

## FOX CHASE CANCER CENTER ADMINISTRATIVE POLICIES AND PROCEDURES

**NUMBER:** FCCC-ADMIN-GEN C-3.00

**TITLE:** CONFLICT OF INTEREST

**EFFECTIVE DATE:** May 1991

**LAST REVIEWED:** June 2019

**LAST REVISED:** January 2018

**REFERENCES:**

- "Conflicts of Interest in Academic Health Centers," A Report by the AHC Task Force on Science Policy, Association of Academic Health Centers, 1990.
- The Johns Hopkins University Intellectual Property Policy, Revised Version, October 27, 1992.
- Federal Register, Vol 59 No. 123, Tuesday, June 29, 1994, Proposed Rules, pgs. 33242 - 33312.
- AAU Taskforce on Accountability, Report on Individual and Institutional Conflict of Interest, 2001
- American Society of Clinical Oncology, Conflict of Interest Policy, Revised March 12, 2005
- Revisions of and Clarifications to the ASCO Conflict of Interest Policy, Journal of Clinical Oncology, Volume 24, number 3, January 20, 2006
- Federal Register, Vol 75, No 98, Friday, May 21, 2010, Proposed Rules, pgs. 28688 – 28712

**POLICY OWNER:** J. Robert Beck, M.D.

**SCOPE:**

Cooperative endeavors between industry and academic institutions have created new opportunities to transfer the results of academic research to the private sector to promote the public good. One aspect of that cooperation, consulting, can be a valuable element in any professional's work life, enhancing his or her intellectual life as well as providing valuable insight to organizations they serve. At the same time, these activities have created perceptions on the part of academe, government, industry and the general public that such activities threaten to compromise the objectivity and obligations of the research enterprise.

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Experience has shown that conflicts of interest are not uncommon, practically unavoidable, and not unique to the academic research institution. Biomedical research, which frequently involves both the invention and testing of diagnostics and therapeutics can produce especially thorny dilemmas for the researcher, the institution and the industrial partner who may be supporting research and clinical development. Over the years, academic research institutions have developed a number of mechanisms designed to manage conflict and provide oversight to consulting activities and, thereby, assure the public that it can rely on the results of biomedical and scientific research. The discussion and procedures below are intended to guide Fox Chase Cancer Center (the "Center"), its staff and board members to avoid or manage conflicts and/or the appearance of conflicts, and examine consulting arrangements so as to avoid compromising the integrity of both the institution and the research enterprise.

### **PURPOSE:**

The Center is committed to the highest ethical standards in the conduct of its research, patient care and business activities. "The results of research must not be compromised by any financial interest that will, or may be reasonably expected to bias the design, conduct or reporting of the research". (FRVol. 59, No 123, 6/28/94). A conflict of interest occurs when there is a divergence between an individual's interests and his or her obligations to Fox Chase such that an independent observer might reasonably question whether the individual's actions or decisions are determined by consideration of personal gain, financial or otherwise. The possibility of a conflict of interest arises when an individual has two or more relationships to the same activity or situation. In such cases, the often perfectly legitimate interests of each relationship may come into conflict. The most common situations in which potential conflicts of interest occur in a research setting relate to those in which a person has a personal or financial interest in the outcome of a research project in which that person is actively engaged.

In addition, continued dedication to the translation of research findings into clinical application has the potential to place institutional officials, trustees and management in conflict, especially when the support of startup companies based on institutional discoveries compete or appear to compete with Center interests.

The purpose of this policy is to allow Fox Chase, its employees, Board Members, consultants and subcontractors to identify those situations in which a potential conflict of interest exists. It is based upon disclosure to Fox Chase of all financial interests, which any individual (which, for this purpose, includes an employee or Board Members, spouse and/or dependent children) has in any matter affecting the Center.

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Consulting outside the institution can be a valuable way to enhance the expertise and professional value of the staff member and can facilitate the transfer of knowledge through academic research to applications for the public good. However, these activities must not detract from the staff member's obligation to Fox Chase nor violate the rights of Fox Chase or its funding organizations to enjoy the benefit of its intellectual property.

## **POLICY:**

### **I. General Principles and Discussion**

#### **A. Conflict of Commitment**

Fox Chase staff members owe their primary professional allegiance to Fox Chase. Their primary commitment of time and intellectual energies should be to research, scholarship, patient care and education. A conflict of commitment exists when external activities are so extensive as to interfere, or appear to interfere, with the individual's work responsibilities to Fox Chase.

