The University of Chicago Hospitals (UCMC) places its trust and confidence in its employed officers, employees, and medical staff members, they shall refrain from actions detrimental to UCMC, provide full disclosure of possible conflicts of interest and exercise care in all relationships with vendors or potential vendors of UCMC.

This policy is separated into three parts and is intended to provide guidance in acceptable conduct for UCMC Associates (defined below) and certain medical staff members. The first part of this policy provides general standards of conduct for UCMC Associates. The second part addresses conflict of interest identification and disclosure for UCMC Associates and Influential Medical Staff Members (defined below). The third part addresses UCMC Associates' conduct with vendors or potential vendors. UCMC Associates and medical staff members should review the entire policy to determine which section most appropriately addresses the conduct in question. This policy supplements but does not replace any other UCMC policy or applicable law addressing the conduct of officers, employees and medical staff members.

This policy is to be read in conjunction with Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies & Services Industries, available on the Intranet on the Office of Medical Center Compliance website. If there is a conflict, the more strict will apply.

Application

This policy shall cover the conduct of all UCMC officers and employees (referred to in this policy as “UCMC Associates”). This policy also covers the conduct of UCMC medical staff members who: (i) have administrative positions at UCMC; or (ii) are appointed to a UCMC committee or advisory panel that will have general or specific input on UCMC’s procurement of items or services; or (iii) have significant influence on UCMC’s procurement of an item or service (collectively, “Influential Medical Staff Members” or “IMSM”). The determination of whether a medical staff member is subject to the requirements of this policy shall be made by the applicable UCMC officer who has responsibility for the committee, or advisory panel, or, in the instance of an individual procurement decision, the UCMC officer who has responsibility for the department where the items or service will be paid for, managed or deployed. UCMC officers shall provide the Director of Internal Audit the names of individuals identified as IMSM in categories (i) and (ii) and shall update the information as membership on committees or administrative positions change. For individuals identified as IMSM in category (iii), the responsible UCMC officer shall inform the physician and the Director of Internal Audit when such determination is made.

General Standards of Conduct

UCMC Associates are expected to refrain from actions detrimental to UCMC, including, but not limited to:

- using funds or property of UCMC;
- using work time compensated by UCMC for personal benefit;
- disclosing UCMC information, including, but not limited to, patient information, non-public business information, personnel information, computer access codes, and quality assurance or peer review information;
- transacting UCMC business on terms that are less advantageous than those competitively available or those available through arms-length dealing;
- accepting anything of value, either in the form of a gift, entertainment or services, from UCMC vendors or potential vendors, that is not specifically permitted under this Policy;
- directly or indirectly soliciting gifts, contributions or other items of value from UCMC vendors in cash or kind in return for initiating or continuing a business relationship with the vendor.

Nothing in this policy prohibits UCMC (with approval from the President) from making contributions to other not-for-profit organizations. The UCMC Development Office and the Office of Legal Affairs has established guidelines for receiving appropriate charitable contributions from UCMC vendors.

Identification and Resolution of Conflicts of Interest

The conflict of interest disclosure procedure set forth below is designed to assist UCMC Associates and IMSM in identifying and fully disclosing any interests that could impair the exercise of their impartial, independent judgment or that could result in a perception that they failed to exercise their impartial, independent judgment in evaluating whether a proposed action is in UCMC’s best interests.

A. Definitions

The following definitions are intended to assist UCMC Associates and IMSM in determining whether a potential conflict of interest exists.

Compensation - includes wages, salary, independent-contractor payments and any other forms of direct and indirect remuneration, as well as gifts or favors that are of more than nominal value or of a type that could create a perception that such gifts or favors are intended to or may interfere with a UCMC Associate's or IMSM's independent judgment in evaluating whether an action is in the best interest of UCMC.

Family Member – means a spouse or domestic partner, any relative (by blood or adoption), or the spouse of any relative (by blood or adoption) of the UCMC Associate or IMSM. This includes, but is not limited to, a UCMC Associate's or IMSM's parents, children, and siblings.

Financial Interest – a UCMC Associate or IMSM has a Financial Interest if the UCMC Associate or IMSM has or seeks to have an ownership interest or a Compensation arrangement that is substantial enough to affect that person's judgment, or that could lead to a reasonable perception that such person's judgment could be affected. The relationship may be direct or indirect, through business, investment or a Family Member. Examples of Financial Interests include, but are not limited to:

- A direct or indirect agreement, understanding, employment relationship, ownership interest or investment interest in any vendor of goods or services that does business with, seeks to do business with, or competes with UCMC;
- A direct or indirect Compensation arrangement with any UCMC affiliate, or with a vendor of goods or services that does business with, seeks to do business with, or competes with UCMC; or
- A *potential* ownership or investment interest in, or Compensation arrangement with, any vendor of goods or services that does business with, seeks to do business with, or competes with UCMC.

Non-Financial Interest – any obligation other than a Financial Interest that is substantial enough to affect that person's judgment, or that could lead to a reasonable perception that such person's judgment could be affected. Such interests will typically involve fiduciary obligations. The interest may be

direct or indirect, through business, investment or a Family Member. Examples of Non-Financial Interests include, but are not limited to:

- A UCMC Associate is a member of the Board of Directors (serving without Compensation) of an entity that competes with UCMC.
- A UCMC Associate's spouse is a corporate officer (serving without Compensation) of another charitable organization that contributes funds to or receives funds from UCMC.
- A UCMC Associate serves on an advisory board of a UCMC vendor.

