

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

CONFLICTS OF INTEREST IN SCHOLARLY, RESEARCH, AND CLINICAL ACTIVITY

Overview

The University of Texas Health Science Center at San Antonio, as an institution of The University of Texas System, and as a recipient of externally sponsored funds, and as a holder of the public trust is committed to the open exchange of ideas and information in an atmosphere free from commercial conflict and influence. As such, it has an obligation to assure that the conduct and products of its scholarly research, clinical activity, and other endeavors are recognized as being free of those outside influences.

Given that the Health Science Center also recognizes that outside activities and relationships of its faculty and staff enhance the mission of the institution, potential conflicts of interest and commitment are inevitable. Those outside activities and relationships, however, should not interfere with an individual's obligations to the Health Science Center.

It is the purpose of this policy to increase the awareness of the Health Science Center community with respect to the potential for conflicts of interest and commitment, and to establish procedures whereby such conflicts may be avoided or properly managed. A cornerstone of this policy is reporting both on an annual basis and on an *ad hoc* basis where an individual's circumstances have changed since the annual report.

Other reports by members of the Health Science Center community for conflict of interest and other purposes are also required by the Health Science Center, The University of Texas System, and the State of Texas. The Health Science Center also has additional policies regarding faculty and staff conduct, use of institutional facilities, consulting, and the like. See "Other Complementary Policies" below for references to these other requirements.

Applicable Regulations

This policy is based on the requirements of the State of Texas laws setting forth standards of conduct (Texas Government Code, Chapter

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

572), the Code of Ethics of The University of Texas System (Regents' *Rules and Regulations*, [Rule 30104](#)), and regulations of the Public Health Service and the National Science Foundation promoting objectivity in research (effective October 1, 1995) available at <http://grants.nih.gov/grants/policy/coi/resources.htm>.

Definitions

CONFLICT OF COMMITMENT: Means a situation where the individual undertakes external commitments that burden, interfere, or detract from the member's primary obligations and commitments to the Health Science Center.

CONFLICT OF INTEREST: Means a situation where the individual has the opportunity to influence the Health Science Center's business, administrative, academic, research, or other decisions in ways that could lead to personal financial gain or advantage or could cause or appear to cause bias in the design, conduct or reporting of research or educational activities.

FACULTY OR FACULTY MEMBER: Any individual who is compensated by the Health Science Center and who holds an academic appointment.

FAMILY: Of a faculty member means spouse, minor children, and other persons living in the same household or financially dependent upon the faculty member.

INDIVIDUAL: Any person including faculty, family, or researcher who has reporting requirements under this policy.

RESEARCH: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

RESEARCHER: Principal Investigator(s) (PI), sub-investigator(s), and any other person (e.g., postdoctoral fellow, other scientist, graduate student) who is responsible for the design, conduct or reporting of research activities.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

SIGNIFICANT FINANCIAL INTEREST: Means anything of monetary value and includes, but is not limited to: salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and, intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

A significant financial interest includes:

1. salary, royalties, or other payments for services from outside the Health Science Center if, when aggregated for the individual and family is expected to equal or exceed \$10,000 from any single source for any 12-month period;
2. equity interest if, when aggregated for the individual and family, equals or exceeds \$10,000 in value as determined by a reasonable measure of fair market value or exceeds 5% ownership in a single entity.
3. for the purposes of research involving human research participants, any payment or equity must be included on the Conflict of Interest Report reported to the IRB as part of the IRB protocol submission. See section below under “Research Involving Human Research Participants”.

Significant financial interest does not include:

1. Salaries paid by the Health Science Center and/or the Veteran’s Administration (VA).
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 on advisory committees or review panels for public or nonprofit entities.
5. Equity interest that does not equal or exceed \$10,000 in value as determined through reference to public prices or other

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity.

6. Any other salary, royalty, or other payments expected over the next twelve months from reporting that do not exceed \$10,000.
7. Any interests held indirectly through funds (such as mutual funds and pension funds) in which the faculty member does not control the selection of investments.

For those individuals who conduct studies using human participants, the institution has additional reporting requirements as discussed in this policy under the section “Research Involving Human Research Participants.” Guidance for those making these reports to the IRB is contained in this policy below.

Fundamental Principles

Perceived or actual conflicts of interest that are not appropriately disclosed, reduced, managed, or eliminated can not only undermine the public’s trust in the Health Science Center, but left unattended may also be violations of policy at The University of Texas System or Board of Regents levels, as well as those of research sponsors or may even be contrary to Texas law. The Health Science Center is committed to safeguarding the public trust and to complying with all policy and statutory requirements. The following principles, therefore, are among those that underlie the Health Science Center’s policy on conflicts of interest and commitment:

1. External activities should not compromise an individual’s ability to perform all the activities expected of him or her as a Health Science Center employee.
2. An individual should not receive remuneration for the conduct of his or her research or clinical activity at the Health Science Center or any other Health Science Center activity except through Health Science Center channels (such as salary).
3. An individual should not conduct research or clinical activity at

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

the Health Science Center or carry on other Health Science Center business under circumstances in which a reasonable person would infer that the Health Science Center activity could have been distorted by the desire for or expectation of direct or indirect external economic advantage. No arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research.

