

**YALE UNIVERSITY POLICY ON  
CONFLICT OF INTEREST**

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## I. 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, staff and students 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 Yale University has formulated the following policy to identify and address actual conflicts of interest and conflicts of 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 significant 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 to establish procedures whereby such conflicts may be avoided or properly managed.

### A. Conflict of Interest<sup>1</sup>

A conflict of interest exists when an individual has a significant financial interest (SFI) that could directly and significantly affect his or her University activities. Generally, this will be when the external interest provides an **incentive** to affect the individual's conduct of his or her University activities 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). 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 properly managed or eliminated.

Conflicts of interest may exist with respect to University financial decisions in which the

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<sup>1</sup> For the policy on Conflict of Commitment, refer to Appendix D.

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 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.

## **B. Fundamental Principles**

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

1. External activities must not compromise an individual's ability to perform all the activities expected of him or her as a Yale employee.
2. An individual may 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 may not conduct research or clinical activity at Yale or carry on other Yale business under circumstances in which there exists an unmanaged conflict of interest.
4. Yale researchers, including students and postdoctoral appointees, may 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 a financial interest.
5. Graduate students may 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 may be used only for Yale activities and purposes, except when the University specifically authorizes other uses.
7. An individual may 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 (See [University Institutional Standards of Conduct](#)).
8. Authors must fully disclose related significant financial interests and outside activities when submitting for publication (including articles, abstracts, manuscripts submitted for publication), in presentations at professional meetings, and in applications for funding. (See [University Guidance on Authorship in Scholarly and Scientific Publications](#))
9. In all scientific and scholarly publications and all manuscripts submitted for publication, authors must acknowledge the sources of support for all activities leading to and facilitating preparation of the publication or manuscript.
10. Participation by any individual responsible for the design, conduct or reporting of research involving human subjects and holding a related significant financial interest that may be affected by the research must receive especially rigorous review and must not compromise the objectivity of the research or the well-being of research subjects. (See *Section on Human Subjects research below*).
11. Research that is proposed to be sponsored by a 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 must be reviewed and approved in advance by the Provost's Committee on Conflict of Interest (COIC). (*See Section on Start-up Companies below*).

### **C. Conflicts of Interest in Human Subjects Research**

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. SFIs held by those conducting the research may 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 any person with an unmanaged conflict of interest is prohibited from participating in the conduct of such research. In addition, research involving human subjects where there is a financial conflict of interest may only go forward if the design and circumstances of the human subjects research are such that they serve to protect both the human subjects and the objectivity of the data obtained. For example, research that includes multiple independent sites, or where the intervention or choice of device is blinded to the investigators, has an independent data and safety monitoring board, or has other such protective elements, may be allowed to proceed with an appropriate conflict of interest management plan. In order to address these special concerns, when human subjects are involved in the research, conflict of interest review will be coordinated with the appropriate Yale Institutional Review Board ([See Policy on Disclosure of Interests in Human Research](#)).

### **D. Start-up Companies**

Individual relationships with "startup" ventures - relatively newly formed, privately held, for-profit companies that often may be based on intellectual property developed by the individual at Yale or elsewhere - present opportunities for development and commercialization of inventions but may also create conflicts of interest and commitment. In particular, while close involvement of the individual is often critical to the further development of the technology, multiple relationships of the individual with the start-up venture magnify the concern regarding the individual's commitment to their University responsibilities.

Generally, use of Yale space by a startup is not permitted, except a startup may use Yale equipment or laboratories 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 Provost's Office. For faculty members, the Faculty Handbook and other relevant policies govern the relationships. Policy guidelines specific to faculty relationships with such ventures appear as Appendix C to this general policy statement.

### **E. High Value Significant Financial Interests**

Income and other financial interests that are large compared to the individual's institutional salary pose a special challenge. They can create a perception that calls into question the individual's commitment and obligation to Yale. Some may find it difficult to believe that such high value interests do not compromise the individual's objectivity. And, indeed, high value financial interests do have the potential for greater bias, and are also inherently more difficult to

manage. The Provost's Committee on Conflict of Interest must therefore pay special attention to high value SFIs, and carefully consider the greater likelihood of conflict they represent.

In order to provide sufficient information to the COIC to enable it to determine whether actual undue bias exists and to recommend appropriate management schemes for relevant conflicts of interest, the Provost's Committee will likely solicit additional detailed information from disclosers whose significant financial interests exceed \$100,000 in the past twelve months and that are related to their institutional responsibilities. Such supplemental questions might request more specificity on the total dollars received, the time that such financial interests demand, a detailed explanation of the relationship of the financial interest to an individual's research or, if the individual is in an academic leadership role, whether and how, the financial interests are related to the purpose of the unit for which the individual has administrative or academic responsibility. In addition, the details of the financial interests will be provided to the Dean of the relevant school and the cognizant Provost or appropriate Vice President.

