

DUKE UNIVERSITY SCHOOL OF MEDICINE
IMPLEMENTATION OF THE DUKE UNIVERSITY
CONFLICT OF INTEREST POLICY RELATED TO RESEARCH

Introduction

The Duke University School of Medicine (Duke) issues this document to implement in the School of Medicine the STATEMENT OF CONFLICT OF INTEREST FOR THE FACULTY OF DUKE UNIVERSITY adopted by the Board of Trustees of Duke University on February 28, 1992 (the “Policy”). A copy of the Policy is attached. In the event that a conflict arises between the Policy and this document, the provision of the Policy shall govern. This document sets forth interpretations of the Policy that apply to individual conflicts of interest, and describes the procedures established for the reporting, management, reduction, or elimination of real or perceived conflicts or potential conflicts of interest. This document applies to all investigators (faculty and non-faculty) who contribute to the design, conduct or reporting of research regardless of funding source; who teach or provide healthcare; and to individuals who make purchasing or contracting decisions at Duke. This policy addresses personal rather than institutional conflicts of interest.

Duke has the responsibility to *identify, manage, reduce, or eliminate any conflicts of interest* that may be created by a financial interest of an individual related to research conducted at Duke. Thus, Duke requires that individuals report any relevant financial interest. Full and accurate reporting is required, whether or not the individual thinks there is a possibility of a conflict of interest. A conflict of interest in research exists when the School, through procedures described below, reasonably determines that a financial interest could affect the design, conduct, or reporting of research project.

Effective interaction between universities conducting research and industry is essential to the translation of research findings. Ensuring the integrity of research findings and prudent stewardship of public funds includes protecting sponsored research from being compromised by the conflicting financial interests of any individual responsible for the design, conduct, or reporting of sponsored research. The purpose of this policy is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct or reporting of research funded under Public Health Services (PHS) grants, PHS cooperative agreements or any other funding source will be biased by any conflicting financial interest of an investigator [45 CFR 50, subpart F]. Duke intends to comply with all applicable regulations and requirements related to conflict of interest. This policy and procedure will be applied in like manner to all research regardless of funding agency or sponsor. In dealing with questions and issues of conflict of interest the regulations and requirements of the specific funding agency or sponsor will be reviewed and applied. Where the regulations or requirements of the funding agency or sponsor conflict with this policy and procedure those of the funding agency or sponsor will take precedence.

Definitions

1. “Individual” means the principal investigator/project director, co-investigators, and any other person who is independently responsible for the design, conduct, or reporting of research. The principal investigator is responsible for identifying other persons who are responsible for the design, conduct, and reporting of the research for which extramural funding is sought.
2. “Immediate family” means spouse or spousal equivalent and dependent children.
3. “Investigator” means the principal investigator and any other person who has overall responsibility for the design, conduct, or reporting of research and includes the investigator’s immediate family.
4. “PHS Awarding Component” means the organizational unit of the PHS that funds the research subject to 45 CFR 50, subpart F.
5. “Research” means a project intended to develop new and generalizable knowledge.
6. “Small Business Innovation Research” (SBIR) program means the extramural research program for small business that is established by the awarding components of the PHS and certain other federal agencies under Public Law 97-219, the Small Business Innovation Development Act as amended and includes the Small Business Technology Transfer (STTR) program, established by Public Law 102-564.
7. “Significant Financial Interest” means receiving anything of monetary value, including, but not limited to
 - Payments for services (e.g., consulting fees, lecture payments, or honoraria);
 - Equity interests (e.g., stocks, stock options, or other ownership interests); and
 - Intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

The term does *not* include:

- Ownership of mutual funds;
- Salary or other remuneration from the school;
- Private Diagnostic Clinic distributions;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities (e.g., NIH). Reporting *is* necessary when a foundation is supported by industry.
- Payments made to the school by outside organizations.

