Introduction

The Duke University Schools of Medicine and of Nursing (Duke) issue this document to implement in the Schools of Medicine and Nursing the STATEMENT OF CONFLICT OF INTEREST FOR THE FACULTY OF DUKE UNIVERSITY adopted by the Board of Trustees of Duke University in May, 2011 (the “Policy”). 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 (COI), and provides an overview for the evaluation and management of real or perceived conflicts or potential conflicts of interest. This document applies to all individuals (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 implementation addresses personal rather than institutional conflicts of interest.

Duke has the responsibility to identify and manage 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 conflict of interest. A conflict of interest in research exists when the School reasonably determines that a significant financial interest (SFI) could affect the design, conduct, or reporting of research.

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. Duke will maintain an up-to-date, written, enforced policy on financial conflict of interest (FCOI) that complies with regulations and requirements related to conflict of interest and make such policy available via a publicly accessible website https://medschool.duke.edu/research/ethics-integrity-compliance/research-integrity-office/coi-related-policiesfaqs. 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.

1. Disclosure of Conflicts of Interest

An annual disclosure form is required from all individuals (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. These include:

a. Paid faculty;
b. Individuals with a financial conflict of interest identified in the previous year;
c. Investigators and other individuals identified on federal grants involved in the design, conduct, or reporting of research;
d. Investigators and other individuals identified on IRB applications involved in the design, conduct, or reporting of research;
e. Individuals with intellectual property (IP) used in research at Duke.
f. Individuals with significant administrative responsibilities that include procurement
activities.
g. Other individuals or categories of individuals that may be designated by the Conflict of Interest Committee.

2. Individuals required to provide an annual disclosure form must include all significant financial interests 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) of >$5,000;
   b. Equity interests (e.g., stocks, stock options, or other ownership interests) in publicly traded companies of >$5,000;
   c. Equity interests in any privately held company (e.g., options, or other ownership interests);
   d. Intellectual property rights (e.g., patents, copyrights, and royalties from such rights);
   and
e. Gifts, gratuities, or donations.

3. Individuals required to submit an annual disclosure form will be contacted via email.

4. Disclosure is accomplished by individuals completing the interactive, online reporting form through the Internet at: https://radapps.duke.edu/coi_form

5. Email reminders will be sent as a courtesy to individuals who have not completed the annual disclosure form. Not receiving an email reminder does not eliminate or alter an individual’s requirement to complete the annual disclosure form.

6. Updating the annual disclosures:
   a. Each individual is responsible for maintaining a current, accurate reporting form with the Conflict of Interest Office.
   b. Within 30 calendar days of discovering, acquiring or establishing any new significant financial interests or changes in any existing significant financial interests that might reasonably be related to their research efforts, individuals must update their COI disclosure form.

7. Investigators with research sponsored by the U.S. Public Health Service (PHS) of the U.S. Department of Health and Human Services also are required to disclose certain information about sponsored or reimbursed travel taken on or after August 24, 2012, but only if the investigator and the travel both meet certain criteria as described: https://medschool.duke.edu/research/ethics-integrity-compliance/research-integrity-office/sponsored-travel-reporting-form.

8. Subrecipients and Other Collaborators as related to National Science Foundation (NSF) and PHS-funded research. Duke will take reasonable steps to ensure that each investigator complies with the applicable regulations. For PHS-funded research, Duke will incorporate a written agreement with any subrecipient terms that establish whether Duke’s FCOI policy or the subrecipient’s FCOI policy will apply to subrecipient Investigators. If the subrecipient’s Investigators must comply with the subrecipient’s FCOI policy, the subrecipient must certify as part of the agreement with Duke that its FCOI policy complies with the PHS FCOI
regulation.

a. If the subrecipient cannot provide such a certification, the agreement between Duke and the subrecipient will state that subrecipient Investigators are subject to the Policy for disclosing significant financial interests that are directly related to the subrecipient’s work for Duke (see 42 CFR § 50.604(a) for grants and cooperative agreements and 45 CFR § 94.4(a) for contracts). With respect to grants or cooperative agreements, this arrangement should be defined in a formal written agreement with each consortium participant.

b. If Duke will be a subrecipient to another entity on a PHS or NSF award/contract, a Duke Investigator or department may receive a form from the prime grantee/contractor asking Duke to certify whether Duke will use its own FCOI policy or whether Duke will use the prime recipient/contractor’s policy. Duke uses its own FCOI policy and does not agree to use or follow any other entity’s FCOI policy, forms, or procedures.

