

**GUIDELINES FOR EXTRAMURAL ACTIVITIES  
OF FACULTY  
UNIVERSITY OF PENNSYLVANIA MEDICAL CENTER  
AND HEALTH SYSTEM**

**I. PURPOSE**

It is the Medical Center's policy to encourage and support appropriate extramural activities on the part of all Medical Center faculty ("Faculty"). Our mission is not only the generation of new knowledge but also the development and transfer of that knowledge to the widest public use and benefit. This process by necessity brings Faculty into frequent contact with a wide variety of extramural agencies and organizations, particularly in the private sector. Questions about potential, apparent or actual conflicts of interest ("Conflicts of Interest") can arise as a result of those contacts. The present guidelines ("Guidelines"), devised under the joint aegis of the Medical Faculty Senate and the Medical Center administration, are intended to orient Faculty to institutional and peer standards, expectations and mores. <sup>?</sup>

The goal of this document is to raise awareness of issues or situations that should be disclosed, reviewed and managed.

The following background statements provide a frame of reference for these guidelines:

**A. INTENT:** These Guidelines are intended to promote extramural activities without compromising Faculty and University interests.

**B. RELATIONSHIP TO UNIVERSITY POLICIES:** The "Conflict of Interest Policy for Faculty Members," which appears on pages 69-76 of the 1999 edition of the *Handbook for Faculty and Academic Administrators of the University of Pennsylvania*, states clearly the overall University policies governing extramural activities in general, and Conflicts of Interest in particular. Similarly, Appendices C and E of the 1993 Policies on Patents and Tangible Research Property of the University of Pennsylvania provide

University Policies on Outside Employment or Consulting Agreements (App. C) and Rules Governing Equity Transactions (App. E). (These policies were published in the *Almanac Supplement*, March 15, 1994). The Medical Center Guidelines are intended only to provide guidance in applying the University policies to activities involving Medical Center personnel.

**C. FACULTY RESPONSIBILITY FOR OTHER LAWS AND REQUIREMENTS:**

Faculty are expected to conduct their activities at all times in compliance with all federal, state, local and University laws and requirements.

**II. OVERARCHING PRINCIPLES**

**A. DISCLOSURE AND CONSULTATION:** Because of that variety and complexity of extramural activities, no set of guidelines can anticipate and deal with all possible situations. Therefore, a major responsibility for faculty is to: (1) disclose their extramural activities in advance; and (2) seek advice when questions arise. In this way many problems and subsequent commentary may be avoided.

**B. PROCESS:** In general, the channels for disclosure and consultation are through the Department Chair, the appropriate Vice Dean, to the Dean of the Medical School and, where approval is required, the University Provost or designee. The University Office of General Counsel and the Medical Center Office of Legal Affairs may also provide guidance.

**III. APPLICABILITY**

**A. FACULTY:** These Guidelines apply to all Faculty who have full-time faculty employment and all full-time members of the academic support staff.

---

<sup>?</sup> Capitalized terms not otherwise defined herein are defined in Section XII of these Guidelines.

**B. FAMILY MEMBERS:** These Guidelines also apply to the immediate family (spouse and dependent children) of Faculty in situations involving Significant Financial Interests in, or Management Positions or Fiduciary responsibilities for, an outside entity.

#### **IV. CONFLICT OF INTEREST SITUATIONS**

**A. RESEARCH-RELATED SITUATIONS:** Some of the Conflict of Interest situations that arise frequently in the Medical Center may occur less frequently in the rest of the University. Many of these situations involve patients and IRB-approved research, the rendering of clinical services, interactions with biotechnology and pharmaceutical firms, and particularly the development and commercialization of a new product or process. Appendix I to this document provides guidelines for the disclosure of Conflict of Interest situations and describes the procedures for making those disclosures. Conflict of Interest situations are categorized as Level I, Level II, Level III and Level IV situations.

**B. OTHER SITUATIONS:** Most of the issues raised by extramural activities are research related, but Conflict of Interest situations, both actual and perceived, also may arise in connection with education or administration. For example, an appointment at another academic institution or compensation for clinical practice activities outside the Clinical Practices of the University of Pennsylvania (“CPUP”) may present a Conflict of Interest.

