

November 24, 2014

COLUMBIA UNIVERSITY POLICY ON INSTITUTIONAL CONFLICT OF INTEREST IN RESEARCH

A. INTRODUCTION

An institutional conflict of interest in research ("Institutional COI") describes a situation in which the financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, may unduly affect or appear to affect the conduct of research or other related activities of the institution. Institutional COIs are of concern when institutional financial interests create the potential for inappropriate influence over the institution's activities. This Policy is intended to protect against risks to research integrity, research participants and the academic mission that may result from Institutional COIs in research.

An institution like Columbia University ("the University"), including its officials, must balance many competing pressures. It engages in relationships with a variety of external entities and individuals that may lead to financial benefit for the institution in many forms, including gifts, business ventures, royalty payments and equity from licensing intellectual property, as well as sponsored educational and research agreements. In addition, university-industry relationships are essential for advancing scientific frontiers and enabling the commercial development of academic discoveries for the benefit of the public. Nonetheless, relationships with external entities or individuals cannot be allowed to compromise, or appear to compromise, the integrity of the University's research and the safety of research participants.

This is a University-wide Policy that applies to all Research conducted at the University and all University Covered Officials, as defined below. Definitions of key terms are provided in Section B below. This Policy does not address the potential conflicts of interest of individual researchers, which are addressed through a separate University policy entitled the Policy on [Individual] Financial Conflicts of Interest and Research.

B. DEFINITIONS

1. **Institutional Conflict of Interest in Research**: An Institutional COI in Research may occur whenever the significant financial interests of the institution, or of an institutional official who has authority to act on behalf of the institution ("Covered Official"), might affect - or reasonably appear to affect - institutional processes for the design, conduct, reporting, review, or oversight of research.
2. **Business**: (a) any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, limited liability company, trust or other for-profit commercial entity; and (b) any not-for-profit entity acting, directly or indirectly, as an agent for, or on behalf of, a commercial entity, or controlled by a commercial entity, i.e., where a commercial entity owns or funds 50% or more of the not-for-profit entity or otherwise controls the not-for-profit entity's activities.

3. **Covered Officials**: The President, Executive Vice Presidents, the Provost and vice-provosts, vice presidents, other senior officers, deans and vice-deans, associate deans and other institutional administrators who have responsibility for oversight of research. Covered Officials also include department chairs, division chiefs, institute and center directors, and chairs and members of research regulatory review committees (“Regulatory Review Committees”) such as the Institutional Review Board, the Conflict of Interest Committee, the Institutional Animal Care and Use Committee, the Institutional Biosafety Committee, the Stem Cell Review Committee, and other similar committees.¹
4. **Oversight of Research**: Responsibility for approval of research proposals, research regulatory approvals, and/or the supervision of faculty and staff participating in research conducted at or under the auspices of the University.
5. **Research**: any systematic investigation designed to develop or contribute to generalizable knowledge, including all basic, applied and demonstration research in all fields of knowledge, sponsored by the University. Research sponsored by the University includes any research: (a) conducted pursuant to an agreement between the University and a third party; (b) supported by funding that is administered through the University (e.g., through the Office of Sponsored Projects Administration (“SPA”), Columbia Technology Ventures (“CTV”), the Clinical Trials Office, University Development and Alumni Relations, or through an individual school, center, institute or department); or (c) requiring review by a Columbia regulatory body (e.g., the Institutional Review Board).

“Research” as defined here excludes unfunded research conducted as part of an individual’s employment at Columbia and not requiring review by a Columbia regulatory body.
6. **Significant Financial Interest (Covered Official)**: A financial interest that relates to Research subject to the Covered Official’s Oversight, as specified below:
 - A. *Royalty payments*, including those received under a University agreement, that in the aggregate have exceeded \$25,000 over the past 12 months, or that are expected to exceed \$25,000 over the next 12 months, and that are from the licensing or sales of a product or service that is the subject of the Research²;
 - B. An ownership interest or entitlement to equity (including options or warrants) in a *publicly held Business* that represents ownership in excess of 5%, or has a value that exceeds \$100,000, where such Business is the sponsor of Research, manufactures or distributes products that are the subject of such Research, or holds the Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) for such products. This does not include diversified financial holdings that are not controlled, influenced or managed by the Covered Official (e.g., mutual funds).

¹ The Trustees of Columbia University are subject to a separate policy on conflict of interest, and therefore are not included as “Covered Officials” in this Policy.