4. Health Science Center researchers, as defined by this policy, must not be precluded from publishing their work by agreements with external sponsors.
5. Graduate students must not be held to non-disclosure of any aspect of their research in their meetings with individuals at the Health Science Center (including members of their dissertation advisory committees).
6. Health Science Center facilities, equipment, and personnel should be used only for Health Science Center activities and purposes, see the *Handbook of Operating Procedures* (HOP), [Section 10.1.3](#), “Personal Use of University Resources, Equipment, and Assets”.
7. An individual should not participate directly in the negotiation of research agreements, technology license agreements, equipment purchases, or other arrangements between the Health Science Center and an organization in which the individual has a significant financial interest.
8. Research involving human research participants should receive especially rigorous review and should be subject to a strong presumption against permitting the participation of any individual holding any financial interest without appropriate review and, in some cases, without an appropriate management plan (see section “Research Involving Human Participants” below).
9. The Health Science Center will not accept research funding that is proposed to be sponsored by a small, privately-held entity in which the faculty member who would conduct such research has

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

a significant financial interest and/or Board seat or other management position unless the researcher provides a compelling reason that the conduct of such research should be under the direction of that researcher.

Research Involving Human Participants

Conflicts of interest related to research involving human participants pose special concerns. The Health Science Center and its researchers have ethical obligations to honor the rights and protect the safety of persons who participate in research. Financial and other interests held by those conducting the research may compromise or appear to compromise the fulfillment of those ethical obligations and the well-being of research participants, as well as the integrity of the research.

Accordingly, there is a strong presumption against permitting any person with related significant financial or other interests to participate in the conduct of such research, particularly if the protocol involves more than minimal risk. Only in rare and compelling circumstances might an exception be made. The Health Science Center has established a rigorous policy and procedure for review of financial and other interests related to research involving human participants. The Institutional Review Boards (IRBs) have the final approval authority regarding whether the conflicting interest and its management plan, if any, are acceptable to allow the research to be approved. IRB policies are intended to supplement this policy. The IRBs work closely with the Conflict of Interest Committee to identify and address all such conflicts. See below the section on “Research Involving Human Research Participants” for additional information on the institutional policy with respect to conflict of interest and human research participants.

Research Sponsored by Start-Up Companies

Faculty relationships with start-up companies-newly-formed, privately-held, for-profit companies based usually but not always on Health Science Center owned intellectual property-frequently present multifaceted conflicts of interest and commitment. Faculty who have ownership, managerial, or Board relationships with a start-up are required by this policy, The University of Texas System “Procedure for Obtaining Approval of Plan to Manage Conflicts of Interest”

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

(<http://www.utsystem.edu/ogc/IntellectualProperty/conflict.htm>), and the Board of Regents ([Rule 90103: "Equity Interests"](#) and [Rule 90104: "Business Participation and Reporting"](#)) to disclose their interest and implement a conflict of interest management plan. For research projects funded by the start-up, there is a strong presumption against conduct of such research in the faculty member's laboratory. To overcome the presumption, the management plan must address the research project and, for Health Science Center-owned intellectual property, a license agreement must be in place with the start-up. The Office of South Texas Technology Management is responsible for the negotiation of license agreements and/or other actions regarding Health Science Center intellectual property. Policy guidelines for faculty relationships with such ventures appear as below under the section "Principles Applicable to Faculty with Relationships with Start-up Companies".

Interactions Between Clinicians and Industry

Industry plays a vital role in drug discovery, technology development, and improving the public health. Relationships with industry that facilitate discovery and evidence-based use of medications and devices, as well as upholding the highest professional standards of ethics and integrity are welcomed by the Health Science Center. Accordingly, the "Guidelines for Interactions Between Clinicians and Industry" have been promulgated. These guidelines seek to preserve and fortify the independence of faculty and trainees, ensure that the most objective information in the care of patients is available, the potential for real or perceived bias in programs of clinical care and education is reduced, and to ensure compliance with appropriate laws and regulations. These guidelines are available in the HOP, [Section 10.1.11](#), "Guidelines for Interactions Between Clinicians and Industry".

Reporting Requirements

On or before December 1 annually or within sixty (60) days of appointment, each faculty member and researcher as defined by this policy, shall complete and submit a [Conflict Of Interest Report \(COI Report\)](#) for the previous calendar year as well as anticipated activities for the current calendar year. The pdf version can be located at http://research.uthscsa.edu/osp/forms/COI_Report_Form.pdf, and the

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

Word _____ version _____ at http://research.uthscsa.edu/osp/forms/COI_Report_Form.doc. If a faculty member or researcher at the time of proposal for external funding or IRB protocol submission has not made the annual report, a COI Report must then be made. Any COI Report must be updated when a new reportable significant financial interest or potential conflict of commitment exists. The faculty member shall include in his/her report the same information for his/her family as disclosed for him or herself.

All COI Reports will be submitted through the appropriate Department Chair or Academic Director to the Dean of the appropriate School (see “COI Report Submission and Review Process” below). The Dean of the appropriate School should also review the submitted Reports.