Staff members at FCCC are obligated by the terms of their employment to have significant presence on campus, to be accessible to other staff and students, to interact with colleagues and to participate in the governance of the institution. In certain instances, permission for extended absences for field research or sabbaticals may be granted by the appropriate Senior Vice President. However, staff members should expect to provide their expertise, time and energy primarily to FCCC.

The specific duties and professional activities that constitute an appropriate and primary commitment will differ across divisions and departments and it has been the policy of the Center to permit faculty members the right to spend up to 15% of the time owed to FCCC to outside scholarly activities without review. Nonetheless, the activities should be based on an understanding between the staff member and his or her senior supervisor. In the case of the Vice Presidents, an understanding should be reached between that individual and the President.

#### **B. Conflict of Interest**

1. Definition of Conflict. There are, broadly, two forms of conflict: individual and institutional.

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- a. An individual will be deemed to have a potential conflict of interest if the individual (or the individual's spouse or dependent child) knowingly receives anything that when aggregated for the individual, the individual's spouse and dependent children equals or exceeds \$5,000 for 12 months. This includes, but is not limited to, salary or other payments for service (e.g. consulting fees or honoraria); equity interests (e.g. stocks, stock options, or other equity interests); debt interests, capital holding or other remuneration or financial consideration, or thing of value for services as an employee, consultant, officer or board member in an entity which will reasonably appear to be directly and significantly affected by the Center's research or other activities. Also included are intellectual property rights of any value (e.g. patents, copyrights and royalties from such rights) related to a matter affecting the Center.
  - b. The term does not include:
    - i. Salary, royalties or other remuneration from Fox Chase;
    - ii. Income from seminars, lectures or teaching engagements sponsored by public or non-profit entities;
    - iii. Income from service on advisory committees or review panels for public or non-profit entities
    - iv. An equity interest that when aggregated for the individual and the individual's spouse and dependent children meets both of the following tests: does not exceed \$5,000 in value as determined through reference to public prices or any other reasonable measure of fair market value; or,
    - v. Salary, royalties or other payments that when aggregated for the individual and the individual's spouse and dependent children over the next 12 months are not to exceed \$5,000.
2. Institutional Conflict of Interest. The Association of American Universities has defined institutional conflict of interest as potentially occurring "when the institution, any of its senior management or trustees, or a department has an external relationship or financial interest in a company that itself has a financial interest in a faculty research project. Senior managers or trustees may also have conflicts when they serve on the boards of (or otherwise have an official relationship with) organizations that have significant commercial transactions with FCCC. The existence (or appearance) of such conflicts can lead to actual bias, or

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suspicion about possible bias, in the review or conduct of research at FCCC.”

There is no threshold below which a member of Fox Chase’s management staff (defined as any individual at a vice presidential level or higher or their direct reports) is exempt from disclosure if the staff member receives any remuneration from a company with which they are also in a position to negotiate the terms of any business agreement, including, but not limited to a license, purchase order or clinical trial.

- a. As a matter of policy, FCCC will not take a board position in any company to which it licenses its technology. However, when appropriate, it may appoint an individual to occupy an observer seat when that seat has been negotiated as part of the overall license arrangement.
3. Examples of conflict. Conflict of Interest may take many forms. Outlined below is a list of situations which commonly arise in academic institutions. This list is comprehensive but is not intended to represent all possible situations that may arise. It is the obligation of the individual staff member to report to the Office of the President any situation which may present a conflict of interest.
  4. Support of Research. Balanced against the enormous promise of a new source of funds for research is a concern that the integrity of research neither be compromised or appear to be compromised by acceptance of money from commercial entities. All arrangements with outside entities for work to be performed with Center resources must preserve certain principles. These principles are best preserved when the Vice President of Business Development is involved as early in the discussion as possible. At minimum, review of all arrangements by the Vice President of Business Development will ensure that no rights are abandoned. No discussion or negotiation of legal or financial terms should go forward without the prior consent of the Vice President of Business Development.
    - a. Free and Open Exchange of Research Results. All agreements with commercial sponsors must ensure that research results are disseminated on an open and timely basis. While provisions may be put into place for delays of publication appropriate to preserve

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intellectual property rights, in all but those cases where the fact of the situation would warrant additional time, that delay may not exceed 90 days.

