

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	November 2005
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	October 2010
Policy 10.1.12	Institutional Conflict of Interest Policy	Responsibility:	Vice President for Research

INSTITUTIONAL CONFLICT OF INTEREST POLICY

Overview

As a recipient of public funds, the Health Science Center has a responsibility to ensure that all its research and business development activities are in the best interest of the community. This policy provides appropriate institutional safeguards to sustain a climate in which sponsored projects, dedicated gifts, research, scholarship, technology transfer and business development are carried out responsibly, and in so doing foster an atmosphere of openness and integrity. Moreover, the institution has a responsibility to ensure that no one should unfairly benefit from the public trust or reputation of the University. Finally, the welfare of human participants in research and the integrity of research will not be compromised, or appear to be compromised, by competing institutional interests or obligations.

Policy

Each institutional financial interest that presents a potential for conflicts of interest, whether real or perceived, must be fully disclosed to the University's Institutional Conflict of Interest Committee. The Office of the Vice President for Research is responsible for administration and support of the Institutional Conflict of Interest Committee. The conflict of interest must be properly identified and managed or eliminated before any contract, sponsored project, dedicated gift, or transaction is executed; any contractual relationship is initiated; or, any action is taken that might be influenced or appear to be influenced by the conflict of interest.

Definitions

INSTITUTIONAL CONFLICT OF INTEREST: Institutional conflicts of interest may occur when the University and any institutional official (such as the President, Vice Presidents, Associate or Assistant Vice Presidents and Deans), senior managers (such as Directors, Chairs of the Institutional Review Board and Chair of Conflict of Interest Committee who make decisions with implications for research and technology transfer), and academic units (schools, departments, centers, institutes, or consortiums) or affiliated organizations have a financial interest in a company that is associated with University research. Examples of potential conflicts include investments in start-up

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companies associated with faculty inventions, ownership in companies that make significant contributions for facilities or endowed chairs, or stock ownership in companies that conduct research at the University. Likewise, faculty, administrators or senior managers may also have conflicts when they serve on the boards of (or otherwise have a formal relationship with) organizations that have or seek to have a financial interest in or benefit from Health Science Center research.

SIGNIFICANT FINANCIAL INTEREST: Consistent with the Health Science Center policy for individual conflicts of interest, (see the *Handbook of Operating Procedures*, [Section 10.1.6](#), “Conflicts of Interest in Scholarly, Research, and Clinical Activity”), a significant financial interest is anything of monetary value, including, but not limited to:

1. Compensation or other payments for services (e.g., consulting fees, honoraria, gifts or “in kind” compensation)
 - a. from a financially interested company;
 - b. or any other purpose not directly related to the reasonable costs of conducting the research or activity (as specified in the agreement); or,
 - c. that in the aggregate has in the prior calendar year exceeded the de minimis amount established in Public Health Services (PHS) regulation (\$10,000), or is expected to exceed that amount in the next twelve months.
2. Equity interests (e.g., stock, stock options, or other ownership interests of any amount in a non-publicly-traded financially interested company).
3. Equity interests in a publicly traded financially interested company of either \$10,000 or 5% equity ownership.
4. Royalty income or the right to receive future royalties under a patent or copyright, where the research is directly related to the licensed technology or work.

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But excludes:

1. Salaries.
2. Royalties or other remuneration from the Health Science Center.
3. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities.
4. Income from service or advisory committees or review panels for public or non-profit entities.
5. Equity interest that, when aggregated for the employee and his or her family, meets both the following tests:
 - a. does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value; or,
 - b. does not represent more than a 5% ownership interest in any single entity.
6. Any other salaries (non-Health Science Center), royalties, or other payments, including consulting fees and expert witness testimony, that, when aggregated for the employee and his or her family over the next twelve months, are not expected to exceed \$10,000 in the aggregate.
7. Any interests in mutual funds where the individual has no control over the selection of holdings.

Major Categories of Conflicts

There are three major categories of conflicts:

1. Stock Holdings – Potential institutional conflicts of interest arise when the Health Science Center owns a significant amount of stock in a specific company with which it has a research or technology transfer relationship.

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2. Equity and Licensing Arrangements – Potential bias arises in the case of decisions about research and technology development where the institution holds relevant equity positions (e.g., non-publicly traded stock or stock options) or has royalty arrangements, and the equity or royalties are derived from institutional inventions, startups, or other institutional resources.
 3. Officials – Potential conflicts involving administrators and other senior management who have or oversee significant financial grant or contract holdings or have decision-making positions with outside companies, and who make decisions with implications for institutional research and technology transfer. The potential source of conflict is between an individual’s personal financial holdings and their institutional responsibilities.

