

APPENDIX

Guidelines for Managing Conflicts of Commitment and Interest

Summary

This document presents guidelines for the interpretation and application of HSC Internal Policy 12.01.09.Z1.04 Conflicts of Commitment and Interest.

1. LIMITATIONS ON OUTSIDE PROFESSIONAL ACTIVITIES

The Texas A&M Health Science Center (HSC) encourages faculty, staff and trainees to become involved in the transfer of knowledge from the HSC to the commercial marketplace. It is an appropriate role for the HSC to facilitate the transfer of knowledge gained through academic research to applications that can benefit the general population. Moreover, experience gained by faculty, staff and trainees in the course of outside professional activities can enhance their teaching and research/ scholarship within the HSC. The process of technology transfer can create the potential for conflicts of commitment and/or interest, however, when there is an opportunity for personal gain on the part of the individual. The intent of HSC Internal Policy 12.01.09.Z1.04 is to minimize conflicts and provide means of managing them when they arise.

An implicit assumption underlying TAMUS Policy 31.05.01 Faculty Consulting, External Employment and Conflicts of Interest is that such outside professional activities are a privilege and not a right and must not detract from an individual's obligation to his or her HSC duties. When any outside activity detracts faculty, staff and trainees from the conduct of their HSC duties, a conflict of commitment can result. Activities such as *pro bono* work, government service in the public interest, and any outside employment unrelated to the individual's HSC responsibilities should be managed so they do not take precedence over the individual's commitment to the HSC.

Outside professional activities can also generate conflicts of interest regardless of the time involved. For example, direction of a program of research or scholarship at another institution that could be conducted appropriately at the HSC as part of a faculty member's normal duties can deprive HSC trainees and colleagues of the benefits of the faculty member's primary intellectual energies. Another example is submitting research proposals through channels other than the HSC to support work that could be performed at the HSC. First, the use of HSC resources in the course of that work is practically unavoidable. Second, it becomes difficult, if not impossible, for the HSC to review and reward the contributions of faculty, staff, and trainees for work managed and/or conducted elsewhere. Third, the action can result in situations that place staff members and trainees in conflicts of interest. For these reasons HSC faculty members are prohibited from serving as principal investigators on

sponsored projects submitted and managed through institutions outside the Texas A&M University System. This stipulation is not intended to limit faculty from participating in multi-site training or research programs. Nor is it intended to apply to circumstances in which the faculty member's research requires access to facilities not available at HSC. A faculty member could apply for a grant under the aegis of an organization other than the HSC if (a) the grant criteria excluded universities as applicants or (b) the competitiveness of the proposal were enhanced by such an arrangement, provided that the grant (1) would bring resources to the HSC or (2) were a small pilot project with the promise of a later application through the HSC. In such cases, full disclosure and approval by the component head is required.

Whenever faculty, staff or trainees are involved in research as part of their outside consulting or business activities, they must establish clear boundaries that separate their HSC and outside obligations, so as to avoid questions about their appropriate use of resources and attributions of products of their work.

2. APPROPRIATE USE OF UNIVERSITY RESOURCES, INCLUDING FACILITIES, PERSONNEL, EQUIPMENT, AND INFORMATION

Faculty, staff and trainees may not use HSC resources, including facilities, personnel, equipment, or confidential information, except in a purely incidental way as part of outside consulting activities or for any other non-HSC purposes. Inappropriate use of HSC resources may include:

- assigning faculty, staff or trainees to tasks for purposes of potential or real financial gain of the individual rather than the advancement of the scholarly field or the trainees' educational needs.
- involving faculty, staff or trainees in outside consulting or business activities without prior approval of the department chair or component dean/director or designee.
- granting to external entities access to HSC resources or services for purposes outside the HSC mission, or offering inappropriate favors to outside entities in an attempt to unduly influence them in their dealings with the HSC.
- using for personal gain or granting unauthorized access to others, of confidential information acquired through conduct of HSC business or research activities. Confidential information includes, but is not limited to, medical, personnel, or security records of individuals; proprietary knowledge about corporate anticipated material requirements or price actions; and proprietary knowledge of possible new sites for government operations or information about forthcoming programs or selection of contractors or subcontractors in advance of official announcements.
- providing preferential access to research results, materials or products generated from HSC teaching or research activities to an outside entity for personal financial gain. This would not preclude appropriate licensing agreements for inventions, or consulting on the basis of sponsored project results where there is significant additional work or expertise involved.

