GUIDELINES ON INSTITUTIONAL CONFLICTS OF INTEREST:
FOR THE LEADERSHIP AND SENIOR ADMINISTRATORS
UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

I. PURPOSE

As stated in the 1993 “Patents and Tangible Research Property Policies and Procedures of the University of Pennsylvania”, the community has endowed the University with certain privileges, resources and assets in the expectation that no single party will derive sole benefit or be unjustly enriched from what the community has endowed to the University. The University of Pennsylvania Health System must ensure that the institution, its leadership, faculty and staff do not enter into a relationship where there may be an actual or perceived conflict of interest with their primary responsibilities and fiduciary obligations to the University, the Health System and its components.

The policy of the Health System is to encourage and support appropriate extramural activities on the part of the Faculty and also on the part of the Health System leadership and administration. (See the “Guidelines for Extramural Activities of Faculty). Concurrent with this policy, the Health System requires that its leadership and administration be aware of and deal appropriately with potential conflict of interest situations, both real and perceived, which may arise in connection with extramural activities.
Two general types of Institutional Conflicts of Interest may be identified. First, the Institution itself, as represented by its leaders, may find that its professional judgments with respect to its academic and public obligations may be affected by its entrepreneurial and its financial aspirations. Second, individuals with supervisory and administrative roles in the Health System (chief executive officer, dean, vice deans, vice presidents, chairs, division chiefs, center directors and other administrators) may become involved in situations in which their academic, administrative or supervisory function is conflicted by or perceived to be conflicted by, the opportunity for personal gain.

The goal of this document is to raise awareness of the issues and situations that should be disclosed, reviewed and managed on behalf of the Health System by the individuals who serve as its leaders and administrators.

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

A. INTENT: These Guidelines are intended to promote extramural activities of the faculty, administration and leadership without compromising the primary interests and obligations of the University, the Health System, and its components.

B. RELATIONSHIP TO UNIVERSITY POLICIES: These Guidelines are designed to aid in applying the cognate University policies. Principal among these are the “Conflict of Interest Policy for Faculty Members” in the Handbook for Faculty and Academic Administrators of the University of Pennsylvania, the 1993 “Patent and Tangible Research Property Policies and Procedures of the University of Pennsylvania”, and the “Financial Disclosure Policy for Research and Sponsored Projects (Almanac, February 6, 2001).
C. RELATIONSHIP TO MEDICAL CENTER AND HEALTH SYSTEM POLICIES: These Guidelines are intended to be read in concert with the “Guidelines for Extramural Activities of Faculty of the Medical Center and the Health System” and with the Medical Center’s Organizational Ethics Code and Procedure and the University, Health System and Medical Center policies referenced therein.

D. FACULTY RESPONSIBILITY FOR OTHER LAWS AND REQUIREMENTS: The Leaders and Senior Administrators of the Health System and its components are expected to conduct their activities at all times in compliance with all federal, state, local laws and University policies and requirements.

E. DEFINITIONS:

1. Leadership and Senior Administrative Persons
Persons in leadership and administrative supervisory and institutional decision-making positions in the Health System refer, for example, to the chief executive officer, dean, vice deans, vice presidents, administrative department directors, chairs, division chiefs, center directors, and other administrators with institutional decision-making responsibilities. An up-to-date list of the Health System and Medical Center Leadership and Senior Administrators to whom this applies will be maintained by the Chief Executive Officer (CEO)/Dean of the Health System.

2. Financial Interests and Significant Financial Interests
Financial Interests are defined as ownership of all or any part of the assets or interests of a commercial entity. Equity interest, which is a type of Financial Interest, generally refers to stock or stock options in external for-
profit corporate entities. These are often biomedical start-up companies that result from intellectual property developed by a particular faculty member or members. Financial Interests also refer to holdings in mature and well-developed business entities. Significant Financial Interests, as defined below, must be disclosed and arranged as described in V. below.

“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). “Significant financial interest” includes a “Significant equity interest” as defined above. For “Covered clinical studies,” “Significant financial interest” also includes “Significant payment of other sorts” (as defined below). The term does not include:

1. salary, royalties, or other remuneration from the University;

2. income from service on advisory committees or review panels for public or non-profit entities; or

3. income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; or

4. 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 constitute more than five percent (5%) ownership interest in any single entity (i.e., the term significant financial interest does include an interest with a value of $10,000 or more and/or an ownership interest of five percent [5%] or more); or

5. 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.