Annual Disclosures

University administrators, senior management, and unit heads of the University shall be required to disclose any significant personal financial interest that might present a conflict on any research or technology transfer program on which they as individuals will directly make or influence an institutional decision whenever they become aware of such potential conflict. The disclosure of this kind of conflict or potential conflict will be on an annual basis, as well as event-based, where significant financial interests are involved. If a financial interest might present a conflict on a sponsored research, clinical study, or technology development program that involves the use of human participants, however, then disclosure must be made immediately regardless of the value of such financial interest.

The President’s Office will collect all disclosures annually. The Vice President for Research would obtain the following annually:

1. A list of the equity holdings from the Office of South Texas Technology Management;
2. A list of the companies that hold option or licensing rights to Health Science Center research; and,
3. A list of major corporate donors that exceed one million dollars.

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The Vice President for Research will review these holdings against the profile of sponsored research programs or clinical trial programs to determine if a potential conflict of interest exists in any areas, and shall notify the heads of those areas thus affected as to the potential conflict. Based on this information, the Vice President for Research will provide a list of companies to the Assistant Vice President for Technology Transfer that research administrators should consult when processing grants and contracts from company sponsors in order to assist in the identification of potential institutional conflicts of interest.

**Institutional
Conflict of Interest
Committee**

The Institutional Conflict of Interest Committee membership, appointed by the Vice President for Research, will include an officer of the institution who has sufficient seniority, expertise, and independence to evaluate competing interests at stake and make credible and effective recommendations. Also, serving on the Committee shall be two representatives from the Health Science Center, and up to four members from the community.

The Committee is responsible for:

1. Reviewing disclosures that present or appear to present an institutional conflict of interest;
2. Reviewing conflict resolution plans that are developed by the affected individual;
3. Documenting the Committee's findings and the basis for the approval of conflict resolution plans, including steps to be taken to manage the conflict or minimize the potential for conflict of interest by reducing or eliminating the interest;
4. Overseeing projects that are managed with respect to conflicts of interest; and,
5. Communicating to the IRB, and to responsible institutional officials, summary information about the nature and amount of the institutional financial interest in human subject research along with the Committee's findings.

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Equity and Licensing Arrangements

The institution will place responsibility for the management of the equity with the Vice President and Chief Financial Officer, who shall handle the investment independently from the research arm of the institution.

The University shall be strictly prohibited from using non-public information to influence or appear to influence the management of its equity share in a company. The amount of equity the University takes in a company may be a potential institutional conflict of interest issue, especially if the company involved is a University-related start-up company. The University should ensure that its equity position in the company is not one such that the University is perceived as a major holder. Equity positions may not exceed 20% without the review of the Committee and subsequent approval of the Vice President for Research, the Assistant Vice President for Technology Transfer, and then by the Vice President and Chief Financial Officer. In no case, however, shall the University be involved in a company at a level greater than 49%. When accepting equity in a start-up company the University will not accept any representation on a company's board of directors nor have any voting rights. However, in the event of the early stage development of a technology in a start-up company, the University may secure "observer rights" or the rights to access company financial and performance reports. The role of a faculty member serving in a management role in such a company shall be governed by other sections of this policy. Management of any equity, whether received through licensing activities or from other sources, shall be the responsibility of the Vice President and Chief Financial Officer. The Committee will on a periodic basis review the institutional equity arrangements and management thereof.

Finally, the University shall use income generated from the sale of its equity holdings in the same manner as it uses licensing income.

General Guidelines for Controlling or Managing Conflicts

Primary methods for conflict resolution could include (but certainly are not limited to):

1. Eliminating the conflict by referring the study to another site that has no institutional conflicts at work, or divesting or sequestering the conflicting financial interest.

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2. Requiring that institutional investments posing a conflict of interest in a research study be “frozen” for a designated period after the termination of the study, with the University allowed neither to sell nor transfer those interests until a time certain, thus providing for a forced attenuation of the research study and its results from the institutional interest.
 3. Disclosing the conflict to sponsors, research subjects, and/or publications and journals.
 4. Providing independent checks or monitors on the research approval and oversight process, such as an independent review and monitoring of the IRB review and continuing review processes.
 5. Providing independent monitoring of the subject recruitment and/or informed consent processes.
 6. Limiting subject recruitment so that it does not target, or even allow, participation by the Health Science Center staff and dependents.
 7. Requiring independent monitoring and oversight of subject-researcher interactions, data gathering, data analysis, and/or data reporting.
 8. Arranging for independent review of all adverse events, including review of subject records on a comprehensive, periodic or sampled basis to assure that reports of adverse events have been timely and properly made.
 9. Requiring revisions to the panel of investigators or the research staff, to lessen any influence that the institutional interest might have over the course and reporting of the research; and/or adopting procedures for the updating of information relating to the institutional conflict, if it appears that the conflict might change in any appreciable way over the course of a research study.