## **II. PROCEDURE**

### **A. Disclosure**

The responsibility for addressing conflict of interest rests, in the first instance, with the individual. An essential step is for the individual involved to make full disclosure of relevant information to the Conflict of Interest Office. 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 required, it will be reviewed by the Provost's Committee on Conflict of Interest (the "Committee"), which will determine what should be done to avoid or manage any conflict of interest appropriately. For certain senior administrators, the Office of the Vice President and General Counsel will conduct the review.

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 authorized individuals in the conduct of their official University responsibilities, and, for faculty with clinical responsibilities at the Yale New Haven Hospital or the Veterans Administration Connecticut Healthcare System, with appropriate officials at those locations; and where required contractually or by law in connection with sponsored funding, with the research sponsors or through public disclosure.

#### **1. Required initial and annual disclosures**

All faculty members with University appointments of greater than 50% time; all faculty who hold administrative positions; all faculty and staff who serve as members of a research reviewing committee (e.g., IRB, IACUC, BSC, COIC, ESCRO, Radiation Safety); and all faculty, staff and students who are responsible for the design, conduct or reporting of research are required to submit an annual external interest disclosure form describing their external activities and financial interests. The disclosures must be in writing, on the forms approved by the Provost, and must be submitted to the Conflict of Interest Office.

Whenever an application for funding of any research project is submitted, each individual responsible for the design, conduct or reporting of the research is required to have an up-to-date disclosure on file with the Conflict of Interest Office.

Any individual carrying out research or other activities supported by the federal Public Health Service (PHS) or supported by another sponsor that mandates compliance with the PHS regulations, must refer to and comply with [Appendix A](#). Any individual carrying out research or other activities supported by the National Science Foundation (NSF) or other sponsor that mandates the NSF policy, must refer to and comply with [Appendix B](#). Any individual that is not carrying out research or other activities supported by PHS or NSF must comply with the procedures as prescribed below in this general procedure.

All faculty, irrespective of funding support, that have relationships with startup companies must also comply with [Appendix C](#). All faculty and full time non-faculty employees must also comply with the Policy and Procedure on Conflict of Commitment contained in [Appendix D](#). All clinical personnel of the Yale Medical Group must also comply with [Appendix E](#).

## **2. Material change from annual disclosure**

Whenever SFIs or internal responsibilities change materially from those described in the annual disclosure, the disclosure should be resubmitted as soon as possible, but no later than 30 days after the individual's knowledge of such events.

## **3. Other required annual disclosures**

Certain senior, non-faculty administrators designated by the President are also required to submit disclosures of outside activities and financial interests and thereafter annually submit disclosures of outside activities and financial interest for as long as the individual continues to be designated by the President as being required to submit such disclosures. 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.

## **4. 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 identified as being responsible for the design, conduct, or reporting of research. If there is any possibility of a conflict of interest with respect to an individual's non-research activities, the individual should consult with his or her supervisor, a senior administrator in the department, the Dean of the School, or the Office of the Vice President and General Counsel. 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](#).

## **B. Review by the Provost's Committee on Conflict of Interest**

The Provost's Committee on Conflict of Interest reviews disclosures submitted to the Conflict of Interest Office to determine whether the Discloser's SFI(s) present(s) a conflict of interest with the Discloser's University responsibilities, and if so, by what means the conflict should be managed, reduced or eliminated. A conflict exists when a SFI could directly and significantly impact the individual's ability to carry out their University responsibilities without undue bias.

The Committee consists of one or more members of the Provost's staff, one or more members of Yale's Institutional Review Board 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 or supporting staff. If necessary, the Committee may discuss disclosure-related matters with the individual involved and may also consult with others who may have relevant information. A Discloser is entitled to meet with the Provost's Committee if he or she wishes.

The Committee will review any SFIs in the context of the individual's overall Yale responsibilities, i.e., academic, clinical or administrative (commonly referred to as an "Activities Review") and with respect to each research award on which the Discloser is identified as responsible for the design, conduct, or reporting of the research to determine if a SFI is related to the award and whether the SFI creates a conflict of interest related to that research award (commonly referred to as "Transactional Review").

### **C. Guidelines for Determining Conflict of Interest on Research Awards**

The Committee will determine whether a Discloser's SFI is related to the funded or proposed research and, if so, whether the SFI is a financial conflict of interest (FCOI). A Discloser's SFI is related to funded or proposed research when the Committee reasonably determines that the SFI: could be affected by the research; or is in an entity whose financial interest could be affected by the research. The Committee may consult with the Investigator in the determination of whether a SFI is related to the research.

A financial conflict of interest exists when the Committee reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research.

Among the factors that should be taken into consideration in the determination of an FCOI include the role of the Discloser and the opportunity to bias the results, the nature of the research being proposed, whether the work is funded by an entity in which the Investigator holds a SFI, and consideration of the value of the SFI in relation to the size and value of the entity. The factors that should be considered include:

1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
2. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
3. Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
4. Where the research involves human subjects whether there are double blind conditions or the

- involvement of a data and safety monitoring board; or
5. Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs); or
  6. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
  7. Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser's technology, the amount of commercialization payments received by the faculty member from that technology, both currently or in the future; or
  8. The number and nature of relationships a Discloser has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
  9. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
  10. Whether other scientific groups are independently pursuing similar questions; or
  11. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
  12. Whether the goal of the project is a comparative evaluation of a technology in which the Discloser has a SFI; or
  13. Whether the project involves a subaward to an entity in which the Discloser has a SFI.