**C. DEALING WITH CONFLICT OF INTEREST SITUATIONS:** The following sections describe general rules for dealing with commonly encountered situations that may present Conflicts of Interest. The examples presented are illustrative only and not intended to be comprehensive.

#### **V. CONSULTING ARRANGEMENTS**

Faculty Members are frequently asked to serve as consultants to Commercial Entities and Non-profit Organizations. Consulting arrangements are generally allowable as long as they are

disclosed in advance and otherwise meet the spirit and letter of the University Handbook for Faculty and Academic Administrators. Some of the frequently encountered problems are:

**A. SIGNING CONSULTING AGREEMENTS:**

1. Faculty may be presented with a consulting agreement at a meeting with officials of a Commercial Entity, and may feel awkward not signing immediately. Nevertheless, Faculty are urged to delay signing until the document has been reviewed by an independent attorney and/or by the appropriate Medical Center or University legal office.

2. Such agreements may contain confidentiality provisions that unduly limit publication rights and dissemination of information. In addition, Commercial Entities may make broad claims to intellectual property rights, limiting those of the Faculty member(s), the University, and those of others (e.g., students and collaborating scientists) by extending to many areas of original and/or derivative research.

3. In brief, Faculty should have the agreement reviewed (or modified) before signing it. This protects the Faculty member's individual interests as well as those of the University, by protecting both intellectual property rights and academic freedom. The University Policies and Procedures on Patents and Tangible Research Property sets forth in greater detail University policies and procedures governing these matters.

**B. REIMBURSEMENT FOR SERVICES:**

1. Acceptance of fees for services rendered may create at least the appearance of a Conflict of Interest. Accordingly, fees should be reasonably related to the time and effort spent.

2. Services to extramural organizations (including service on advisory boards and committees) generally should be compensated (if at all) by agreed-upon dollar amounts rather than by other types of compensation (such as stock options or equity in a commercial entity). Sometimes, however (especially with start-up companies), stock options or equity may be the only compensation available.

3. In accordance with the University Conflict of Interest Policy for Faculty Members, all external activities and reimbursement arrangements (except those specifically listed on the Fully-Employed Faculty Annual Report of Extramural Activity (“Annual Report”) as exempt) must be disclosed as part of the Annual Report process.

4. If Equity is offered for services rendered, or if the Faculty member has more than one financial relationship with a particular company, the consulting arrangement must be disclosed prior to signing the agreements. The process for this prior disclosure is the same as the annual disclosure, beginning with the Department Chair and proceeding through the Senior Vice President for Academic and Clinical Affairs, to the Dean of the Medical School and, where approval is required, the University Provost or designee.

5. The amount of reimbursement is not necessarily a problem, although very large sums may raise questions about the amount of time and intellectual effort expended on the outside activity.

**C. LONG-TERM CONSULTING ARRANGEMENTS:** An ongoing, consulting relationship is more likely to raise Conflict of Interest concerns than a one-time consultation; therefore, it is even more critical that appropriate disclosure is made.

**D. USE OF UNIVERSITY PERSONNEL, FACILITIES OR PROPERTY:** Faculty must avoid misusing University resources in performing consulting activities. Misuse of University resources might include, for example, undue use of secretarial and other

University employee time, use of laboratory or computer equipment and supplies, or the time and effort of students, other trainees, technicians, or staff.

## **VI. RESEARCH SPONSORED BY A COMMERCIAL ENTITY**

While this type of sponsored research is important and indeed encouraged, it must comply with the guidelines and requirements for all sponsored research within the University. These are outlined in the University Handbook for Faculty and Academic Administrators, the Research Investigators Handbook (1990) published by the Office of Research Administration, and the University Patent and Tangible Research Property Policies and Procedures. Some of the overlapping roles and responsibilities that may create Conflicts of Interest are described below. Written approval of dual relationships with Commercial Entities may be granted in certain circumstances and with pre-approval and appropriate oversight and management by the Provost or designee, in consultation with the Dean of the Medical School and the Conflicts of Interest Standing Committee of the Advisory Board to the Center for Technology Transfer.