Potential Conflict of Interest – means any Financial Interest or Non-Financial Interest.

B. Disclosures Obligations

Each UCMC Associate and IMSM has an obligation to disclose in writing Potential Conflicts of Interest as they are identified. Such disclosures should be in writing, and submitted to the reporting entity identified below. In addition to this ongoing obligation to disclose, UCMC Associates and IMSM will be required to periodically review this policy and complete a conflicts disclosure form upon the following:

- For all employees: Upon employment with UCMC.
- For UCMC officers, Level IV and Level III employees and all Purchasing Department staff: Upon appointment to a position of UCMC officer, manager or Purchasing Department staff if employed on the date of such appointment. In addition, this category of individuals shall also complete a written disclosure on an annual basis.
- Influential Medical Staff Members: Upon appointment to a UCMC administrative position; upon appointment to a committee or advisory group that may influence UCMC's procurement of items or services; and/or, upon a determination by the applicable UCMC officer that a medical staff member has significant

influence over a specific procurement decision.

The Director of The Internal Audit Department and a representative of Human Resources will implement the disclosure process.

C. Acceptance and Review of Disclosures by Director

All disclosures required by Section B other than the general disclosure of all UCMC Associates upon employment shall be made or forwarded to the Director of The Internal Audit Department (Director) or the Director's designee. With respect to the disclosure collected upon the UCMC Associate's employment with UCMC, Human Resources staff will collect the disclosure and forward to the Director only those disclosures that disclose a Potential Conflict of Interest. The Director shall conduct a preliminary assessment of each disclosure and may, as appropriate, consult with other UCMC senior leadership (e.g., appropriate personnel in compliance, legal affairs, or human resources) to evaluate the disclosure and the potential impact on UCMC interests. If necessary, the Director, in consultation with appropriate UCMC personnel, shall develop a plan to address the potential conflict, which may include: (i) documenting, or requiring the appropriate party to document, why the proposed business activity is in the best interest of UCMC without regard to the Potential Conflict of Interest; (ii) advising the disclosing UCMC Associate or IMSM not to participate in a particular UCMC business activity; (iii) documenting that the Potential Conflict of Interest could not reasonably be determined to impact a UCMC business activity in a manner that is not in the best interest of UCMC. The Director shall maintain the confidence of such disclosures, and shall only disclose the information necessary to carry out the purposes of this policy. The Director shall keep records of the activities under this Section C and periodically report such activity to the UCMC Board of Trustees or one of its Committees.

Vendor Relationships

UCMC recognizes that from time to time vendors who have or desire to have a relationship with UCMC may extend certain business courtesies to UCMC Associates. In some instances, such business courtesies may result in an appearance of impropriety. In other cases, such business courtesies could not reasonably be determined to inappropriately influence a vendor's existing or proposed relationship with UCMC. This section of the policy is intended to provide guidelines to UCMC Associates in appropriate conduct with respect to the acceptance of business courtesies.

For the purposes of this section, business courtesies are items or services provided by the vendor for the benefit of the UCMC Associate and include, but are not limited to, travel, event tickets, entertainment, food and/or meals.

A. Prohibited Conduct. As stated in Section III above, UCMC Associates may not accept anything of value or solicit gifts, contributions, or other items of value from a vendor or potential vendor. Specifically, a UCMC Associate may not on his/her own

behalf or on behalf of a Family Member:

1. Solicit or request, directly or indirectly, any business courtesy or other item of value or suggest or imply that a business courtesy or other item of value is necessary in order for the vendor to conduct business with UCMC.
2. Accept cash or cash equivalents from a vendor or potential vendor.
3. Accept any business courtesy from a vendor or potential vendor that does not fall under Sections B or C.

B. Acceptable Conduct. UCMC Associates may:

1. Deminimus Exception. Accept business courtesies with a total retail value of \$50 or less in any one year from an individual or organization that currently has or proposes to have a business relationship with UCMC, but only if total business courtesies from all vendors during the year for the UCMC Associate do not exceed \$250. This provision does not apply if a business courtesy is prohibited by Administrative Policy 05-08, Vendor Relations Policy.
2. Gifts of Food. Accept modest gifts of food from an individual or organization that currently has or proposes to have a business relationship with UCMC if:

- The gift is made available to an entire department or office for consumption on site;
- The frequency of such gifts to all members of the department or office is no more than once a year; and
- The gift is unrelated to a specific marketing of a product or service.

For the purposes of this section, modest gifts include the following and their equivalents: popcorn tins, a box of chocolates or candy, or a small selection of fruits. Modest gifts would not include catered lunches or dinners.

Note: This acceptable conduct exception only applies to the prohibition under Section A(3) above, not to the prohibitions under Section A(1) or A(2).

