I. SCOPE

This document establishes policy guidelines and procedures for conflict of interest issues pertaining to consultants.1 In general, conflicts of interest relate to the potential for self-gain usually, but not always, of a fiscal nature. Potential for self-gain can serve to undermine the judgment or objectivity of faculty, administrators, researchers, or consultants such that their mission and dedication to academic values and activities of the University are compromised. Furthermore, not only bias, but the appearance of bias in research, may undermine public trust in the University.

The opportunity for consultants, who aid investigators or scholars, to receive financial or other personal rewards from their other endeavors is not intrinsically unacceptable, as long as it does not adversely affect their objectivity, integrity, or professional commitment. Hence, participation in a situation with opportunity for personal gain does not constitute an unacceptable situation of itself; it is the potential stimulus for unacceptable behavior that must be addressed.

II. DEFINITIONS2

A. Conflict of Interest

A potential or actual conflict of interest exists when commitments and obligations to the University or to widely recognized professional norms are likely to be compromised by a person's other interests or commitments, especially economic, particularly if those interests or commitments are not disclosed.

B. Consultants

A person (which includes a corporation or other entity) who has been engaged for pay or other considerations to work on a project is defined to be a consultant on that project if the person's activities significantly affect the course of the project. Illustrations (by no means exclusive) of such activities include advice on the interpretation of data, the construction of equipment, and the direction the program should take.

A person whose only function is to give a talk to project personnel, or to a wider audience that includes project personnel, is not considered a consultant, even if that person's remuneration comes in whole or in part from project funds.

Collaborators and co-authors are not considered consultants.
C. Immediate Family

Dependents, the spouse, and all members of the household are considered members of the immediate family. Circumstances or relationships that must be disclosed or resolved as to a consultant usually must also be disclosed or resolved if the consultant knew or should have known that a member of his or her immediate family had such a relationship.

D. Program Director

The Program Director, usually the principal investigator, is the person who actually enlists the services of the consultant.

E. Unit Head

The Unit Head, usually the chair of the department, the director of the center or the dean, is the person to whom the program director reports.

III. POLICY

A. Consultants retained by the University of Pittsburgh are required to make regular, timely, and full confidential disclosures to their program director of all significant outside interests and activities related to their consulting or research responsibilities that may give rise to conflicts of interest. Typical potential conflict of interest situations are illustrated on the Conflict of Interest Statement for Consultants.

B. This Policy also imposes the obligation on program directors, unit heads, and other supervisory administrators-themselves subject to the policy and its disclosure requirements-to not encourage or condone impermissible conflicts in their consultants.

C. Noncompliance with the requirements or provisions of this Policy may be sanctioned in the same way as noncompliance with any other University policy, including removal from the particular project, letter of reprimand, probation, suspension, or initiation of steps leading to termination of employment or contractual relationships.

IV. GUIDELINES

A. Obligations

A person who accepts a consultant appointment has an obligation to arrange other activities or commitments so as not to conflict with his/her commitment to the University. While employment outside the consulting contract is common, some types of outside interests may generate a conflict of interest and must be disclosed.

B. Confidentiality

In order to encourage disclosure of potential conflicts without unduly intruding on the privacy of consultants or their families, disclosures shall be treated confidentially and shared only to the extent necessary for review and to consider and resolve any conflicts.
C. Subsequent Disclosure

Financial, personal, or professional relationships that raise a potential conflict of interest or its perception shall be accurately disclosed in all formal communications relating to the sponsored research, including those in professional journals.

D. Withdrawal from Decisions

Consultants shall not exercise decision-making authority or exert influence concerning any University relationship affecting a company in which they or members of their immediate family have a personal or professional interest.

V. PROCEDURES

A. General

All consultants must disclose any outside interests and commitments that may generate conflicts of interest and submit them to the supervising program director or unit head upon employment. The Conflict of Interest Statement must be refilled with each reappointment and whenever new facts create a potential or actual conflict of interest.