**A. RESEARCH SUPPORT:** If a Faculty member applies for or already has research support from a Commercial Entity, then that sponsored research generally should be the only relationship with the Commercial Entity. In other words, Faculty must not accept consulting fees from, hold Equity or other Significant Financial Interests in, or serve in a Management Position or Fiduciary capacity for, a Commercial Entity at the same time they receive research support from that Commercial Entity, without the prior written approval of the University Provost or designee (including the adoption of appropriate management and oversight procedures). If the participation is approved, the Faculty member must comply with any terms and conditions imposed by the University or the Medical Center. In general, Faculty who serve as Investigators for a Commercial Entity may accept a seat on the scientific advisory board of that Commercial Entity, provided that the position is not a Management Position for, and does not create a Fiduciary responsibility to, the Commercial Entity.

**B. USE OF UNIVERSITY RESOURCES:** When a Faculty member is involved in product development for a Commercial Entity, the University may require review and oversight to protect against diversion of University resources, such as equipment, supplies, students, trainees, and other personnel.

**C. INVOLVEMENT OF STUDENTS AND TRAINEES:** Faculty must take special care to avoid inappropriate involvement of students and trainees, including post-doctoral fellows, in commercially-sponsored research in which the Faculty member has a Significant Financial Interest. To avoid even the appearance of a Conflict of Interest, Faculty members should seek advice from their Department Chair and the appropriate Vice Dean and ask for independent monitoring. Independent monitoring of student involvement in commercially-sponsored research may be provided by the Office of the Dean on a case-by-case basis.

**D. INVOLVEMENT IN CLINICAL STUDIES:**

1. Although clinical studies are a subset of research, and therefore subject to the same requirements as apply to other research (including research sponsored by a Commercial Entity) there are aspects of clinical studies that deserve special emphasis.

2. Faculty are encouraged to participate in the research and development of new products or processes, but they generally should not also be involved, directly or indirectly, in Clinical Studies of products or processes of which they were the principal architects. Stated differently, a Faculty member may be the inventor of a new commercially applicable product or may conduct Clinical Studies, but generally may not do both for the same product.

3. Faculty generally should not hold a Significant Financial Interest in, or serve in a Management Position or Fiduciary capacity for, a Commercial Entity that has rights to the product or process they are evaluating.

## **E. PUBLIC DISCLOSURE:**

1. Research support by a Commercial Entity must be acknowledged in all public forums in which the research is discussed, including conferences, publications, lectures, interviews and testimony before policy makers.
2. Grant applications submitted to a federal agency must disclose all relationships between an Investigator and a Commercial Entity that supports the Investigator's research.
3. Prior or current federal support of research should be disclosed to any Commercial Entity that contemplates sponsoring the same or related research.

## **VII. EXTRAMURAL CLINICAL PRACTICE AND ACADEMIC ACTIVITIES**

Unless otherwise approved by the Dean of the School of Medicine fully employed Faculty (standing Faculty and standing Faculty-clinician educators) may not be compensated for clinical practice activities outside of the Clinical Practices of the University of Pennsylvania (“CPUP”) or CPUP-approved practice plans. This includes 'moonlighting' activities even if carried out during off hours or on weekends. Faculty must be aware that this is well established University policy.

Similarly, a full-time Faculty member's part-time employment by another academic institution requires consultation with, and the concurrence of, the Department Chair and Dean.

## **VIII. TESTIMONY IN LITIGATION**

Medico-legal work is viewed by the University as an extramural activity. Therefore, Faculty members must disclose the extent and frequency of their medico-legal work retrospectively each year to their Department Chair and, through the Senior Vice President for Academic and Clinical Affairs, to the CEO/Dean on the annual disclosure form. This is to allay



any concerns about possible violations of the University "one-day-in-seven" policy. Individual departments may have their own policies, within the framework of University policy, that further regulate the amount of time that Faculty may commit to such activities and that state whether witness fees must be paid into the departmental practice plan or may go directly to the Faculty member.