**D. Management of Significant Financial Interests that Pose a Conflict of Interest**

If a conflict of interest exists, the Committee will determine by what means – such as the individual's recusal from decisions affecting the conflicting entity, 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 order to mitigate undue bias. In making those determinations, the Provost's Committee will be guided by the principles discussed in this Policy and in the Faculty Handbook, and may be informed by the deliberations of the relevant Institutional Review Board (IRB), as appropriate. The Committee will also take into consideration whether the Discloser's ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;



- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that create financial conflicts;
- For research projects involving human subjects research, use of a data and safety monitoring board;
- Double-blind conditions;
- Provisions to conduct the work simultaneously at multiple sites;
- Written disclosure of the conflict to all individuals working on the research project; and
- Annual reports on the research progress to the Committee.

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, to the relevant Principal Investigator in the case of sponsored research, and to the appropriate Dean and Department Chair where conflicts of interest arise with respect to teaching, clinical, or administrative responsibilities. In the case of clinical responsibilities, the Committee may also inform Yale New Haven Hospital, Veterans Administration Connecticut Healthcare System or the Yale Medical Group. The Committee will also communicate with the Office of Grant and Contract Administration the fact that the disclosure has been reviewed and its summary determination, but not the substance of the disclosure.<sup>2</sup> The Committee will keep a record of the disclosure and other relevant information for at least three years.<sup>3</sup> If the Committee prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

If the individual is not satisfied with the decision of the Committee, he or she may request in writing to the Committee that the matter be referred to the Provost for a decision. A written statement of the findings and recommendations of the Committee shall accompany any matter referred to the Provost, with copies to the individual, and the appropriate Dean and Department Chair. The Provost will notify the individual, the Committee, and the Dean and Department Chair of his or her decision 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.

#### **E. Significant Financial Interest**

Any individual carrying out research or other activities supported by the federal Public Health Service (PHS) or supported by another sponsor that mandates compliance with the PHS regulations, must refer to [Appendix A](#) for the definition of SFI and for specific procedures

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<sup>2</sup> For certain federal grants and contracts, the University will be required to certify that financial conflicts of interest have been addressed.

<sup>3</sup> Records of disclosures by investigators involved in certain federally-sponsored research that are used as the basis for the University's certification that it has addressed any financial conflicts of interest with respect to the funded research must be kept for at least three years beyond the termination or completion of the sponsored award.

applicable to PHS funding. Any individual carrying out research or other activities supported by the National Science Foundation (NSF) or other sponsor that mandates the NSF policy, must refer to Appendix B for the definition of SFI and for specific procedures applicable to NSF funding.

### **1. Significant financial interest means:**

A financial interest consisting of one or more of the following interests of the Discloser (including those of the Discloser's spouse and dependent children) that reasonably appear to be related to his or her institutional responsibilities (including teaching, administration, research or clinical care):

- (i) **With regard to any publicly traded entity**, a *significant financial interest* exists when the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$10,000. For purposes of this definition, remuneration includes salary, and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, etc.); or

When the value of any equity interest in the entity as of the date of disclosure exceeds \$10,000 or represents more than a 5% ownership interest in the entity; equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

- (ii) **With regard to any non-publicly traded entity**, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$10,000, or when the Discloser holds **any** equity interest (e.g., stock, stock option, or other ownership interest).
- (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income greater than \$10,000 related to such rights and interests.
- (iv) With respect to the Discloser only, a *significant financial interest* exists if the Discloser is a member of the Board of Directors or serves as a fiduciary officer of any entity.

### **2. Intellectual Property Rights Assigned to Yale**

Income from intellectual property rights assigned to Yale and agreements to share in royalties related to such rights: Yale does not treat these particular interests in and of themselves as "significant." However, depending upon certain circumstances, Yale may take intellectual property rights into consideration as a factor in determining whether or not a financial conflict of interest exists. Also, because Yale's Institutional Review Boards (IRBs) may consider intellectual property rights in their review of human research protocols and for purposes related to the protection of research participants, intellectual property interests should be disclosed.

### **3. Other Activities/Financial Interests**

The following activities/financial interests are not considered significant and do not have to be disclosed:

- (i) Salary or other remuneration paid by Yale to the Discloser if the Discloser is currently employed by Yale;
- (ii) Financial interests or activities not related to one's academic or professional work at Yale;
- (iii) Reimbursed or sponsored travel expenses;
- (iv) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Discloser does not directly control the investment decisions made in these vehicles;
- (v) Income from lectures, seminars or teaching engagements sponsored by public or non-profit entities, including other academic institutions;
- (vi) Income for service on advisory committees (including scientific advisory committees) or review panels for public or non-profit entities, including professional associations;
- (vii) Income for book royalties, editorial activities (e.g., journal editorships or editing compilations of scholarly papers) or authorship activities (e.g., advances) from publishing companies (for profit or non-profit). ***Remuneration for editorial or authorship activities received from or funded by entities not primarily engaged in the publishing business (including providers/producers of continuing medical education (CME), medical communications and other commercial enterprises such as pharmaceutical or medical device companies) must be disclosed; or***
- (viii) Compensated activities and income derived from Government or non-profit research entities such as the Veterans Administration Connecticut Healthcare System, the Howard Hughes Medical Institute, or the Pierce Foundation.

