YALE UNIVERSITY POLICY ON
CONFLICT OF INTEREST AND CONFLICT OF COMMITMENT

PRINCIPLES

Yale University believes that a great university should reach out to the world. Accordingly, the University encourages its faculty to seek and participate in sponsored research, to consult widely, and to engage in other activities that may benefit not only the participants but also the University itself, and the larger public. In many cases, non-faculty employees also consult or engage in other outside activities. While Yale recognizes the benefit of such activities, it is also committed to ensuring that they are conducted properly and consistently, in accordance with the principles of openness, trust, and free inquiry that are fundamental to the autonomy and well-being of a university and with the responsible management of the University’s business.

The number of faculty and staff engaged in sponsored research, in consulting, or in other interactions with external organizations is substantial. The interests and commitments of the various parties engaged in such activities or affected by them – the individual, the University community, industry, the government, and the public – are complex and not necessarily coincident; occasionally, these interests may conflict with and threaten to compromise the University’s core missions and the atmosphere of free inquiry that Yale considers vital. It is sometimes difficult to draw the line between the responsibilities of a faculty or staff member to Yale and to external organizations. Under these conditions the possibility of perceived or real conflict of interest or conflict of commitment is significantly heightened.

In pursuit of its own mission, and consistent with the requirements of external agencies, particularly the federal government [1], Yale University has formulated the following policy to identify and address potential, actual and apparent conflicts of interest and commitment. The fundamental premise of this policy is that each member of the Yale community has an obligation to act in the best interest of the University and in furtherance of the University’s mission, and must not let outside activities or outside financial interests interfere with those obligations. This policy is intended to increase the awareness of faculty, staff and students to the potential for conflicts of interest and commitment, and to establish procedures whereby such conflicts may be avoided or properly managed.

CONFLICT OF COMMITMENT AND CONFLICT OF INTEREST

Recognizing Conflict of Commitment

A conflict of commitment occurs when the commitment to external activities of a faculty or staff member adversely affects his or her capacity to meet University responsibilities. This form of conflict is easily defined and recognized since it involves a perceptible reduction of the individual’s time and energy devoted to University activities.
Yale’s Faculty Handbook provides guidance about the amount of time that may be given by faculty members to outside activities; it stipulates, for example, that a faculty member may not accept salaried employment at another institution while a full-time employee of Yale, that faculty may not spend more than one day in a seven-day work week on consulting activities, and that faculty ownership or management of private enterprises is subject to review and to limitations. It is important to recognize, however, that the obligations of Yale faculty move beyond the letter of these obligations to their spirit. The University requires that its faculty will meet their classes, but it also expects that they will be available to students outside of the classroom, will carry their share of committee responsibilities, will remain productively involved in their research and other scholarly pursuits, and, where applicable, will meet their clinical obligations. External activities that compromise or diminish a faculty member’s capacity to meet these obligations represent a conflict of commitment.

Full-time non-faculty employees are expected to satisfy all of the requirements of their jobs, and should not permit outside activities to interfere with the performance of their Yale obligations. Some departments prohibit staff employees from consulting or engaging in other outside employment because of the likelihood of such interference. Other departments may permit certain outside activities, with appropriate notice to and written approval by the employee’s supervisor, so long as they do not interfere with employees’ Yale obligations. The Yale Personnel Policies and Practices Manual sets forth the University’s general expectations about staff and the avoidance of conflicts in performance of their duties in its Section 505. (http://www.yale.edu/ppdev/PersPracWeb/505.html)

### Recognizing Conflict of Interest

A conflict of interest exists when an individual has an external interest that affects or provides an incentive to affect the individual’s conduct of his or her University activities. Conflicts of interest can arise naturally from an individual’s engagement with the world outside the University, and the mere existence of a conflict of interest does not necessarily imply wrongdoing on anyone’s part. When conflicts of interest do arise, however, they must be recognized, disclosed and either eliminated or properly managed.

Conflicts of interest may exist with respect to University financial decisions in which the individual is involved, for example, regarding investments, loans, purchases or sales of goods or services, and financial accounting decisions. They may also exist with respect to non-financial University matters, including in particular the conduct of research, the care of patients, the protection of human research subjects, and the treatment of students and faculty colleagues. Conflicts may also exist with respect to matters with both financial and non-financial implications, such as decisions about the use of University equipment and facilities and the negotiation of research agreements and license agreements.

For purposes of this policy, an individual’s economic interests include his or her interest in obtaining, maintaining or increasing the value of relationships such as employment, independent contractor or consultant; management positions, board
memberships and other fiduciary relationships with for-profit organizations; ownership of stock or other securities and other financial interests such as loans or royalties; and any other activity from which the individual receives or expects to receive remuneration. They also include such interests on the part of the individual’s spouse and his or her financially dependent children.

**External economic interests** are those economic interests that do not involve the University as an institution. For example, although employment is an economic interest, an individual’s employment by the University is not an external economic interest; hence, the incentives that derive from the individual’s Yale employment do not create conflicts of interest for purposes of this policy. Some external economic interests do not create actual conflicts of interest because they do not affect Yale research, Yale financial decisions or other Yale activities. For example, there is not a conflict of interest with respect to a Yale financial decision by an employee where the external economic interest consists of a very small investment interest and the effect of the Yale decision on the organization is very small, e.g., ownership of 50 shares of IBM stock in the context of a Yale decision to buy ten IBM personal computers. There would also be no conflict of interest where the Yale employee who has the interest is not in a position to affect the Yale decision, e.g., an employee who does not in fact arrange or make recommendations for equipment purchases has no conflict of interest with respect to such purchases even if he or she has a significant economic interest in an equipment vendor.