## **IX. RECUSAL FROM DECISION-MAKING**

Faculty members must recuse themselves from decisions that could affect a third party in which they have a Significant Financial Interest, or for which they serve in a Management Position or a Fiduciary role. Such decisions might involve, for example, the purchase of products made by a particular vendor, scientific peer review of grants or contracts to a Commercial Entity in which the Faculty member has a Significant Financial Interest or one of its competitors, or advising a journal whether to publish an article about a product or process of a Commercial Entity or one of its competitors.

## **X. DISCLOSURE AND APPROVAL OF CERTAIN EXTRAMURAL ACTIVITIES**

Faculty members may from time to time seek to hold a Significant Financial Interest in, or a Management Position or Fiduciary role for, an existing Commercial Entity, or they may plan to establish and hold such an interest or obligation in a new Commercial Entity. In all instances, such relationships must be disclosed through the usual channels. The following general principles apply:

**A. TIME COMMITMENT:** The commitment of time and effort to any such extramural activity must be carefully estimated and disclosed to the Department Chair, so that the need for subsequent monitoring may be assessed.

**B. VENDOR RELATIONSHIPS:** Any proposed vendor relationship between a component of the University and such a Commercial Entity must be reviewed and approved by the Senior Executive Vice President for Academic and Clinical Affairs.

**C. CLINICAL STUDIES:** Faculty serving as Investigators in Clinical Studies must disclose any Significant Financial Interest in, and any Management Position or Fiduciary role for, a related Commercial Entity to their Department Chair and the IRB. Failure to disclose will disqualify the Faculty Member as an Investigator on that project.

## **XI. MANAGING CONFLICTS OF INTEREST**

As discussed above, relationships not defined or excluded by these Guidelines may be approved by the Provost or designee, in consultation with the Medical School Dean, provided that appropriate management and oversight procedures are adopted. Management and oversight of actual or apparent Conflicts of Interest may include: (1) public disclosure of the Investigator's financial interests; (2) prior scientific evaluation and ongoing monitoring of the research protocol by independent reviewers; (3) modification of the research protocol; (4) exclusion of Investigators from all or part of any research that could significantly affect their financial interests; and/or (5) divestiture of Significant Financial Interests and severance of relationships that create actual or apparent conflicts.

## **XII. SOME DEFINITIONS**

As used in these Guidelines, the following terms have the following meanings:

? **Clinical Study** means any study involving human subjects (including a study to establish bioavailability or bioequivalence) that may be submitted to FDA in support of an application for approval to market a new drug or device. "Clinical Study" does not include research designed to study basic physiology in normal subjects or patients suffering from disease.

? **Commercial Entity** means a corporation, partnership, or sold proprietorship engaged in commercial activities.

- ? **Equity** means a partial or total ownership interest in a Commercial Entity, such as shares of stock or securities, stock options, warrants, and other rights to purchase stock or securities.
- ? **External Health Care Provider** means a provider of health care items or services (for example, a hospital, nursing home, home health agency, hospice, clinic, or other health or professional service company) that is not affiliated with the University.
- ? **Fiduciary** means a position of trust within a Commercial Entity or Non-profit Organization requiring that all actions and decisions be based solely on the best interests of that entity or organization. Individuals with a Fiduciary duty must act prudently and in good faith at all times when acting on behalf of the entity or organization.
- ? **Investigator** means any one engaged in sponsored or unsponsored research.
- ? **Intellectual Property** includes any product, process, or information which is or may be patentable or subject to similar legal protection.
- ? **Management Position** means a position with an entity from which the person holding the position (1) has authority or responsibility for administrative, supervisory or other management activities, or (2) has influence, control or authority to make policy, award grants or contracts, or otherwise significantly influence the entity.
- ? **Non-Profit Organization** means a non-governmental, tax exempt entity such as a charitable foundation, research institute, academic institution or health care provider.
- ? **Significant Financial Interest** means anything of monetary value, including, but 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., payments, copyrights and royalties from such rights). The term does not include:

(i) salary, royalties, or other remuneration from the University;

(ii) income from service on advisory committees or review panels for public or non-profit entities; or

(iii) income from seminars, lectures or teaching engagements sponsored by public or nonprofit entities; or

(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 \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value; and does not constitute more than five percent (5%) ownership interest in any single entity; or

(v) salary, royalties or other payments that when aggregated for the individual and the individual's spouse and dependent children are not expected to exceed \$10,000 during the next twelve-month period.