## APPENDIX A

### YALE UNIVERSITY

#### CONFLICT OF INTEREST PROCEDURES APPLICABLE TO PUBLIC HEALTH SERVICE FUNDING

The federal Public Health Service (PHS) has adopted regulations (42 CFR Part 50 and 45 CFR Part 94) on *Promoting Objectivity in Research*. These regulations describe the actions an individual and the institution must take in order to promote objectivity in research. The regulations apply to all grants, cooperative agreements, and research contracts (but not Phase 1 Small Business Innovation Research or Small Business Technology Transfer program grants) funded by the PHS. The regulations require that applicants for PHS funding (e.g., funding from the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control, et al.), prior to application for PHS funds, disclose to the institution any significant financial interests related to their institutional responsibilities.

#### Definitions

Solely for those applying for or receiving funds from the PHS, ***Institutional responsibilities*** means an Investigator's professional activities on behalf of the Institution (e.g., teaching, administration, research or clinical care). Specifically, these include:

- Externally sponsored research or scholarly activities (includes activities such as proposing, conducting, and analyzing research and disseminating results);
- Departmental/University research (includes participation in study sections, peer review of manuscripts, or effort on non-sponsored research);
- Instruction/University Supported Academic activities (including preparation for and presentations of formal and informal courses to students/trainee groups, mentoring students and trainees, and participation in resident training);
- Clinical service activities such as performing services for the Yale Medical Group and affiliated hospitals;
- Administrative activities including serving as Department Chair, Program Director, or service on institutional committees, participation in department activities or faculty advisory boards, etc.; or
- Special Service activities on behalf of the University including institutional community service.

Institutional responsibilities do not include:

- Volunteer individual community or public service unrelated to one's responsibilities on behalf of the University; or
- Other activities over and above or separate from responsibilities in the primary position.

***Investigator*** means the project director or principal Investigator and any other person, regardless

of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants. The Principal Investigator (Project Director), upon consideration of the individual's role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.

The definition of Significant Financial Interest set forth herein replaces II[E] of the general policy and procedure.

***Significant Financial Interest*** means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities (e.g., consulting and other outside compensated professional work including service on Scientific Advisory Boards or similar boards directly related to one's University research or scholarship; or service in external professional organizations and societies related to one's work):

- (i) **With regard to any publicly traded entity**, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- (ii) **With regard to any non-publicly traded entity**, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- (iii) **With regard to intellectual property rights and interests** (e.g., *patents, copyrights*), a *significant financial interest* exists upon receipt of income of greater than \$5,000 related to such rights and interests;
- (iv) **With respect to the Investigator only** (but not the Investigator's spouse or dependent children), a *significant financial interest* exists if the Investigator is a member of the Board of Directors or serves as a fiduciary officer of any entity.

(2) **Any reimbursed or sponsored travel** (i.e., that which is reimbursed to or paid on behalf of the Investigator, the Investigator's spouse or dependent children), **related to the Investigator's responsibilities**, if the cost or value received from a single entity exceeds \$5,000 for the preceding twelve (12) months. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of Higher Education as defined at 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education. The details of this

disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

(3) The term *significant financial interest* does not include the following types of financial interests:

- (i) Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- (ii) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- (iii) Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
- (iv) Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

### **Disclosure**

Prior to the submission of an application for funding from a PHS agency, the Principal Investigator and all other Investigators must have disclosed to the Conflict of Interest Office an up-to-date listing of their Significant Financial Interests [SFI] (and those of their spouse and dependent children), as defined above. Any new Investigator, who, subsequent to the submission of an application for funding from a PHS agency, or during the course of the research project, plans to participate in the project, must similarly disclose their SFI to the Conflict of Interest Office promptly and prior to participation in the project.

Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of SFI at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to Yale, pursuant to this Policy, or in a subsequent disclosure of SFI (e.g., any financial conflict of interest [FCOI] identified on a PHS-funded project that was transferred from another Institution), and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Each Investigator who is participating in the PHS-funded research must submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

### **Review by the Provost's Committee on Conflict of Interest**

The Provost's Committee on Conflict of Interest will conduct reviews of disclosures submitted to the Conflict of Interest Office. The Committee will review any SFI that has been identified in a disclosure; these interests will be compared to each PHS research award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if a SFI is related to the award and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award.

### **Guidelines for Determining "Relatedness" and Financial Conflict of Interest**

The Committee will determine whether an Investigator's SFI is related to the PHS-funded research and, if so, whether the SFI is a financial conflict of interest. An Investigator's SFI is related to PHS-funded research when the Committee reasonably determines that the SFI: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The Committee may involve the Investigator in the determination of whether a SFI is related to the PHS-funded research.