As these examples indicate, external economic interests create conflicts of interest when they provide **an incentive to** the individual to affect a University decision or other activity (for example, because of the possibility of personal gain), and when the individual has **the opportunity to affect** the University decision or other activity (for example, because he or she is the decision-maker or the principal investigator for a research project). In the first example cited above, there was opportunity but no significant incentive, while in the second example, there was incentive but not opportunity.

**Fundamental Principles**

The following principles are among those that underlie the University’s policy on conflicts of interest and commitment:

1. External activities should not compromise an individual’s ability to perform all the activities expected of him or her as a Yale employee.
2. An individual should not receive remuneration for the conduct of his or her research or clinical activity at Yale or other Yale activity except through University channels (such as salary).
3. An individual should not conduct research or clinical activity at Yale or carry on other Yale business under circumstances in which a reasonable person would infer that the Yale activity could have been distorted by the desire for or expectation of direct or indirect external economic advantage.
4. Yale researchers, including students and postdoctoral appointees, must not be precluded from publishing their work by agreements with external sponsors or on
account of the interest of an external organization in which a faculty mentor or supervisor has an economic interest.

5. **Graduate students must not be held to non-disclosure of any aspect of their work in their meetings with individuals at Yale (including members of their dissertation advisory committees).**

6. Yale facilities, equipment, and personnel should be used only for Yale activities and purposes, except when other uses are specifically authorized by the University.

7. An individual should not participate directly in the negotiation of research agreements, license agreements, equipment purchases or other arrangements between the University and an organization in which the individual has a significant financial interest.

8. Research involving human subjects should receive especially rigorous review, and should be subject to a strong presumption against permitting the participation of any individual holding a related significant financial interest. (See below).

9. **The University will apply a rebuttable presumption against accepting research that is proposed to be sponsored by a small, privately-held entity in which the faculty member who would conduct such research has an equity interest or Board seat or other significant financial interest. (See below).**

Conflicts of interest related to research involving human subjects pose special concerns. The University and its researchers have ethical obligations to honor the rights and protect the safety of persons who participate in research conducted at the University. Financial interests held by those conducting the research or the research’s sponsor may compromise or appear to compromise the fulfillment of those ethical obligations and the well-being of the research subjects, as well as the integrity of the related research. Accordingly, there is a strong presumption against permitting any person with related significant financial interests to participate in the conduct of such research, particularly if the protocol involves more than minimal risk. Only in rare and compelling circumstances might an exception be made. The University’s Human Investigation Committee, which is charged with reviewing and monitoring human subjects research conducted at the School of Medicine, has established a rigorous policy and procedure for review of financial interests related to human subjects research performed at the University or by University researchers. These policies and procedures are intended to supplement the Yale University Policy on Conflict of Interest and Conflict of Commitment. Relevant excerpts of the policy are included as an appendix to this document. The Human Investigation Committee works closely with the Provost’s Committee on Conflict of Interest to identify and address all such conflicts. Similar policies are in place at the University’s other institutional review boards, which primarily review research involving no more than minimal risk to human subjects.

Faculty relationships with startup companies – newly-formed, privately-held, for-profit companies based on Yale intellectual property – frequently present multifaceted conflicts of interest and commitment. Policy guidelines specific to faculty relationships with such ventures appear as an appendix to this general policy statement. These are related to and in part derived from longstanding policies, set forth in Section X.D.4 of the Faculty Handbook, with respect to faculty relationships with any private enterprise.
The Appearance of Conflict of Interest

There are certain cases in which the appearance of conflict of interest is present even when no conflict actually exists. Such apparent conflicts can do almost as much damage as actual ones, undermining the credibility of research and scholarship as well as University financial decisions and calling into question the integrity of an individual or the University or both. For this reason, it is important for an individual, in evaluating a potential conflict of interest, to consider how it might be perceived by others. Apparent conflicts of interest must be avoided, and the same rigorous evaluation must be applied to situations in which there is a potential for such misunderstanding as is applied to situations in which there is the potential for actual conflict.

PROCEDURE

Disclosure

The responsibility for avoiding conflict of interest or commitment rests, in the first instance, with the individual. An essential step in addressing an actual or apparent conflict of interest or commitment is for the individual involved to make full disclosure of relevant information to the appropriate supervisor. As described in greater detail below, certain individuals are required to make regular, annual disclosures, with updates as needed; others need only disclose on an ad hoc basis. When a disclosure is received, the supervisor will review it and forward it to the Provost’s Office for review by the Provost’s Committee on Conflict of Interest and Conflict of Commitment (the “Committee”), and/or other cognizant office, which will determine what should be done to avoid or manage the conflict appropriately. (See below.) For certain senior administrators, the review will be conducted by the Office of the Vice President and General Counsel.

1. Required annual disclosures

All faculty members with University appointments of greater that 50% time; all faculty who hold administrative positions; and all faculty and non-faculty personnel who are responsible for the design, conduct or reporting of research (being “engaged in research”) are required annually to submit a conflict of interest/conflict of commitment disclosure describing their external activities and significant financial interests. The annual disclosures must be in writing, on the forms approved by the Provost.[3] Faculty members, investigators, and non-faculty personnel who are engaged in research must submit the annual disclosure forms to their departmental chair, who will then review them and forward the forms to the Provost’s Office as provided below. When the disclosing individual is a departmental chair in the School of Medicine, the disclosures go to the Dean, who will then review them and forward the forms to the Provost’s Office. Where the individual is a Dean or departmental chair in the FAS, the disclosures should be submitted directly to the Provost.
Certain senior, non-faculty administrators designated by the President are also required to submit annual disclosures of outside activities and financial interests. These disclosures must be prepared on the Conflict of Interest Disclosure Form for Senior Administrators and submitted to the Office of the Vice President and General Counsel. The form will be provided to those administrators who are designated to submit them.