Reporting of Conflicts of Interest

1. An annual reporting form is required from:
 - a. Duke University School of Medicine paid faculty;

- b. Individuals with a conflict of interest identified in the previous year;
 - c. Investigators and other individuals identified on federal grants involved in the independent design, conduct, or reporting of research;
 - d. Investigators and other individuals identified on IRB applications involved in the independent design, conduct, or reporting of research; and
 - e. Individuals with intellectual property (IP) managed by Duke
2. Individuals required to provide an annual reporting form must include all financial interests of \geq \$600 for themselves and their immediate family. Financial Interest means receiving anything of monetary value, including, but not limited to any:
- a. Payments for services (e.g., consulting fees, lecture payments, advisory board payments, or honoraria);
 - b. Equity interests (e.g., stocks, stock options, or other ownership interests);
 - c. Intellectual property rights (e.g., patents, copyrights, and royalties from such rights); and
 - d. Gifts, gratuities, or donations.

The term does *not* include:

- a. Salary or other remuneration from the School;
 - b. Private Diagnostic Clinic distributions;
 - c. Ownership of mutual funds;
 - d. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
 - e. Income from service on advisory committees or review panels for public or nonprofit entities (e.g., NIH). Reporting *is* necessary when a foundation is supported by industry; and
 - f. Payments made to the School by outside organizations.
3. The Conflict of Interest Office will distribute an announcement of the need to complete the annual reporting form on February 1st to individuals required to report. Reporting forms are due March 1st.
4. Reporting is accomplished by individuals completing the interactive, online reporting form through the Internet. Individuals unable to access the online reporting form must contact the Conflict of Interest Office.
5. Email reminders will be sent to individuals who have not completed the annual reporting form.
6. Updating the annual reporting form:
- a. Each individual is responsible for maintaining a current, accurate reporting form with the Conflict of Interest Office.

- b. Within 10 business days of establishing any new relationship or changes in any exiting relationships that might constitute or lead to a real or perceived overlap with their research efforts, individuals must update their COI reporting form to reflect the new relationship or change.

Review of Reporting Forms

1. Reporting forms are analyzed by the Conflict of Interest Office staff to first determine if an overlap with research efforts and external relationships might exist and thus create a real or apparent conflict of interest. Annual reporting forms are first analyzed by computer, using algorithms that take into account the nature of the relationship between individuals and outside entities as well as the dollar value those relationships might represent. If possible conflicts are identified, they are further analyzed, first by computer and then, depending on the results, by the Conflict of Interest Office staff and the Conflict of Interest Committee. These analyses classify conflicts as either simple or complex. The Conflict of Interest Office maintains guidelines that have been reviewed and approved by the Conflict of Interest Committee on the classification of simple conflicts.
2. Simple conflicts are managed by issuing a standard management plan to the individual with the conflict. A standard management plan will require that the individual take certain steps, which may include one or more of the following: (1) follow-up with the IRB, IACUC, and/or Office of Research Administration (ORA); and (2) disclosure of the conflict to research participants, academic journals and manuscript reviewers, audiences of conferences and seminars, and sponsors. Standard management plans, which are issued by the Conflict of Interest Office, are reported and reviewed by the Conflict of Interest Committee at monthly convened meetings. The Conflict of Interest Committee may accept or modify these plans as necessary.
3. Complex conflicts require careful consideration by the Conflict of Interest Committee. After confirming the accuracy and completeness of the reporting form and possibly obtaining additional information from the individual, the Conflict of Interest Committee will convene a meeting and develop a custom management plan to manage, reduce, or eliminate the conflict.
4. The management plan details the conditions or restrictions imposed upon the individual in the conduct of the project or in the relationship with the business enterprise or entity. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:
 - a. Public disclosure of significant financial interests;
 - b. Monitoring of research by independent reviewers;
 - c. Modification of the research plan;
 - d. Disqualification from participation in all or a portion of the research;
 - e. Divestiture of significant financial interests; or
 - f. Severance of relationships that create actual or potential conflicts.

5. All management plans will be acknowledged by the individual, tracked over time, and monitored. Management plans may also be audited. Management plans will also be shared, as appropriate, with departmental chairs, supervisors, the IRB, the IACUC, the ORA, and the School Administration. Management plans are issued to individuals, but they are conflict-specific. Thus, an individual may have more than one conflict and more than one management plan.