Review after disclosure must take place promptly and help consultants determine which interests are not in conflict, which conflicting interests may be permissible, and which conflicting interests place him or her at risk of jeopardizing the integrity of his/her academic or administrative work.

The choice of accurate disclosure in place of prohibitions is based on the assumption that once a conflict is recognized, it can be avoided or resolved. Disclosures shall be kept confidential, except to the extent necessary to review, consider, and resolve any conflicts. The conflict of interest definition, guidelines, and procedures at all times shall be read and interpreted in coordination with the University Research Integrity Policy (11-01-01), the Technology Transfer Policy (11-02-01), Continuing Medical Education guidelines, and other relevant policies.

B. Program Directors

Program directors shall:

1. be responsible for ensuring that consultants involved in their research projects submit a Conflict of Interest Statement through them upon appointment or reappointment and thereafter at least annually;

2. notify their unit heads if specific consultants have conflicting outside interests, based on affirmative answers and additional details in the Conflict of Interest Statement; and

3. determine whether unit heads wish to review the detailed information provided by the consultant and, if so, notify the consultant that the unit head will be reviewing the submitted Conflict of Interest Statement.

C. Unit Heads
Unit heads (or senior designees acting on their behalf) in a timely fashion shall:

1. review all Conflict of Interest Statements for real, apparent, or potential conflicts of interest;

2. request and document additional details including precise dollar figures for ownership interests or remuneration if such details appear necessary for a sound determination of the presence or absence of an impermissible conflict of interest;

3. meet with individual consultants to discuss collegially how potential or actual conflicts shall be resolved; and

4. recommend and initiate action to resolve the apparent, potential, or real conflict.

Any program director who disagrees with the recommendation of his/her unit head for resolving a consultant's conflicts of interest may appeal once to the next higher level of administration.

D. Consultants

All consultants must complete a Conflict of Interest Statement with each appointment or reappointment, and thereafter annually, and submit it promptly to their program director or unit head, as appropriate. If, in the judgment of the consultant, a potential or actual conflict arises, the Conflict of Interest Statement should be updated promptly. The unit heads receiving these forms are required to keep them in a secure place.

E. Review Procedure

The Provost of the University has the ultimate authority to determine how conflicts of interest should be prevented or resolved.

CONFLICT OF INTEREST SUMMARY
FOR CONSULTANTS

UNIVERSITY OF PITTSBURGH
(Policy 11-01-04)

All consultants must read this Conflict of Interest Summary carefully and must sign the Conflict of Interest Statement on the reverse of this page. The completed Statement is to be submitted to the supervising Program Director. All personal information therein will be confidential.

I. CONFLICT OF INTEREST DEFINED

In general, conflicts of interest relate to the potential for self-gain usually, but not always, of a fiscal nature. Potential for self-gain can serve to undermine the judgment or objectivity of faculty, administrators, researchers, or consultants such that their mission and dedication to academic values and activities of the University are compromised. Furthermore, not only bias, but the appearance of bias in research, may undermine public trust in the University and may prove harmful to the consultant's reputation.
A potential or actual conflict of interest exists when commitments and obligations to the University or to widely recognized professional norms are likely to be compromised by a person's other interests or commitments, especially economic, particularly if those interests or commitments are not disclosed.

II. ILLUSTRATIVE CONFLICTS OF INTEREST

Not all outside interests and financial relationships place the consultant in conflict with his/her obligations to the University and to their profession. Not all conflicting interests are necessarily impermissible. Timely and complete disclosure of potential conflicts of interest may be a satisfactory remedy and protects the consultant from suspicion and accusations of breach of professional integrity. Below is an illustrative list of situations and actions that should be disclosed because they can be viewed as potential conflicts of interest.

1. Accepting gratuities or special favors from companies or individuals who might be affected by the consultant's judgments in the course of his/her consultanthip at the University.

2. Giving well-paid lectures for companies or organizations whose economic or political interests might be affected by the consultant's evaluative work in the course of his/her consultanthip at the University.