2. **Required disclosures other than in annual disclosure process**

- **Material change from annual disclosure.** Whenever significant financial interests, external activities, or internal responsibilities change materially from those described in the annual disclosure, the disclosure is to be updated as soon as possible [4], in writing. Updates should be submitted according to the same procedure as the annual disclosures, described above. Whenever possible, individuals should attempt to disclose expected changes or newly anticipated conflicts before they occur, and seek advice from the Committee on the restrictions that may result from any anticipated new significant financial interest, before accepting such a financial interest. Whenever an application for funding of a new research project is submitted, the investigator will be required to certify that he or she has submitted a complete and accurate annual disclosure, and that the new research project does not present the potential for any actual or apparent conflicts of interest not already identified in the annual disclosure.

- **Human subjects research protocols.** Principal investigators and key research personnel involved in human subjects research at the School of Medicine are required to complete and submit Protocol-Related Conflict of Interest Disclosure forms or related screening forms to the Human Investigation Committee (“HIC”) at the time of the submission of each protocol to the HIC. These disclosures are intended to supplement, not replace, the annual disclosure described above.

- **Ad hoc disclosures by those not required to file annual disclosures.** Postdoctoral appointees, non-faculty employees other than designated senior administrators, and students are not required to submit annual disclosure forms unless they are responsible for the design, conduct, or reporting of research. They are required, however, on an ad hoc basis, to disclose potential and actual conflicts of interest relating generally to University research (including, for example, the use of research facilities and involvement of students in startup-company sponsored research), University financial decisions, and other matters whenever they arise. If there is any doubt about the existence of an actual or apparent conflict of commitment or conflict of interest, the individual should submit a disclosure for review by his or her supervisor, a senior administrator in the department, the Dean of the School, the Office of the Vice President and General Counsel, or the Provost’s Committee on Conflicts of Interest and Conflicts of Commitment.
The confidentiality of the disclosures will be respected as far as possible. In particular, the information on the forms will not be shared except with those who have a need to know.

**Initial Review of Disclosures**

The chair, senior administrator, supervisor, or other recipient of an annual or other disclosure [5] (the “initial reviewer”) should review the information in the disclosure to determine if a conflict of commitment exists. The initial reviewer may, but is generally not required to, review the disclosure to identify any apparent conflicts of interest, before forwarding it to the Provost’s Office.

**Conflict of Commitment.** If the initial review suggests that a conflict of commitment exists, the initial reviewer should discuss the conflict with the individual, and take steps to assure that any actual conflict is eliminated. If the initial reviewer is unable to assure the elimination of the conflict of commitment, he or she should consult with the appropriate dean or director (or in the case of an FAS chair, with the Provost’s Office); if the dean or director is unable to assure the elimination of the conflict of commitment, he or she should consult with the Provost’s Office.

**Conflict of Interest.** When the disclosure relates to research activities, the initial reviewer (the chair, dean or supervisor) is not required to review the substance of the disclosure for possible conflict of interest; he or she may instead merely note that the disclosure was received and forward it to the Provost’s Office. The initial reviewer is encouraged, however, to assist in the review process by commenting on the substance of the disclosure based on his or her knowledge of the circumstances. In some cases, the initial reviewer’s clarification of the facts will significantly speed up the review of a potential conflict of interest.

When the disclosure relates to University financial decisions or other non-research activities, the initial reviewer shall review the disclosure, identify actual and apparent conflicts, and develop a written plan that would eliminate or manage the identified conflicts. This plan could, among other possibilities, (i) authorize the individual to participate, under the reviewer’s oversight, in a matter as to which the conflict exists, or (ii) instruct the individual not to participate in the decision or other matter relating to the conflict. The plan and disclosure shall be forwarded for a final decision to the Provost’s Office, in the case of a faculty member or researcher, or to the University Officer responsible for the reviewer’s school or department in the case of non-faculty personnel who are not responsible for the design, conduct or reporting of research.

Whether or not the initial review indicates that an actual or apparent conflict of interest exists, the initial reviewer will forward the disclosure form (or a written record of an oral disclosure), together with any comments by the initial reviewer, to the Provost’s Office.
Review by the Provost’s Office

Review of disclosures forwarded to the Provost’s Office will be conducted by the Provost’s Committee on Conflict of Interest and Conflict of Commitment. This Committee consists of one or more members of the Provost’s staff and one or more faculty members selected by the Provost, together with additional individuals selected by the Provost. The Committee may delegate review of routine matters to one of its members from the Provost’s staff. If necessary, the Committee will discuss disclosure-related matters with the individual involved and may also consult with others who may have relevant information. The individual in entitled to meet with the Provost’s Committee if he or she wishes.

The Provost’s Committee will determine whether an apparent or actual conflict of interest exists, and, if so, by what means – such as the individual’s abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee – the conflict should be avoided or managed. In making those determinations, the Provost’s Committee will be guided by the principles discussed in this statement and in the Faculty Handbook and will be informed by the relevant deliberations of the HIC.

If the Committee determines that a conflict exists, it will communicate this determination and the means it has identified for eliminating or managing the conflict, in writing, to the individual, the initial reviewer who referred the case, and the appropriate dean or department chair. The Provost’s Committee will also communicate to the appropriate Office of Grant and Contract Administration the fact that the disclosure has been reviewed (or, if applicable, referred for further review as described below) and its summary determination (e.g., “no conflict,” “conflict managed”), but not the substance of the disclosure.[6] The Provost’s Committee will keep a record of the disclosure and other relevant information for at least three years.[7] If the Provost’s Committee prescribes monitoring of the activity, it will describe specifically how the monitoring shall be performed and what records are to be kept.

If the individual is not satisfied with the decision of the Provost’s Committee, he or she may request that the matter be referred to the Provost for a decision. Any matter referred to the Provost in this way shall be accompanied by a written statement of the findings and recommendations of the Provost’s Committee, with copies to the individual, and the appropriate Dean. The Provost will notify the individual, the Provost’s Committee, and the Dean of his or her decision, ordinarily within three weeks after receiving the Committee’s report.

