INTRODUCTION

The policy of the University of Pennsylvania Health System is to encourage and support appropriate extramural activities on the part of the Faculty and the Health System leadership and administration (see “Guidelines for Extramural Activities of Faculty,” revised 2000, and “Guidelines on Institutional Conflicts of Interest: For the Leadership and Senior Administrators,” updated 2001). Concurrent with this policy, the Health System requires that Faculty and 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.

This form (or Version A for non-faculty) is to be completed by persons in leadership and administrative supervisory and institutional decision-making positions in the University of Pennsylvania Health System (e.g., the chief executive officer, dean, vice deans, vice presidents, administrative department directors, chairs, division chiefs, center directors, executive directors, corporate staff leadership, and other administrators with institutional decision-making responsibilities). A complete list of Health System and Medical Center Leadership and Senior Administrators to whom this report applies will be maintained by the Executive Vice President of the University of Pennsylvania for the Health System, Dean of the School of Medicine.

The following activities need NOT be reported:

(a) Compensation received through the Clinical Practices of the University of Pennsylvania, Children’s Hospital of Philadelphia-Practice Associates, the Veterans Administration Medical Center, the Howard Hughes Medical Institute, or any component of the University or its Health System;

(b) Teaching and lecturing at affiliated hospitals in accordance with the terms of affiliation agreements;

(c) Participation in Continuing Medical Education programs under School of Medicine sponsorship (please note that these programs have their own conflict of interest policies);

(d) Participation in study sections, councils, and site visits sponsored by the NIH, similar federal agencies, or academic/scientific societies;

(e) Compensation for the following activities: (1) external reviewer of a department or a unit at another academic institution; (2) service on a certifying board or for an accrediting agency; (3) authoring a chapter or a monograph in your area of professional interest, or editing a reference volume or textbook in your area of expertise.

DEFINITIONS

Defined terms are italicized on the questionnaire.

“Covered clinical study” means any study of a drug or device in humans submitted in a marketing application or reclassification petition subject to FDA regulations (21 CFR Part 54) that the sponsor or FDA relies on to establish that the
“Equity interest,” which is a type of financial interest, generally refers to stock or stock options in external for-profit corporate entities.

“Extramural activities,” “extramural engagements” and “consulting” include, but are not limited to, business engagements, teaching (including Continuing Medical Education not sponsored by the University of Pennsylvania School of Medicine, clinical practice activities, and acting as an expert witness).

“Financial interests” are defined as ownership of all or any part of the assets or interests of a commercial entity.

“Immediate family” is defined as spouse and dependent children.

“Outside organization” is defined as any organization other than the University of Pennsylvania, the Health System or its corporately owned entities (e.g., Pennsylvania Hospital, Clinical Care Associates, etc.), as well as education affiliations or research relationships with CHOP-PA, VAMC, and HHMI. Outside organizations that compete with the University or the Health System are those that are involved in education, research, or patient care.

“Position” means an ownership position, a fiduciary duty (e.g., holding an office or a seat on a board of directors), or a management or decision-making responsibility.

“Significant equity interest” means any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices (generally, interests in a nonpublicly traded corporation) during the time the clinical investigator is carrying out the study and for one (1) year following completion of the study.

“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.

******COMPLETE ENCLOSED QUESTIONNAIRE******
Fully employed senior administrators and members of the leadership of the University of Pennsylvania Health System must answer all questions. All questions relate to the reporting period noted above, unless specified otherwise.

If you answer YES to any questions, please provide an explanation where indicated or attach a separate statement. If you are uncertain whether an activity should be reported, check YES and describe the situation. Please include in your descriptions: (1) the names of the organizations involved; (2) the nature of the outside positions and fiduciary responsibilities you have in the organizations; and (3) the extent to which any of these engagements are continuing and extend beyond this reporting period.

***Do you believe you have a conflict of interest? ___ YES ___ NO***

Please continue.

A1. Did you accept any extramural engagements or serve as a consultant for any outside organization, either for-profit or non-profit?

   YES ___  NO ___

A2. If the answer to A1 is YES, please indicate the name(s) of the outside organization(s), describe the nature of your extramural engagement or consulting arrangement, and answer the following questions for each extramural engagement or consulting arrangement. [Attach separate sheets as necessary]

   A2.1. Have you previously disclosed, in writing, and received approval for the extramural engagement or consultation?

      YES ___  NO ___  If YES, please describe and include supporting documentation.

   A2.2. Were you paid or otherwise compensated by the outside organization?

      YES ___  NO ___

   A2.3 Does this constitute a significant financial interest?

      YES ___  NO ___  If YES, please describe and include supporting documentation.

   A2.4 Was this extramural engagement carried out exclusively on your own time (non-working time, such as vacation or holidays), or during regular working hours?

      OWN TIME: YES ___  NO ___  If YES, please specify and indicate total number of days during the reporting period for each engagement.

