

BCM Policies and Procedures

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02.9.10 - Human Resources: Conflict of Interest

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Conflict Of Interest - College Personnel

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I. PURPOSE

Baylor College of Medicine offers its personnel opportunities to engage in a wide variety of activities both in our institution and outside of it. These activities can greatly benefit the College and, at the same time, advance the individual's professional skills. In some instances, however, these same opportunities can present an apparent or an actual conflict of interest.

It is essential that all activities be conducted free from any conflict of interest or the appearance of a conflict. In order to protect the objectivity of Covered Personnel who are engaged in these activities, and to preserve the integrity of the College, all Covered Personnel must manage any apparent conflict and avoid any actual conflict of interest.

In an effort to provide guidance in effecting this philosophy, the following examples are provided to illustrate apparent or actual conflicts of interest that may arise in various activities. This policy identifies apparent conflicts and provides management strategies for dealing with them. Covered personnel may propose alternative management strategies in their disclosure forms. Actual conflicts must be avoided.

II. DEFINITIONS

"Business" means any non-College corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other legal entity organized for profit or non-profit, whether or not for the provision of health care, education or biomedical research, and whether or not affiliated with the College.

"College" means Baylor College of Medicine or a clinic, hospital or other health care facility or entity owned or controlled by Baylor College of Medicine.

"College Site(s)" means any academic or clinical department, division, center, and section located at the College or any facility for the delivery of health care owned or controlled by the College.

"Covered Personnel" shall mean College faculty who are employees of the College, researchers covered by College assurances, selected staff members (Exempt Staff,

Professional Level staff, all staff in Finance, Internal Audit, Human Resources, Information Technology, and Purchasing, all Ungraded Staff and all staff receiving Staff 1 or Staff 2 Faculty benefits), and others who are working for or who are using facilities provided by the College and engaged in activities covered by this Policy.

"Clinical Validation Research" means any research involving human subjects for the evaluation of modalities of medical care, including, but not limited to, diagnostic tests, drug therapies, medical procedures, surgical procedures, or medical devices. It includes Phase I-IV clinical trials and any other human subjects research conducted for evaluative purposes.

"Financial Interest" is an interest in a Business consisting of: (1) any stock, stock option or similar ownership interest in such Business, but excluding any interest arising solely by reason of investment in such Business by a mutual, pension, or other institutional investment fund over which the Covered Personnel does not exercise control; or (2) receipt of, or the right or expectation to receive, any income from such Business (or from an agent or other representative of such Business), whether in the form of a fee (e.g., consulting), salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty or other interest derived from the licensing of intellectual property, rent, capital gain, real or personal property, or any other form of compensation, or any combination thereof.

For the purpose of this Policy, intellectual property is covered as a financial interest upon disclosure to the Baylor Licensing Group or its equivalent in any other institution. Financial interests of Covered Personnel also include such interests held by a spouse, minor or dependent children, and by trusts created by Covered Personnel or spouses.

"Industry" means companies and their representatives, which sell pharmaceuticals, or medical devices or provide services that are pertinent to clinical care.

"Meal(s)" shall include food (breakfast, lunch or dinner), snacks, and drinks of any kind.

"Personal Gift(s)" shall include, but is not limited to, cash, electronic devices, services, promotional items, and hospitality (such as meals and tickets to sporting events or other forms of entertainment).

"Trainees" means all students, residents, and fellows.

"Travel" shall include registration, transportation, lodging, meals, and entertainment.

III. CONFLICT OF INTEREST IN RESEARCH

A. Individual Conflicts of Interest

Apparent Conflict which must be managed:

1) Receiving research support from, or having a Financial Interest in, a Business that sponsors the Covered Personnel's research, whether basic research or research using

animal or human subjects.

Management Strategy: In any journal article, abstract, transcript or other form of publication or at presentations at scientific meetings or other forms of public presentation, Covered Personnel must disclose the fact that they have received research support or have a Financial Interest of greater than \$1000 per annum from any Business which sponsored the research. The Covered Personnel's apparent conflict must also be disclosed to research subjects in the IRB-approved consent form for that research study.

Actual Conflict which must be avoided:

2) Engaging in Clinical Validation Research while having any Financial Interest whose value may be dependent upon the results of that research. These restrictions do not apply to (i) the ownership of securities in a publicly traded company if such securities have a value of less than \$10,000 or (ii) indirect investment in such companies or intellectual property rights through pension plans, mutual funds, etc. over which the investigator has no control as to the purchase or sale of the securities in question.