A financial conflict of interest exists when the Committee reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

In determining if an Investigator's SFI is related to PHS-funded research, and if so, whether the relationship creates a FCOI, the Committee considers the role of the Investigator and the opportunity (if any), to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. In addition, the Committee may also consider the following factors:

1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
2. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
3. Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
4. Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
5. Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs); or
6. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
7. Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Investigator's technology, the amount of commercialization payments received by the faculty member from that technology, both currently or in the future; or
8. The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or

9. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
10. Whether other scientific groups are independently pursuing similar questions; or
11. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
12. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a SFI; or
13. Whether the project involves a subaward to an entity in which the Discloser has a SFI.

### **Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest**

If a conflict of interest exists, the Committee will determine by what means – such as the individual’s recusal from decisions affecting the conflicting entity, 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 order to mitigate undue bias. In making those determinations, the Provost’s Committee will be guided by the principles discussed in this Policy and in the Faculty Handbook, and may be informed by the deliberations of the relevant Institutional Review Board (IRB), as appropriate. The Committee will also take into consideration whether the Investigator’s ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;
- c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- d) Modification of the research plan;
- e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f) Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- g) Severance of relationships that create financial conflicts;
- h) For research projects involving human subjects research, use of a data and safety monitoring board;
- i) Double-blind conditions;
- j) Provisions to conduct the work simultaneously at multiple sites;
- k) Written disclosure of the conflict to all individuals working on the research project; and
- l) Annual reports on the research progress to the Committee.

If the Committee determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator (Project Director), and the appropriate dean or department



chair. The Conflict of Interest Office will keep a record of the disclosure and other relevant information for at least three years. If the Provost's Committee prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

If the individual is not satisfied with the decision of the Committee, he or she may request that the matter be referred to the Provost for a decision. A written statement of the findings and recommendations of the Committee shall accompany any matter referred to the Provost, with copies to the individual, and the appropriate Dean or Department Chair. The Provost will notify the individual, the Committee, and the Dean or Department Chair of his or her decision after receiving the Committee's report.

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

No expenditures on PHS awards will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the Committee necessary to manage the Conflict of Interest. The Conflict of Interest Office will communicate with the PHS Awarding Component to notify it of the existence and the nature of a Financial Conflict of Interest and whether the conflict has been managed, reduced, or eliminated.

The Conflict of Interest Office will keep a record of Investigator disclosures of financial interests and the Committee's review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for three years from the date the final expenditures report is submitted for grants, for three years from the date of final payment for contracts, or, where applicable, for time periods as otherwise specified in relevant PHS Regulations.

### **Public Accessibility to Information Related to Financial Conflicts of Interest**

Prior to the expenditure of any funds under a PHS-funded research project, Yale will ensure public accessibility, via a publicly accessible Web site or by written response to any requestor within five business days of a request, of information concerning any SFI disclosed that meets the following three criteria:

- (i) The Significant Financial Interest was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel by the University in the grant application, progress report or any other report submitted to the PHS by the University;
- (ii) Yale has determined that the Significant Financial Interest is related to the PHS-funded research; and
- (iii) Yale has determined that the Significant Financial Interest is a Financial Conflict of Interest.

The information that Yale will make available via a publicly accessible Web site or in a written

response to any requestor within five days of request will include, at a minimum, the following:

- (i) The Investigator's name;
- (ii) The Investigator's title and role with respect to the research project;
- (iii) The name of the entity in which the Significant Financial Interest is held;
- (iv) The nature of the Significant Financial Interest; and
- (v) The approximate dollar value of the Significant Financial Interest in the following ranges: \$0-\$4,999; \$5,000-9,999; \$10,000 - \$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

If Yale uses a publicly accessible Web site to comply with the public disclosure requirements of the PHS regulations, the information posted will be updated at least annually, and within sixty days of receipt or identification of information concerning any additional SFI of the senior/key personnel for the PHS-funded research project that had not been previously disclosed, or upon the disclosure of a SFI of senior/key personnel new to the PHS-funded research project, if it is determined by the Committee that the SFI is related to the PHS-funded research and is a Financial Conflict of Interest.

If Yale responds to written requests for the purposes of public accessibility, it will ascertain from the Investigator that the information provided is current as of the date of the correspondence, and will note in its written response that the information is subject to updates, on at least an annual basis and within 60 days of the Yale's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the SFI's of an individual, as limited by this Policy, will remain available, for responses to written requests or for posting via Yale's publicly accessible Web site for at least three years from the date that the information was most recently updated.

### **Reporting of Financial Conflicts of Interest**

Prior to the expenditure of any funds under a PHS-funded research project, Yale will provide to the PHS Awarding Component an FCOI report compliant with PHS regulations regarding any Investigator's SFI found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan. While the award is ongoing (including any extensions with or without funds), Yale will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes in the management plan.

For any SFI that is identified as conflicting subsequent to an initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), Yale will provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that Yale has implemented a management plan and the Investigator has agreed to the relevant management plan.