C. All Other Business Courtesies: Disclosure and Approval Requirements

All UCMC Associates offered business courtesies falling outside of the acceptable business courtesies outlined in Section B above must disclose such offer in writing with a good faith estimate of the value of the courtesy to the UCMC Associate's Level III

supervisor or immediate supervisor, whichever is a higher level UCMC position (the “**Supervisor**”). All such disclosures must be made prior to receipt or immediately upon receipt of the business courtesy. If the business courtesy falls under Section A (1) or A(2), or if the Supervisor believes the offered business courtesy would lead to an appearance of impropriety, the Supervisor should require the UCMC Associate to refuse or return the courtesy, dispose of the courtesy, or, if necessary, require UCMC to reimburse the vendor for the value of the courtesy. Otherwise, the Supervisor may, at his or her option, permit the acceptance of the business courtesy. The Supervisor shall maintain records of all business courtesies approved under this Section C and shall forward the information periodically to the Director. In the case of the President, he or she shall make all disclosures to the General Counsel.

All business courtesies received in connection with B above or approved through this Section C are exempt from Conflict of Interest disclosure obligations set forth in Section IV.

D. Confidentiality

Completed conflict and business courtesy disclosure forms shall be maintained in files, which are safeguarded from disclosure to unauthorized persons or for unauthorized uses.

Possible Violations by Others

UCMC Associates have a duty to report to the Director if and when they become aware of possible violations of this policy by UCMC Associates or IMSM. These reports should be in writing, and will be treated confidentially.

Disciplinary Actions

Failure to adhere to the requirements of this policy shall lead to disciplinary actions that may include removal from office, termination of employment, or loss of administrative positions.

Authority, Interpretation, Implementation, and Revision

This policy will be interpreted by The Office of Legal Affairs and the Compliance Officer, as appropriate.

Kenneth J. Sharigian

President

Issued: August 1992 Conflict of Interest

Revised: September 2010

Reviewed: September 2010 Administrative Policy 00-12

Business Partner (Vendor) Management Program

1 POLICY:

To establish a protocol for activities among Business Partner (vendor) representatives, hospital staff, and physicians throughout NorthShore University HealthSystem (NorthShore) hospitals to assure the safety and security of our environment, the confidentiality of protected health information, and the continuity of quality patient care and services. NorthShore management, public safety, physicians, and hospital staff are responsible for cooperating with and enforcing the Business Partner Management Program policy. Any violation of policy is subject to disciplinary/corrective action. Business Partner representatives are required to register, complete competency and other credentials requirements as applicable for Business Partner (vendor) type and adhere to the compliance aspects detailed in the NorthShore Business Partner's Guide as communicated through the NorthShore Business Partner (vendor) management program system (**REPtrax**). Department staff are required to refuse any Business Partner representatives not displaying an authorized REPtrax temporary visitation identification badge. If a representative refuses to comply, contact Public Safety and/or the Purchasing department.

2 SCOPE:

NorthShore departments where Business Partner representatives make hospital on-site visits for sales, in-service education, service or other activities. This policy is not applicable to construction contractors or Business Partner representatives at non-hospital sites.

3 DEFINITIONS:

Business Partner (Vendor) Representative: A bona fide representative of a company who visits NorthShore for the purpose of soliciting, marketing, or distributing information regarding goods or services; Business Partner's with contracts or services for construction are excluded from this policy unless otherwise directed to comply.

REPtrax: Web-based common platform that creates a community between hospitals and Business Partner representatives. REPtrax is a technology that communicates NorthShore requirements to Business Partner representatives.

4 PROCEDURE:

| | <u>Action</u> | <u>Responsibility</u> |
|--|---------------|---|
| A. Business Partner Initial Requirements for NorthShore Hospital Visitation | | |
| 1. Business Partner (vendor) representatives are instructed by Purchasing to register on-line with REPtrax prior to conducting business at any NorthShore hospital. By completing the Business Partner registration process, the representative agrees to comply with criteria in the NorthShore Business Partner's Guide, including completing competency and other credentials requirements as applicable for Business Partner (vendor) type, and all the rules and regulations set forth in this and other NorthShore policies. | | Purchasing |
| 2. Representatives, in order to be approved and to continue doing business at NorthShore, provide current registration requirements electronically into the REPtrax system coordinated by Purchasing. | | |
| B. Business Partner On-Going Requirements for NorthShore Hospital Visitation | | |
| 1. Business Partner/Business Partner representatives who are listed as an excluded Individual/Entity by the Office of the Inspector General or other government agency are not approved as a Business Partner of NorthShore. | | Purchasing; Affected Department Head; Business Partner Representative |
| 2. Business Partner representatives conduct routine business at NorthShore during Purchasing's normal business hours, 8:00 a.m. to 4:00 p.m. Monday thru Friday. | | |
| 3. Upon arrival and departure , Business Partner representatives are required to check in/out at a REPtrax terminal and obtain an authorized REPtrax temporary visitation identification badge. Business Partners are required to visibly display this badge (at or above the waist height) while on NorthShore premises. The badge is valid for the time of the visit only. The badge includes the REPtrax name logo, Business Partner representative name, their company name, area the representative will be accessing, facility, location and displays an expiration time and date . | | |

