
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

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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**