The Provost’s decision will be final, and any failure by the individual to adhere to the decision will be cause for disciplinary action, including, in severe cases, termination.

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Notes:

[1] A number of external organizations have developed policies requiring disclosure of potential conflicts of interest. In particular, the Public Health Service ("PHS") and the National Science Foundation ("NSF") have issued proposed or final rules on this subject. Research sponsored by PHS, NSF or any other Federal agency must be conducted in accordance with applicable Federal regulations.

[2] This policy applies to all faculty, staff and students, as well as to postdoctoral appointees, visiting faculty and others working at Yale who may technically be neither employees nor students of the University.

[3] The Provost may set the dates for submission of annual disclosures by the various Schools and Departments, so that all disclosures are not submitted at the same time.

[4] In the case of faculty members engaged in federally-sponsored research, the disclosure should be updated within 30 days of any change if it is not possible to provide an updated disclosure in advance of assuming any such related interest.

[5] All such disclosures should be in writing. If a disclosure is made orally, it should be reduced to writing as soon as possible.

[6] For federal grants and contracts, the University will be required to certify that potential conflicts of interest have been disclosed and addressed.

[7] Records of disclosures by investigators involved in federally-sponsored research that are used as the basis for the University’s certification to federal sponsors that it has addressed any potential conflicts of interest with respect to the funded research must be kept for at least three years beyond the termination or completion of the research.
APPENDIX I

CONFLICTS OF INTEREST

Examples

The University has not attempted to develop an exhaustive list of fixed rules on potential conflicts of interest, because each situation depends on its specific facts. The following examples are intended to illustrate the principles underlying the University policy. Individuals who have questions about how this policy applies to a particular activity should seek advice from the Office of the Provost. (Note that some of the activities in these examples may also represent conflicts of commitment.)

The activities described in examples 1 through 6 below represent actual conflicts of interest that are inconsistent with University policy and may not be undertaken.

1. A researcher uses his laboratory at Yale to do product-testing research, paid for by a company in which he is a 20% owner and founder, which seeks to validate advertising claims made about a product sold by that company.

2. A clinician makes patient referrals to a diagnostic company in which she or her immediate family has a significant ownership interest.

3. An employee directs the purchase of supplies for the University toward a business in which he or his immediate family has a significant financial interest.

4. An employee managing a design and construction project participates in the selection of an architectural firm in which her spouse is a partner.

5. A faculty member acts as the thesis or dissertation advisor to a graduate student for a research project, suggested by the faculty member, that the faculty member expects to substantially enhance the value of a company in which the faculty has a significant interest.

6. A researcher conducts clinical research on a product developed by her and licensed to an external organization in which she owns equity or has other direct relations including consulting.

Activities such as those in examples 7 through 10 below may represent conflicts of interest, but in many cases would be permitted to go forward after disclosure with appropriate safeguards against bias of University activities and with continuing oversight.
7. A researcher conducts federally- or foundation-sponsored non-clinical research on a product developed by a company for which he is a consultant.

8. A researcher who is a member of a company’s scientific advisory board conducts non-clinical research sponsored by that company.

9. An employee manages a design and construction project involving an architectural firm in which his spouse is a partner, when the Yale employee did not participate in the selection of the firm for the project.

10. A researcher conducts federally- or foundation-sponsored basic research on a University invention that has been licensed to a company for which he consults, and on which he receives a share of University royalties.

It is important to understand that the above examples are meant to be only that – examples – and that there are many other situations different in nature and kind from the above. It is assumed that individuals who have questions about how this policy applies to a particular activity will seek advice from the Office of the Provost.
Introduction:

All members of the Yale University research community should be sensitive to the potential impacts of financial interests and/or non-financial relationships with commercial sponsors or other external entities on the conduct of research and the participation and protection of human research subjects. In compliance with federal regulations and guidance, and University policy, the HIC considers such relationships and determines whether they might influence the outcome of a research project involving human subjects, the objectivity of the investigator during the performance of such a project, or the investigator’s interactions with research subjects who participate in the project. Accordingly, the HIC solicits and reviews relevant information regarding the financial interests of all investigators and key study personnel participating in a protocol involving human research subjects prior to approving or re-approving that protocol.

Definitions:
“Key study personnel” means those persons involved in the design, conduct, and/or the data analysis of the research involving human subjects.

“Financial interests” that may be considered to be conflicts include, but are not limited to, the following: ownership of stocks, bonds, options, patent or royalty interests, receipt of consulting, honoraria or speaking fees, salary, subject accrual rewards and/or penalties, loans, lectureships, memberships on boards of directors or scientific advisory boards.

The Role of the HIC:

The HIC is the primary authority at the Yale School of Medicine responsible for ensuring that human research subjects are protected in accordance with federal regulations, University policies, and ethical principles. One of the primary responsibilities of the HIC is to ensure that human research subjects receive all information needed to provide informed consent. The HIC’s consideration of the investigators’ financial interests is intended to ensure 1) that the informed consent process provides the subjects with the facts necessary to make a knowledgeable and sound decision as to whether they wish to participate in the study, and 2) that no conflict exists that would otherwise compromise the protection of human subjects.
The HIC’s consideration of investigators’ financial interests as they relate to human subject research complements, but does not supplant, the deliberations of the Provost’s Committee on Conflict of Interest (the “COI Committee”), which is responsible for reviewing the financial disclosures of all faculty members in accordance with the University Policy of Conflict of Interest and Conflict of Commitment.

