

APPENDIX O: FINANCIAL CONFLICT OF INTEREST POLICY

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Financial Conflict of Interest Policy – Duke University

1. *Introduction*

Duke University (Duke) is committed to ensuring that members of the Duke faculty and staff are provided an open and productive environment in which to conduct teaching, patient care, and research, and carry out administrative responsibilities. The concern with conflict of interest (COI) reflects the complexity of our society, relations with each other and outside institutions, legal obligations and developments, and the significance of the issue to the public.

Conflict of interest, which arises when a secondary objective could affect the performance of a person's primary mission, is a normal part of human existence. The potential for financial gain is one of many potential incentives that can lead to bias in a subjective activity, often subtle and unrecognized by the affected individual. Duke is committed to advancing knowledge, including accelerating the translation of novel research ideas into practice. The application of knowledge, its dissemination and utilization, involves engagement with outside institutions and persons. Thus, Duke must have policies that both encourage interaction with outside institutions and persons, and at the same time define ground rules so individuals have clear boundaries within which to operate. There should be a balance between engagement with outside entities that may have economic incentives, and the academic and professional expectations of faculty and staff at Duke, so that research, education, clinical care, and administrative responsibilities are performed in a manner that maintains the utmost in integrity and objectivity, with the public's interest and the protection of patients and human research volunteers always being the highest priority.

This policy is intended to be consistent with federal and state law. Where there is a discrepancy, the applicable federal or state law or rule of the funding agency will take precedence, unless the law or rule is less restrictive than Duke's more stringent standard.

Conflict of commitment, nepotism, and institutional conflict of interest are addressed in other policies and procedures.

2. *Definitions*

Financial Conflict of Interest: A financial interest that could directly and significantly affect the design, conduct or reporting of funded research, or the performance of duties and responsibilities on behalf of Duke. A financial COI can exist in a variety of situations, including the following examples:

- (i) **Clinical Care:** A financial interest that could directly and significantly affect decision-making in regard to clinical care, particularly with regard to the selection of medication or a device. Most typically, this financial interest will be the receipt of an honorarium

(for speaking or consulting) or a royalty arrangement related to intellectual property. For the purpose of this policy, issues regarding fee-for-service medicine will not be included.

- (ii) **Education:** A financial interest that could directly and significantly affect a mentoring relationship or educational presentations. Examples of such presentations are lectures, web-based teaching, and review articles.
- (iii) **Purchasing:** A financial interest that could directly and significantly affect a purchasing decision. Examples of such decisions are purchases of equipment, supplies, and services.
- (iv) **Research:** A financial interest that could directly and significantly affect the design, conduct, or reporting of research. Financial COI is present in a situation in which a primary interest or responsibility is affected, perhaps unduly, by a secondary interest or responsibility. This means that a subjective component of a primary interest (e.g. research) is affected, or potentially affected, by a financial secondary interest, either ongoing (e.g. consulting) or where there is the potential for increased valuation (of stock or an option). Financial COI is present when the outcome of the research could affect future income or the value of an asset (including an option for equity).

Individual: Any person who is independently responsible for making decisions regarding research, education, purchasing, clinical care, or administrative responsibilities. For any one individual, the policy includes a financial interest of any immediate family member (spouse or spousal equivalent, and dependent children) as if any financial interest of that family member were one of the individual.

Research: A project intended to develop new and generalizable knowledge or to be presented in support of regulatory applications.

Financial Interest: Anything of monetary value or potential monetary value that reasonably appears to be related to the individual's duties and responsibilities, including, but not limited to:

- Payment for service (e.g., a consulting fee, lecture payment, or honorarium), except as otherwise excluded by this policy;
- A gift (e.g., money, hospitality, or a physical item);
- An equity interest (e.g., stock, stock option, security, or other ownership interest);
- An intellectual property right (e.g., a patent, copyright, or royalty from such right); and
- Other interests as determined by Duke. For example, a financial interest may only have potential to be of value, like an option in a non-publicly traded company. Because this potential value may be an economic incentive, a situation like this is considered a financial interest.

The term does *not* include:

- Ownership of a share in a mutual fund;
- Salary or other remuneration from Duke or another accredited institution of higher education;
- Salary or other remuneration from the U.S. Department of Veterans Affairs or another federal, state, or local government entity; and
- A distribution from Private Diagnostic Clinic, PLLC.

3. ***Governing Principles***

Statement of Policy

It is the policy of Duke that an individual has an obligation to avoid any financial COI for which an approved management plan cannot or has not been developed and approved, through the appropriate COI committee, and implemented by the individual and all involved parties.