The Conflict of Interest Committee

The Conflict of Interest Committee is charged with protection of the integrity of Duke's research and educational missions, as well as the integrity of the organization and the individual. The Committee is advisory to the Chancellor for Health Affairs and the Dean of the School of Medicine. The Conflict of Interest Committee is appointed by the Chancellor for Health Affairs. The Committee consists of faculty members and at least one member of the community at large. The Chair of the Conflict of Interest Committee is appointed by the Dean of the School of Medicine and is a voting member of the Committee. The Committee may utilize consultants as it finds necessary. Consultants are non-voting. Committee members must declare any conflicts they have with business brought before the Committee. Those committee members with conflicts do not participate in discussion except to provide information requested by the Committee and do not vote on any issue where they have a conflict. The Committee must have a quorum defined as at least 3 voting members present to conduct business. A simple majority of the members present is required for a motion to be approved. In evaluating conflict of interest and determining the appropriate management the Committee is charged with establishing specific operational guidelines and standards consistent with University and School policy, and federal and state regulations.

Monitoring

The Conflict of Interest Committee requires monitoring of documented conflicts of interest involving individuals for whom a conflict of interest management plan has been instituted. Standard monitoring will involve review of instituted management plans at the next annual reporting or when ever an individual updates their report. Monitoring of the management plan will determine whether the relationship between significant financial interests and sponsored research has changed or is expected to change, and to update the management plan based on new information from the investigator and new policy or standards established by the Committee. The initial monitoring is done by the Conflict of Interest staff. If based on review of the updated information no changes in the management plan are this is noted in the file and reported to the Committee. If based on the update changes are required the staff will determine whether conflict is simple or complex and follow the corresponding process for new conflicts. The Committee may require a project specific monitoring process when it believes such a plan is warranted.

Noncompliance

Noncompliance with Disclosure Policies and Procedures

1. The reminder of annual requirement for complete and accurate reporting is emailed during the February call for reporting. The final deadline for reporting is March 1st.
2. The Notice of Noncompliance is sent the first week of March to all individuals who have not submitted a COI reporting form.
3. The Notice of Noncompliance will be logged into the Conflict of Interest database and copied to the:
 - a. Chief Compliance Officer;
 - b. Chair of the department if individual is faculty;
 - c. Immediate supervisor if individual is non-faculty;
 - d. Institutional Animal Care and Use Committee (IACUC)
 - e. Office of Research Administration (ORA); and
 - f. Institutional Review Board (IRB).
4. Starting on April 1st, no new grants will be processed by ORA and no new IRB or IACUC submissions will be processed for noncompliant individuals until the reporting form is completed. The Chief Compliance Officer and Dean will be notified of the continuing noncompliance.
5. Starting on May 1st, no grant funds will be disbursed for noncompliant individuals until the reporting form is completed. The Chief Compliance Officer and Dean will be notified of the continuing noncompliance. In addition (or if the individual does not have funding), other progressive disciplinary action may be initiated.
 - a. The Dean may institute progressive disciplinary action consistent with Institutional policy as deemed appropriate in the case of continued noncompliance.
 - b. Noncompliance with COI Office and/or COI Committee requests for additional information may be approached using steps similar to noncompliance with annual reporting policies.
 - c. Noncompliance with the requirement for timely updating of the annual reporting form may be approached using steps similar to noncompliance with annual reporting policies.
 - d. Progressive disciplinary action will be taken if it is determined by the Dean that reporting forms are deliberately misleading either by understatement or omission of information related to a conflict of interest.

Noncompliance related to Conflict of Interest Management Plans

1. An individual will be considered noncompliant if he or she fails to provide written acknowledgment of the management plan.
2. An individual will be considered noncompliant if he or she fails to provide the COI Office and/or COI Committee with requested documentation of compliance as stated in a management plan.

3. A Notice of Noncompliance will be sent to the individual five (5) business days after the third unsuccessful request for documentation or acknowledgement.
4. The Notice of Noncompliance will be entered into the COI database and copied to the:
 - a. Chief Compliance Officer;
 - b. Chair of the department if individual is faculty;
 - c. Immediate supervisor if individual is non-faculty;
 - d. ORA; and
 - e. IRB.
5. The issue of noncompliance with the management plan will be considered by the COI Committee, which may make one or more of the following recommendations:
 - a. Provide the individual with another opportunity to respond;
 - b. Recommend a cessation of disbursement of the individual's grant funding;
 - c. Refer the case to the Dean for progressive discipline action as appropriate under institutional policy.