| <u>Action</u> | <u>Responsibility</u> |
|--|--|
| 4. Under no circumstances are Business Partner representatives allowed to proceed directly to departments in the hospital. Furthermore, Business Partner representatives are not permitted to conduct business in public access areas (i.e., atrium, cafeteria, elevators, hallways, etc.) except for approved Business Partner display area. Business Partner representatives are not allowed to enter patient care areas without specific permission from an authorized department representative. While in patient care areas, the Business Partner representative is accompanied by a NorthShore employee at all times and follows any internal policies of that department including appropriate attire. | Purchasing; Affected Department Head; Business Partner Representative |
| 5. Off-Hours Business Partner Visitation: Business Partner representatives with scheduled and/or urgent activities at the hospital before/after normal business hours (8:00 a.m. to 4:00 p.m., Monday – Friday) should follow the current hospital process and obtain their REPtrax badge prior to accessing the hospital location. | Purchasing; Affected Department Head; Business Partner Representative; Public Safety |
| 6. Business Partner representatives park in designated areas and abide by the facility's parking regulations. | Purchasing; Affected Department Head; Business Partner Representative |
| 7. Gifts and Gratuities: Medical staff, employees, aka "covered persons" do not accept gifts, services or other things of value that may influence decisions made on behalf of NorthShore. Covered persons may accept gifts from Business Partners that have a nominal value. (Refer to NorthShore Code of Ethics and Business Conduct, Conflict of Interest Policy, Corporate Compliance Policy Manual) | |
| 8. The Purchasing Department is responsible for the negotiation and procurement of medical/surgical supplies, equipment, and services at NorthShore. Medical/surgical representatives are required to discuss products and services with Purchasing Department staff to determine opportunities at NorthShore. Purchasing collaborates with hospital staff and coordinates further discussion if deemed appropriate. Departments contacted directly by Business Partner representatives refer the contact to Purchasing to collaborate and coordinate further discussion. Adequate lead time (30 days) is required by Purchasing to prepare and negotiate with Business Partner representatives prior to new products or trials. | |
| 9. Business Partner representatives must have a prior appointment scheduled by mail, email or telephone before proceeding to the department. Representatives are encouraged to confirm appointments in advance. Purchasing is not responsible for contacting individuals at the request of representatives for appointment scheduling. "Tailgating" or "Piggybacking" where one Business Partner representative officially registers but is accompanied by other representatives of that company who have not registered is prohibited. | |
| 10. An appointment with one NorthShore staff member does not grant permission to other NorthShore staff members. | |
| 11. Loitering in corridors, cafeterias, and other areas in an attempt to facilitate a non-scheduled meeting with a staff member is prohibited. | |
| 12. The Business Partner representative must leave the area immediately upon completion of an appointment. Before exiting the facility the representative must check out in REPtrax. | |
| 13. Supplies and/or equipment are not to be left for evaluation without an authorized purchase requisition or no-charge purchase order. | |
| 14. All equipment/supply requests are coordinated through the Purchasing Department and received by the Receiving area. Equipment/supplies furnished by the Business Partner have current (as applicable) FDA approval, be within the product expiration date, and are in a clean, sterile (as applicable) and unopened condition at the time it is brought into the hospital. All clinical equipment is inspected by the appropriate NorthShore department (i.e. Bio-Med, etc.) and inspected for electrical safety prior to use. | |
| 15. NorthShore assumes no responsibility for supplies or equipment left by Business Partner in the organization for the purpose of evaluation. It is the responsibility of the Business Partner, unless agreed to by the Purchasing Department, to deliver, install, and remove the equipment or supplies upon completion of the evaluation. | |
| 16. Supplies/equipment shipped by Business Partners and/or brought into the facility and furnished to operating departments by representatives without obtaining prior approval from the department director, manager, and/or an authorized purchase order from Purchasing are deemed to be "no-charge" items. | |

Action

Responsibility

- 17. To ensure that consignment inventories are accurately documented and kept up to date, a purchase order authorized by Purchasing is required for all consignment products. NorthShore is not liable for consignment products left on the premises without purchase order approval.

Purchasing; Affected Department Head; Business Partner Representative

C. Monitoring of Business Partner Conduct

- 1. Staff will assist in monitoring the Business Partner representatives level of compliance. In the event that a staff member observes a Business Partner representative in an area without a REPTrax identification badge, the staff member should do the following:
 - a. Ask the Business Partner representative if they are aware of the REPTrax system in use at NorthShore. If not, direct them to the REPTrax terminal to check in.
 - b. Ask the Business Partner representative for his/her name and Business Partner name and request that they leave the area immediately. Notify Purchasing or other authorized REPTrax system user of the event for entry into the REPTrax system.
 - c. Purchasing or other authorized user enters in REPTrax system details including dates for the situation.
 - d. Uncooperative Business Partner representative may be escorted off the premises by contacting Public Safety.

NorthShore Staff; Public Safety

D. Monitoring/Disciplinary Action of Business Partner Conduct

- 1. Monitor REPTrax Business Partner representatives scores and also investigate any reported violation of this policy. Business Partner representatives who fail to comply with NorthShore requirements are subject to losing their business privileges at NorthShore. NorthShore reserves the right to restrict the representative and the company they represent from NorthShore property.
- 2. Initiate action for failure to comply with progressive disciplinary actions:
 - a. Scores are generated for Business Partner representatives for various inappropriate actions (e.g., no appointment).
 - i. Every offense generates an automatic email to the Business Partner representative and designated NorthShore staff.
 - b. Review REPTrax scores periodically for disciplinary action that could include the following:
 - The Purchasing Department suspending the Business Partner representative’s privileges at NorthShore facilities for sixty (60) days, requesting a replacement Business Partner representative and sending a notice of violation to the district manager.
 - The Purchasing Department revoking the Business Partner’s privileges to have representatives at NorthShore facilities for a period of time to be determined by NorthShore. Notice will be sent to the district manager.
 - Another representative/co-marketer will not be allowed to detail products labeled with the name of a suspended Business Partner during the Business Partner’s suspension period.
- 3. Business Partner may contact the Senior Vice President of Purchasing to appeal for reinstatement.
- 4. Immediate action, including a FDA report, will be taken if the infraction warrants such action.
- 5. Communicate with appropriate Administrative and/or Physician staff:
 - a. Impending actions
 - b. Causes of action
 - c. Feedback from Administrative and/or Physician staff
- 6. Coordinate and document final details for vendor meeting.
- 7. Conduct an interview with the affected representative and his/her management staff.
- 8. Advise vendor representative of disposition of the issue.