- b. Appropriate Use of Center Resources (including scientific or clinical facilities, personnel, equipment and information). Staff members may not use graduate students, postdoctoral fellows or other staff members for the purpose of potential or real financial gain of the staff member rather than the advancement of the scholarly field or students' educational needs. Nor may students or staff be used for outside consulting or business activities except in the context of an institutionally approved research support agreement. Further, no staff member may use or grant unauthorized access to others of confidential information acquired through conduct of Center business or research activities. Confidential information includes, but is not limited to, medical, personnel, or security records of individuals; proprietary knowledge about corporate material requirements or price actions; and proprietary knowledge of the business decisions of the Center or information about forthcoming programs or selection of contractors or subcontractors in advance of official announcements. No senior administrative staff member may receive compensation of any kind from a company with which they are also simultaneously managing a business relationship on behalf of the Center.
  - c. Scientific Objectivity. Scientific objectivity is essential to the conduct of research and the guidance of students and associates. To the extent that the financial interests of a staff member and a corporate sponsor are intermingled, the scientific objectivity of the staff member can be called into question.
5. Clinical Trials. Clinical Trials are particularly sensitive when the principal investigator (the individual(s) who have direct influence over the development and conduct of the trial and analysis of results) has real or perceived personal financial interest in the outcomes. 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 the external organization. In these situations, the principal investigator must take steps to guarantee

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objective evaluation of the agent or device. In keeping with the recommendations of the American Society of Clinical Oncology (ASCO), any restrictions on a clinical trial investigator begins with the accrual of the first patient into the trial and extends through the first publication of trial results, either as a peer-reviewed meeting presentation or a journal article. Integrity should be protected by an independent oversight group for evaluation and monitoring of the research whenever:

- a. a staff member is involved in clinical trials of his or her inventions;
- b. a company licensed to use a faculty member's invention is sponsoring the trial;
- c. there may exist a reason to question a faculty member's objectivity;
- d. the outcome of the trial could be seen as determining existing or potential research support; or
- e. Such testing is referred to other members of the staff member's department or division.

6. Disclosure and Ownership of Intellectual Property. It is the Center's policy to encourage the transfer of intellectual property as a means of enhancing the public good and obtaining funds for research. Most of the research conducted at the Center is supported directly or indirectly by sponsors and organizations with specific requirements for the handling of intellectual property. Accordingly, all potentially patentable inventions created or discovered by staff members in the course of their activities at the Center and with the use of Center resources, must be disclosed to the Center in a timely manner. Ownership of these inventions must be assigned to the Center regardless of the source of funding. Revenue from the successful commercialization of invention is shared with inventors according to the Center's policy found at Center Policies and Procedures, Section III, Number 12.
7. Purchase of Goods and Services. The Center strives to be fair in its dealings with all vendors of goods and services. While the Center may take into consideration a number of factors in addition to cost when purchasing a good or service, it is inappropriate for any staff or board member to exert pressure on the Center to purchase a good or service for the sole reason that the staff or board member, or a member of their families, stands to gain, financially or otherwise. Similarly, it is inappropriate to provide advantage to one vendor over another by

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providing one with information not available to all bidders, whether or not the staff or board member will gain by disclosing such information.

8. Gifts. All donations of goods and services must be disclosed to the Department of Institutional Advancement which will, as appropriate, generate a letter of thanks as well as all documents required by the Internal Revenue Service and other interested governmental entities.
9. Commercial Sponsorship of Meetings. Meetings organized with the support of a commercial entity require that Fox Chase control the content, quality and scientific integrity of the program along with the selection of presenters and moderators of the program. The audience must receive a disclosure of the financial relationship between Fox Chase and the Company; and individual speakers and moderators and the Company; and the relationships that individual faculty members have with the producer of any commercial product discussed by the speaker during the presentation. No promotional activities will be permitted in the same room as the educational activity. Care should be taken to ensure that the Fox Chase name and logo are used only in situations that further the institutional mission. In the case of activities involving Continuing Medical Education (CME), a specific disclosure policy and procedure shall be followed which is available through the Temple Health Office of Continuing Medical Education.
10. Licensing of Center inventions and discoveries. The Center is dedicated to transferring its technology through a robust process based upon well-established business principles. Especially in the case of startup companies, support by Center faculty and management staff is a prerequisite for success. However, all faculty and staff are expected to accord the Center their primary professional loyalty. No member of the faculty or management staff should seek to influence the Center's technology transfer decisions in ways that lead to personal gain.