Identification of Potential Conflicts of Interest

An individual will be required to report to Duke her/his financial interests on an annual basis and at the time of a reportable change. The information reported may be compared to information provided by companies or the government. Duke reserves the right to request additional information, as deemed necessary.

Establishment of Conflict of Interest Committees

A conflict of interest committee will be appointed for each of the School of Medicine, the Campus, and Duke administrators. In addition to the other powers listed in this policy, these committees are advisory and report to the Dean of the School of Medicine, the Provost, and the President, respectively. These senior officials are also responsible for formally naming members of the three committees, with the approval of appropriate faculty committees.

Procedures for Conflict of Interest Operations

Implementation procedures for this policy and the relevant COI committees will be determined by each committee, with the approval of the appropriate senior official or her/his designee. Financial thresholds for relationships requiring management will be included in the operating procedures for each COI committee.

Management of Potential Conflicts of Interest

When a potential financial COI exists, the applicable conflict of interest committee will take appropriate action, which may include the elimination of the financial conflict of interest, approval of a management plan, or adoption of an alternative course of action.

This Financial Conflict of Interest Policy replaces the following:

Faculty Conflict of Interest Policy (approved by the Board of Trustees in February 1992)

Conflict of Interest and Commitment Policy for Officers and Employees with Administrative Responsibilities (approved by the Board of Trustees in 2007)

Duke University Conflict of Interest Disclosure Form

Annually, faculty members and certain staff members are required to submit a conflict of interest disclosure form electronically. The link below will provide access to submit the form or update your current year form when a change of status has occurred.

Please follow this link to access your disclosure form: https://radapps.duke.edu/coi_form

Login using your NetID and NetID password. *If you are unsure of your NetID or NetID password, contact the DHTS Help Desk at (919) 684-2243 or the OIT Help Desk at (919) 684-2200.* For other technical assistance, please use the following information: <http://rad.duke.edu/support/coi-assistance>

Institutional Conflict of Interest in Research Policy – Duke University

1. Introduction

An institutional conflict of interest ("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 affect or appear to affect the research, education, clinical care, business transactions, or other activities of the institution. Institutional COIs are of significant concern when financial interests create the potential for inappropriate influence over the institution's activities. This policy is intended to protect against exposure from risks related to Institutional COIs as they may affect research performed at or under the auspices of the University.

An institution like Duke University ("Duke"), including its officials, must balance many competing pressures. It engages in relationships with a variety of sponsors 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 to the benefit of the public. Nonetheless, while generally part of legitimate educational, research, and business activities, relationships with external entities or individuals cannot be allowed to compromise, or appear to compromise, the integrity of the Duke's primary missions, including the safety and integrity of its research, education, and clinical care.

2. Definitions

Institutional Conflict of Interest in Research: An Institutional COI in Research may occur whenever the financial interests of the institution, or of an institutional official who has authority to act on behalf of the institution, might affect—or reasonably appear to affect—institutional processes for the design, conduct, reporting, review, or oversight of research.

Covered Officials: This Institutional COI in Research Policy applies to the Board of Trustees, President, Chancellor for Health Affairs and Vice Chancellors, the Provost and vice-provosts, other senior officers, Deans and vice-deans, associate deans and other institutional administrators, particularly insofar as the individuals have oversight of research, with special attention to human subjects research, at the University. This policy will also require review of conflicts of interest involving department chairs, division chiefs, institute and center directors, Institutional Review Board chairs, the COI and Institutional COI committee chairs, the chair of the Institutional Biosafety Committee, the chair of the Stem Cell Review Committee, and chairs of other similar committees that might be created in the future.

Officials with Oversight of Research: Covered officials with responsibility for the supervision of faculty and staff participating in research conducted at or under the auspices of the institution. Of particular importance in defining an "official with oversight of research" are supervisory roles like evaluation and management of promotion, pay raises, and the assignment of job responsibilities.

Significant Financial Interest (individual): For covered officials, "significant financial interest" is defined as being consistent with Duke University's faculty conflict of interest policy and procedures. Areas of consideration include: payments, honoraria, royalties (even through the institution), equity, options and warrants, board of directors and management positions, and gifts.