Purchasing

Assistant Vice President, Purchasing/Designee

Assistant Vice President, Purchasing/Designee; Affected Department Head

Action

Responsibility

- 9. Advise Administrative and/or Physician staff of final outcomes.
- 10. The Senior Vice President of Purchasing reserves the right to accelerate the disciplinary process or to add additional disciplinary provisions.

Assistant Vice President,
Purchasing/Designee;
Affected Department
Head

E. Disciplinary Action for NorthShore Staff

- 1. NorthShore staff found to be not in compliance or supportive of this policy will be reported to their supervisor for action. Depending on the severity of the situation, corrective action up to and including termination may be warranted. Purchasing will work in conjunction with the appropriate parties to determine the appropriate corrective action.

Assistant Vice President,
Purchasing; Affected
Department Head;
Human Resources

F. REPtrax Terminals

- 2. Maintain REPtrax terminals at each facility. If found to be not operational – call the Information Systems Helpdesk at 5170 or in need of badge supplies - call Material Services - 2238 at Evanston Hospital, 2847 at Highland Park Hospital, and 5640 at Glenbrook Hospital.

Information Systems;
Material Services

5 ATTACHMENT:

None

6 DISTRIBUTION:

Administrative Directives Manual

7 POLICY RESPONSIBILITY

Assistant Vice President of Purchasing

In Coordination With:

Professional Staff
Public Safety

8 REFERENCES:

Internal

External

- Health Care Industry Representatives in the Operating Room (OR Manual)
- NorthShore Business Partner’s Guide
- NorthShore Code of Ethics and Business Conduct (Corporate Compliance Manual)
- NorthShore Conflict of Interest Policy (Fiscal Manual #1.06)

None

9 REVISION:

The organization reserves the right to unilaterally revise, modify, review, or alter the terms and conditions of the policy within the constraints of law, with or without reasonable notice.

10 APPROVAL:

| | | |
|--|---|-------------------------|
| <u>Nancy Semerdjian</u> Signature | <u>Chief Nursing Officer</u> Title | <u>10/20/08</u> Date |
| <u>Thomas C. Keeler, MD</u> Signature | <u>President, Professional Staff</u> Title | <u>10/26/08</u> Date |
| <u>Jeffrey Hillebrand</u> Signature | <u>Chief Operating Officer</u> Title | <u>10/29/08</u> Date |

11 DATES:

Origination: 01/08 **Last Review:** 10/08 **Next Review:** 10/11

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| Date Established 6/02 | Date Revised 2/09 |

Subject: **CONFLICT OF INTEREST**

I. POLICY

It is the policy of NorthShore University HealthSystem (NorthShore) that all Covered Persons avoid engaging in any activity, practice or conduct which conflicts or appears to conflict with the interests of the Corporation, its customers, or its vendors. This policy is intended to supplement, but not replace any provision of Illinois law governing charitable, not-for-profit corporations.

II. SCOPE

This policy applies to all NorthShore Covered Persons, as defined below, and is to protect the interest of the Corporation related to a transaction or arrangement that might benefit or potentially benefit the private interest, financial or otherwise, of a Covered Person. This policy provides a basic structure of preventive techniques in those areas where conflict of interest or impairment of independent judgement can occur. It is designed to help protect assets and individuals associated with NorthShore and prevent the loss of NorthShore tax exempt status, image tarnishing, and civil and criminal prosecution. NorthShore expects that employees and others represent the organization in a positive and ethical manner, and represent the Corporation without personal interest in a transaction or arrangement. In addition, all Covered Persons have an obligation to report any situation which they believe to be a violation of this policy.

III. DEFINITIONS:

- A. **Conflict of Interest** - A conflict of interest is any situation in which financial or other personal considerations may compromise or appear to compromise a Covered Person's (1) business judgement; (2) delivery of patient care; or (3) ability to do his or her job. An actual or potential conflict of interest occurs when an employee is in a position to influence a decision that may result in a personal gain for that individual or for an immediate family member as a result of business dealings.
- B. **Covered Persons** - Covered Persons means all directors, officers, employees and volunteers.
- C. **Immediate Family Member** - For the purpose of this policy, immediate family member shall mean a Covered Person's spouse, ancestors, children, grandchildren, great-grandchildren, siblings (whether whole or half blood), and the spouses of children, grandchildren, great-grandchildren, and siblings.