“Significant payment of other sorts” means payments made by the sponsor of a “Covered clinical study” to the investigator of the institution to support activities of the investigator that have a monetary value of more than $25,000, exclusive of the costs of
conducting the “Covered clinical study” or other clinical studies, (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria) during the time the clinical investigator is carrying out the study and for one (1) year following the completion of the study.

II. OVERARCHING PRINCIPLES

A. DISCLOSURE AND CONSULTATION: Because of the variety and complexity of extramural activities, no set of guidelines can anticipate and deal with all possible situations. Therefore, a major responsibility for those who represent the Health System or any of its components is to: (1) disclose conflict of interest situations when they arise, whether potential, apparent, or actual, and (2) seek direction at the appropriate levels on how to manage the situation appropriately.

B. PROCESS: The channels for disclosure, consultation and management are through the normal reporting lines for the individuals in leadership and administrative supervisory roles in the Health System.

III. APPLICABILITY

A. LEADERSHIP AND ADMINISTRATION: These Guidelines apply to leadership and senior administrative persons who are so designated by the Chief Executive Officer of the Health System (See I.E.1). For those persons designated who are also full time faculty, both these Guidelines and the “Guidelines for Extramural Activities for Faculty” and other University policies apply.

B. FAMILY MEMBERS: These Guidelines also apply to immediate family (spouse and dependent children) of the leadership and administrative individuals indicated above.
IV. CONFLICT OF INTEREST SITUATIONS

A. SITUATIONS ALREADY COVERED: The “Guidelines for Extramural Activities of Faculty”, revised in 2001, Sections IV through X, describe conflict of interest situations likely to be encountered by faculty. Similar situations may arise for the leadership and administrators in the Health System. The concepts expressed in the Guidelines for Faculty with respect to disclosure and management also apply to those individuals who serve in leadership and institutional decision-making roles. Therefore, all persons in leadership and administrative roles must be familiar with the “Guidelines for Extramural Activities of Faculty.”

B. INSTITUTIONAL CONFLICTS OF INTEREST: Persons in leadership and senior administrative roles represent the Institution. Because of their supervisory and institutional decision-making functions, such persons also encounter conflict of interest situations beyond those faced by most faculty. Examples of these situations are described in the following sections. These Guidelines cannot cover all situations that will arise. Individuals in leadership and senior administrative roles must themselves be alert to possible conflict of interest situations, disclose them and seek appropriate management measures through their reporting lines.

C. CONFLICT OF COMMITMENT: As pointed out in the Association of Academic Health Centers Report on Conflicts of Interest and Institutional Decision Making, 1994, “an inherent element of any conflict of interest is a conflict of commitment, which most often involves time. …A conflict of
commitment exists when the external or other activities and the undertakings of an academic staff member (meaning leadership or administration) are so substantial or demanding as to interfere, or appear to interfere, with the individual’s responsibilities to the university or its students.” Persons with leadership and senior administrative responsibilities in the Health System must always be aware of the possibility of conflict of commitment in their extramural engagements, and disclose in writing and review these on a regular basis, no less than annually, with the persons to whom they directly report.

D. **FINANCIAL INTERESTS:** Financial Interests (see definition above) in extramural entities may be accepted by the University of Pennsylvania through its Trustees, under circumstances that the Trustees deem appropriate. Equity is acceptable as long as the overall arrangement is structured to minimize the University’s exposure to liability and the potential for conflict of interest. Health System leadership and administration must make sure that information about possible receipt of a Significant Financial Interest (See I.E.2) is transmitted through the appropriate channels to the University Administration and, where appropriate, Trustees.

Leadership and senior administrative individuals with institutional decision-making responsibilities may not receive through purchase, gift or other transaction any financial interest in a start-up enterprise that is based on a license agreement with the University for intellectual property developed by a subordinate. Ownership of such a financial interest could be perceived as a potential inducement to favoritism. If the person in the supervisory or institutional decision-making role is also a co-inventor of the property, the issue of financial interest should be addressed on a case-by-case basis to ensure that appropriate processes are developed to
minimize potential conflicts of interest. In contrast, an individual faculty member may hold an equity interest in a commercial enterprise that has a license agreement with the University for technology based on that faculty member’s own invention.

E. **FIDUCIARY RESPONSIBILITIES:** As outlined in the 1993 “Patent and Tangible Research Property Policies and Procedures of the University of Pennsylvania”, the Institution, (referring here to the University, the Health System and its components) generally does not accept a position on the Board of Directors of a company that is based on licensed technology deriving from a faculty member’s invention. Exceptions to this policy require the approval of the appropriate University officers in consultation with General Counsel.