3. DISCLOSURE AND OWNERSHIP OF INTELLECTUAL PROPERTY

The HSC wishes to encourage faculty, staff and trainees to be involved in technology commercialization as part of their HSC duties. To manage and minimize conflicts over intellectual property rights, all potentially patentable inventions created or discovered by faculty, staff or trainees in the course of their HSC activities, or with use of HSC resources, must be disclosed to the HSC on a timely basis as per HSC Rule 17.02.01.Z1 Intellectual Property, Patents, Copyrights, Information Technology, and Classified Proprietary Research. Institutional management of the commercialization of technologies developed using HSC resources allows contractual obligations to sponsors to be fulfilled, and reduces the potential for individual conflicts of interest, since the institutional managers of the assets do not have personal financial interests in the outcomes of licensing processes nor do they participate in making academic or future research decisions (see HSC Internal Policy 17.02.01.Z1.01 Management of Technology Commercialization Through Patents and Licensure of Intellectual Property).

4. FACULTY, STAFF AND TRAINEE INVOLVEMENT IN TRANSACTIONS BETWEEN OUTSIDE ENTITIES AND TAMHSC

Faculty, staff and trainee involvement in gifts, sponsored projects, technology licensing or certain procurement arrangements between the HSC and an outside entity, where the involved individual (or the individual's immediate family members as determined by the Internal Revenue Service (<http://www.irs.gov/charities/foundations/article/0,,id=136955,00.html>) has any consulting or employment relationships with, and/or significant financial interests in, that entity, raises particular questions of conflicts of interest; such situations require special *ad hoc* disclosures, review and approval. For this purpose, "significant financial interests" in an entity means:

- any current or pending ownership interests (including shares, partnership stake, or derivative interests such as stock options) in a privately-held entity (e.g., in a "start up" company).
- any current or pending ownership interests (including shares, partnership stake, or derivative interests such as stock options) in a publicly-traded entity, amounting to at least one-half percent (0.5%) of that entity's equity or at least \$10,000 in ownership interests (except when the ownership interest is managed by a third party such as a mutual fund).
- any other income amounting to at least \$10,000 per year, including for example honoraria, licensing or royalty income.

NOTE: Where a faculty member, staff member or trainee participates in research involving human subjects, and has **any** financial interest in the sponsor (or a member of the immediate family has such an interest), that interest must be disclosed on an ad hoc basis, regardless of its value (see Section 7).

Additionally, faculty, staff and trainees seeking funding from an external sponsor must ensure compliance with that sponsor's disclosure requirements.

Prior to the HSC entering into any of the following arrangements, the involved faculty member, staff member or trainee must submit to the component dean/director or designee a complete written disclosure of his or her (or his or her immediate family member's) consulting or employment relationship with, and/or significant financial interest in the outside entity, the nature of the proposed transaction, and the means by which the individual will ensure separation of his or her HSC role from the their (or family members, as described above) role or interests in the company:

- gifts to the HSC of cash or property which will be under the control, or will directly support the teaching, research or training activities of a faculty member, staff member or trainee from an entity in which that individual (or members of the immediate family as described above) has a consulting or employment relationship with, and/or significant financial interests (as defined above) in.
- sponsored project proposals in which any of the involved investigators (or members of their immediate families as described above) have a consulting or employment relationship with, and/or significant financial interests in (or, in the case of research involving human subjects, **any** financial interest in) the proposed sponsor, or with proposed subcontractors, vendors, or collaborators.
- HSC technology licensing agreements with companies for which the faculty, staff or trainee inventor (or members of the immediate family as described above) has a consulting or employment relationship with, and/or significant financial interests in.
- sole-source procurement of materials or services from an outside entity, or procurements involving a privately-held entity where the faculty member, staff member or trainee involved in the procurement (or members of the immediate family as described above) has a consulting or employment relationship with, and/or significant financial interests in, the proposed supplier.