Significant Financial Interest (institutional):

- A. Royalties: Institutional COI may be present when the institution has agreements to receive milestone payments and/or royalties from the sales of an investigational product that is the subject of the research;
- B. Non-publicly traded equity: When, through its technology licensing activities or investments related to such activities, the institution has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a non-publicly traded company that is: i) the sponsor of research at the institution, or ii) the manufacturer of a product to be studied or tested at or under the auspices of the institution;

- C. Publicly traded equity: When, through technology licensing activities or investments related to such activities, the institution has obtained an ownership interest or an entitlement to equity (including options or warrants) exceeding \$100,000 in value (when valued in reference to current public prices, or, where applicable, using accepted valuation methods), in a publicly-traded company that is i) the sponsor of research at the institution, or ii) the manufacturer of a product to be studied or tested at or under the auspices of the institution.
- D. Gifts from sponsors: When the institution has received substantial gifts (including gifts in kind) from a potential commercial sponsor of research or a company that owns or controls products being studied or tested, or an individual affiliated with these companies. The following circumstances should be evaluated:
 - 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.

3. *Identification of Potential Institutional Conflicts of Interest*

The following significant financial and fiduciary interests of the institution warrant formal review for potential Institutional COI with respect to research:

Significant financial interests for the institution.

Significant financial interests on the part of covered officials responsible for the oversight of research.

Situations when an investigator, research administrator, or Duke institutional official with research oversight authority participates materially in a procurement or purchasing decision involving major institutional purchases from, or non-routine supply contracts with, a company that sponsors research at the institution, or whose product is being studied or tested in human subjects research at the institution.

In addition to those circumstances indicated above, other financial relationships with research sponsors may warrant formal scrutiny, depending on the circumstances. In general, the institution should assess the potential for conflict of interest and weigh the magnitude of any risk to the research's integrity.

Although the listed circumstances are potential areas of concern, the goal of this policy is not to preclude Duke 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, and as otherwise appropriate, mitigate any actual or apparent conflicts of interest that may result. All gifts should be accepted in conformance with these policies and accepted by the development office for record-keeping purposes. All faculty and staff members are accountable for adhering to the institutional gift policy.

4. *Establishment of an Institutional Conflict of Interest Committee*

In order to review and manage Institutional COIs, a committee will be established that includes members who are not employed by Duke as well as senior Duke employees. A member of the General Counsel's Office will be a non-voting participant. The Committee will be advisory to the University Board of Trustees, which holds final authority regarding questions of Institutional COIs.

5. *Management of Potential Institutional Conflicts of Interest*

The reasons to manage Institutional COIs include: 1) To maintain the highest possible standards in research; 2) To adhere to all applicable federal and state regulations; 3) To maintain the primacy of the university's educational mission; 4) To protect the reputation and credibility of the University, its faculty and staff. Based on those needs, the following basic principles will be applied in the management of potential Institutional COI:

- A. When Duke itself has a significant financial interest:
 - a. Human Subjects Research: There is a “rebuttable presumption” that human subjects research should not be carried out at Duke when the institution has a significant financial COI. In those situations where Duke faculty have unique capabilities, or where there are unique resources at the institution, the research may be performed at Duke after the establishment of a formal institutional management plan. This plan will include establishment of an oversight board for the project made up of non-Duke individuals. Other management steps may be required (e.g. use of a non-Duke IRB, external monitoring, etc).
 - b. Non-Human Subjects Research: Because research subject safety is not an issue in the case of non-human subjects research, the primary reasons to manage Institutional COI focus on protection of the integrity of the University’s research and educational missions. If a decision is made by the Institutional Conflict of Interest Committee that the potential value of a line of research exceeds the potential risks related to Institutional COI, management will usually include some form of oversight external provided from outside Duke. The level of oversight should be proportional to the risk to the institution’s reputation and/or educational mission.
- B. When an individual in a supervisory administrative role has a conflict of interest:
 - a. Human Subjects Research: In this situation, there is not the same “rebuttable presumption” made that the work cannot be performed, since in most cases alternative supervision can be arranged. The Institutional Conflict of Interest Committee should review the administrator’s role in relation to the research and to the researchers, the nature of the administrator’s conflict of interest, and should then formulate a plan so that an appropriately objective administrator can oversee the research for the institution.
 - b. Non-Human Subjects Research: In most cases for this circumstance, an alternative administrator should be identified, and the conflicted administrator should voluntarily recuse themselves. The situation should be reviewed by the Institutional Conflict of Interest Committee to be certain no bias will introduced that could affect the research, the researchers, or any students working on the research project. If there is potential for bias or pressures, particularly in the case of a student, alternative supervision should be arranged by the Committee.