Each faculty member shall also indicate on the *Certification of Proposal* submitted with each proposal or agreement for external project funding that each faculty member and/or researcher associated with the project has met these reporting requirements.

**COI Report
Submission and
Review Process**

It is the responsibility of each Dean or his/her designee to coordinate the annual reporting process within their School. Faculty members and other researchers are to complete and submit the COI Report to their department Chair or Academic Director for signature who will forward them to the Dean or his/her designee. The same process shall be followed for any revised or new COI Reports that are submitted outside of the annual cycle because of a change in significant financial interests or when the annual report was not completed.

Faculty members and other researchers must make the report annually and as significant changes occur. The faculty member and researcher shall include in his/her COI Report the same information for his/her family as defined by this policy.

Upon receipt of each annual or updated COI Report, the Dean or his/her designee will forward them to the Office of Sponsored Programs (OSP) as designee of the Office of the Vice President for Research.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

The OSP is the central repository for all COI Reports. If no significant financial interests or potential conflict of commitment is reported, no additional action will be required of the faculty member unless a significant change occurs prior to the due date of the next annual COI Report. If required by an external funding agency, notice of review will be forwarded to the agency in accordance with that agency's policy.

COI Reports for senior administrative officials shall be requested by the OSP.

The OSP, on behalf of the Office of the Vice President for Research, will make an initial review of all COI Reports submitted. Those reports identifying real or potential conflicts of interest or commitment will be submitted to the Conflict of Interest Committee for review and disposition (see "Conflict of Interest Committee" below). Generally, identified real or potential conflicts of interests and commitments fit into two categories:

1. Significant financial interest or potential conflict of interest that is allowable because the reportable items reflect generally accepted practices and are generally minimal in their personal financial impact on the faculty member. Examples of such interests may include a faculty member receiving royalties for published scholarly work and other writings or a faculty member receiving royalties under approved institutional royalty-sharing policies. The Committee may seek additional input from the faculty member, the department Chair or Academic Director, and any other persons as are necessary. When the faculty member indicates that his or her research or scholarly activities involve the utilization of human subjects, the Director of the IRB must also be consulted.

In these instances, it is likely that no further review will be required, but records will be maintained, identifiable to any grant awarded to the faculty member, showing that review has taken place. No additional action will be needed by either the Committee or the faculty member unless a significant change occurs prior to the due date of the next annual COI Report. If required by the external funding agency, notice of review will be

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

forwarded to the agency in accordance with that agency's policy.

2. Questionable significant financial interest or apparent conflict of commitment reported may or may not be manageable after review. It is likely that extensive review will be required by the Committee. The process of such review may require consultation with the individual's department Chair and Dean and may or not require further information and discussion with the individual faculty member. Where the COI Report indicates that human subjects are used in the individual's research or scholarly activities, the Director of the IRB will be consulted. The committee may also consult with the Office of South Texas Technology Management and others, as necessary.

After the Conflict of Interest Committee has fully reviewed the matter, a recommendation will be forwarded to the appropriate Dean and the Office of the Vice President for Research regarding disposition of the reported actual or potential conflict. Such disposition may include requesting that the potential or actual conflict of interest be managed according to a management plan developed by the faculty member in conjunction with the OSP and within the guidelines promulgated by The University of Texas System Office of General Counsel (OGC).

The Assistant Vice President for Research and Sponsored Programs, OSP, in consultation with the Office of Legal Affairs, will work with the individual in drafting a management plan that is in accordance with the requirements of the Texas Education Code, [Rule 51.912](#) and the applicable Regents' [Rules and Regulations](#).

Elements included in the plan are:

1. Identification of the sources of real or potential conflict, such as compensation received, relationship to company, and the like.
2. Current research projects, if applicable to conflict situation.
3. Resolution of potential or real conflicted roles (the management criteria).

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

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4. Discussion of future research or other roles as they relate to current plan (what steps need to be taken by the individual in the future).
 5. Any other ongoing requirements.
 6. Written acceptance of the plan by the individual, their Academic Chair or Director, and the Academic Dean or Executive Committee Member, as appropriate.

A brief outline of the terms of sponsorship or the “deal” in the records will be maintained, identifiable to any externally funded award in which the individual participates showing that a review has taken place; that the Conflict of Interest Committee has made a recommendation to the Dean and the Vice President for Research, and that a final decision regarding disposition or management of the conflict has been made and approved by the Vice President for Research. If required by an external funding agency, notice of disposition will be forwarded by the OSP in accordance with the external funding agency’s policy. In accordance with the section below, it may also be necessary to seek approval from The University of Texas System Board of Regents.

Prior to the first anniversary of the plan or earlier if deemed necessary, the Vice President for Research will appoint a Monitoring Committee to develop and review the management plan. This Committee should be made up of:

1. The Chair/supervisor, when applicable;
2. A voting Conflict of Interest Committee member. The Conflict of Interest Committee would accept nomination suggestions from the department Chair; and
3. A representative from the Office of Legal Affairs.