3. Undertaking evaluative research as a consultant when the consultant or the consultant's immediate family3 has a financial, managerial, or ownership interest in the company sponsoring the research or in the company producing the product tested.

4. Providing privileged or otherwise special access to information gained by the consultant in the course of his/her consultanthip to an entity in which the consultant has a political or financial interest.

5. Purchasing by the consultant, costs to be paid by the University, of equipment, instruments, or supplies from a firm in which the consultant has a significant financial or other interest.

6. Influencing the negotiation of contracts between the University and outside organizations with which the consultant has a financial interest or other relationship.

7. Hiring, or influencing the hiring of, a member of the consultant's family as a participant on the project.

The above examples are by no means exhaustive, but they are exemplary of potential conflicts of interest that must be disclosed, forswn, or otherwise resolved prior to the conflict materializing.

CONFLICT OF INTEREST STATEMENT
FOR CONSULTANTS
(Policy 11-01-04)

I have read the list of illustrative conflict of interest situations and actions on the reverse of this page. I have carefully reviewed my own situations in light of these illustrations. (Check appropriate box
To the best of my knowledge and belief, I am involved in no situations or actions that might be regarded as a potential conflict of interest with my anticipated duties as a consultant to the University of Pittsburgh.

It appears that I am involved in some situations or actions that might be regarded as a potential conflict of interest with my expected duties as a consultant to the University of Pittsburgh. Details of each of these situations and/or actions are as follows (if necessary, continue on another sheet).

1.

2.

3.

I agree to notify the University of Pittsburgh, through the Program Director, promptly if any new situation or actions that might be regarded as a potential conflict of interest with my duties as a consultant to the University should develop at any time during my consultantship.

NAME (Please print or type) _____________________________________________

HOME ADDRESS __________________________________________________________

EMPLOYING UNIVERSITY OF PITTSBURGH UNIT _______________________________

PRIMARY (OUTSIDE) EMPLOYER ______________________________________________

ADDRESS _________________________________________________________________

SIGNATURE ______________________________________________  DATE __________

CERTIFICATION OF CONFLICT OF INTEREST STATEMENT
FOR CONSULTANTS
(To be sent to Office of Research)
(Policy 11-01-04)
Statement of Program Director

I certify that the consultant named on the attached Conflict of Interest Statement is retained by me and, after discussion of the policy, to the best of my knowledge and belief does not have any conflicts of interest or has reported and resolved them.

SIGNATURE ______________________________ DATE __________

NAME (Please type or print) ______________________________

SCHOOL _____________________________ DEPARTMENT ________________________
(e.g., Engineering, Pharmacy, etc.)

CAMPUS ADDRESS ______________________________

Statement of Unit Head

I certify that the person named above reports to me and to the best of my knowledge and belief the consultant named on the attached Conflict of Interest Statement does not have any conflicts of interest or has reported and resolved them.

SIGNATURE ______________________________ DATE __________

NAME (Please type or print) ______________________________

TITLE ________________________________

1 This policy is a modified version of the initial proposal by the Conflict of Interest Committee, University of Pittsburgh, Health Sciences Schools, with amendments by the University Research Council and the TAF Senate Committee. Some of the language of the proposal and of this policy has been taken from the "Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research" by the Association of American Medical Colleges, Copyright 1990, AAMC, Washington, D.C.

2 Conflicts of Interest in Academic Health Centers: Policy Paper #1. Washington, D.C.: 1400 Sixteenth Street, NW, Suite 410, Washington, D.C. 20036 (1990). These definitions of conflict of interest and the guidelines stated below were formulated in 1990 by the Association of Academic Health Centers. The definition and guidelines are being used with the permission of the Association. Some revisions have been made to adapt the language of the definition and guidelines to the University of Pittsburgh.

3 Dependents, the spouse, and all members of the household are considered members of the immediate family. Circumstances or relationships that must be disclosed or resolved as to a consultant usually must also be disclosed or resolved if the consultant knew or should have known that a
member of his or her immediate family had such a relationship.