## **Training Requirements**

Each Investigator must complete training on *The Yale Conflict of Interest Policy Applicable to Public Health Service Funding*. For PHS Investigators, Yale has imbedded training on conflict of interest into its annual disclosure form. Each Investigator must complete the disclosure form prior to engaging in research related to any PHS-funded grant, and immediately (as defined below) when any of the following circumstances apply:

- 1) Yale revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators (training will be completed in the manner and within the time frame specified in communications announcing such changes) ;
- 2) An Investigator is new to Yale (training must be completed through completion of the disclosure form within 30 days of joining Yale); or
- 3) Yale finds that an Investigator is not in compliance with this Appendix to Yale's Conflict of Interest Policy or a management plan issued under this Appendix (training must be completed within 30 days in the manner specified by the COIC).

## **Subrecipient Requirements**

Yale shall as part of a written subrecipient agreement with a subrecipient under a PHS prime award, establish whether the financial conflicts of interest policy of Yale or that of the subrecipient will apply to the subrecipient's investigator(s). If the subrecipient relies on its conflicts of interest policy, the subrecipient shall certify as part of the subrecipient agreement, that its policy complies with 42 CFR Part 50 and 45 CFR Part 94, as appropriate. In either case, the subrecipient agreement will include time periods to meet the disclosure and/or Financial Conflict of Interest reporting requirements of Yale to PHS.

## **Failure to Comply with Yale's Conflict of Interest Policy Applicable to Public Health Service Funding**

Whenever an FOIC is not identified or managed in a timely manner, including, for example, because the underlying Significant Financial Interest is not disclosed timely by an Investigator or, because an FCOI was not timely reviewed or reported by a sub-recipient or by Yale); or because an investigator failed to comply with a management plan; then Yale will complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted during the period of noncompliance was biased in the design, conduct, or reporting of such research. The Provost will appoint one or more individuals to determine if the research was biased. If bias is found, Yale will develop and implement a plan to mitigate the bias. Yale will notify the PHS Awarding Component promptly and will submit a mitigation report to the PHS Awarding Component within 120 days of the determination of noncompliance.

No expenditures of funds on PHS awards will be permitted unless the Investigator has complied with the Disclosure requirements of this Appendix and has agreed, in writing, to comply with any Committee-approved FCOI management plan.

In any case in which the Department of Health and Human Services determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution as required by the PHS regulations, Yale will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the research and to request an addendum to previously published presentations.

Any failure by an individual to adhere to this Policy may be cause for disciplinary action, including, in severe cases, termination.

## APPENDIX B

### YALE UNIVERSITY

#### CONFLICT of INTEREST PROCEDURES APPLICABLE TO NATIONAL SCIENCE FOUNDATION FUNDING (NSF)

The National Science Foundation (NSF) requires each grantee institution employing more than fifty persons to maintain an appropriate written and enforced policy on conflict of interest and that all conflicts of interest for each award be managed, reduced or eliminated prior to the expenditure of the award funds. Therefore, for every NSF application for funding, each Investigator must disclose to the Conflict of Interest Office all significant financial interests of the Investigator (including those of the investigator's spouse and dependent children):

- (i) That would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or
- (ii) In entities whose financial interests would reasonably appear to be affected by such activities.

#### Definitions

The term “**Investigator**” means the principal investigator, co-principal investigators, and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.

For those applying for or receiving funds from the NSF, the definition of Significant Financial Interest described herein replaces II[E] of the general policy and procedure. The term “**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 interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). With respect to the Investigator only (and not the investigator's spouse and dependent children), a *significant financial interest* exists if the Investigator is a member of the Board of Directors of any entity, or serves as a fiduciary officer of such an entity.

The term does not include:

- (i) Salary, royalties or other remuneration from the applicant institution;
- (ii) Any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
- (iii) Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- (iv) Income from service on advisory committees or review panels for public or nonprofit entities;
- (v) An equity interest that, when aggregated for the investigator and the investigator's

- spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or
- (vi) Salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the twelve month period.

## **Disclosure**

All Investigators must have a current financial disclosure on file with the University's Conflict of Interest Office at the time the proposal is submitted to NSF. Financial disclosures must be updated during the period of the award, either on an annual basis, or as new reportable significant financial interests are obtained.

## **Review by the Provost's Committee on Conflict of Interest**

The Provost's Committee on Conflict of Interest (the Committee) will review financial disclosures, determine whether a conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the Committee reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities<sup>4</sup>.

## **Guidelines for Determining Conflict of Interest**

The Committee will determine whether an Investigator's SFI is related to the NSF-funded research and, if so, whether the SFI is a financial conflict of interest. An Investigator's SFI is related to NSF-funded research when the Committee reasonably determines that the SFI: could be affected by the NSF-funded research; or is in an entity whose financial interest could be affected by the research. The Committee may involve the Investigator in the determination of whether a SFI is related to the NSF-funded research or educational activity.

A financial conflict of interest exists when the Committee reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the NSF-funded research or educational activity.

