Institutional Conflict of Interest in Research Implementation - Duke University

1. Introduction

An institutional conflict of interest (ICOI) describes a situation in which the financial interests of an institution or an employee of the institution, 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. ICOI is of significant concern when financial interests create the potential for inappropriate influence over the institution’s activities. This implementation document (the “Implementation”) is based on Duke University’s ICOI in Research Policy (the “Policy”) in order to protect against exposure from risks related to ICOI as they may affect research performed at or under the auspices of Duke University (“Duke”).

2. Institutional Conflict of Interest Office

Duke will maintain one or more offices to manage day-to-day operations regarding financial conflict of interest (COI). One office, selected by the President, will be responsible for the ICOI review and management process. This ICOI office will be responsible for coordinating and performing an administrative review of potential ICOI, and will prepare management plans as required in collaboration with the ICOI Committee chair (or his/her designee). The ICOI office will also prepare summary reports for use by the ICOI Committee. Reports will be made no less than annually to the President and the Executive Committee of the Duke Board of Trustees (“Trustees”).

3. Institutional Conflict of Interest Committee

In order to review and manage ICOI, an ICOI Committee (the “Committee”) will consist of at least seven but not more than nine members. All members of the Committee (including ex officio members) shall be voting members. Ex officio members of the Committee shall be the chairs of the Campus COI Committee, the School of Medicine COI Committee and the COI Oversight Committee. An attorney in the Office of Counsel will be a non-voting participant, and the chair of the ICOI Committee may invite other Duke employees to attend meetings and participate in non-voting capacities. A proxy vote may be allowed for members who cannot attend a meeting in the discretion of the Committee’s chair.

Additional members of the Committee will consist of:

(1) At least one member of the School of Medicine faculty and at least one member of the Duke faculty other than the School of Medicine; and

(2) At least two members who are not employed by Duke (“external members”) and who are not active Trustees of Duke.
The President of Duke, following consultation with the Executive Committee of the Academic Council, shall appoint Committee members (other than ex officio members) from a list of nominees submitted by the Committee to the President. The Committee will construct its list of nominees from recommendations submitted by an ad hoc nominating committee appointed by the Committee chair from Committee members and including both internal and external members.

The President of Duke will designate the Committee chair, who will be selected from the chairs of the Campus or School of Medicine Conflict of Interest Committees. Members (other than ex-officio members) will serve a three year term and may be re-appointed to successive three year terms. Members may serve past their term until new members are appointed. The Committee will be advisory to the Trustees, which hold final authority regarding questions of ICOI.

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.

The ICOI Committee will report directly to the Executive Committee of the Trustees, with copies to the President and the Provost.

4. Management of Reporting of Potential Institutional Conflicts of Interest

There are two broad categories of ICOI in research: Conflicts that affect Duke directly, and conflicts that relate to certain employees who have oversight responsibilities. Each category is discussed below.

(a) Conflicts that affect Duke directly:

(1) Gifts: All gifts to Duke must be processed through one of the institutional development offices. Gifts of $10,000 or more from a sponsor of research, will be reported to the ICOI Office quarterly.

(2) Licensing agreements: Licensing agreements are executed by the Duke Office of Licensing and Ventures (OLV). OLV will provide a report at least quarterly of exclusive license agreements to the ICOI Office.

(3) Equity holdings: Duke receives equity holdings from time to time as consideration in licensing agreements. OLV will provide a report at least quarterly of new and existing agreements in which Duke receives equity. In some cases, the results from a single study can significantly change the value of the equity. For this reason, the potential for an ICOI is often inherent in these situations. This potential ICOI is managed by a process in which researchers and administrators who oversee the research are removed from any management or administrative decisions regarding equity.
(b) Conflicts that relate to certain Duke employees who have oversight responsibilities:

(1) Covered Officials: For purposes of the Policy and this Implementation, a “Covered Official” is a member of the Trustees, the 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 institutional oversight of research at Duke. The Policy and this Implementation will also require review of potential conflicts involving department chairs, division chiefs, certain institute and center directors, Institutional Review Board (IRB) chairs, the COI and ICOI committee chairs, and other identified committee chairs as deemed appropriate by the ICOI Committee chair.

(2) Reporting: For Covered 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 ICOI Office and managed as appropriate.

5. Management of Rules Related to ICOI

This Implementation is maintained under the authority of the Trustees. Changes in the document can be made by majority vote (with at least one external member voting in favor) of the ICOI Committee members present, while the Trustees retain the rights of review and approval.

6. Management of Gifts with Potential ICOI

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

(a) Does the gift potentially or actually affect the faculty or staff’s objectivity (in perception or reality)?

(b) Is the 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.

(c) The gift report is reviewed for the potential to influence the design, conduct, or reporting of research.

(d) If it is determined that the gift has potential for ICOI, the following considerations should be reviewed for management plan requirements:

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(1) Disclosure in publications, press releases, presentations, IRB protocols, and grant applications from Duke;

(2) Recusal from decision making by a Covered Official;

(3) If overlap with human subject research being performed at Duke, refer to Section 8.

7. Management of Individuals with ICOI

ICOI is to be considered when a Covered Official has a personal COI in a domain that overlaps with research being performed under their supervision or authority.

(a) Management plans should address:

(1) The extent of recusal expected of the Covered Official with COI;

(2) Appropriate disclosure or communication with relevant faculty and staff;

(3) Notification of the IRB and others as appropriate;

(4) The provision of an institutional “safe haven” for affected faculty, staff, and students to discuss their concerns related to the COI; and

(5) Elimination or resolution of the conflict.

(b) Covered Officials who have fiduciary responsibility to a non-Duke entity that overlaps with their professional responsibilities at Duke are required to receive the permission of their Department Chair or Supervisor before agreeing to serve, and will be issued a formal management plan approved by the ICOI Committee.

8. Procedures Regarding Institutional Conflicts and Human Subjects Research

When Duke has a potential or actual ICOI relating to research that involves human subjects, that may affect human subjects, or is otherwise determined to be other than minimal risk for ICOI, and when that research involves licensed intellectual property or equity holdings by Duke, the default ICOI position is that the research should be done at an institution other than Duke. If there are compelling circumstances that justify 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), other arrangements can be considered. In a situation with compelling circumstances, the resulting management plan should include the following strategies:

(a) Disclosure of the ICOI in the informed consent document;

(b) Use of an external IRB, with administrative review by the local IRB 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"), an external data safety monitoring board with ICOI oversight, or similar review committee to perform the normal duties of a data safety monitoring board, and also to consider ICOI 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 ICOI in public presentations and publications;

(f) Disclosure of the ICOI to all sites in a multi-site study.