Communication with External Sponsors and Agencies

1. Conflicts of interest will be managed, reduced, or eliminated in accordance with this policy, and all reports required regarding the resolution of the conflict of interest will be submitted to the sponsor as required by the sponsor's policy.
2. For PHS-funded research, Duke will certify in each application for funding that it has a written and enforced process to identify and manage, reduce, or eliminate conflicts of interest. Duke will report to the NIH Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by Duke, will assure the NIH that the conflict has been managed, reduced, or eliminated prior to expenditures of any funds, and will report any interests identified as conflicting subsequent to the initial report within 60 days of being identification. Upon request Duke will make information available to HHS regarding all conflicts of interest related to PHS-funded research and how those interests have been managed, reduced, or eliminated.
3. For NSF-funded research, Duke will report conflicts that cannot be satisfactorily managed, reduced, or eliminated.
4. Collaborators/subrecipients/subcontractors of a research project must provide a certification from their institutions to Duke that they are in compliance with applicable Federal policies regarding individual Significant Financial Interest reporting and that their portion of the project is in compliance with their institutional policies which must be provided upon request.
5. If the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

6. Duke agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias.
7. All records of individual financial reporting forms and of actions taken by the institution related to the reporting shall be retained by the Conflict of Interest Office for at least three years after the date of submission of the final expenditures report, the termination or completion of the project to which they relate, or the resolution of any government action involving those records, whichever date is latest.
8. In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by applicable federal regulation, the Institution must require the Investigator(s) involved to disclose the conflicting interest in each public presentation and publication of the results of the research.
9. Individuals who feel that an issued management plan is inappropriate may request that the Conflict of Interest Committee reconsider the matter. In such cases, the individual will have the opportunity to bring new or additional information to the attention of the committee, or to present alternative perspectives. The process for reconsideration is not an appeal process, however, because it is not referred to a higher authority. The Committee will consider each request for reconsideration, but is not obligated to honor every request.

Appeal of a Conflict of Interest Committee Decision

If an investigator wishes to appeal the determination of the Committee, the investigator must submit a written appeal detailing the basis for the appeal to the Chancellor for Health Affairs or his/her designee within ten (10) calendar days of receipt of the decision. The decision of the Chancellor is final. This policy and procedure is an exclusive mechanism for resolution of Conflict of Interest. Other Institutional policies and procedures can not be invoked in an effort to readjudicate the determinations of the Committee and Chancellor.

This policy does not supersede or establish an alternative to any existing regulations, policies or procedures for handling fiscal improprieties, the ethical treatment of human or animal subjects, criminal matters, or personnel actions.

Effective Date:

Review/Revision History:

Appendix: Conflict of Interest Operational Guidelines and Standards (As of 1/1/2008)

For the purposes of COI reporting, immediate family members (spouse or spousal equivalent, and dependent children) should be included on a faculty member's form. For example, a \$10,000 payment from a pharmaceutical company to a college-age child for summer employment should be reported on the faculty member's annual COI reporting form.

In the guidelines that follow, the same rules apply for University and Health System staff as for University faculty, but the term "faculty" is used for simplicity of presentation.

Payments

Payments from non-Duke sources within a calendar year (honoraria, stipends, consulting fees, etc.), other than reimbursements for travel and other direct expenses, must be reported to the School no later than at the time of annual reporting (February of each year). The *de minimis* threshold is the equivalent of receipt of an IRS Form 1099 (required for payment of \geq \$600 within a calendar year). Should payments exceed \$600 from a business entity or individual, but no Form 1099 is received, the payment (and business relationship) must still be reported to the School on the annual COI Reporting Form.

Payments from subsidiary companies and contractors should be reported as coming from the parent company. For example, if "Company A" hires a contractor to run a conference, and the honorarium check comes from the meeting organizers, the money should still be attributed to the "Company A" and should be included on the COI reporting form. In some cases, meetings may have multiple sponsors, each of whom makes contributions that are not easily distinguishable. In those cases where an honorarium is involved, the meeting itself (or its coordinating company) should be noted on the reporting form.

Payments made to an intermediary business entity for services performed by a faculty member should be reported on the annual COI reporting form. For example, if Company A pays "Faculty Consultants, Inc" for a faculty member's research design work, and Faculty Consultants then distributes a portion of the money to the faculty member, the entire amount paid by Company A to Faculty Consultants for that faculty member's efforts should be the basis of the annual report.