B. Institutional Conflicts of Interest

Actual Conflict which must be avoided:

3) Engaging in the review or oversight of College decision-making in a particular research activity while having a Financial Interest in a Business for which the activity is being conducted, or while having intellectual property related to the subject matter of the research. This includes decisions about allocating College resources to projects or activities where the decision maker may be influenced by the potential for personal financial gain.

Actual Conflict which must be avoided

4) Those individuals who participate in College investment management (including, but not limited to, the Chief Investment Officer and his staff, the members of the Investment Committee of the Board, the Board and staff of BCM Technologies, and the staff of the Baylor Licensing Group) may not be involved in the supervision of College research activities.

Apparent Conflict which must be managed

5) Conducting research at BCM when the College has an active management role in the company which is the sponsor of the research or has intellectual property rights in the product being tested.

Management Strategy: For all such research protocols, the IRB must be informed of the apparent conflict. At a minimum, if approved by the IRB, such information must be included in the consent form. Additionally, the IRB may at its discretion impose additional requirements (including, but not limited to, the appointment of an independent DSMB) upon the research to protect human subjects and to ensure the objectivity of the research. Because the investigators proposing the research may be unaware of the College's management roles and property rights, College administration will be responsible for notifying both the IRB and the principal investigator when this apparent conflict exists.

IV. CONFLICT OF INTEREST IN CLINICAL PRACTICE

Apparent Conflict which must be managed:

1) Practice of medicine outside the College, or rendition of medical services for any other Business.

Management Strategy: These activities are permitted if conducted as part of, or explicitly permitted under, the Baylor Covered Personnel's employment contract with the College or upon approval in writing of the Covered Personnel's chair and dean.

Actual Conflict which must be avoided:

2) College Personnel must consciously and actively divorce clinical care decisions from any perceived or actual benefits expected from any Business. The Office of the General Counsel or the Conflict of Interest Committee should be consulted concerning questions about the applicability of this rule. Further rules detailing this policy are found in Section V. on Conflicts of Interest in Interaction with Industry.

Actual Conflict which must be avoided:

3) Referral of patients that violates any federal or state law (including, but not limited to, 42 U.S.C sec.411 Subpart J and its interpretive regulations, commonly referred to as Stark I and Stark II) to any Business or accepting any gifts or compensation (other than normal professional fees) for ordering any diagnostic or therapeutic intervention for a patient

V. CONFLICTS OF INTEREST IN INTERACTIONS WITH INDUSTRY

1) Application and Purpose

This section applies to all Covered Personnel and all Trainees who are engaged in the delivery of healthcare as they interact with Industry both on and off a College Site. Additionally, this section applies to all persons attending events, partially or fully, sponsored by the College.

2) Personal Gifts

Actual conflict which must be avoided:

Covered Personnel and Trainees must not receive or accept Personal Gifts of any kind from Industry.

Apparent conflict which must be managed:

A College Site may receive and accept educational materials, such as books and anatomical models, from Industry. The educational materials may acknowledge the source of the gifts.

3) Free Drug Samples

Actual conflict which must be avoided:

Covered Personnel and Trainees must not receive or accept free pharmaceutical samples (prescription or over-the-counter) directly from Industry.

Apparent conflict which must be managed:

Clinical College Sites may receive or accept drug samples directly from Industry. All College Sites that do so must set up a central repository to distribute the drug samples and to facilitate timely patient access to optimal therapeutics. The College Site must determine the central repository's formational and operational guidelines, which must not conflict with the guidelines of any relevant College affiliated institution.

4) Industry Support of (including the provision of Meals at) All Events at the College

Actual conflict which must be avoided:

Covered Personnel and Trainees must not receive or accept financial support directly from Industry for or at events at the College. This includes, but is not limited to, all funds for hospitality, such as meals.