² *Royalty Payments* do not include royalties or other income received from an independent publishing Business arising out of authoring, editing or reviewing publications (print or electronic).

- C. Any ownership interest or entitlement to equity (including options or warrants) in a *privately held Business*, where such Business is the sponsor of Research, manufactures or distributes products that are the subject of such Research, holds the IND or IDE for such products, or holds a license or other contractual interest in the technology that is the subject of such Research;
 - D. Compensation from a Business for consulting, service on an advisory board, or for any other reason, that in the aggregate has exceeded \$25,000 over the past 12 months, or that is expected to exceed \$25,000 over the next 12 months, where the Business is the sponsor of Research, manufactures or distributes products that are the subject of such Research, holds the IND or IDE for such products, or holds a license or other contractual interest in the technology that is the subject of such Research; and
 - E. Service as an officer, manager, member of the board of directors, or in any other *fiduciary or managerial role* for a Business, whether or not remunerated, where the Business is the sponsor of Research, manufactures or distributes products that are the subject of such Research, or holds the IND or IDE for such products.
7. **Significant Financial Interest (Institutional)**: A financial interest related to Research that meets any of the following criteria:
- A. *Royalty Payments*: Royalties, milestone payments, license fees, or other payments associated with intellectual property in excess of \$100,000 over the past 12 months or anticipated to exceed \$100,000 over the next 12 months that are from the licensing or sales of a product or service that is the subject of the Research.
 - B. *Publicly traded equity*: Ownership interest or an entitlement to equity (including options or warrants) exceeding \$100,000 in value, in a *publicly-traded Business*, obtained through the University's technology licensing activities or investments related to such activities. Publicly traded equity held by the Columbia University Investment Management Company (IMC) is not a Significant Financial Interest in light of the structural separation between the IMC and research administration at the University.
 - C. *Non-publicly traded equity*: Ownership interest or an entitlement to equity (including options or warrants) in a *non-publicly traded Business*, obtained through the University's technology licensing activities or investments related to such activities. Non-publicly traded equity held by the IMC is not a Significant Financial Interest in light of the structural separation between the IMC and research administration at the University.
 - D. *Gifts from corporate sponsors*: When the institution has received or expects to receive a gift (including a gift in kind) valued in excess of \$500,000 from a Business that owns or controls products being studied or tested in Research. The following circumstances should be evaluated³:

³ Although the enumerated circumstances 1-3 are potential areas of concern, the goal of this policy is not to preclude the University from accepting philanthropy from companies that sponsor research, or that own or control products that are being studied or tested. Rather, the policy is intended to require the institution to develop means of identifying and examining such circumstances, and of managing, through disclosure, separation of responsibilities,

November 24, 2014

1. Whether a gift is of sufficient magnitude that even when held in the general endowment for the benefit of the entire institution, it might affect, or reasonably appear to affect, oversight of research at the institution;
2. Whether a gift is held for the express benefit of the college, school, department, institute or other unit where the research is to be conducted; or
3. Whether any institutional official who has the authority, by virtue of his or her position, to affect or appear to affect the conduct, review or oversight of the proposed research has been involved in solicitation of the gift.

C. IDENTIFICATION OF POTENTIAL INSTITUTIONAL CONFLICTS OF INTEREST

1. **Covered Official Significant Financial Interests (SFIs):** Covered Officials are expected to self-disclose when they have a Significant Financial Interest that relates to Research subject to the Covered Official's Oversight. The University has or will develop a number of mechanisms through which such disclosures may be made, at the time of sign-off on research proposals and/or other relevant times. Special procedures may apply to senior officers of the University, such as the President, Provost, Executive Vice Presidents, and Deans, who currently must complete an additional annual disclosure form.
2. **Institutional SFIs:** Institutional SFIs that relate to Research may be identified through intake forms submitted by relevant administrative offices, e.g., Columbia TechVentures and Office of Alumni and Development, as cross-referenced against information routinely collected through research administration processes and University databases.

D. ESTABLISHMENT OF AN INSTITUTIONAL CONFLICT OF INTEREST COMMITTEE ("ICOI COMMITTEE")

A Committee shall be established by the University to review and manage potential Institutional COIs. The ICOI Committee shall include senior officers of the University, including at least one senior representative from a number of schools, including at least one representative from Columbia University Medical Center, one from Arts & Sciences, and one from the School of Engineering and Applied Sciences. The Committee will be staffed by the Office of Research Compliance and Training. Non-voting participants shall include representatives from the Office of the General Counsel; the University's technology transfer office, Columbia TechVentures; Alumni and Development; and other research administration offices as appropriate.

and as otherwise appropriate, any actual or apparent conflicts of interest that may result. All gifts should be accepted in conformance with these policies and accepted by the Office of Alumni Relations and Development for record-keeping purposes. All faculty and staff members are accountable for adhering to the University's gift policies.