Factors that may be taken into consideration in this determination include the role of the Investigator and the opportunity to bias the results, the nature of the research being proposed, and consideration of the value of the SFI in relation to the size and value of the entity. Other factors that might be considered include:

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<sup>4</sup> Institutions must maintain records of all financial disclosures made by investigators involved in NSF sponsored research and of all actions taken to resolve conflicts of interest for at least three years beyond the termination or completion of the sponsored award to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.

1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
2. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
3. Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
4. Where the research involves human subjects whether there are double blind conditions or the involvement of a data and safety monitoring board; or
5. Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial outlook (excluding Phase I SBIRs and STTRs); or
6. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
7. Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser's technology, the amount of commercialization payments received by the faculty member from that technology, both currently or in the future; or
8. The number and nature of relationships a Discloser has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
9. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
10. Whether other scientific groups are independently pursuing similar questions; or
11. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
12. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a SFI; or
13. Whether the project involves a subaward to an entity in which the Discloser has a SFI.

### **Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest**

If a conflict of interest exists, the Committee will determine by what means – such as the individual's recusal from decisions affecting the conflicting entity, 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 order to mitigate undue bias. In making those determinations, the Provost's Committee will be guided by the principles discussed in this Policy and in the Faculty Handbook, and may be informed by the deliberations of the relevant Institutional Review Board (IRB), as appropriate.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;

- c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- d) Modification of the research plan;
- e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- g) Severance of relationships that create financial conflicts;
- h) For research projects involving human subjects research, use of a data and safety monitoring board;
- i) Double-blind conditions;
- j) Work being conducted simultaneously at multiple sites;
- k) Written disclosure of the conflict to all individuals working on the research project; and
- l) Annual reports on the research progress to the Committee.

If the Committee determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator (Project Director), and the appropriate dean or department chair. The COI Office will keep a record of the disclosure and other relevant information for at least three years. If the Committee prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

If the individual is not satisfied with the decision of the Committee, he or she may request that the matter be referred to the Provost for a decision. A written statement of the findings and recommendations of the Committee shall accompany any matter referred to the Provost, with copies to the individual, and the appropriate Dean and Department Chair. The Provost will notify the individual, the Committee, and the Dean and Department Chair of his or her decision after receiving the Committee's report.

Any failure by an individual to adhere to this Policy may be cause for disciplinary action, including, in severe cases, termination.

No expenditures of funds on NSF awards will be permitted unless the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the Committee necessary to manage the Conflict of Interest.

Yale will keep NSF's Office of the General Counsel appropriately informed if it finds that it is unable to satisfactorily manage a conflict of interest.



## APPENDIX C

### POLICY APPLICABLE TO FACULTY WITH RELATIONSHIPS WITH STARTUP COMPANIES

One important aspect of the University's research endeavors is to enable the dissemination of research and new technologies to the benefit of society. Licensing activities and the start-up of new companies to further develop new technologies are important means of accomplishing this goal. Faculty relationships with "startup" ventures - relatively newly formed, privately held, for-profit companies that often are based on intellectual property developed by the faculty member at Yale or elsewhere -- present opportunities for development and commercialization of inventions but may also create conflicts of interest and commitment. In particular, while close involvement of the faculty member is often critical to the further development of the technology, multiple relationships of the faculty member with the start-up venture magnify the concern regarding the faculty member's commitment to their University responsibilities. This Policy, the Faculty Handbook and other relevant policies govern the following relationships.

1. **Equity interests.** Faculty may hold equity interests in startups that license intellectual property developed either at Yale or at other entities. Such equity ownership must be promptly disclosed (i.e., within 30 days) to the COI Office on the prescribed form. Faculty accepting equity in such ventures should recognize that their ability to conduct research sponsored by that venture - especially research involving human subjects - may be restricted because of the conflict created by their ownership interest in the sponsoring entity. Therefore Yale faculty should consult with the Provost's Committee on Conflict of Interest ("the Committee") prior to accepting either an equity interest or financial sponsorship of research by the entity.
2. **Membership on Boards of Directors.** Faculty may be permitted to serve on the Board of Directors of a startup (or, as the Faculty Handbook provides, of any company). 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. A faculty member who has personally 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 - **may 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 the University.
3. **Service as an Operating Officer.** A full-time faculty member may 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.

4. **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 full-time by a startup in which the faculty member has an SFI. 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. These circumstances must be approved in advance by the Provost.
5. **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 SFI, to conduct research that overlaps with the fellow's university research or is to be conducted on University premises. The Provost must approve in advance any proposed employment of a post-doctoral fellow or associate by a startup.
6. **Use of Yale space.** Use of Yale space by a startup is not permitted, except as provided in the next paragraph.
7. **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 Provost.

## APPENDIX D

### POLICY AND PROCEDURE ON CONFLICT OF COMMITMENT

#### A. Policy

The responsibility for addressing conflict of commitment rests, in the first instance, with the individual. An essential step is for the individual involved to make full disclosure of relevant information to the Conflict of Interest Office. 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 approval by the Provost 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. Deans and Department Chairs are responsible for ensuring that faculty meet their University obligations.

