

# **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.

## ***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, as well as senior Duke employees (tenured faculty or senior administrators). 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. The President of the University will designate the committee chair, who will be a voting member of the Committee. Members will serve renewable three year terms. The Board will be advisory to the University Board of Trustees, which holds final authority regarding questions of Institutional COIs. The quorum for voting shall be: 1) At least one external member, and 2) at least 4 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 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. In addition, all gifts, regardless of amount, that are donated with stipulations regarding a category of research, or in support or recognition of a specific investigator, should be reported to the COI Office. 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. [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's 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. The management and administration of these equity holdings is the responsibility of a Licensing Investment Committee appointed by the President, with the input of the Chancellor and the Provost. Decisions relating to the management and administration of these investments are made by the Committee without communication with or input from faculty or administrators who have any connection with the relevant research. Committee members who do have a connection with the relevant research must recuse themselves from attendance and voting on matters with which they have a personal conflict. DUMAC, LLC, the University's investment management company, is the custodian of all equity certificates but has no responsibility for the administration and management of these investments.

##### 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
  - 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.