E. ICOI COMMITTEE REVIEW

Institutional and Covered Official SFIs must be reviewed by the ICOI Committee for potential ICOI, with the exception of those SFIs set forth in Section F below. The ICOI Committee review must assess the potential risks to research integrity and human subjects presented by an institutional SFI to determine whether the SFI constitutes an ICOI. In keeping with recommendations by leading university associations, including the American Association of Universities and the American Association of Medical Colleges⁴, this Policy adopts a rebuttable presumption against the conduct of Research in the presence of an institutional conflict of interest. The presumption may be rebutted by a reasonable determination that the risks may be mitigated through appropriate management or elimination of the ICOI, as follows:

1. Where the University itself holds the SFI, the ICOI Committee may determine that one or more of the following actions is appropriate:
 - a. Divestment of the SFI, if feasible;
 - b. Disclosure of the ICOI in informed consent processes;
 - c. Use of an external IRB;
 - d. Independent monitoring of the study, particularly endpoint assessments;
 - e. Use of an external Data Safety Monitoring Board (“DSMB”) or similar review board to evaluate the design, analytical protocols, and primary and secondary endpoint assessments, and to provide ongoing evaluation of the study for safety, performance issues and the reporting of results;
 - f. Disclosure of the ICOI in public presentations and publications, and to all individuals, including (but not limited to) graduate students and other trainees, engaged in the design, conduct or reporting of the research;
 - g. Disclosure of the ICOI to other centers in a multi-center trial;
 - h. Disclosure to the sponsors of the research as required by the sponsor and all applicable regulations and laws;
 - i. Such other actions that the Committee deems to be appropriate, consistent with the principles articulated in this Policy.

2. Where a Covered Official holds the SFI, the ICOI Committee may determine that one or more of the following actions is appropriate:
 - a. designation of a “safe haven” (e.g. a non-conflicted senior individual) with whom the investigator can address ICOI-related concerns;
 - b. Modification of the role of a conflicted Covered Official, to minimize involvement with the Research at issue;
 - c. Such other actions that the Committee deems to be appropriate and consistent with the principles articulated in this Policy, including but not limited to any actions identified in paragraph E.1.

⁴ Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research: A Report of the AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research (2008) at 15. The Report also notes: “Although this report focuses on those conflicts that arise in the context of human subjects research ... institutions should strongly consider making the principles and processes recommended in this report applicable to all research. Protection of integrity and public trust are indeed values that underpin all academic research, irrespective of whether the particular challenges associated with human subjects research are present.” (*Id.* at 4)

November 24, 2014

Any management plan for a project involving human subjects research must explicitly address how any risks to human subjects are being mitigated.

The ICOI Committee and the University should make every attempt to resolve institutional conflicts in a manner that enables research to proceed at the University. However, if the ICOI Committee finds that an ICOI cannot be managed, and divestment is not feasible, then the affected research should not proceed at the University.

The ICOI Committee may develop precedents and standard operating procedures for handling particular COI issues, and may expedite review for subsequent cases involving those issues. The ICOI Committee will document its findings and the basis for its decision with respect to any research. If such research involve human subjects, such documentation will be made available to the IRB. The IRB may impose more, but not less, stringent requirements than the ICOI Committee.

F. SPECIAL REQUIREMENTS: REGULATORY REVIEW COMMITTEES

Where the Covered Official is the chair or a member of a Regulatory Review Committee *and* the Covered Official holds an SFI that relates to Research subject to review by the Covered Official's Committee, the Covered Official must recuse him or herself from any deliberations or review of the related Research. No ICOI Committee review is required in such cases.

G. ENFORCEMENT

Violations of the requirements of this Policy by any employee or officer shall, if not resolved, subject the employee to review and, where appropriate, corrective action and/or sanctions permitted by University policy, including (for those covered by its terms) the University Code of Academic Freedom and Tenure.

H. POLICY REVIEW

The President of the University may, in consultation with the Executive Vice President for Research, require reviews of this Policy and its implementation.,