Institutional Conflict of Interest in Research Implementation – Duke University

1. Introduction

An institutional conflict of interest ("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 affect or appear to affect the research, education, clinical care, business transactions, or other activities of the institution. Institutional COIs are of significant concern when financial interests create the potential for inappropriate influence over the institution's activities. This implementation document is based on the University's Institutional Conflict of Interest Policy in order to protect against exposure from risks related to Institutional COIs as they may affect research performed at or under the auspices of the University.

2. Conflict of Interest Office

The University will maintain one or more offices to manage day-to-day operations regarding conflict of interest. One office, selected by the President, will manage processes regarding institutional COI. This office will perform an administrative review of potential institutional COIs and will prepare a draft management plan in collaboration with the Institutional COI Committee Chair (or his/her designee). The office will also prepare summary reports for use by the Institutional COI Committee. Regular reports will be made no less than annually to the President and Board of Trustees.

3. Institutional Conflict of Interest Committee

In order to review and manage Institutional COIs, a seven member committee will be established that includes at least two members who are not employed by Duke ("external members"), who should also not be members of the Board of Trustees. A member of the General Counsel's Office will be a non-voting participant. The chairs of the Campus, Administrative, and School of Medicine Conflict of Interest Committees will be voting members. The other two members will be tenured faculty, one from the School of Medicine, one from the University but not the School of Medicine. The President of the University will designate the committee chair, who will be a voting member of the Committee. The committee chair is selected between the chairs of the Campus and School of Medicine Conflict of Interest Committees. Members (other than ex-officio) will serve renewable three year terms. Members may serve past their term until new members are appointed. The Committee will be advisory to the University Board of Trustees, which holds final authority regarding questions of Institutional COIs. The quorum for voting shall be: At least one external member and at least four employee members **OR** two external members, and at least three employee members. Decisions of the Committee shall be by majority vote of members present. Appointments to the committee will be made by the University President or his/her designee, in consultation with the Executive Committee of the Academic Council (ECAC), and with approval of nominees by the Executive Committee of the Board of Trustees. The primary reporting line of authority for the Institutional COI Committee will be through the Executive Committee of the Board.

4. Management of Reporting of Potential Institutional Conflicts of Interest

There are two broad categories of Institutional COI in Research: Conflicts that affect the institution directly and those that relate to institutional officials who have oversight responsibilities.

Ascertainment of Direct Institutional COIs:

Gifts: All gifts to Duke University must be processed through one of the institutional development offices. When a gift of \$10,000 or more comes from a sponsor of research, the Conflict of Interest Office should be notified by the development office. A list of all gifts will be produced by the development office and distributed to the COI Office on a regular basis. The list of research sponsors will be maintained by the COI Office, drawing from the SPS database. All donations over \$100,000 should also be reported to the COI Office as early in the development phase as possible but no later than upon receipt. [Gift amounts are the results of totals for each calendar year.]

Licensing agreements: Licensing agreements are executed by the Duke Office of Licensing and Ventures. OLV will provide a report at least quarterly of new and existing agreements (including equity holdings, royalty payments, other payments, and their stipulations) to the Conflict of Interest Office.

Equity holdings: The University receives equity holdings from time to time as consideration in licensing agreements. In some cases, the results from a single study can significantly change the value of the equity. For this reason, the potential for an Institutional COI is often inherent in these situations. This potential COI is managed by a process in which researchers and administrators who oversee research are removed from any management or administrative decisions regarding equity. To manage and administer these equity holdings and manage potential institutional conflicts of interest regarding private equity secured through licensing agreements, DUMAC, Inc. (Duke's investment management firm) will maintain a relationship with a third party custodian manager whereby the University is blinded to the holding or selling of the equity. Any communication with the management firm will be filtered through the Office of Internal Audit.

Ascertainment of Institutional COIs involving Institutional Officials:

Covered Officials: The Institutional COI in Research Policy applies to the Board of Trustees, President, Chancellor for Health Affairs and Vice Chancellors, the Provost and vice-provosts, other senior officers, Deans and vice-deans, associate deans and other institutional administrators, particularly insofar as the individuals have oversight of research at the University. This policy will also require review of conflicts in interest involving department chairs, division chiefs, institute and center directors, Institutional Review Board chairs, the COI and Institutional COI committee chairs, the chair of the Institutional Biosafety Committee, the chair of the Stem Cell Review Committee, and chairs of other similar committees that might be created in the future. The list defining covered officials should be reviewed on an annual basis by the Institutional COI Committee.

Reporting: For institutional officials, review will begin with the annual individual COI reporting form. For individuals who have oversight responsibilities, their declared external relationships will be compared with the list of sponsors of research. If there is overlap between their external relationships and their supervisory/oversight roles, the situation will be reviewed by the Institutional COI Committee.