## **Appendix I**

### **GENERAL GUIDELINES FOR DISCLOSURE AND MANAGEMENT**

**Conflicts of Interest** policies are set forth in the section on "Conflict of Interest Policy For Faculty Members" in the University Handbook for Faculty and Academic Administrators (1989), Section E, pages 33-40 and apply to all Standing Faculty, Standing Faculty-Clinician Educators, and all full-time members of both the Associated Faculty and Academic Support Staff. The Medical Center Guidelines provide examples of activities that may not be covered by the general obligations of Faculty discussed in the Handbook and serve as examples only. They are not a comprehensive compilation.

Conflict of Interest situations not covered by the examples in these Guidelines will be resolved in light of the general obligations of Faculty as noted in the Handbook, the Policy Manual of the Hospital of the University of Pennsylvania, and the Policies and Procedures on Patents and Tangible Research Property (1993). General guidance is provided by categorizing potential conflict situations as Level I, II, III, or IV activities.

**Mandatory Disclosures:**

Whatever level of activity is involved, the following disclosure requirements apply:

A. Significant Financial Interests, or Management or Fiduciary positions, held by Faculty in a Commercial Entity must always be disclosed in public presentations and publications concerning research sponsored by that entity.

B. Significant Financial Interests in a Commercial Entity, and any potential restrictions on publication (including pre-review requirements) must always be disclosed to students and other Faculty who are invited to participate in the conduct of research sponsored by that entity.

Level I refers to activities of Faculty that need not be reported. These are listed on the School of Medicine Annual Report of Extramural Activity form. Unless there are also other relationships with the extramural entity that would raise Level II, Level III or Level IV concerns, Level I activities are as listed on the current version of the Annual Report Form.

Level II activities will ordinarily be permitted but they must be reported on the School of Medicine Annual Report of Extramural Activity form. Externally sponsored research in which a Faculty member participates is also subject to the standard Medical Center and University processes of review and approval (e.g., for the protection of human subjects, care and use of laboratory animals, biosafety, and the like). Unless there are also other relationships with the entity that would raise Level III concerns, Level II activities include, but are not limited to:

- a) Participating as an Investigator in any research supported by a Commercial Entity or external Non-profit Organization;
- b) Serving for compensation as a committee member or consultant for a Non-profit Organization;
- c) Serving for compensation as a journal editor or peer reviewer;
- d) Receiving fees for serving as a consultant or expert witness in litigation;
- e) Holding a Significant Financial Interest or Fiduciary position in a Commercial Entity.

Level III consists of relationships that generally must have prior approval and may be permitted with additional management and oversight procedures, after reporting on the forms identified for Level II and review and approval by the Provost or designee, in consultation with the Dean of the Medical School and the Conflict of Interest Standing Committee of the Advisory Committee to the Center for Technology Transfer. Level III activities include, but are not limited to:

- a) Holding a Significant Financial Interest in a Commercial Entity while serving as an Investigator on research supported by that Entity, clinical studies involving a product or process to which that Entity has rights;
- b) Serving in a Management Position or Fiduciary capacity for a Commercial Entity while serving as an Investigator on research supported by that Entity, or on clinical studies involving a product or process to which that Entity has rights;
- c) Serving as a consultant to an entity supporting the Investigator's research. [See C.2 of University Patent Policy.]

**Level IV: Prohibited Activities:**

- a) An Investigator may not serve on the Board of Directors or in any Fiduciary capacity of a Commercial Entity with intellectual property rights to the Investigator's research while the Investigator's research is sponsored by that entity. [University Patent Policy, E. 1. 1.]
  
- b) Investigators and their immediate families may not collectively hold more than 50% ownership interest in a Commercial Entity sponsoring the Investigator's Clinical Studies on a product or technology in which the Commercial Entity holds intellectual property rights. [University Patent Policy E. 1.2.]
  
- c) A Faculty member may not receive more than 15% of annual salary per year in consulting fees from any one Commercial Entity in which the Faculty Member holds a Significant Financial Interest and for which the Faculty Member is conducting Clinical Studies on a new product or process.