Common sense must prevail in the interpretation of these provisions. Regardless of the dollar amounts, if an independent observer might question whether the faculty member's, staff member's or trainee's professional actions or decisions are determined by considerations of personal gain, the relationship should be disclosed and approval sought for the proposed transaction.

When such proposed arrangements are disclosed, the component dean/director or designee shall, in consultation with the Vice President for Academic Affairs, determine an appropriate resolution for the situation. Either the component dean/director or designee or the Vice President of Academic Affairs may convene an *ad hoc* committee to advise the faculty member, staff member or trainee on any such proposed arrangements. The committee may include other members of the faculty, staff or trainees, and/or individuals not otherwise affiliated with the HSC, as long as none of them has vested interests in the outcome of the proposed arrangements.

5. SITUATIONS RAISING QUESTIONS OF SCIENTIFIC OBJECTIVITY

In cases where the HSC has approved arrangements as described in Section 4 above, or in Clinical Technology Assessment agreements (clinical trials) in which the investigators have any personal financial interests (including consulting or employment relationships), the scientific objectivity of the individual's activities may be questioned. To address these situations, oversight committees may be established by the component dean/director or designee to 1) review the appropriateness of the proposed activity, 2) to monitor the conduct of the activity (including use of trainees), and 3) to ensure open and timely dissemination of the research results.

Clinical trials and other research involving human subjects raise particularly sensitive issues in those cases where the investigator has any personal financial interests. Regardless of the dollar amounts involved, outcomes and financial interests must be disclosed to the component dean/director or designee. The demand for new therapeutics requires that agents be developed and tested. The processes that must be followed in the testing and development of therapeutics raise an inherently contradictory situation for faculty, staff and trainees, since frequently the inventors of therapies or medical devices are those who do research on the disease in question, are the leaders in the field, and are the most qualified to carry out pre-clinical and clinical testing. Also, the most qualified laboratories and individuals to conduct trials may receive, or be candidates to receive, research support from an external organization.

The faculty member, staff member or trainee (and the component dean/director or designee to whom the disclosure is made) must take appropriate steps to guarantee objective evaluation of the agent or device, especially for advanced clinical trials (FDA phase II and phase III). Testing might involve other faculty, staff or trainees of the department or division, but if the individual is a department chair or division chief, the referral for testing the therapy/device to another individual (particularly to a junior individual) may carry implied coercion. Integrity should be protected by an independent oversight group for evaluation and monitoring of the research. Therefore, it is recommended that an *ad hoc* committee be appointed by the component dean/director or designee) whenever:

- a faculty member, staff member or trainee is involved in clinical trials of his or her inventions.
- a company licensed to use a faculty, staff or trainee's invention is sponsoring the trial.
- there may be a question about the faculty member's, staff member's or trainee's objectivity.
- the outcome of the trial could be seen as influencing existing or potential research support.
- such testing is referred to other members of the faculty member's, staff member's or trainee's department or division.

Under appropriate circumstances, the HSC may require that the investigator either divest any financial interest or not perform the work at the HSC.

6. INTERACTIONS WITH INDUSTRY UNRELATED TO EMPLOYMENT

6.1 Site Visits and Educational Workshops Provided by Industry

Site visits by industry to the HSC, or by faculty, staff and trainees to industry sites are necessary to keep faculty, staff and trainees up to date on the latest technologies and advancements in products and services. Faculty, staff and trainee visits to industry sites can be valuable opportunities to become familiar with new technologies, and to assess the potential of the industry host to become a collaborative partner for purposes of licensing or sponsored research agreements. Faculty, staff and trainees may solicit site visits and industry may request permission for purposes of demonstrating new technologies, and for educational purposes, provided specific guidelines for such visits are met:

- All visits by industry to the HSC require a written invitation, with specific outlines for the purpose of the visit, the tools, equipment and products to be demonstrated, and the length of the visit.
- Written requests may be directed to a faculty member, staff member or trainee, but permission for such a visit must be obtained from the department chair, associate dean and dean/director or designee.
- Visits to industry sites by a faculty member, staff member or trainee, require written invitation. All invitations must be routed through the department chair, associate dean and approved by the dean/director or designee of the HSC component.