Potential conflict which must be managed:

College Sites may receive and accept financial support for events at the College, as long as the following requirements are satisfied:

- (a) The person responsible for the College Site must give written approval for an application for such support in advance and is responsible for ensuring that the events meet the requirements contained in this subsection;
- (b) All Industry support must be given to the College Site hosting the event;
- (c) The College Site hosting the event, not Industry, must control the event's program;
- (d) Industry supported events must be free of any actual or perceived conflict of interests and must fully comply with Accreditation Council for Continuing Medical Education ("ACCME") standards for objectivity regardless of whether formal CME credit is awarded or not. These standards include: 1) the speaker must disclose any financial conflicts of interest he or she has with commercial entities; 2) the physicians participating in these events must have full control of the content; and 3) the event must present objective information that is as free as possible of bias or marketing influences;
- (e) Industry support must be acknowledged by the host of the event in advance publicity (announcements or literature), at the event and in any resulting reports or publications; and
- (f) Industry that donates such support may be present at the event and may have a location at the event to distribute promotional material, as long as the location does not distract from the event, but Industry must not make promotional presentations during the event.

5) Participation and Attendance at Events Not at a College Site with Industry Support

Actual conflict which must be avoided—Compensation for Attendance Only:

Covered Personnel or Trainees must not receive or accept compensation, travel expenses

or any Personal Gift directly from the Industry for their attendance at any event not at a College Site, except as allowed below.

Apparent conflict which must be managed—Support from Organizations for Attendance Only:

Covered Personnel and Trainees may receive or accept Industry support for attendance at an event not at a College Site, as long as the following requirements are satisfied:

- (a) Industry support must be provided by a direct grant to a sponsoring academic institution or professional organization or society hosting the event;
- (b) Sponsoring academic institution or professional organization or society must manage and control the approval of the speaker, topic, location and Meals for the event and must ensure that the speaker provides a fair and balanced discussion; and
- (c) Industry support must be acknowledged by the event's host in advance publicity (announcements or literature), at the event and in any resulting reports or publications, and Industry representatives may be present at the event, but they cannot make promotional presentations.

Apparent conflict which must be managed—Support from College Sites for Attendance Only:

Covered Personnel and Trainees may receive or accept support from Industry for attendance at events not at a College Site so long as the following requirements are satisfied:

- (a) Industry support must be directly provided to a central fund of the appropriate College Site;
- (b) The College Site must determine the allocation of the funds;
- (c) The College Site must determine that the event has educational merit;
- (d) The College Site must select the Covered Personnel or Trainees as the recipient; and
- (e) Recipient of the funds must not be subject to an implicit or explicit *quid pro quo*.

These requirements do not apply to national or regional merit-based awards. Therefore, Covered Personnel and Trainees may apply to events not at a College Site and hosted by national organizations, which are also sponsored Industry, where the application or award process is competitive and the national organization selects the recipient. Similarly, Covered Personnel or Trainees may accept direct support from professional organizations or societies that are supported by Industry as long as they do so in accordance with those entities' rules.

Apparent conflict which must be managed—payment for services provided:

Covered Personnel and Trainees who provide services at such events not at College Sites may accept only fair market compensation for the specific, legitimate services they provided during an event. This compensation must be commensurate with the person's time and effort. Additionally, the terms of the participant's service arrangement must be in writing and that agreement must be approved by their supervisor in advance.

6) Industry Access to Covered Personnel and Trainees at the College

Apparent conflict which must be managed:

College Sites may provide Industry access to the site, the events at the site and the

Covered Personnel or Trainees at the site only under the following conditions:

- (a) Industry must have an appointment with a specific individual prior to arriving at the College Site;
- (b) Immediately upon arriving at the site, Industry must check-in;
- (c) Industry must not have access to patient care areas and must only interact with Covered Personnel and Trainees in designated non-patient care areas;
- (d) Industry must follow all the additional access rules of the College Site they visit; and
- (e) College Sites may provide device manufacturer representatives access to patient care areas only for purposes of providing technical assistance and only under the following conditions:
 - a. Representatives must have an appointment with or invitation from a physician who is satisfied with their level of skill and knowledge of the product; and
 - b. Representatives must not be present during any patient care interaction, unless there has been prior disclosure to and consent by the patient, and then, only to provide in-service training or assistance on devices and equipment.

VI. CONFLICTS OF COMMITMENT

Apparent Conflict which must be managed:

- 1) Covered Personnel entering into consulting agreements with, or assuming positions or employment with, or becoming an officer or director of, another Business.

