

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)