6.2 Funding of Events by Industry

Many events planned and executed by HSC components require funds exceeding available resources. Industry sponsorship of such events is often required for the events to be successfully planned and executed. Event funding does not grant industry permission to advertise at such events.

- Event funding is not permitted if the funds are directed to a specific individual, or for a specific activity occurring at the event. All event funding must be directed to a general fund. Acknowledgement of industry for providing such event funding can be made in general announcements related to the events yet cannot be tied to specific activities (such as a lecture, symposium, or dinner) within the funded event.
- Industry may request permission to fund or sponsor events at the HSC. Such requests will be in writing and permission must be granted by the appropriate department chair, associate dean, and dean/director or designee of the HSC component. Such requests should provide details of the event to be funded or sponsored, and the nature of the funding or sponsorship. Such funding or sponsorship cannot be tied to specific individuals attending or organizing such events, or to specific activities occurring during the event.
- Faculty, staff or trainees who receive reimbursement or remuneration for presentations associated with site visits (e.g. honoraria) must report them as

consulting activities, following [System Regulation 31.05.01](#) related to external consulting and employment.

- Industry may sponsor teaching excellence awards when members of the HSC component identify awardees.
- Trainees may be reimbursed for reasonable costs associated with travel associated with site visits, and may receive reasonable remuneration associated with awards for excellence in research or clinical practice, if approved by the department chair, appropriate associate dean or designee and dean/director or designee of the HSC component.
- Trainees may receive scholarship funding from industry when members of the HSC component identify potential awardees.

6.3 Non-Monetary Gifts from Industry (including pharmaceutical samples, food, and other in-kind forms of gifts)

Non-monetary gifts from industry offered at vendor fairs, vendor booths at clinical and scientific meetings and as “free-sample” items are generally permissible if the financial worth of such gifts is <\$50. Corporate sponsorship provides for many activities required by the accreditation process to introduce faculty, staff and trainees to new technologies and products. Sponsorship often involves providing equipment or products that HSC components could not afford to purchase to test their efficacy. Larger non-monetary gifts (such as equipment and clinical supplies) in support of research or clinical activities may be made to the HSC component or a department within the component as long as the gifts do not require continuing interactions with specific faculty, staff or trainees, and no report-back to industry is required or expected. Additionally, such gifts should be reported to the component business office and HSC Office for Institutional Advancement as they may be eligible for reporting in the HSC financials. This gift process is independent of equipment or products supplied under sponsored research and service agreements not covered in this policy.

- Faculty, staff and trainees should use discretion in deciding whether to accept non-monetary gifts from industry. Any gifts requiring or implying broader access to faculty staff and trainees at future events are unacceptable.
- Gifts of equipment or clinical supplies may be offered to the HSC component through a specific faculty member, staff member or trainee, but the gifts should be made to the HSC component dean/director or designee, and not to the faculty, staff or trainee member or their department.

6.4 Gifts from Industry in Support of Research or Education

All gifts in support of research or education must be unrestricted and for research or educational purposes only. Gifts should not cover funds or materials directed to targeted research or educational endeavors, the latter which will fall into the category

of educational or research grants, not covered in these guidelines. In addition, the ability to provide high-level continuing education courses to medical/dental residents and the clinical community can depend on funding that could not be provided exclusively through institutional sources. Corporate sponsors may provide funds that allow components to have nationally recognized lecture programs. These funds must be unrestricted, however, and their use placed at the discretion of the component dean/director, or designee.