Management Strategy: Such agreements or arrangements must be approved in advance and in writing by the Covered Personnel's supervisor (or by the President of the College if the Covered Personnel is a Vice President, Dean, Departmental Chair or Center Director). If the relevant agreement involves providing professional services, then it (a) must provide for the rendition of actual services in exchange for appropriate compensation and (b) should not be entered into with the primary intention of securing the endorsement of the Covered Personnel or of exploiting his or her College affiliation. All agreements, whether or not they involve providing professional services, must be structured so as to not interfere with the Covered Personnel's ability to perform his or her College duties. As a general rule, the total effort devoted to all such activities shall not exceed twenty percent (20%) of the Covered Personnel's total effort.

Actual Conflict which must be avoided:

- 2) Accepting any duties outside the College which can require or have the appearance of requiring Covered Personnel to utilize proprietary or confidential information including, but not limited to, data, processes, procedures, or methods of the College and its affiliates, or of entities to which the College owes an obligation of confidence.

Actual Conflict which must be avoided:

- 3) Covered Personnel having an ownership interest in any Business which competes with the College.

VII. Other CONFLICTS

Apparent Conflict which must be managed:

1) A Covered Personnel acquiring an interest in, or having a consulting or other financial relationship with, a Business that is a supplier of goods, services or financing to the College, or that shares researchers, data, or facilities with the College, or that is engaged in the same fields of interest as is the College.

Management Strategy: Contracts between the College and the Business must be negotiated free of self-interest (e.g. they must be negotiated on behalf of the College by someone other than the individual who has the relation with the Business) and must be approved by the individual's supervisor and any other person whose approval is required under the College's delegation of authority policy. The attention of all approvers must be called to the apparent conflict. This includes contracts involving the use of College equipment, personnel or other facilities by a Business.

Apparent Conflict which must be managed:

2) Making personnel decisions (e.g., hiring, promoting, changing salary, terminating) about a relative (spouse, child, parent, or sibling) or a significant other (a domestic partner with whom one resides or someone with whom one has a serious romantic relation).

Management Strategy: Those decisions must be reviewed by one's supervisor and by the Vice President for Human Resources. Those reviews must be documented.

Actual Conflict which must be avoided:

3) Permitting one's College affiliation to be used by a Business in connection with a marketing, investment or commercial venture.

Actual conflict which must be avoided:

4) Providing a gift of more than a de minimus value (\$100) to, or providing entertainment for, employees, officers or directors of any Business which provides goods or services to the College, or any branch of national, state or local government, under circumstances that could be construed as bribery, or, in the case of governmental entities, impermissible lobbying activities.

VIII. ADMINISTRATION OF POLICY

The President of the College shall appoint a Conflict of Interest Committee that shall have responsibility for administering and interpreting this Policy. The Conflict of Interest Committee shall meet as often as its Chairman shall determine, and it shall periodically report on its activities to the President, to the Academic Council, and to the Audit Committee of the Board of Trustees of the College.

In the event of a violation of this policy, the College will take whatever corrective action is necessary to protect the integrity of the institution itself and its research and clinical projects and enterprises. In addition, it may at its discretion impose penalties upon the violator. The penalties for such violations may range from reprimand to termination and may depend upon the severity of the violation and what can be known about the intentions

of the violator.

Because this policy does not treat all potential conflicts of interest by way of specific provisions, the Conflict of Interest Committee strongly encourages all College Personnel to seek advice on transactions which may present actual or apparent conflicts of interest before committing to such transactions. Questions concerning the Conflict of Interest Policy should be addressed to the Chair of the Conflict of Interest Committee.

Any exceptions to these policies must be approved in advance by the Conflict of Interest Committee and will be reported periodically to the Audit Committee of the College's Board of Directors. Decisions of the Committee may be appealed to the President of the College through the electronic conflict of interest disclosure system.

The Conflict of Interest Committee is administratively supported through the Office of Research Compliance. The Potential Conflict of Interest Disclosure Statement is available through the Biomedical Research and Assurance Information Network (BRAIN). Covered Personnel must have an Enterprise Computing Account (ECA) password to log on to the site. All Covered Personnel must complete an initial disclosure statement. Any new instance of these activities must be disclosed as they arise by revising the disclosure statement and must be evaluated to avoid actual conflicts and to manage potential conflicts. In addition, Covered Personnel are required to review their disclosure statement at least annually and to update it as necessary. Similarly, supervisors of any College Site which accepts any support from Industry described in Section V of this policy must disclose such support annually.