All financial interests of any kind in companies arising from or licensing Center technology shall be disclosed to the Vice President of Business Development, and, in the case of the Business Development office, to the President. Each case shall be examined on its own merits and take into consideration a variety of factors including the reason for the proposed

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transaction, the nature of the invention, the market for the technology being licensed, the nature of the inventor's or management staff member's interest in and involvement with the licensee company, and the relation of the faculty member's future research or the management staff's commitment to the success of the company to the interests of the licensee company. For example, the nature of Center technology frequently requires that inventors and business development staff assist the licensee company in its development efforts. Inventors often become consultants to and have a financial relationship with the licensee by receiving consulting fees from or equity in the company. While the Center recognizes that careful review of these relationships is essential, it also supports the commercial development of academic inventions and the involvement of inventors in that process.

**C. Procedure for Managing Conflicts of Interest.**

In the case of potential conflict of interest or commitment, the President of FCCC shall be responsible for administering all matters. All disclosures shall be kept confidential, in separate file under the control of the Office of the President. They shall not be made part of any personnel record or the basis for any review of the performance of the individual staff member. Access to these records shall be made available on to Board Members, the President or his designee or a properly authorized governmental body, acting under statutory or regulatory authority. Records will be maintained for three (3) years unless the materials are subject to governmental action. Disclosures shall be required of all Staff and Board Members as follows:

1. By Board Members. All Board Members of FCCC shall be required to complete a Conflict of Interest Disclosure Form at the time of appointment, annually and whenever a new potential conflict arises. This Disclosure Form shall be submitted to the President of FCCC or his designee. The President of his designee shall, in turn, be responsible for reporting such disclosures to the Governance and Leadership Committee and report to the Executive Committee of the Board of Directors. The Chairman of the Governance and Leadership Committee shall make the disclosure a matter of record and report to the Board of Directors in the manner provided by the By-laws of FCCC.

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2. By Employees. All scientists, physicians and administrative employees at the management level, and above, of FCCC shall be required to complete a Conflict of Interest Form at the time of employment, annually and whenever a new potential conflict arises and submit such disclosure forms to the Chief Academic Officer or his designee.
3. By Consultants and Subcontractors. Consultants and subcontractors shall certify to FCCC that they are not in a position to influence Center business, research or other decisions in ways that could lead to any form of personal gain for them or their family or give improper advantage to others to the Center's detriment.

**D. Guidelines for the Resolution of Conflicts.**

In the case of an individual, if FCCC determines that a staff member (spouse and/or dependent child) has a significant financial interest in a project on which that member is working or if the staff member is proposing to spend more than 15% of the member's time on a project, it will work with that member and the other participants in the project in attempting to establish appropriate conditions to assure that an impartial outside observer would be able to review the facts of the situation and conclude that there is no reasonable basis for concluding that the separate individual interests of the member (spouse or child) have affected FCCC's research or other activities. In determining whether a financial interest is significant, FCCC will give due regard to any standards established by the NIH and NSF, but may, in appropriate circumstances, apply stricter standards than the recommended ones.

Resolution of conflicts will be achieved when the interests of the Center are in balance with the interests of the staff or board member. Each matter must be judged on its own merits and with proper regard for the specific set of facts in each situation of potential conflict.

Resolution will be achieved which satisfies the reasonable and prudent person who judges the situation with full knowledge of all the facts of the situation.

From time to time, conditions or restrictions may be imposed on individuals to manage conflicts of interest. These include, but are not limited to:

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1. Public Disclosure of Significant Financial Interests:
  - a. Monitoring of research by independent reviewers;
  - b. Modification of the research plan;
  - c. Disqualification from participation in all or a portion of the research;
  - d. Divestiture of significant financial interests; and
  - e. Severance of relationships that create actual or potential conflicts.

When a potential conflict is identified, the Conflict of Interest Committee will review the facts of a reported potential conflict and make specific recommendations. The Committee shall forward a written recommendation to the President within 30 days following their decision.

2. As it relates to the Institution, on a case by case basis, the President or Chief Academic Officer, working with the Governance and Leadership Committee of the Board of Directors shall establish a review group comprised of members of the board, senior officers and external counsel to which a disclosure of a potential institutional conflict will be disclosed. As appropriate, the review group shall appoint additional members from outside the institution to ensure that the review is perceived by the reasonable person to be fair, balanced and in the interest of the public. This group shall be responsible for assessing potential conflicts, and weighing risks and benefits of the proposed activity. Options for managing a perceived conflict may range from not conducting the proposed research at FCCC to establishing a research monitoring process to ensure that the research does not undermine the integrity of the work and the Center.

