Fully-Employed Members of the Faculty and Academic Support Staff
of the University of Pennsylvania Health System

Annual Report of Extramural Activity

During the Fiscal Year 2004-2005

NAME ______________________________________________________________

DEPARTMENT/CENTER/DIVISION _____________________________________

FACULTY TITLE AND RANK __________________________________________

PERIOD COVERED: July 1, 2004 - June 30, 2005

Fully-employed faculty must answer all questions related to the reporting period in question unless specified otherwise. Return completed forms to your department chair.

If you answer YES to any questions, please provide an explanation where indicated or attach a separate statement. If you have a question as to 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.

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 product is effective (including studies that show equivalence to an effective product) or that make a significant contribution to the demonstration of safety.

“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.

“Investigator” means a principal Investigator, co-principal Investigator, or others (e.g., individuals with supervisory or oversight function in the context of a large grant) responsible for the design, implementation and reporting of the proposed research or clinical investigators or sub-investigators directly involved in treatment or evaluation of research subjects, including staff, who are responsible for obtaining the informed consent of human subjects.

“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 QUESTIONNAIRE WHICH BEGINS ON NEXT PAGE********

Revised 2001
QUESTIONNAIRE

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

A1. Are you a fully-employed faculty member? Fully-employed faculty categories:
tenured, tenure-track, clinician-educator, research track and tenure of title faculty who receive their
compensation from the University or from a University-approved practice plan.

YES ____  NO ____

If the answer is NO, please answer Questions A13, A13.1, A13.2 and A14 only. Then sign the form and return
the form to your department chair.

If the answer is YES, go to questions A2-A18.

A2. Did you accept any extramural engagements or serve as a consultant for any outside organization(s), either
for-profit or non-profit?

YES ____  NO ____

A3. If the answer to A2 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]

A3.1 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.

A3.2 Were you paid or otherwise compensated by the outside organization?

YES ____  NO ____

A3.3 Does this constitute a significant financial interest?

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

A3.4 Does the relationship extend beyond—either before or after—the current reporting period?

YES ____  NO ____  If YES, please describe the extent of your commitment.
A4. 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, for how many days? ____

A5. Did you hold a faculty appointment at another institution?
   
   YES ____ NO ____
   
   If YES, please indicate name of institution, the faculty rank and your duties.

A6. 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 each commitment.

A7. 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 describe and indicate number of days.

A8. 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.

A9. Did you do medical-legal work, for example, provide 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?
A10. What is the total number of days for which you received compensation for extramural activities during the 2004-2005 fiscal year, including all of the above?

_____ Days

A11. Did you, or a member of your immediate family have an equity interest or a position in a for-profit or not-for-profit outside organization?

YES ____ NO ____ If YES, please describe.

A11.1 If the answer is YES, does the outside organization(s) do business with any component of the University of Pennsylvania or the Health System?

YES ____ NO ____ If YES, please describe.

YES ____ NO ____ If YES, please describe.

A12. If the answer to A11 is YES, does the outside organization(s) compete with any component of the University of Pennsylvania or the 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.

A13. 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.

A13.1 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.

A13.2 Does this constitute a significant financial interest?

YES ____ NO ____ If YES, please describe and include supporting documentation.
A14. 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.

A15. Did you receive any significant payments of other sorts by a sponsor of a covered clinical study?

YES ____  NO ____  If YES, please describe.

A16. Did you conduct research sponsored by a commercial organization?

YES ____  NO ____

A16.1 IF YES, do you or any member of your immediate family have any other relationship to that commercial organization, such as a significant financial interest or equity interest, management position, fiduciary duty?

YES ____  NO ____  If YES, please describe and include dollar amounts.

A17. Did you have an equity interest or position in any health care or research facility?

YES ____  NO ____  If YES, please describe.

A17.1 Does this constitute a significant financial interest?

YES ____  NO ____  If YES, please describe.

A18. Did the performance of any of the above activities involve the use of University facilities, equipment, or the services of other University personnel?

YES ____  NO ____  If YES, please describe.

PLEASE SIGN BELOW AND RETURN THE FORM TO YOUR DEPARTMENT CHAIR

Signature  Date