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| Date Established 6/02 | Date Revised 2/09 |

Subject: **CONFLICT OF INTEREST**

IV. PROCEDURE GUIDELINES

It is impossible to list all the specific instances prohibited by this policy. Covered Persons of NorthShore are expected to represent the organization in a positive and ethical manner, and represent the Corporation without personal interest in a transaction or arrangement. Business dealings with outside entities should not result in unusual gains. Unusual gains refer to bribes, product bonuses, special fringe benefits, unusual price breaks, and other windfalls designed to ultimately benefit the employer, the employee, or both. Certain nominal benefits are allowed in accordance with this policy (Section IV A 6).

- A. The following activities are prohibited for Covered Persons under this policy:
1. Utilizing or contracting with any outside vendors, agencies, consultants, etc., that are owned by a Covered Person of NorthShore or has related interests, directly or indirectly, through a business, investment or immediate family member (except as allowed by Section IV B).
 2. Appropriating, using, or permitting others to appropriate or use, any funds, property, or time compensated by NorthShore or of other assets for any purpose that is know to be unlawful or for personal gain or benefit.
 3. Failing to disclose in writing any personal interest, direct or indirect, in any corporation, partnership, or other entities, whether business or not-for-profit, doing business or seeking to do business with NorthShore except where such interest is comprised solely of securities in a publicly traded business corporation or partnership and such interest does not exceed 5% of any class of shares or other securities outstanding. In this context, indirect personal interest means a beneficial ownership or creditor interest controlled by a Covered Person, either through an immediate family member, nominee or trust.

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| Date Established 6/02 | Date Revised 2/09 |

Subject: **CONFLICT OF INTEREST**

FISCAL MANUAL Policy and Procedures

4. Discussing or sharing business related materials and other confidential NorthShore information (i.e., non-public business information, personnel information, patient information, computer access codes, computer system information, quality assurance information, peer review data, etc.), except through normal channels with appropriate prior authorization, either directly or indirectly, to anyone inside or outside the organization who does not have a legitimate business need-to-know. Any improper transfer of material or disclosure of information, even though it is not apparent that a Covered Person has personally gained by such action, is prohibited.
5. Consistent with federal and state law, contributing by or on behalf of NorthShore, any money, services or property to any candidate for, or holder of federal, state or local offices, or to any political organization, party or committee, including the purchase of tickets to political dinners or other political fund raising events, or the purchase of advertising space in such programs. Personal contributions to Political Action Committees (PAC) can be made, but they cannot in any manner be reimbursed by NorthShore.
6. Accepting outside gifts or solicitation for themselves or others without legitimate business purpose or accepting special discounts/loans from any outside vendors/agencies that compete with the interests of NorthShore.

Examples of acceptable items include, but are not limited to:

- Lunch/Dinner with vendor as long as the invitation is extended by the vendor.
- Gifts of a nominal value such as calendars, pens, key chains, etc.
- Occasional tickets to events (i.e., sporting, art, etc.), as long as these activities are approved by the department's Assistant Vice President.

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Subject: **CONFLICT OF INTEREST**

Examples of unacceptable items include, but are not limited to, free travel, lodging, automobiles, or special discount or loan that could be construed as a bribe or payoff. A gift such as cash equivalent is not acceptable. The Senior Vice President or designee should review any gift/solicitation in question.

7. Making or initiating any payment with NorthShore funds for any purpose other than as described by the document supporting the payment, or expected payment for goods or services rendered and of real benefit; or the unauthorized giving of any gift paid with NorthShore funds.
8. Failing to properly disclose, record, or account for any NorthShore corporation assets, liabilities, revenues, expenses or funds in an accurate and timely fashion.
9. Engaging in any relationships or circumstances, which may create or give the appearance of a conflict of interest.
10. Transacting business on behalf of NorthShore with terms and conditions which are not of arms-length dealing and/or which are significantly less advantageous than competitively available for goods or services of like grade and quality.
11. Engaging directly or indirectly during work hours or away from work in any conduct that is disloyal, disruptive, competitive or damaging to NorthShore.
12. Using NorthShore property to conduct personal business during work hours or outside of work.

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- B. The following activities are prohibited for Covered Persons unless prior, full, accurate disclosure is made by a Covered Person in writing and is approved by the Chief Compliance Officer and the Corporate Compliance Committee:
1. Having or owning a beneficial interest, directly or indirectly, in any partnership, corporation, or other entity, whether a business or not-for-profit entity either doing business, or seeking to do business, with NorthShore, except where such interest is comprised solely of securities in a publicly traded corporation or partnership and such interest does not exceed five percent (5%) of any class of shares or other securities outstanding. In this context, “indirectly” means a beneficial ownership or creditor interest controlled by a Covered Person either through an immediate family member, nominee or trust.
 2. Serving at any time as an incorporator, director, officer, partner, employee or consultant of any partnership, corporation, or other entity, whether a business or not-for-profit entity, doing business or seeking to do business with NorthShore.
 3. Serving or being asked to serve as an incorporator, director, officer, principal, proprietor, associate, employee, member or consultant of any firm, entity or corporation that is a competitor of NorthShore. Membership on the medical staff of other hospitals is beyond the scope of this policy, as long as the physician complies with other portions of this policy.
 4. Accepting any material gifts, gratuities, or excessive entertainment in cash or in kind (including free goods or vendors’ services) by any present or potential vendor. Some examples of extravagant entertainment are: personal expenses paid by a vendor; personal use of a vendor’s lodging facilities; abnormally frequent and/or lavish dinners and other forms of entertainment.