The Monitoring Committee will be staffed by the Assistant Vice President for Research and Sponsored Programs.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

The Monitoring Committee will review the facts regarding the COI Report form and subsequent Monitoring Plan; conduct an interview using a specialized questionnaire, [Management Oversight Questionnaire](#); and, make a report to the Conflict of Interest Committee.

Prior to the interview, the individual will be asked to provide relevant information regarding publications, intellectual property generation and graduate student progress to the Monitoring Committee.

Updates to the individual’s conflict of interest record are made on a case-by-case basis (quarterly and/or annually) depending on the type of conflict or potential conflict identified.

Consideration of Institutional Conflicts of Interest

Concurrent with the review of individual reports, the potential for institutional conflict of interest will be considered. Examples of institutional conflict of interest include situations where the Health Science Center owns equity in a start-up company or where institutional officials have relationships with a company that seeks to do business with the Health Science Center. Where there is the likelihood of an institutional conflict of interest, the COI Report will also be referred to the Health Science Center Institutional Conflict of Interest Committee for disposition under the HOP, [Section 10.1.12](#), “Institutional Conflict of Interest Policy”.

Special Circumstances Requiring Additional Reviews and Approvals

The University of Texas System Board of Regents has implemented a State of Texas legislated policy that requires development and submission of a plan for management of conflicts of interest when a faculty member participates in the business of or has a financial interest in a company that proposes to sponsor research at or license technology from the Health Science Center. Specifically, this applies to Health Science Center faculty or staff who acquire equity in, or serve as a board member, officer, or key employee of a company that sponsors the faculty member’s research or proposes to license technology from the Health Science Center. It is the responsibility of the faculty member to disclose such a relationship at the time a proposal or agreement for support is presented for review and approval to the OSP, which will

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

further advise the faculty member on the procedures for compliance with these conflict management plan requirements. In the case of a proposed technology licensing agreement, such COI report shall be made to the Assistant Vice President, Office of South Texas Technology Management.

Conflict of Interest Committee

The President shall appoint a Conflict of Interest Committee to advise the Health Science Center on conflict of interest/commitment issues, to consider COI Reports that indicate a possible conflict of interest/commitment, and any other such tasks as assigned by the President. The Committee shall be composed of at least nine voting members including administrative personnel, one faculty member from each of the Schools, one member external to the Health Science Center who is involved in research activities in a San Antonio institution or corporation, and one community representative. The Assistant Vice President for Research and Sponsored Programs, the Director of the IRB, the Assistant Vice President Transfer, Technology Management, and the Chief Legal Officer will serve as ex-officio non-voting members of the Committee. The Committee shall be chaired by one of the appointed faculty members and will report to the Vice President for Research.

Compliance Responsibility

The Health Science Center anticipates that individuals subject to this policy will comply fully, promptly, and at least annually with the provisions of this policy. Instances of deliberate breach of this policy, including failure to submit a COI Report (either annually or when changes in financial interests require it); failure to provide additional information needed by the Health Science Center; knowingly filing an incomplete, erroneous or misleading COI Report; knowingly violating the state law, Regents' *Rules and Regulations*, or this policy; or failure to comply with prescribed monitoring processes will subject the faculty member to disciplinary action under Health Science Center policy and The University of Texas System Regents' *Rules and Regulations*, as well as possible enforcement actions mandated by a granting agency. Such disciplinary action might be as severe as dismissal from the faculty, debarment from eligibility for federal funds, and possible prosecution under state or federal law.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

Confidentiality

To the extent permitted by law, all COI Reports, other records, and information submitted will be maintained confidentially. However, any COI Report, other records, and information will be made available to an agency funding research of the faculty member upon written request of the agency and otherwise as required by law. In addition, where human subject involvement is contemplated and a real or apparent conflict exists, the COI Report and other related records and information will be forwarded to the IRB by the Committee. As well, when the faculty member holds a VA appointment and a real or apparent conflict exists, the COI Report and other related records and information will be forwarded to the appropriate official at the VA. These records may also be subject to the Texas Open Records Act.

Guidance for Faculty and Administrators in Identifying and Resolving Actual or Potential Conflicts of Interest/Commitment

While each COI Report of real or potential conflicts of interest and commitment is reviewed and judged separately, there are a number of issues that frequently arise. There is often a common resolution to these issues. See section below, "Guidance for Conflict Resolution" that provides guidance for identifying and resolving actual or potential conflicts of interest and commitment.

Record Retention

The central repository for all COI Reports and related information, where gathered, will be either the Office of the Vice President for Research or the Office of Legal Affairs, and will be retained for a period of at least seven (7) years.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

**Research
Involving Human
Research
Participants**

All members of the Health Science Center research community should be sensitive to the potential impacts of financial interests and/or non-financial relationships with commercial sponsors or other external entities on the conduct of research and the participation and protection of human research subjects. In compliance with federal regulations and guidance, and Health Science Center policy, the Institutional Review Boards (IRBs) must consider such relationships and determine, in conjunction with the Health Science Center Conflict of Interest Committee whether they might influence or appear to influence the outcome of a research project involving human subjects, the objectivity of the investigator during the performance of such a project, or the investigator's interactions with research subjects who participate in the project. Accordingly, the IRBs solicit and review relevant information regarding possible conflict of interests of all investigators and key study personnel participating in a protocol involving human research subjects prior to approving or re-approving that protocol.