**Review of Disclosure Forms**

Disclosure forms are analyzed by the Conflict of Interest Office staff to determine if disclosed SFIs are related to the disclosing individual’s research and, if related, whether the SFI is a COI.

**Management**

1. According to Federal rules, any FCOIs in PHS funded research must be managed prior to expenditure of any federal funds. For PHS-funded research projects, prior to the expenditure of funds, Duke will provide the PHS Awarding Component a report of any FCOI determined to be related to the project and ensure that a management plan has been implemented in accordance with the University policy and this implementation.

2. Simple FCOIs are managed by issuing a standard management plan to the individual with the FCOI. Standard management plans, which are issued by the Conflict of Interest Office, are reported and reviewed by the Conflict of Interest Committee by consent agenda at convened meetings, usually monthly. The Conflict of Interest Committee may accept or modify these plans as necessary.

3. Complex FCOIs require full review by the Conflict of Interest Committee and could also require input from Department Chair, IRB or other individuals involved in the research.

4. The management plan details the conditions or restrictions imposed upon the individual in the conduct of the research project or in the relationship with the business enterprise or entity. The management plan for PHS-sponsored research will also include a determination that the FCOI does or does not meet federal criteria for reporting to the PHS.

5. All management plans will be acknowledged by the individual, tracked over time, and monitored. Management plans may be audited. Management plans will also be shared, as applicable, with departmental chairs, supervisors, the IRB, the IACUC, the ORA, School Administration and others with a clear need to know. 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.

6. 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 such requests.
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 Deans of the Schools of Medicine and Nursing. The Conflict of Interest Committee is appointed by the Chancellor for Health Affairs. The Committee consists of faculty members from the Schools of Medicine and Nursing. The Designated Institutional Official for Conflict of Interest will be Chair of the Committee and is a voting member of the Committee. The Committee may utilize non-voting consultants as it finds necessary. 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 ongoing monitoring of documented conflicts of interest involving individuals, for whom a conflict of interest management plan has been instituted until the completion of the research project, including reporting of results in publications and presentations. Standard monitoring will involve review of instituted management plans at the next annual reporting or whenever an individual updates his/her 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 Office staff. If, based on review of the updated information, no changes in the management plan are needed 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

1. FCOI will be managed, reduced, or eliminated in accordance with applicable regulations and this implementation. The format and content of all reports will be consistent with the requirements of the awarding sponsor when any noncompliance is discovered.
2. If a completed disclosure form is not received within 30 days of the due date for disclosure, no new grants will be processed by ORA for noncompliant individuals until the reporting form is completed.
3. An individual will be considered noncompliant if he or she fails to provide written acknowledgment of the management plan.
4. 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.
5. The issue of noncompliance with disclosure or the management plan will be considered by
Business Managers, Department Chairs, IRB, the COI Committee or others as appropriate to the circumstances.

Communication with External Sponsors and Agencies
The format and content of all reports will be consistent with the requirements of the awarding sponsor.

Training Requirements
Per PHS regulations, Duke will require that each Investigator (as defined by the regulation), including subrecipient Investigator(s), must complete training prior to engaging in PHSNIH-funded research.

Public Accessibility of FCOI Policy and FCOI Information related to PHS-funded research
Duke will respond to written requests within 5 business days of receipt of the request for information as defined in regulations concerning FCOIs held by senior/key personnel. Requests must include the grant and names of the individuals for whom the information is requested.

Record Retention
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 7 years after the date of submission of the applicable COI disclosure form.

This document 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.

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