Such gifts must be unrestricted and for research or educational purposes only, and must be deposited and managed in an account of the HSC or affiliated health system.

6.5 Participation in Education by Industry Representatives

Awards for student research competitions at professional meetings may be sponsored by industry as long as panels not comprised of industry members judge the competitions. Industry may choose student winners they wish to sponsor from the overall pool of winners. Teaching awards sponsored by industry are permissible to provide acknowledgement to the student or faculty receiving them. As with competitions, industry may not participate in assessing nominees for teaching awards, but may choose to sponsor a specific winner of such an award once members of a professional group or educators identifies the winners. Such awards may be given to the winners directly, and if awards are made off-campus, reasonable travel and hotel costs may be covered by industry.

Educational workshops can improve teaching. Industry may be present at educational workshops, but may only be present to answer technical questions relating to product operation or function.

7. CERTIFICATION OF COMPLIANCE

At the time of academic appointment, hiring, or matriculation, all faculty, staff and trainees must certify to their component dean/director or designee their compliance with the HSC policy related to conflicts of commitment and interest. Faculty, staff and trainees must disclose information about their (and immediate family members as defined by the Internal Revenue service (<http://www.irs.gov/charities/foundations/article/0,,id=136955,00.html>)) interests in outside entities that are sponsors of their teaching or research programs, or that are otherwise involved in current, proposed or pending transactions with the university in which they are involved. In addition, faculty, staff and trainees must disclose if they have served as principal investigators or managers of outside research or business activities in their professional fields, or if they have involved trainees or staff in their outside consulting or business activities. Faculty, staff and trainees should provide this information for confidential review by the HSC and for such other purposes as are required by law, contract or regulation. In components where the established review mechanism includes the department chair and/or a faculty committee, faculty members may request that the certification and disclosures be reviewed by the component dean/director or designee instead.

Faculty, staff and trainee members must disclose to their component dean/director or designee (with a copy to the department chair) on an *ad hoc* basis current, proposed or pending situations that may raise questions of conflict of commitment or interest, as soon as the faculty, staff or student member knows of such situations.

8. RESPONSIBILITIES OF THE COMPONENT DEANS/DIRECTOR

Each component dean/director or designee is responsible for collection and review of initial certifications as well as *ad hoc* disclosures, and (in consultation with the Vice President for Academic Affairs for education and training related disclosures and the Vice-President for Research and Graduate Studies for research related disclosures) for the management of conflicts that arise. The dean/director or designee should use his or her discretion and knowledge of local conditions to set up a system that works well for the component. Each component's plans for distribution, receipt, processing, and review of disclosure forms shall be submitted to and approved by the Vice President for Academic Affairs. The review process in each component may be assigned to an associate dean or designee and/or to a faculty review committee. However, if for reasons of confidentiality, a faculty member wishes to have his or her disclosure reviewed personally and exclusively by the component dean/director or designee, that option must be made available.

All faculty, staff and trainees will be reminded in writing by the dean/director or designee, on an annual basis, to disclose any potential conflicts of commitment or interest as they occur. Disclosures should be maintained on file by the component dean/director or designee.

9. RESPONSIBILITIES OF THE VICE PRESIDENT FOR ACADEMIC AFFAIRS

The Vice President for Academic Affairs is the HSC officer responsible for interpreting and overseeing implementation of and compliance with HSC Internal Policy 12.01.09.Z1.04 Conflicts of Commitment and Interest. He or she is responsible for reviewing and approving each component's process for implementing the Internal Policy, for consulting with component deans/director or designees to determine appropriate strategies for managing conflicts, and for reporting annually to the Academic Affairs Administrative Council on the effectiveness of the policy throughout the HSC. In addition, the Vice President for Academic Affairs shall adjudicate situations in which a faculty member, staff member or trainee wishes to appeal a decision of a component dean/director or designee. The Vice President for Academic Affairs shall work with component deans/director or designees to ensure that this policy is implemented with reasonable consistency across the HSC.