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5. Participating in any outside activities that could reasonably interfere significantly with the Covered Person’s work time obligation to NorthShore. (Presentations to, as well as, other forms of participation in the activities of professional societies and learned organizations are encouraged.)
6. Proposing to do business with a firm or entity which employs or is controlled by a Covered Person’s friends or immediate family members.
7. Hiring one’s immediate family members, or causing one’s immediate family members to be hired in a manner that violates NorthShore policies on such matters.
8. Establishing any bank account or other undertaking in the name of NorthShore, or using or referencing NorthShore’s tax exempt status or tax identification number without prior disclosure and approval.
9. Any other situations or circumstances which could reasonably be said to have the potential of affecting a Covered Person’s independence of judgment with respect to NorthShore business.

V. COMPENSATION

- A. A voting member of the board of directors who receives compensation, directly or indirectly, from the Corporation for services is precluded from voting on matters pertaining to that member’s compensation.
- B. A physician who is a voting member of the board of directors and receives compensation, directly or indirectly, from the Corporation for services is precluded from discussing and voting on matters pertaining to that member’s and other physicians’ compensation. No physician or physician director, either individually or collectively, is prohibited from providing information to the board of directors regarding physician compensation.
- C. A voting member of any committee whose jurisdiction includes compensation matters and who receives compensation, directly or indirectly, from the Corporation for services is precluded from voting on matters pertaining to that member’s compensation.

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VI. PERIODIC REVIEWS

To ensure that the Corporation operates in a manner consistent with its charitable purpose and that it does not engage in activities that could jeopardize its status as an organization exempt from federal income tax, periodic reviews shall be conducted. The periodic reviews shall, at a minimum, include the following subjects:

- A. Whether compensation arrangements and benefits are reasonable and are the result of arm’s-length bargaining.
- B. Whether acquisitions of provider services result in inurement or impermissible private benefit.
- C. Whether third party arrangements conform to written policies, are properly recorded, reflect reasonable payments for goods and services, further the Corporation’s charitable purposes and do not result in inurement or impermissible private benefit.
- D. Whether agreements to provide health care and agreements with other health care providers, employees, and third party payors further the Corporation’s charitable purposes and do not result in inurement or impermissible private benefit.

VII. WRITTEN DISCLOSURES

Two types of written disclosures are required to be made by Covered Persons under this policy:

- A. On an annual basis, the Chief Compliance Officer will require all designated Covered Persons to complete, sign and return the conflict of interest disclosure statement (attached Exhibit A). Timely and accurate completion of this statement, that identifies a person’s financial interests or otherwise which may represent a potential conflict of interest, is mandatory. Completed statements shall be returned to the Chief Compliance Officer within 15 days. Such information will be reviewed and acted upon as necessary by the Chief Compliance Officer and the Corporate Compliance Committee.
- B. The circumstances described in Section IV B are required to be disclosed in writing promptly whenever they occur. Covered Persons who are directors and officers shall make written disclosure to the Chief Compliance Officer.

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Disclosure must occur prior to any meeting of the board of directors or board committee at which action on the transaction in question is to be taken. Non-physician Covered Persons who are employees and physicians who are Covered Persons shall make written disclosures to the Chief Compliance Officer. Physicians who are Covered Persons should also copy their Department Chairman and Chief of Staff. The Chief Compliance Officer shall respond in writing as promptly as possible with a copy to the appropriate Department Chairman and Chief of Staff. The Chief Compliance Officer shall discuss such disclosures with the Corporate Compliance Committee.

Written disclosures and responses may be done in memo form. Accurate and full disclosure of all facts is required. Action or implementation on what was disclosed may not be taken until written approval by the Chief Compliance Officer, and then only in accordance with the terms of such approval. If disapproved, the action may not be taken.

VIII. REPORTING AND INVESTIGATION

Each department head is responsible for compliance in his or her areas of responsibility. In addition, all Covered Persons have an obligation to report any situation which they believe to be a violation of this policy. Such reports shall be made in writing as promptly as possible to the Chief Compliance Officer, shall be confidential and should be signed by the person making the report. A Covered Person should not assume that an apparent violation has been reported by someone else. The Chief Compliance Officer, upon receiving a signed report of an apparent violation shall promptly and thoroughly investigate, taking the nature of the alleged violation into account and shall involve investigative resources as deemed appropriate including, without limitation the Internal Audit department and/or Public Safety. Completion of such investigation shall be given a high priority and a written summary of each completed investigation, with recommendations for action or no action, shall be made to the Corporate Compliance Committee. The Chief Compliance Officer shall inform the Audit Committee of each completed investigation. In such investigations, all Covered Persons have an obligation to cooperate and disclose all information related to such interest and the relationship.