Payments from the federal government and its agencies do not generally need to be reported. Payments from the Duke Private Diagnostic Clinic are also exempt from reporting (unless it acts as an intermediary for a consulting arrangement).

If the entity making payments to the faculty or staff member has no likelihood of a business relationship with Duke University (for example, if the company has no business activities in North America), it does not need to be reported on the annual form. The goal is to evaluate external relationships that might overlap with Duke professional responsibilities like research, purchasing, or teaching.

Personal payments of \geq \$10,000/year from an external entity (business or individual) require a management plan when the faculty member receives research support from the same entity or

when a relationship exists between the entity and the faculty member's federally-funded research. In most cases this management plan will mandate disclosure of the relationship in situations where there is an overlap with the Duke activity. This could include disclosure to potential research subjects, to the IRB, to agencies from which grant support is requested, to journals (with submitted manuscripts), and to audiences for verbal presentations.

Payments of \geq \$25,000/year from an external entity means there will be a rebuttable presumption the employee cannot be Principal Investigator on research related to that entity's products or intellectual property. If some other Duke faculty member is the PI, and if the PI is independent of relationships with the conflicted employee, in some cases the conflicted Duke employee will be able to participate in the investigative staff. Situations where a case can be made that there are compelling circumstances to justify allowing a conflicted investigator to proceed as PI require COI Committee review and approval. If the research is allowed to proceed, a management plan will mandate disclosure of the relationship to potential research subjects, to the IRB, to agencies from which grant support is requested, to journals (with submitted manuscripts), and to audiences for verbal presentations.

Royalties

Royalties for inventions and patents can be complicated in terms of COI. A faculty member must report all external relationships involving royalties as part of their annual COI reporting. This is true even if the royalties come through Duke or some other non-profit entity (i.e. a company with a license to Duke-owned intellectual property pays Duke as a result of that license, and Duke in turn transfer some portion of the royalties to the faculty member). On one level, the amount of royalties may reflect the company's ability to market the product, while on the other hand further research by the Duke faculty member might make the royalty stream more lucrative. To assess the risks of COI, the COI Committee will review all situations where there is an overlap between a research project and royalty revenues (or potential revenues).

Equity: Publically-Traded Companies

Faculty members with fair market equity holdings \geq \$10,000 in a publically-traded company are subject to the same rules if they had received \geq \$10,000 in payments/year, and holdings at this level should be reported on the annual COI Reporting Form. The same situation applies with \geq \$25,000 in equity in a publically-traded company (with the same rebuttable presumption described in the payment policy for \geq \$25,000 above). Holdings of immediate family members should be aggregated for determining value.

Mutual funds are excluded from this reporting process.

If a company grants equity of a certain value or number of shares in lieu of payments, in the first year after the transfer the equity will be treated as if it is a payment. Thereafter it will be treated as equity. For example, if a faculty member was given 10,000 shares of a \$4.00 stock in lieu of cash, during the first year after the stock transfer this would be considered a cash payment of \$40,000.

If an individual proposes to do research where equity holdings create a conflict of interest (or overlap of interests), they may dispose of or sell the stock. Once the stock is sold, any increase in the equity's value as a result of the faculty member's research would be irrelevant. However, as noted above, equity given in lieu of cash payments is counted as a payment for the first year.

Equity: Privately-Held Companies

Because it may be difficult to determine market value for fair privately-traded companies, all related equity holdings in privately-traded companies must be reported in the annual COI reporting process. In most cases, any equity in a non-publically traded company is treated as if it exceeds the \$25,000 threshold, although this may be discussed with the COI Committee on a case-by-case basis.

Options

Because options are volatile and complex, all stock options (even for a single share) must be reported on the annual COI reporting form. These will be evaluated by the COI Office and Committee in order to determine the approximate value. Management plans will be required in most cases where research is proposed related to the company in which the options are held.

Patents and Intellectual Property

When a faculty member has a patent or significant intellectual property that is or might be licensed, this situation should be reported on the annual COI Reporting Form. If the patent (or intellectual property) has not been licensed or optioned, in most cases research related to the IP can continue. Once the IP has been licensed or optioned, the situation must be reviewed and approved by the COI Committee before the faculty member can engage in further related research.

SBIR/STTR

Because the SBIR/STTR grants create complex relationships, a separate policy has been created. Please see the SBIR/STTR policy when considering an application for either of these grant categories.