**Role of Investigators and Key Study Personnel:**

For all protocols submitted to the HIC, including new protocols and those submitted for reapproval, each participating investigator and key study person must read this Protocol-Related Conflict of Interest policy. Each participating investigator and key study person who answers “no” to all of the questions below must sign the Protocol for Research Application Form or the Request for Reapproval Form in the space noted on the form as “COI signature.” A signature in this space indicates that no actual or perceived COI exists. Individuals who answer “yes” to any of the questions listed below are required to complete and sign a Protocol COI Form and submit it to the HIC as part of the application package or request for reapproval. Investigators and key study personnel affiliated with Yale are reminded of the separate obligation to complete the annual disclosure form required by the University Policy on Conflict of Interest and Conflict of Commitment.

Before the HIC meeting at which a protocol is scheduled for consideration, the HIC Chair will review the Protocol COI Form, if one is submitted, to determine if there are related actual or potential conflicts. The Chair will evaluate such conflicts and, if necessary, provide a summary to the Committee. The Committee will determine (1) whether the conflict is permissible in the context of the protocol, and, if so, (2) whether the conflict warrants disclosure to potential subjects as part of their informed consent process. The HIC Chair will share relevant information with the Provost’s Committee on Conflict of Interest, which may make additional findings and recommendations regarding actual and potential conflicts of interest. Note again, however, that completion and submission to the HIC of this protocol-specific form does not relieve investigators of their responsibility to make disclosures to the COI Committee as outlined in the University Policy.

Note: In the Protocol-Related COI process, the confidentiality of investigators and key study persons will be respected. Financial disclosure forms will be kept in confidential files, and information will be shared only on a need-to-know basis.

July 26, 2002
APPENDIX III

CONFLICT OF INTEREST PRINCIPLES APPLICABLE TO FACULTY WITH RELATIONSHIPS WITH STARTUP COMPANIES

Faculty relationships with “startup” ventures – relatively newly formed, privately held, for-profit companies that are based on intellectual property developed at Yale – present opportunities for development and commercialization of inventions but may also create conflicts of interest and commitment. The following policy guidelines govern faculty relationships with such ventures.

1. **Equity interests.** Faculty may hold equity interests in startups that license intellectual property developed at Yale. Such equity ownership must be promptly disclosed to the Provost. Faculty accepting equity in such ventures should recognize that their ability to conduct research sponsored by that venture – especially research involving human subjects – will be restricted because of the conflict created by their ownership interest in the sponsoring entity.

2. **Membership on Boards of Directors.** Faculty may be permitted to serve on the Board of Directors of a startup. In accordance with the policy stated in the Faculty Handbook with respect to all for-profit companies, the prospect of Board membership must be disclosed in advance to the Provost’s Office, and a Board seat may be accepted only with permission of the Provost, because of the fiduciary obligation that the seat creates and its potential for conflict with the faculty member’s Yale duties and obligations. The Provost may seek the advice of the Committee on Conflict of Interest before acting on such a request. A faculty member who has assumed a Board seat should recognize that his or her ability to conduct research at Yale that is sponsored by the venture – especially research involving human subjects – will be restricted because of the conflict created by the fiduciary relationship with the venture. Faculty members who assume Board seats on startups should also be sensitive to the need to recuse themselves from all Board decisions that involve conflicting duties to the startup and to the University.

3. **Service as an Operating Officer.** A full-time faculty member should not serve as an operating officer of a startup (or, as the Faculty Handbook provides, of any company) while not on leave. If a faculty member believes it is essential for the success of the venture to serve as an operating officer, he or she should request a full or partial leave from the Provost for a specified period of time, consistent with policies on leave in the Faculty Handbook. Such a leave would be without compensation by the University. The Provost may seek the advice of the Committee on Conflict of Interest before acting on such a request.
4. **Consulting relationships, including Scientific Advisory Board membership.** Consulting agreements (including scientific advisory board memberships) between a faculty member and a startup in which the faculty member holds equity or has a Board seat should receive prior review and approval from the Provost’s Committee on Conflict of Interest, which may recommend restrictions on the proposed agreement.

5. **Student employment by a startup.** Except in special and unusual circumstances, students under a faculty member’s direction, paid for by a faculty member’s grant, or in a faculty member’s research group, may not be employed part- or fulltime by a startup in which the faculty member has an equity interest. Such special circumstances might exist, for example, where the student sought summer employment with the startup and planned to work in a field unrelated to his or her academic program.

6. **Employment of postdoctoral fellows and associates by a startup.** Postdoctoral fellows and associates under a faculty member’s direction, paid for by a faculty member’s grant, or in a faculty member’s research group, should not be employed by a startup, in which the faculty member has an equity interest, to conduct research that overlaps with the fellow’s university research or is to be conducted on University premises. Any proposed employment of a post-doctoral fellow or associate by a startup should be reviewed in advance by the Committee on Conflict of Interest.

7. **Use of Yale space.** Use of Yale space by a startup should not be permitted.

8. **Use of Yale equipment or laboratory training.** A startup may use Yale equipment or laboratories only subject to a written agreement with the University, and with strict limitations as to time and extent and only after review and approval by the Committee on Conflict of Interest.