      REGULAR WORKING HOURS: YES ___  NO ___  If YES, please specify and indicate total number of days during the reporting period for each engagement.
A2.5 Does the relationship extend beyond—either before or after—the current reporting period?

YES ____ NO ____ If YES, please describe the extent of your commitment.

A2.6 Does the *outside organization* do business with any component of the University of Pennsylvania or Health System?

YES ____ NO ____ If YES, please describe.

A2.7 Does the *outside organization* compete with any component of the University of Pennsylvania or Health System? Organizations that compete with the University or the Health System are those that are involved in education, research, or patient care.

YES ____ NO ____ If YES, please describe.

A3. What is the total number of days for which you received compensation for extramural activities during the 2004-2005 fiscal year?

____ Days

Please specify the amount of compensation you received for each extramural activity.

A4. Did the performance of any of the extramural activities described on this form involve the use of University or Health System facilities, equipment, or support staff, including those within your own office or department, or the services of other University or Health System personnel?

YES ____ NO ____ If YES, please describe.

A5. Did you hold an administrative role, including but not limited to Medical Director, were you employed, or did you hold a faculty appointment at any other institution or company?

YES ____ NO ____

If YES, please indicate name of institution, job title and duties, and describe the extent and duration of your commitment.

A5.1 Does the institution or company do business with any component of the University or the Health System?

YES ____ NO ____ If YES, please describe.
A5.2 Does the institution or company compete with any component of the Health System or University?

YES ____ NO ____ If YES, please describe.

A6. Did you or did a member of your immediate family have an equity interest or position in a for-profit or a not-for-profit outside organization that is a company that does business with or competes with any component of the University of Pennsylvania or the Health System?

YES ____ NO ____ If YES, please describe.

A7. Do you or a member of your immediate family have an equity interest or position in an outside organization that is a company that owns intellectual property rights derived from a faculty member or any other employee of the University of Pennsylvania or the Health System?

YES ____ NO ____ If YES, please describe.

A8. Did you conduct any research sponsored by a commercial organization or did you oversee, supervise, or otherwise have administrative responsibility for commercially sponsored research?

YES ____ NO ____ If YES, indicate name of the commercial organization and name of the grant.

A9. If the answer to A.8 is YES, do you or any member of your immediate family have any other relationship to that commercial organization, such as significant financial interest or equity interest, management position, or fiduciary duty?

YES ____ NO ____ If YES, please describe.

A10. Do you or any member of your immediate family have any employment relationship or significant financial interest or equity interest in any start-up enterprise or established company that has licensed from the University intellectual property developed by your subordinate (a person whose work you supervise or oversee)?

YES ____ NO ____ If YES, please describe.

A11. Did the performance of any other extramural relationships, not described on this form, involve the use of University or Health System facilities, equipment, or support staff, including those in your office or department, or the services of other University or Health System personnel?

YES ____ NO ____ If YES, please describe.
Faculty members are asked to answer the following additional questions. Please refer, by question number, to any relevant information provided in your answers above.

B.1. Were you paid or otherwise compensated by an outside organization as a visiting professor or invited lecturer during the 2004-2005 fiscal year?

YES ____ NO ____ If YES, please provide the number of days ____ and specify the amount of compensation you received for each engagement.

B.2. Did you teach course work or carry out other teaching activities for which you were compensated by an outside organization?

YES ____ NO ____ If YES, indicate name of institution and the number of days ____ of your commitment.

B.3. Did you receive compensation for Continuing Medical Education work not sponsored by the School of Medicine or another academic institution or learned society? Compensation here includes gifts and travel in addition to monetary considerations.

YES ____ NO ____ If YES, please indicate number of days (this number should be included in the total in A.3). ____

B.4. Did you engage in any clinical practice activities outside of CPUP or a University-approved practice plan for which you received compensation?

YES ____ NO ____ If YES, please describe and indicate number of days. ____

B.5. Did you do medical-legal work, for example, providing testimony, depositions, or written opinion on medical cases, for which you received or will receive direct compensation?

YES ____ NO ____ If YES, what is the total number of days for which you received compensation for medical-legal work?

B.6. Were you involved in any clinical trials sponsored by an outside organization and conducted under the auspices of the University?

YES ____ NO ____ If YES, please describe.
B.6.1 If YES, did you, or did any member of your immediate family, have an equity interest in, or any other relationship to, the sponsoring organization?

YES ____ NO ____ If YES, please describe.

B6.2 Does this constitute a significant financial interest?

YES ____ NO ____ If YES, please describe.

B.7. Were you involved in any clinical trials sponsored by an outside organization and not conducted under the auspices of the University?

YES ____ NO ____ If YES, please describe.

B.8. Did you receive any significant payments of other sorts by a sponsor of a covered clinical study?

YES ____ NO ____ If YES, please describe.

PLEASE SIGN BELOW AND RETURN THE FORM TO YOUR DEPARTMENT CHAIR

__________________________________________
Signature

__________________________________________
Date