Role of the IRB

The IRB is the primary authority at the Health Science Center responsible for ensuring that human research participants are protected in accordance with federal regulations, University policies, and ethical principles. One of the primary responsibilities of the IRB is to ensure that human research participants receive all information needed to provide informed consent. The IRB's consideration of the investigator's financial interests is intended to ensure: 1) that the informed consent process provides the subjects with the facts necessary to make a knowledgeable and sound decision as to whether they wish to participate in the study, and 2) that no conflict exists that would otherwise compromise the protection of human subjects.

The IRB's consideration of investigators' financial interests as they relate to human subject research complements, but does not supplant, the deliberations of the Health Science Center's Conflict of Interest Committee, which is responsible for reviewing the financial disclosures of all researchers in accordance with the Health Science Center's policy on conflict of interest and commitment

The IRB has the final authority to decide whether the conflicting interest

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

and its management plan, if any, allow the research to be approved.

Role of Researchers, including Faculty

For all protocols submitted to the IRB, including new protocols and those submitted for re-approval at continuing review, each researcher must complete Form X, [Human Use Research Protocol Related Conflict of Interest Supplemental Form](#) whenever a conflicting interest exists with an external entity associated with the study, regardless of funding or regulatory oversight. Researchers are reminded of the separate obligation to complete the annual disclosure form required by the Health Science Center’s policy on conflict of interest and commitment.

Process

Prior to the IRB meeting at which a protocol is scheduled for consideration, the IRB staff will review the IRB documents and, if a disclosure is made, submit it to the Health Science Center Conflict of Interest Committee, through the Assistant Vice President for Research and Sponsored Programs, for review, comment, and, if necessary, further disposition.

As part of its deliberations, the IRB will review any potential conflicts disclosed along with the recommendations of the Health Science Center Conflict of Interest Committee (including a management plan, if applicable) to determine: (1) the effect of the interests on the protection of participants; (2) whether the conflict is permissible in the context of the protocol; and, if so, (3) whether the conflict warrants disclosure to potential subjects as part of the informed consent process. Any special requirements (such as disclosure to potential subjects) will be subsequently reported to the Health Science Center’s Conflict of Interest Committee.

Note: During this process, the confidentiality of researchers will be respected. Financial disclosure forms will be kept in confidential files, and information will be shared only on a need-to-know basis.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

Principles Applicable To Faculty With Relationships With Start-up Companies

Faculty and other researchers (collectively referred to as “Faculty”) relationships with "start-up" ventures, relatively newly formed, privately held, for-profit companies that are based on intellectual property developed at the Health Science Center, present opportunities for development and commercialization of inventions but may also create conflicts of interest and commitment. The following policy guidelines govern faculty relationships with such ventures. (Definition of equity is that contained in the definition of “Significant Financial Interest”.)

1. Equity Interests: Faculty may hold equity interests in start-ups that license intellectual property developed at the Health Science Center. Such equity must be promptly disclosed to the Conflict of Interest Committee via the OSP. Faculty accepting equity in such ventures should recognize that their ability to conduct research sponsored by that venture, especially research involving human subjects, will be restricted because of the conflict created by their ownership interest in the sponsoring entity.
2. Membership on Boards of Directors or Service as an Operating Officer: Faculty may be permitted to serve on the Board of Directors or as an Operating Officer of a start-up. A faculty member who has assumed a Board seat or serves as an Operating Officer should recognize that his or her ability to conduct research at Health Science Center that is sponsored by the venture, especially research involving human subjects, will be restricted because of the conflict created by the fiduciary relationship with the venture. Faculty members who assume Board seats or serve as Operating Officers of start-ups should also be sensitive to the need to recuse themselves from all Board decisions that involve conflicting duties to the start-up and to the University. Consulting arrangements are also subject to the requirements of HOP, [Section 10.1.8](#) “Conflict of Commitment (Faculty and A&P Staff)”.
3. Consulting Relationships, including Scientific Advisory Board Membership: Consulting agreements (including scientific advisory board memberships) between a faculty member and a start-up in which the faculty member holds equity or has a Board

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

seat should receive prior review and approval from the Vice President for Research or designee, who may recommend restrictions on the proposed agreement. Consulting arrangements are also subject to the requirements of HOP, [Section 10.1.8](#), "Conflict of Commitment (Faculty and A&P Staff)".