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FISCAL MANUAL Policy and Procedures

IX. PENALTIES FOR VIOLATION

Violations of this policy will subject the person involved to penalties. Directors or officers of NorthShore may be disciplined up to and including removal from office. Employees may be disciplined up to and including termination. Physicians who are Covered Persons may be disciplined up to and including loss of professional administrative positions, NorthShore compensation and/or all procurement authority, as appropriate. Consistent with any provisions of the NorthShore Professional Staff By-Laws as may be applicable, in extreme cases, violations of this policy by physicians who are Covered Persons may subject them to the loss of their NorthShore Professional Staff appointment. Violations of this policy include:

- A. Engaging in any conduct prohibited by Section IV A.
- B. Failing to fully disclose, accurately, or in a timely manner, those activities or situations described in Sections IV B and V B and/or initiating action on a disclosed matter prior to receiving the written approval of the Chief Compliance Officer.
- C. Failing to timely and accurately complete the conflict of interest disclosure statement described in Section VII A and in Exhibit A attached to this policy.
- D. Failing to report and/or failing to timely report known apparent violations of this policy.
- E. Failing to cooperate in an investigation.
- F. Making reports of violations known to be false or failing to accurately sign a report of violation.

In addition to the above penalties, NorthShore may pursue all legal and equitable remedies as may be appropriate.

X. RESPONSIBILITY: Corporate Compliance Department

The organization reserves the right to unilaterally revise, modify, review, or alter the terms and conditions of the policy within the constraints of the law.

APPROVAL:

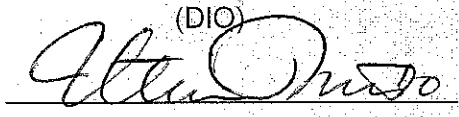
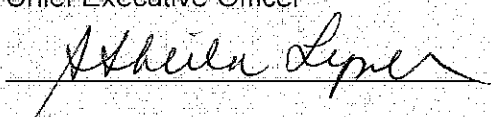
Mark R. Neaman
Signature

President & CEO
Title

February 25, 2009
Date

Mercy Hospital and Medical Center
Chicago, Illinois

ADMINISTRATIVE POLICY NUMBER XXXI

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| Subject: THE RELATIONSHIP BETWEEN GME AND INDUSTRY (VENDOR RELATIONSHIPS) | |
| Original Issue Date: 08/08 | |
| Revision Date: | |
| Initiated by: Steven R. Potts, D.O.FACP Designated Institutional Official (DIO) | Approved by: Sister Sheila Lyne, RSM President Chief Executive Officer |
|  |  |

I. ACGME PRINCIPLES AND REQUIREMENTS

- A. Policies relating to sources of educational support appear to affect what physicians believe and how they behave. The ACGME's six general competencies provide a framework to guide the conduct of the relationships maintained by residency programs and their sponsoring institutions with industry.
- B. Professional Requirements:
 - 1. Ethics curricula must include instruction in and discussion of published guidelines regarding gift-giving physicians.
 - 2. Full and appropriate disclosure of sponsorship and financial interests is required at all program and institution-sponsored events, above and beyond those already governed by the Standards for Commercial Support and promulgated by the ACGME. Likewise, full disclosure of research interests must be published in keeping with the local policies of institutional review boards and following the recommendation of the AAMC Task Force on Financial Conflicts in Interest in Research.

Review Dates: _____

Initials: _____

3. Programs and sponsoring institutions must determine through policy, which contacts, if any, between residents and industry representatives may be suitable, and exclude occasions in which involvement by industry representatives or promotion of industry products is appropriate.

C. Practice-Based Learning and Improvement and Medical Knowledge Requirements:

1. Clinical skills and judgment must be learned in an objective and evidence-based learning environment.
2. Residents must learn how promotional activities can influence judgment in prescribing decisions and research activities through specific instructional activities.
3. Residents must understand the purpose, development, and application of drug formularies and clinical guidelines. Discussion should include such issues as branding, generic drugs, off-label use and use of free samples.

D. Systems-Based Practice Requirements:

1. Sponsoring institutions and programs must develop policies to assure that clinical skills and judgment are learned in objective and evidence-based clinical and teaching environments free from inappropriate influence. These policies must clarify the differences between education and promotion.
2. Teaching institutions must ensure that programs have sufficient funds from appropriate sources to conduct their educational activities.
3. Resident curricula should include how to apply appropriate considerations of cost-benefit analysis as a component of prescribing practice.
4. Advocacy for patient rights within health care systems should include attention to pharmaceutical costs.

E. Interpersonal and Communications Skills Requirements:

1. Resident curricula should discuss and reflect on managing encounters with industry representatives.
2. Illustrative cases of how to handle patient requests for medication, particularly with regard to direct-to-consumer advertising of drugs, should be included in communication skills curricula.

II. MERCY HOSPITAL AND MEDICAL CENTER GME POLICY STATEMENT

- A. Graduate Medical Education residency and fellowship programs will not participate in any MHMC sponsored events in which commercial and pharmaceutical companies provide meals, other types of food, pens, imprinted paper, or any gifts or other materials.
- B. Residents will not have contact with commercial or pharmaceutical sales representatives (PSRs) during their normal work hours.
- C. Commercial and pharmaceutical companies may provide educational materials for student or resident use, so long as the company name does not appear on the item.
- D. Companies may provide unrestricted educational grants to departments.
- E. Speakers for any MHMC sponsored event must disclose any links to commercial and pharmaceutical companies.
- F. Graduate Medical Education will provide an educational program for all residents and fellows regarding appropriate interactions with commercial and pharmaceutical companies and the ethics of dealing with possible conflicts of interest, and the rationale behind these. This educational program will include a web-based educational module and approved alternative courses.
- G. Companies may not use official MHMC communication means to advertise or circulate information about events.
- H. There will be a progressive system of corrective action for a program that fails to comply with the policy.