Under appropriate circumstances persons in leadership and administrative positions may accept a fiduciary capacity (for example, a seat on a board of directors or a position as an officer) in an extramural entity on his or her own behalf. Such extramural duties need to be weighed carefully on a case-by-case basis. A person with leadership or senior administrative responsibility who wishes to accept a fiduciary role in an extramural business entity on his or her own behalf should first consult with his or her supervisor. The information provided during the consultation should include the nature of the position offered, the extent of time and resources required to perform the duties of the position, and the relationship, if any, of the extramural entity to the University of Pennsylvania, the Health System, or its components. If the supervisor approves acceptance of a fiduciary role in a corporate entity that has a relationship to the University, the Health System or its components, the person accepting the position has the responsibility (1) to establish procedures with his or her supervisor to ensure that he or she will be screened from participation in any decisions
made by the University with respect to that corporate entity, and (2) to ensure that similar procedures are established by the corporate entity shielding him or her from participation in decisions pertaining to the University, or the Health System and its components.

Special care must be taken with respect to fiduciary roles in certain kinds of extramural business entities. For example, it is inappropriate for a faculty member’s supervisors to serve in a fiduciary capacity for a start-up company based on the intellectual property of that faculty member. Similarly, acceptance of a fiduciary role in an extramural entity may not be appropriate, if that entity could be construed as in competition with the University or its Health System. Persons in leadership and senior administrative positions should seek guidance and approval through their reporting lines before accepting a fiduciary role in an extramural entity. Please see the Handbook for Faculty and Academic Administrators and Guidelines for Extramural Activities of Faculty for additional guidance.

F. CAPITALIZATION AND TECHNOLOGY TRANSFER: It is inappropriate for the Health System or any component to invest by contribution or by loan in an extramural entity that derives in part or in whole from an invention of a faculty member or administrator. Any exceptions to this general statement will require approval and management at the highest Health System and University levels. Investments to be made with spendable or allocable resources normally will be put into internal development, and not into the development of extramural entities unrelated to the mission of the Health System and the University.

G. OTHER CAPITAL VENTURES: On occasion, it will be in the interest of the Health System to use institutional resources to foster cooperative programs with other entities. Capital investments by the Health System or
component parts will require the approval of the Health System and, where appropriate, University officials.

H. EXTRAMURAL ENGAGEMENTS AND CONSULTING ARRANGEMENTS: Persons in leadership and administrative positions (excluding faculty who are governed by University policies) may accept extramural engagements with either for-profit or not-for-profit organizations, including consulting, under the following circumstances. First, all extramural engagements including consulting must be fully disclosed to and approved by the supervisor. No extramural engagement may be approved that is perceived to be in conflict or competition with the purposes and directions of the University or the Health System, and all extramural engagements must be conducted so as to observe the confidentiality and the intellectual property rights of the University and the Health System.

If the individual is to be paid for the extramural engagement by the external organization, another condition must be met. The engagement is to be carried out exclusively on non-working time, such as vacation, holidays or other non-working times as agreed upon with the supervisor.

If payment for services is not offered to the person considering the extramural engagement, the supervisor should decide to approve or not approve the request based upon whether the engagement will result in benefit to the Health System in proportion to or exceeding the time and effort required. If so, such engagements may be carried out during regular work hours.

For approved engagements, supervisors may decide on a case-by-case basis whether travel and incidental expenses should be paid by the external organization, the Health System or by other means.
If an extramural engagement with a not-for-profit organization is contemplated, but the activity and the external organization have no relationship to the purposes or mission of the University of Pennsylvania Health System, the engagement should be carried out on the person’s own time, not on work time, and without using University or Health System resources.

The use of University of Pennsylvania Health System logos, trademarks and other materials in the conduct of extramural engagements is prohibited unless specifically approved in writing by the supervisor and by the Chief Marketing Officer. Similarly, no endorsement by the University of Pennsylvania or the Health System is implied or given to any external organization with which an individual has an engagement.

Each supervisor with oversight of persons covered by this policy shall report annually to his or her supervisor in writing on all extramural engagement decisions made during the previous year. Each supervisor is required to maintain appropriate records.

V. MANAGING CONFLICTS OF INTEREST

For individuals in leadership and administrative positions, management of conflict of interest situations will be carried out consistent with the policies described in the “Guidelines for Extramural Activities of Faculty.” The four levels of mandatory disclosure (Appendix I) and the definitions set forth in Section XII of the “Guidelines for Extramural Activities of Faculty” apply to individuals in leadership and administrative positions as well as to faculty.