9. **Research funding from a startup and testing of faculty-generated intellectual property licensed to a startup.** There is a strong presumption against accepting research funding in the form of grants, subcontracts, or gifts, from a startup in which the faculty member proposing the research has an equity interest or a Board seat (or other significant financial interest as defined below), if the research is to be done in the faculty member’s research group, or the faculty member’s students or postdoctoral fellows or associates would participate in the funded research projects. Rigorous restrictions also apply to human subjects research and non-human subjects research that involves testing, when the faculty member has a related financial interest. The presumption is applied as follows:

   A. **Human subjects research.** Where the proposed research involves human subjects, the presumption against permitting a related startup to sponsor the research is particularly strong. Any equity interest in the startup
company (including stock options, warrants and instruments convertible into equity), or a non-equity financial interest of over $10,000 in a year (whether derived from consulting fees, honoraria, royalties, or in some other vehicle), will almost always preclude the financially interested faculty member from conducting human subjects research sponsored by the startup. The presumption may be overcome only in rare and compelling circumstances, as judged by the Conflict of Interest Committee and the cognizant Institutional Review Board (IRB), and where the Committee and IRB are satisfied that effective controls to mitigate any possible effects of the conflict can and will be implemented. Such circumstances might include, for example, that the researcher is uniquely qualified to perform the experimental procedure. In such circumstances, the Conflict of Interest Committee will consider whether the researcher should divest himself or herself of the equity interest, or place the equity in a blind trust for an appropriate period of time. The presumption is less likely to be rebutted when the object of the conflicted research is testing of a device or compound for public validation or other similar purpose.

B. **Research not involving human subjects.** When a startup proposes to sponsor research to be conducted by a faculty member who holds equity or a Board seat in the company, and which involves neither human subjects nor validation testing, the presumption may be rebutted if, in the judgment of the Conflict of Interest Committee appropriate controls are in place (see C, below), and one of the following sets of conditions is met:

i. the research is of a fundamental or basic nature; the research is not directly related to the financial success of the startup; and the faculty member’s relationship with the company is otherwise limited (i.e., does not involve multiple additional entanglements such as consulting agreements and scientific advisory board membership); so that the likelihood of any distortion of the research endeavor is minimal; or,

ii. the faculty member’s equity interests in a venture are so diluted that his or her control or influence over the firm’s decisions and the possible benefit from Yale-based activity are negligible, and the faculty member’s relationship with the company is otherwise limited (see above); or

iii. the research is essential to maintain the continuity of a research effort related to the licensed intellectual property during a short interval of time (normally under six months), while the research activity is being established in the startup;
and during this period it is subject to oversight of non-interested peers appointed by the COI Committee.

Except in extraordinary circumstances, the presumption may not be rebutted when the research in question has as its object the testing of an invention in which the faculty member has a royalty or other interest in a startup, or a Yale invention that is licensed to a startup in which he or she has an equity interest. For purposes of this proviso, “testing” is intended to describe doing research designed to validate to the public or perform a similar function regarding an invention created at Yale and licensed to a startup company. (The same restrictions would generally apply to testing undertaken for a publicly held company holding a license from Yale.)

C. Controls. In each case in which the Conflict of Interest Committee recommends that research be permitted to proceed despite the presumption against such research, it shall ensure, in addition to measures adopted by the Committee or (for human subjects research) the cognizant IRB, and complete compliance with the other strictures of this policy on startups, the following:

i. the research agreement contains no restrictions on publication other than those sanctioned by the Faculty Handbook;

ii. all individuals working on the research project are provided a written notice that the research is being sponsored by a venture in which the faculty member has an ownership interest or fiduciary relationship;

iii. before the Committee makes a recommendation that the research be allowed to proceed, the faculty member provides the Committee a written description of the proposed research and an assurance of his or her compliance with the restrictions set forth above; and thereafter, provides the Committee written reports on the progress of the research, listing related peer-reviewed publications and grants, no less frequently than annually; and

iv. all other management measures deemed appropriate by the Committee and cognizant IRB are in place. Examples of such measures are requirement of a data safety monitoring board, in the case of human subjects research; an oversight committee to review data, publications and other issues; requirement of disclosure in publications; and commitment of equity to a blind trust for a period of time.
APPENDIX IV

Policy on Interactions between Clinical Personnel of the Yale Medical Group and Industry

Date Approved: August 17, 2010
Date Effective: September 1, 2010

I. Introduction

The Yale Medical Group (YMG) strives to provide the highest quality health care to its patients. Through its clinical activity, YMG also supports the medical education, training, and clinical research missions of the Yale School of Medicine (YSM). In some cases, interactions between YMG clinicians and industry\(^1\) can promote these missions and have a positive impact on patient care. Indeed, Yale University encourages its faculty “to consult widely, and to engage in other activities that may benefit not only the participants but also the University itself, and the larger public.”\(^2\) These interactions with industry, however, must adhere to the highest ethical and professional standards and must be intended and designed to enhance patient care, to improve the practice of medicine, or to support medical education.

The purpose of this Policy is to increase the awareness of YMG clinicians about the potential for conflicts of interest arising from relationships with industry and to establish parameters for these relationships so that actual or potential conflicts may be avoided or properly managed.

II. Policy Statement

It is the policy of the Yale Medical Group to promote principled interactions with industry that support the clinical and educational missions of the School of Medicine and to protect these missions from interactions that create actual or perceived conflicts of interest. The complexities of relationships with industry preclude YMG from identifying all circumstances in which a conflict of interest may arise or in which an interaction may be inappropriate. The principles outlined in this Policy should guide all relationships or interactions between YMG clinicians and industry. For additional guidance or clarification on this Policy, YMG clinicians should consult with their Department Chair or Section Chief, or with the YMG Chief Medical Officer.

\(^1\) In this Policy, the term “industry” means biomedical, pharmaceutical, and medical device companies and any other companies that make products used in the treatment of patients or the provision of medical care.

III. Scope of the Policy

a. This Policy applies to all physicians, PAs, APRNs, RN’s, midwives, or other clinicians who practice in the Yale Medical Group (hereinafter “Clinical Personnel”).

b. This Policy supplements the University’s policies on conflict of interest. While this Policy addresses many aspects of industry relationships, Clinical Personnel are expected to comply with all other University policies and principles relating to interactions with industry including, but not limited to:
   i. University Policy on Conflict of Interest and Conflict of Commitment;
   ii. Policy 2201: Gifts from External Parties to Employees;
   iii. Policy 3201: General Purchasing;
   iv. Policy 3205: Vendor Selection; and
   v. Standards of Business Conduct.