4. Student Employment by a Start-up: Except in special and unusual circumstances, students under a faculty member's direction, paid for by a faculty member's grant, or in a faculty member's research group, may not be employed part- or full-time by a start-up in which the faculty member has an equity interest. Such special circumstances might exist, for example, where the student sought summer employment with the start-up and planned to work in a field unrelated to his or her academic program.
5. Employment of Post-doctoral Fellows and Associates by a Start-up: Post-doctoral fellows and associates under a faculty member's direction, paid for by a faculty member's grant, or in a faculty member's research group, should not be employed by a start-up, in which the faculty member has an equity interest, to conduct research that overlaps with the fellow's University research or is to be conducted on Health Science Center premises. Any proposed employment of a post-doctoral fellow or associate by a start-up should be reviewed in advance by the Vice President for Research or his designee.
6. Use of Health Science Center Space, Equipment, or Laboratories: Only in extraordinary circumstances, may a start-up use Health Science Center space, equipment, or laboratories. In those circumstances, a written agreement must be put into place with strict limitations as to time and extent and only after review and approval by the Vice President for Research or his designee. Such written agreement may require lease or rental costs.
7. Research Funding from a Start-up and Testing of Faculty-Generated Intellectual Property Licensed to a Start-up: There is

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

a strong presumption against accepting research funding in the form of grants, subcontracts, or gifts, from a start-up in which the faculty member proposing the research has an equity interest or a Board seat (or other significant financial interest as defined below), if the research is to be done in the faculty member's research group, or the faculty member's students or post-doctoral fellows or associates would participate in the funded research projects. Rigorous restrictions also apply to human subject research and non-human subjects research that involves testing, when the faculty member has a related financial interest. The presumption is applied as follows:

- A. Human Subject Research: Where the proposed research involves human subjects, the presumption against permitting a related start-up to sponsor the research is particularly strong. Any financial or equity interest in the start-up company will almost always preclude the financially interested faculty member from conducting human subjects research sponsored by the start-up. The presumption may be overcome only in rare and compelling circumstances, as judged by the Conflict of Interest Committee and the cognizant IRB, and where the Committee and IRB are satisfied that effective controls to mitigate any possible effects of the conflict can and will be implemented. Such circumstances might include, for example, that the researcher is uniquely qualified to perform the experimental procedure. In such circumstances, the Conflict of Interest Committee will consider whether the researcher should divest himself or herself of the equity interest, or place the equity in a blind trust for an appropriate period of time.

- B. Research Not Involving Human Subjects: When a start-up proposes to sponsor research to be conducted by a faculty member who holds equity or a Board seat in the company, and which involves neither human subjects nor validation testing, the presumption may be rebutted if, in the judgment of the Conflict of Interest Committee appropriate controls are in place (see C, below), and a condition such as one of the following is met:

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

-
- i. the research is of a fundamental or basic nature, the research is not directly related to the financial success of the start-up; and the faculty member's relationship with the company is otherwise limited (i.e., does not involve multiple additional entanglements such as consulting agreements and scientific advisory board membership); so that the likelihood of any distortion of the research endeavor is minimal; or,
 - ii. the faculty member's equity interests in a venture are so diluted that his or her control or influence over the firm's decisions and the possible benefit from Health Science Center-based activity are negligible, and the faculty member's relationship with the company is otherwise limited (see above); or
 - iii. the research is essential to maintain the continuity of a research effort related to the licensed intellectual property during a short interval of time (normally under six months), while the research activity is being established in the start-up; and during this period it is subject to oversight of non-interested peers appointed by the Conflict of Interest Committee; or
 - iv. any other circumstance identified by the Conflict of Interest Committee as relevant to a particular condition.

Except in extraordinary circumstances, the presumption may not be rebutted when the research in question has as its object the testing of an invention in which the faculty member has a financial interest in a start-up, or a Health Science Center invention that is licensed to a start-up in which he or she has an equity interest. For purposes of this proviso, "testing" is intended to describe doing research designed to validate to the public or perform a similar function regarding an invention created at the Health Science Center and licensed to a start-up company. (The same restrictions would generally apply to testing undertaken for a publicly held company holding a license from the Health Science Center.)

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

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- C. Controls: In each case in which the Conflict of Interest Committee recommends that research be permitted to proceed despite the presumption against such research, it shall ensure, in addition to measures adopted by the Committee or (for human subjects research) the cognizant IRB, and complete compliance with the other strictures of this policy on start-ups, the following:
- i. the research agreement contains no restrictions on publication other than normal delays for review of confidential information or potential patentability;
 - ii. at the project inception, all individuals working on the research project are provided a written notice from the faculty member that the research is being sponsored by a venture in which the faculty member has an ownership interest or fiduciary relationship;
 - iii. before the Committee makes a recommendation that the research be allowed to proceed, the faculty member provides the Committee a written description of the proposed research and an assurance of his or her compliance with the restrictions set forth above; and thereafter, provides the Committee written reports on the progress of the research, listing related peer-reviewed publications and grants, no less frequently than annually; and
 - iv. all other management measures deemed appropriate by the Committee and required by the cognizant IRB are in place. Examples of such measures are requirement of a data safety monitoring board, in the case of human subject research; an oversight committee to review data, publications and other issues; disclosure requirements in publications; and commitment of equity to a blind trust for a period of time.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

**Guidance for
Conflict
Resolution**

There is a potential for conflict in many relationships between a faculty member or other researcher (collectively referred to as “faculty member”). In many cases, the potential for conflict is removed merely by the act of making a report. In other cases, a management plan that reduces the potential for conflict may be required and, in rare instances, the conflict may need to be eliminated in its entirety.