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10. Approval of a management plan for institutional officials having significant financial interests in organizations sponsoring research at the Health Science Center by an appropriate Vice President who does not, directly or indirectly, have the individual holding a significant financial interest in the sponsoring organization reporting to that office. Upon recommendation by the Committee, this Vice President should determine whether the significant financial interests in an investigational product or in a sponsor of human subjects' research may be managed effectively or should be eliminated. If the Vice President finds that an official should be permitted to hold a significant financial interest in an investigational product or commercial research sponsor even though the official will not be formally recused from research-related responsibilities, this information shall be communicated to the IRB.

 11. Review of financial interests of IRB members.
 - a. The Committee should apply a presumption against significant individual financial interests in an investigational product or a commercial sponsor of the institution's human subjects' research.

 - b. IRB members are required by federal regulation to recuse themselves from voting upon or participating in any deliberations concerning protocols in which they have conflicting interests.

 - c. The Health Science Center requires that the IRB Chair polls the IRB about potentially conflicting financial interests prior to the start of each meeting and to document member's responses in the meeting minutes. When possible, the Vice President for Research will provide the IRB Chair with a list of the research sponsors in which one or more IRB members hold a significant financial interest, to ensure that recusal occurs when necessary.

The Committee will apply the following principles to determine whether a financially interested individual or the institution has demonstrated

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compelling circumstances that justify allowing that individual or the Health Science Center to conduct human subjects' research.

1. Magnitude of Risk: The institution should determine the nature and degree of scrutiny required for any of these relationships or interests by assessing the potential for conflict of interest and weighing the magnitude of any risk to human subjects.
2. Rebuttable Presumption: The rebuttable presumption against financial interests in human subjects' research may be rebutted when the circumstances are compelling and the Committee has approved an effective conflict management plan.
3. Evaluation Criteria: When considering a request by a financially-interested individual to conduct human subjects research, the circumstances that the Committee should evaluate include:
 - a. the nature of the research;
 - b. the magnitude of the interest and the degree to which it is related to the research;
 - c. the extent to which the interest could be directly and substantially affected by the research;
 - d. the degree of risk to the human subjects involved that is inherent in the research protocol;
 - e. the extent to which the interest is amenable to effective oversight and management; and,
 - f. whether the individual is uniquely qualified by virtue of expertise and experience and the research could not otherwise be conducted as safely or effectively without that individual.
4. Compelling circumstances to allow the institutional conflict depend upon:

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- a. the nature of the science;
 - b. the nature of the interest;
 - c. how closely the interest is related to the research;
 - d. the degree of risk that the research poses to human subjects;
 - e. the degree to which the interest may be affected by the research; and,
 - f. whether the institution is uniquely qualified, by virtue of its attributes (e.g., special facilities or equipment, unique patient population) and the experience and expertise of its investigators, to conduct the research and safeguard the welfare of the human subjects involved. (Even when found uniquely qualified, conflicts should be avoided whenever possible and, managed closely if permitted.)
5. External Monitoring of Single/Primary Site Trials: Serving as the sole or primary performance site might be justified under compelling circumstances (e.g., when the research is an early-stage or feasibility trial and the expertise of institutional investigators is essential to the research). In such a case, however, the Committee should approve the circumstances, and if advisable, the research should be subject to monitoring by an oversight body with external members (e.g., a data and safety monitoring board).
6. External IRB Review: When the Committee has determined that compelling circumstances exist, the institution should consider the desirability of contracting with an external IRB to provide a second level of review and oversight.
7. Other Financial Relationships That May Warrant Close Scrutiny:
- a. When an investigator, research administrator, or institutional official with research oversight authority participates materially in a procurement or purchasing decision involving

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major purchases from, or non-routine supply contracts with, a commercial entity that sponsors human subjects research at the institution; or,

- b. When the institution has received substantial gifts (including gifts in kind) from a potential commercial sponsor of human subjects research.
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