IV. Gifts

a. Clinical Personnel shall not accept personal gifts from industry representatives\(^3\) under any circumstances.

b. In this Policy, the term “gift” means any item, product, or service, regardless of the nature, purpose, or value, except in the limited circumstances described below. The term includes, but is not limited to, pens, pads, and other promotional items; cash; food and drink, except in the limited circumstances described in Section V of this Policy; entertainment such as tickets to events, golf, and other sports outings; hotels, transportation, and other travel expenses, except in the limited circumstances described in Section XI of this Policy; stock, equity, and other ownership interests; discounts on products or services.

c. The following are not considered “personal gifts” under this Policy:
   i. Books, charts, or other materials used for patient care or for training purposes may be accepted if distributed through the relevant department;
   ii. Payments for contractual services may be accepted if the engagement complies with this policy (see the Consulting and Industry-sponsored Educational Programs sections below); and
   iii. Unrestricted educational funds provided to a School of Medicine department.

V. Meals

a. Industry-supplied or supported food or drinks are considered personal gifts and may not be accepted by Clinical Personnel on-campus or off-campus, except in the limited circumstances discussed below.

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\(^3\) In this Policy, the term “industry representatives” means all sales, marketing, or other personnel who promote industry products.
b. Industry-supplied food or drinks may only be accepted:
   i. if provided in connection with attendance at programs compliant with the Accreditation Council on Continuing Medical Education (ACCME) Standards for Commercial Support;
   ii. as a reasonable and necessary travel expense associated with services rendered in accordance with Section XI of this Policy (e.g., approved consulting activity); or
   iii. if provided in connection with attendance at scientific or professional society meeting events open to all meeting attendees.

VI. Consulting
a. Clinical Personnel may consult with industry subject to the following requirements:
   i. the engagement must be governed by a written agreement specifying the service(s) to be provided and the compensation to be paid;
   ii. payment must be at fair market value and must be commensurate with the time and effort for the contractual services; and
   iii. Clinical Personnel consulting for industry must disclose the engagement as required under this Policy and the Policy on Conflict of Interest and Conflict of Commitment.

b. Consulting engagements involving compensation without commensurate time and effort are considered personal gifts and are prohibited under this Policy.

VII. Drug Samples
a. Clinical Personnel may accept free drug samples from industry for distribution to patients, particularly those who lack financial access to the medications, with the following limitations:
   i. Clinical Personnel should be cautious in distributing medications that are not on formulary since distribution of non-formulary drugs to patients may encourage use of costlier medications;
   ii. Free drug samples may never be sold; and
   iii. Free drug samples may never be used by Clinical Personnel for themselves or family members, except when prescribed and/or dispensed by a physician.

VIII. Site Access by Industry Representatives
a. Industry representatives are permitted in non-patient care areas by appointment only. Appointments will be permitted only on the invitation of Clinical Personnel.

b. Industry representatives are strictly prohibited from entering patient care areas except in the limited circumstances described below:
i. The purpose of the industry representative’s presence must be to provide in-service training or assistance to Clinical Personnel on devices or equipment;

ii. Clinical Personnel must be present at all times during the patient care interaction; and

iii. Disclosure must be provided to the patient (or to his/her family) that industry representative(s) may be present in the procedure area.

For the purpose of this Policy, in-service training and interactions with industry to evaluate devices or equipment are not considered “educational programs” and are not subject to the requirements in the sections pertaining to education (below).

IX. Industry Support of Continuing Medical Education

a. All industry-sponsored continuing medical education (CME) events on the Yale campus must be compliant with the Accreditation Council on Continuing Medical Education (ACCME) Standards for Commercial Support in effect on September 1, 2010. The following is a summary of selected ACCME Standards (last revised in 2007):

   i. All decisions concerning educational needs, objectives, content, methods, evaluation and speaker must be free of commercial influence (ACCME Standard 1.1);

   ii. All persons in a position to control the content of an educational activity must disclose all relevant financial relationships to the provider of the CME and to the audience at the beginning of the educational activity (ACCME Standards 2.1, 6.1);

   iii. All conflicts of interest must be identified and resolved prior to the educational activity being delivered (ACCME Standard 2.3);

   iv. Product-promotion material or product-specific advertisements of any type are prohibited in or during CME activities (ACCME Standard 4.2);

   v. Educational materials that are part of a CME activity, such as slides and handouts, may not contain any advertising, trade name, or a product-group message (ACCME Standard 4.3);

   vi. The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial entity (ACCME Standard 5.1); and

   vii. The CME provider may not use commercial support to pay for travel, lodging, or other personal expenses of attendees (ACCME Standard 3.12).

   (The full text of the Standards is available at http://www.accme.org/)

b. In addition to the aforementioned ACCME Standards, industry-sponsored CME events on the YSM campus must also comply with the following provisions:
i. Gifts or compensation may not be provided solely for attendance at the meeting or lecture; and

ii. Industry funds to support the specific educational activity must be given directly to the University in accordance with University policy and may not be provided directly to Clinical Personnel.

c. The YSM Center for Continuing Medical Education (Yale CME) is the exclusive provider of accredited continuing professional development for Clinical Personnel.