Following are a series of examples of possible conflict and potential resolution of such conflicts. These examples are not all inclusive but do represent many of the more common conflict situations and solutions to such conflict and, as such, deserve careful consideration by faculty members.

Possible Conflict

- Situations where the faculty member is invited to advise or serve an organization doing business in the general area of the member’s Health Science Center responsibilities or in a related area.
- Situations where a faculty member is offered a position on a scientific or administrative board of a commercial organization that supports research in the faculty member’s department.
- Situations where a faculty member is offered research support from an organization in which the faculty member serves as a director, a member of an advisory board or as a consultant, or in which the faculty member holds a significant equity position.
- Situations where the faculty member occupies a position in an enterprise doing business in the area of the faculty member’s Health Science Center responsibilities or in a related area.
- Situations where the faculty member is involved in independent business ventures as owner, operator or major investor, particularly if the corporation is doing business with the Health Science Center.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

-
- Situations in which a faculty member, while serving as consultant to an external organization has access to unpublished, privileged information from a colleague that has potential commercial value and wishes to provide that information to the external organization.
 - Situations where a faculty member directs students, postdoctoral fellows, or other trainees into a research area or other activity from which the member may realize personal financial gain. A conflict may arise if students are directed to areas of lesser scientific or scholarly merit to enhance the potential for monetary gain or if the financial potential exists only for the member.
 - Situations where the faculty member is asked to assume executive or managerial positions with outside organizations that might seriously divert the faculty member’s attention from Health Science Center duties or create other conflicts.
 - Situations where a faculty member is participating in research on a technology owned or contractually obligated to a business in which the faculty member or family has a consulting relationship, holds a stock or similar ownership interest, or has any other financial interest, other than receipt of a Health Science Center supervised sponsored research agreement or royalties under institutional royalty sharing policies.
 - Situations where a faculty member conducted a sponsored research project involving human subjects awarded to the Health Science Center from a business in which the faculty member or family holds a stock or similar ownership interest.

Conflict of Commitment

Conflict of commitment is more difficult to assess than conflicts of interest. Generally, such conflicts are apparent in the failure of individuals to discharge fully the role and duties expected of them. Examples of actual or potential conflict of commitment include:

- Commitments that involve frequent or prolonged absence from

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

the Health Science Center on non-Health Science Center business.

- Commitments that engage a substantial portion of the time a faculty member is expected to spend in Health Science Center related activities and that thereby dilute the amount or quality of participation in the instructional, scholarly, or other work of the Health Science Center.

Potential Resolutions of Conflict of Interest/Commitment

When an actual or potential conflict of interest or commitment is identified through review of a COI Report, there are many alternatives available for resolution of the conflict. At a minimum, the review process will determine whether a significant financial interest could affect the design, conduct, or reporting of the research or scholarly activities of the faculty member and determine what conditions or restrictions, if any, should be imposed to manage such interests. In the case of conflicts that may affect work to be performed under a sponsored agreement, any conditions or restrictions to resolve or manage conflicts must be determined and implemented before the expenditure of any funds awarded that agreement. Examples of conditions or restrictions that may be imposed as part of a plan to manage actual or potential conflict of interest or commitment include:

1. Public disclosures of significant financial interest.
2. Monitoring of research by independent reviewers.
3. Modification of the research plan.
4. Informing students and trainees of significant financial interest and giving them the option not to participate in the project.
5. Disqualification from participation in all or a portion of the research project or other scholarly activity in question.
6. Divestiture of significant financial interest.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

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7. Severance of relationships that create actual or potential conflict.

Managing Conflicts of Interest in Clinical Trials

Because of the unique nature of clinical studies involving drugs and devices, conflicts of interest must be managed such that there is no perception, real or imagined, of conflict and that the human research participants are fully informed. The following guidance highlights that managing actual and potential financial conflict of interest depends on two factors: the degree of the financial interest and the individual's role in the clinical study. The table below should be used to assist individuals in determining what actions would be required if a conflict did exist, including the need for a conflict of interest management plan and whether that plan would require divestment of the conflict or recusal from study activities. An independent assessment of an individual's potential or actual conflict should be made for each clinical study; this may result in the need for more than one plan for the individual in question.

Potential Management Plan Options

1. Disclosure of financial interest to co-investigators, research study staff, research residents or students.
2. Prohibit individual researcher from any involvement with recruitment or consenting of potential subjects.
3. Preclude an individual from serving as principal investigator for the conduct of the study; consider function of associate investigator with restrictions on certain activities.
4. Require disclosure of conflict of interest to potential study subjects.
5. Require an independent data safety monitoring committee.
6. Require an independent oversight committee to review interim data analysis, publications, and other designated issues.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