In the case of institutional conflict involving FCCC management or trustees, actions may range from isolating/recusing the official from knowledge of, or decision making regarding research performed at the institution to reducing equity holdings or royalty interests due to the institution.

3. Reporting Fulfillment of Sponsor Requirements. In the case of PHS or NSF awards, FCCC will report to the PHS Awarding Component the existence of any conflicting interest (but not the nature of the interest or other details) found by FCCC and assure that the interest has been managed, reduced or eliminated.

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For any interest that Fox Chase identifies as conflicting subsequent to the initial report, a supplementary report will be made and the conflicting interest managed, reduced or eliminated, at least on an interim basis, within sixty days of that identification.

4. Activities, such as pro bono work, government service in the public interest, and any outside employment unrelated to the staff members' responsibilities to FCCC, should be managed so that they do not take precedence over the staff member's primary commitment to FCCC, or expose staff members to conflict of interest or other legal problems. As noted in Section III, any consulting work should be based upon an understanding between the individual and his or her Program Vice President or supervisor. Staff members participating in research studies or other projects subject to a confidentiality agreement with FCCC or a third party (such as a research sponsor) are not permitted to enter into consulting arrangements with any other person or entity to discuss any aspect of the agent or study covered by the confidentiality agreement.

All consulting agreements not otherwise prohibited by this Policy are subject to prior approval by FCCC.

- a. Staff members entering into formal or informal consulting arrangements involving compensation from outside individuals or entities, who are also doing business with the Center, shall provide written notice and a description of the arrangement to the Vice President of Business Development or other designee prior to entering into the arrangement. In the case of the staff of the Office of Business Development, disclosure shall be made to the Office of the President.
- b. The existing policy limiting consulting to a maximum of 15% of the annual work time of any FCCC employee or agent, unless such limitation is waived, is hereby reaffirmed.
- c. No FCCC employee or agent has the right to engage in consulting activities requiring use of the laboratories, facilities or other personnel or resources of FCCC, except as part of an approved Sponsored Research collaboration governed by an appropriate agreement.
- d. Each consulting arrangement must acknowledge the right of FCCC to obtain a general assignment of the rights in any invention made either solely or jointly by the consultant.

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- e. FCCC will not be obliged to grant any intellectual property rights to a commercial entity as the result of the consultancy.
- f. The parties to any consulting agreement must acknowledge that the consultant may not make use of any intellectual property of FCCC or its laboratories, facilities or other personnel or resources in connection with the consultancy, without the prior written approval of FCCC, which FCCC may deny in its sole discretion.
- g. The parties to any consulting agreement must acknowledge that they will conduct the consultancy in compliance with the Conflict of Interest policy of FCCC.
- h. The compensation paid to a consultant, including equity, if any, is solely a matter between the parties to the consulting agreement, although, and except in the case of management staff of the Center, the amount of such compensation may have consequences arising from FCCC's procedures relating to the research of the consultant, as provided in the portions of this policy relating to Conflict of Interest.
- i. Upon receipt of notice from staff members of proposed formal or informal consulting arrangements with any person or entity in the business of making or providing advice regarding investments, FCCC will provide the staff member with information regarding legal restrictions on disclosure of confidential information to investors and investment advisors.

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## Downloadable Disclosure of Interest Form

[Report of Outside Interests, Activities or Relationship Form](#) [PDF]

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Reviewed by the Board of Directors: March 17, 2011

Updated: October 2010

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**APPROVALS:**

*Note: The signed original of this policy is on file in the Hospital Management Office*

Approved by:

\_\_\_\_\_  
Richard I. Fisher, M.D.  
President and CEO

\_\_\_\_\_  
Date Signed

\_\_\_\_\_  
James Helstrom, M.D.  
Chief Medical Officer

\_\_\_\_\_  
Date Signed

\_\_\_\_\_  
Judith Bachman  
Chief Operating Officer

\_\_\_\_\_  
Date Signed

\_\_\_\_\_  
Anne Jadwin, RN, MSN, AOCN, NE-BC  
Vice President of Nursing/Chief  
Nursing Officer

\_\_\_\_\_  
Date Signed

\_\_\_\_\_  
J. Robert Beck, M.D.  
Deputy Director, Chief  
Administrative Officer

\_\_\_\_\_  
Date Signed

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