X. Industry-sponsored Educational Programs (off-campus)

a. Clinical Personnel Participation in Off-campus Educational or Training Programs (Organizer, Author, Speaker)

Clinical Personnel may actively participate (e.g., by giving a lecture, organizing the meeting) in industry-sponsored meetings or lectures only if all of the following requirements are met:

i. Financial support by industry must be fully disclosed at the meeting by the sponsor;

ii. The meeting or lecture’s content, including slides and written materials, must be determined solely by the participating Clinical Personnel with no influence from the sponsor;

iii. The lecturer must promote objective scientific and educational activities and discourse;

iv. Clinical Personnel must not be required by the industry sponsor to accept advice or services concerning teachers, authors, or other educational matters including content as a condition of the sponsor’s contribution of funds or services;

v. If Clinical Personnel are organizing the meeting, then they must ensure that attendees in the audience are not compensated or otherwise materially rewarded for attendance (e.g., through payment of travel expenses, or provision of food or gifts);

vi. If Clinical Personnel are organizing the meeting, then they must ensure that gifts of any type are not distributed to attendees before, during, or after the meeting or lecture;

vii. The engagement must be governed by a written agreement or memorandum specifying the service(s) to be provided. Compensation must be limited to reimbursement of reasonable and necessary travel expenses as described in Section XI of this Policy, and an appropriate honorarium;

viii. The lecturer must explicitly describe all of his or her relevant financial interests (recent, existing, or planned) to the audience prior to the lecture; and

ix. Clinical Personnel actively participating in industry-sponsored meetings or lectures must disclose the engagements and total annual compensation as
required under the University Policy on Conflict of Interest and Conflict of Commitment.

b. Clinical Personnel Attendance in Off-campus Educational or Training Programs

Clinical Personnel may attend off-campus industry-sponsored programs only if all of the following requirements are met:

i. The program must be primarily educational and designed to provide evidence-based medical or scientific information or to promote evidence-based clinical care and/or to advance scientific research;

ii. The industry sponsor may not reimburse the travel expenses of attendees; and

iii. Attendees may not receive gifts or other compensation for attendance.

c. Clinical Personnel should not attend or participate in industry-sponsored off-campus events for primarily promotional/marketing purposes.

XI. Travel Expenses

a. Clinical Personnel may not accept travel funds from industry, except for legitimate reimbursement of reasonable and necessary travel expenses in the following circumstances:

i. to provide services rendered in accordance with the terms of a written agreement (e.g., approved consulting activity); or

ii. for in-service training or on-site inspection and demonstration of capital equipment or devices.

XII. Authorship

a. Clinical Personnel are prohibited from being listed as an author on an article unless they make a substantive contribution to the content of the article. Industry representatives or others retained by industry that contribute to an article on which Clinical Personnel appear as authors must be listed as contributors or authors on the article and their industry affiliation must be disclosed in the published article.

b. The practice of being named as an author on an article that contains substantial portions written by someone who is not listed as an author (i.e., ghostwriting) is unacceptable under all circumstances.

XIII. Scholarships/Fellowships/Other Educational Funds for Trainees

a. Industry support for scholarships, fellowships, or other educational programs for trainees must comply with all of the following:

i. The funds must be given directly to the School of Medicine Department or Section in accordance with University policy and may not be provided directly to the trainee;
The Department, Section, or Program must determine that the conference or training has educational merit;

iii. The industry donor may not have any input or involvement in the selection of the individual(s) that will receive the funding; and

iv. The recipient of the funds may not be subject to any implicit or explicit quid pro quo (i.e., “no strings are attached”).

b. In situations where a scholarship for participation in an educational program is administered by the industry sponsor, the application must be approved in advance by the Department Chair or Section Chief.

XIV. Disclosure of Industry Relationships

a. Clinical Personnel must disclose industry relationships in accordance with the University Policy on Conflict of Interest and Conflict of Commitment (view the policy at http://provost.yale.edu/conflict-policy).

b. Disclosure in publications: For articles submitted for publication in a professional journal, Clinical Personnel must adhere to the financial interest disclosure requirements of the journal. In the event that the journal does not have a disclosure requirement, Clinical Personnel must adhere to the disclosure requirements recommended by the International Committee of Medical Journal Editors in effect on September 1, 2010.

c. Disclosure in presentations: For presentations given in connection with a meeting of a professional society, Clinical Personnel must adhere to the financial interest disclosure requirements of the society. In addition to any requirements of the society, the disclosure must comply with the ACCME Standards and the presentation must include a slide with the disclosure information.

d. Disclosure to patients: Clinical Personnel must disclose all relevant financial interests to patients. The timing, method, and content of the disclosure shall be determined by the individual program.

e. Disclosure to students/trainees: Clinical Personnel must disclose all relevant financial interests to students and trainees. The timing, method, and content of the disclosure shall be determined by the individual program.

f. Disclosure to the public: The University will disclose to its patient communities information regarding the industry relationships of Clinical Personnel that relate their University responsibilities. The format and mechanism for such disclosures remain to be determined, but may include public websites, informational brochures, etc.

XV. Enforcement

a. Suspected violations of this Policy shall be referred to the relevant Department Chair and/or the Dean’s Office for review. Depending on the nature of the alleged violation, the Department Chair or Dean’s Office, as applicable, may coordinate with other appropriate University committees or offices in the review.
b. Violations of this Policy will be subject to corrective or disciplinary action by the School of Medicine. The corrective or disciplinary action(s) imposed will in each case depend on several factors, including:
   i. The seriousness of the violation;
   ii. Whether the violation was a first or repeat offense;
   iii. Whether the violation was inadvertent or deliberate; and
   iv. The magnitude of the harm caused to the School of Medicine and Yale University.

c. Potential corrective and disciplinary actions that may be imposed, singly or in any combination, for a violation of this Policy include, but are not limited to:
   i. Further education or training for the individual on the requirements of this Policy and/or on conflict of interest principles;
   ii. Written reprimand;
   iii. Correction of disclosure information published by the individual;
   iv. Restrictions on the individual’s external professional relationships;
   v. Restrictions on the individual’s supervision of other faculty, staff, students, and/or trainees;
   vi. Restrictions on the individual’s research or clinical activities;
   vii. Removal of the individual from University administrative positions; or
   viii. Other corrective and disciplinary actions available under applicable University policies, up to and including termination.