7. Required equity to be placed in a blind trust for a specified period of time.

8. Required financial divestiture.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

Guidelines for Managing Conflicts of Interest: Clinical Studies

Increasing Financial Interest → → → → → → → → → → → → → →			
Increasing Responsibility in Clinical Trial	<p>Involved with study planning, data analysis, data interpretation, or critical writing/editing of manuscript such that authorship is expected. (e.g., principal investigator, steering committee member, biostatistician)</p>	<p>If personal income¹, equity interest², and gifts combined are or are expected to be valued at <u>less than or equal to \$10,000</u> annually during the project period³</p> <p align="center">OR</p> <p>If indirect income⁴ is or is expected to be valued at <u>less than or equal to \$15,000</u> annually during the project period</p> <p align="center">OR</p> <p>If patent on studied indication or owner/part-owner of company developing drug, device or procedure and not-yet-approved drug, device or procedure and pilot study to inform pivotal clinical trial</p>	<p>If personal income, equity interest, and gifts combined are or are expected to be valued at <u>greater than \$10,000</u> annually during the project period</p> <p align="center">OR</p> <p>If indirect income is or is expected to be valued at <u>greater than \$15,000</u> annually during the project period</p> <p align="center">OR</p> <p>If patent on studied indication or owner/part-owner of company developing drug, device or procedure and either</p> <ul style="list-style-type: none"> • clinical trial leading to data in support of FDA approval or • post-marketing trial to refine or support expanding indications
	<p>Overseeing local or central coordination study activities, consenting subjects, limited or no review of manuscript such that authorship is not expected. (e.g., site principal investigator, study coordinator, programmers, information analysts)</p> <p>Technical operator (e.g., surgeon, procedural specialist) in an unblinded study whose actions directly impact study outcomes</p>	<p>If personal and indirect income, equity interest, and gifts combined are or are expected to be valued at <u>less than or equal to \$25,000 annually</u> during the project period</p> <p align="center">OR</p> <p>If patent on studied indication or owner/part-owner of company developing drug, device or procedure and not-yet-approved drug, device or procedure and pilot study to inform pivotal clinical trial</p>	<p>If personal or indirect income, equity interest, and gifts combined are or are expected to be valued at <u>greater than \$25,000</u> annually during the project period</p> <p align="center">OR</p> <p>If patent on studied indication or owner/part-owner of company developing drug, device or procedure and either</p> <ul style="list-style-type: none"> • clinical trial leading to data in support of FDA approval • post-marketing clinical trial to refine or support expanding indications
	ACTION REQUIRED →	Disclosure and Conflict Management Plan †	Plan must include Divestment or Recusal ††

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

For the following trial-related activities (and the presence of any potential financial conflict), disclosure and a conflict of interest management plan[†] are not necessary. There is no need to divest or recuse.

- Blinded rater measuring outcomes
- "On-call" investigators responding to emergent subject adverse events
- Administrative Principal Investigator of departmental research division coordinating clinical trials, but with no direct study responsibility

[†]For faculty in supervisory roles who may have mentoring or educational influence over others, the plan should include steps to manage mentoring/educational conflicts, as well as research conflicts.

^{††}When an individual decides to retain the financial interest but recuse themselves, a “recusement” management plan is required to assure that the financial conflicted individual has no real or perceived influence over those conducting the study and that those conducting the study have free and unrestricted right to analyze, interpret, and publish the data.

¹ Personal income is in addition to Health Science Center salary. The income can be from any organization or company that could benefit, appear to benefit, is benefited by, or appears to be benefited by the research activities or the results of the research.

² Equity interest includes all stock options. Pre-IPO stock offerings are valued in present dollar terms and should be less than 5% of the total outstanding equity.

³ Project period is defined as one month after the publication of the primary study results in a peer-reviewed journal.

⁴ Indirect income includes payments received and directed to the Health Science Center in which the donation could or could appear to benefit the faculty member; this includes any Health Science Center discretionary accounts.

Other Complementary Policies

The Health Science Center and the University of Texas System have promulgated other policies that relate to this policy. Specific reference is made to the HOP and its specific policies as follows:

- [Section 10.1.2](#), “Code of Ethics and Standards of Conduct”
- [Section 10.1.3](#), “Personal Use of University Resources, Equipment, and Assets”

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	January 2009
Policy 10.1.6	Conflicts of Interest in Scholarly, Research, and Clinical Activity	Responsibility:	Vice President for Research

-
- [Section 10.1.3](#), “Giving and Receiving Benefits”
 - [Section 10.1.5](#), “Political Activities”
 - [Section 10.1.9](#), “Outside Activities for Pay and Relationships which may Involve Potential Conflict of Interest”
 - [Section 10.1.7](#), “Conflict of Interest Statements for Non-Academic Staff” [applicable to persons authorized to execute contracts on behalf of the Health Science Center or to those persons who exercise discretion with regard to the award of contracts or other pecuniary transactions]
 - [Section 4.5.16](#), “Appointment of Relatives (Nepotism)”
 - [Section 10.1.12](#), “Institutional Conflict of Interest Policy”
 - [Section 10.1.11](#), “Guidelines for Interactions Between Clinicians and Industry”
 - [Section 12.1.1](#), “Intellectual Property Policy”
 - Regents’ *Rules and Regulations* Concerning Intellectual Property ([Rule 90103](#): “Equity Interests” and [Rule 90104](#): “Business Participation and Reporting”)
 - The University of Texas System “[Procedure for Obtaining Approval of Plan to Manage Conflicts of Interest](#)”