5. Management of Rules Related to Institutional Conflict of Interest

This implementation document is maintained under the authority of the University Board of Trustees. Changes in the document can be made by majority vote of the Institutional Conflict of Interest Committee members present, while the University Board of Trustees retains the rights of review and approval.

6. Management of Gifts with Potential Institutional COI

Once a significant gift to the institution has been identified that might have, or be perceived to have, an overlap with research being performed by faculty or staff at Duke, a review of the situation should be performed. Considerations should include:

- a) Does the gift potentially affect the investigator's work inappropriately? For example, a gift to the Divinity School by a corporate sponsor would be unlikely to affect research taking place in the School of Medicine, while a major gift designated for an investigator's home department might.
- b) Are the sponsor and recipient of the gift aware that no *quid pro quo* is allowed? A gift cannot be substituted for a sponsored research agreement, particularly as a means to circumvent indirect cost expectations. If a gift is designated for a specific lab or investigator, both should be notified that communication of research results can only occur through public forums like publications or presentation at an open public meeting. In addition, the gift should be acknowledged in all publications, presentations, and grant applications where products from the donor are included or affected.
- c) If the gift might be perceived to influence the design, conduct, or reporting of the research, consideration should be given as to whether it should be accepted. If the research involves human subjects, a particularly high standard should be set before the gift can be accepted.

- d) If it is determined that the gift has potential for institutional COI, but can be accepted, the following considerations should be reviewed by the Institutional COI Committee:
 - (1) Should the presence of the gift be noted in publications, press releases, presentations, and grant applications from Duke? If so, how will the appropriate parties be notified of this expectation?
 - (2) Does the gift create a situation where recusal from decision making by an institutional official should be expected?
 - (3) Does the gift overlap with human subjects research being performed at Duke? If so, refer to Section 8.

7. Management of Individuals with Institutional Conflicts of Interest

When an institutional official has a personal COI in a domain that overlaps with research being performed under their supervision or authority, the situation should be reviewed for institutional COI considerations. Examples of concern would be a department chairperson who has a financial relationship with an external entity and whose department performs research in a scientific domain served by that company. Faculty working in the department might thus be biased to favor that company's products in their research in order to curry the chair's favor in promotion and allocation of resources (e.g. laboratory space or discretionary funds).

- a. Management plans should address:
 - (1) The extent of recusal expected of the individual with COI;
 - (2) The mechanism for making the relevant faculty and staff aware of the institutional COI (for example, posting on a web site or a notice by e-mail to affected parties);
 - (3) Notification of the Pre-Award Office (for grants), public relations office, and (if appropriate) the institutional review board (IRB);
 - (4) The provision of an institutional "safe haven" for affected faculty and staff to discuss their concerns related to the COI; and
 - (5) Whether the overlapping relationship is an appropriate one for an individual in that particular organizational position.
- b. Faculty and staff who have fiduciary responsibility to a non-Duke entity that overlaps with their professional responsibilities at Duke should receive the permission of the University President (or their designee) before agreeing to serve, and should have a formal management plan approved by the Institutional COI Committee.

8. Procedures Regarding Institutional Conflicts and Human Subjects Research

When the University has an institutional conflict of interest, particularly licensed intellectual property or significant equity holdings, the default position on research that is greater than minimal risk is that it should be done at some other institution. If there are compelling circumstances that justifies the work being done at Duke (for example, a unique patient population, a piece of equipment that would be hard to duplicate, or a particular technical or professional skill on the part of an investigator), arrangements can be considered. In a situation with compelling circumstances, the resulting management plan should generally include the following strategies:

- a. Disclosure of the institutional COI in the informed consent document.
- b. Use of an external Institutional Review Board (IRB), with notification of the local IRB. In cases where the research is being done at multiple institutions, the IRB at one of the other study sites could serve as the primary IRB. The Duke IRB can perform a secondary review for consistency with internal Duke policies.
- c. External monitoring of the study, particularly endpoint assessments.
- d. Use of an external Data Safety Monitoring Board plus (DSMB-Plus) or similar review committee to perform the normal duties of a data safety monitoring board, but also to consider COI issues. The DSMB-Plus should evaluate the design, analytical protocols, primary and secondary endpoint assessments, and provide ongoing evaluation of the study for safety, performance issues and the unbiased reporting of results.
- e. Disclosure of the institutional COI in public presentations and publications.
- f. Disclosure of the institutional COI to other centers in a multi-center trial.