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.

#### B. Procedure

All faculty members with University appointments of greater than 50% time; all faculty who hold administrative positions must make full disclosure of their external activities to the Conflict of Interest Office. The Conflict of Interest Office will prepare a summary report of an individual's external activities from the disclosure. This report will be provided to the relevant Dean or Chair for a determination of whether a conflict of commitment exists. If such a conflict exists, the Dean or Chair will discuss with the individual steps to be taken to resolve the matter. The Dean or Chair may consult with the Provost's Office as appropriate.

## APPENDIX E

### Policy on Interactions between Clinical Personnel of Yale Medicine and Industry

Date Approved: August 17, 2010

Date Effective: September 1, 2010

Date Revised: June 1, 2022

#### **I. Introduction**

Yale Medicine (YM) strives to provide the highest quality health care to its patients. Through its clinical activity, YM also supports the medical education, training, and clinical research missions of the Yale School of Medicine (YSM). In some cases, interactions between YM clinicians and industry<sup>1</sup> 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.”<sup>2</sup> 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 YM 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 Yale Medicine 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 YM 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

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<sup>1</sup> 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.

<sup>2</sup> Yale University Policy on Conflict of Interest, August 2012, <https://your.yale.edu/policies-procedures/other/yale-university-policy-conflict-interest>

interactions between YM clinicians and industry. We understand that these relationships are complex, and individuals may need additional support in understanding their unique situations. For guidance or clarification on this Policy, YM clinicians should consult with their Department Chair or Section Chief, the YM Senior Director of Compliance, the Deputy Dean of Clinical Affairs or their designee.

### **III. Scope of the Policy**

- a. This Policy applies to all physicians, PAs, APRNs, RN's, midwives, or other clinicians who practice in Yale Medicine (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
  - ii. Policy 2201: Gifts from External Parties to Employees;
  - iii. Policy 3201: General Purchasing;
  - v. University Institutional Standards of Conduct.

### **IV. Gifts**

- a. Clinical Personnel shall not accept personal gifts from industry representatives<sup>3</sup> 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, notepads, 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:

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<sup>3</sup> In this Policy, the term "industry representatives" means all sales, marketing, or other personnel who promote industry products.

- 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.
- 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.
- b. Consulting engagements involving compensation without commensurate time and effort are considered personal gifts and are prohibited under this Policy.
- c. Consulting may include working directly with a company to train other physicians in new surgical techniques involving novel devices, or in use of other medical devices (e.g., imaging equipment). In such settings industry-provided educational materials may be appropriate, the audience should be comprised of physicians who have already purchased the equipment in question, and no CME credits should be attached.

## **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.
- c. For the purpose of this Policy, in-service training and interactions with industry to evaluate devices or equipment are not considered “Industry sponsored 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**

- a. **Speaker Bureaus:**
  - i. Clinical Personnel may not give lectures for industry-sponsored “speaker bureaus” which involve contractual relationships to give talks in which the topic(s) are determined and/or the content is provided by the industry sponsor.
  - ii. Clinical Personnel are strongly discouraged from attending speaker bureau events. If they attend, they must pay for their own food and drinks.
- b. **Clinical Personnel Participation in Educational Programs (Organizer, Author, Speaker)** Clinical Personnel may actively participate (e.g., by giving a lecture, organizing the meeting) in industry-sponsored educational meetings, training programs 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 participating Clinical Personnel must have full control and authority over the meeting or lecture’s topic and content. Slides and written materials, must be determined solely by the participating Clinical Personnel with no influence from or requirement for prior approval by 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. The engagement must be governed by a written agreement or memorandum specifying the service(s) to be provided. The written agreement or memorandum may not include a clause that allows the sponsor to dictate what the Clinical Personnel says. Compensation must be limited to reimbursement of reasonable and necessary travel expenses as described in Section XI of this Policy, and an appropriate honorarium;
  - vii. 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
  - viii. 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.
- c. **Clinical Personnel Attendance in Educational Programs** Clinical Personnel may attend 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, food or other compensation for attendance.

- iv. Clinical Personnel should not attend or participate in industry-sponsored 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;
  - ii. 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 (view the Policy at <https://your.yale.edu/policies-procedures/other/yale-university-policy-conflictinterest>).
- 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 YM Senior Director of Compliance and the Deputy Dean of Clinical Affairs or their designee. . If based on your disclosure it is determined that your financial interests are relevant and require disclosure to patients, you will receive detailed instructions from the YM Senior Director of Compliance.
- 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.

- g. ***Open Payments***: Clinical Personnel should be aware of CMS Open Payments which is a national disclosure program created to promote transparency of payments made to providers by certain entities such as drug and medical devices companies. Clinical Personnel are encouraged to use the publicly available Open Payments Search Tool to see all payments made to them by such companies. The tool can be accessed at <https://openpaymentsdata.cms.gov/search>.

## **XV. Enforcement**

- a. Suspected violations of this Policy shall be referred to the Yale Medicine Compliance Department for review. Depending on the nature of the alleged violation, the Yale Medicine Compliance Department 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.