

**DUKE UNIVERSITY**  
**FINANCIAL CONFLICT OF INTEREST IMPLEMENTATION GUIDELINES**

**1. Purpose and Scope**

Duke is committed to preserving the public’s trust that research is conducted without bias and with the highest scientific and ethical standards.

The purpose of this implementation document is to provide guidance on the interpretation and application of the Duke Policy on Faculty Conflicts of Interest (COI) and Conflicts of Commitment (COC) in Research (“the Policy”).

A copy of the Policy is available on the [DOSI-COI website](#).

In the event of a conflict between the Policy and this guidance, the Policy shall govern. Where a regulation or requirement of a funding agency or sponsor conflicts with the Policy or this guidance, the regulation or requirement will take precedence, except if it is less restrictive than Duke’s standard.

Defined terms found in this document are set forth throughout and in Section 16.

**2. Disclosure Process**

All Covered Individuals must submit an annual disclosure form. Covered Individuals are:

- 1) Regular-rank tenure and non-tenure track faculty members.
- 2) Individuals granted Principal Investigator status and Duke employees providing material benefits to externally funded research projects. This will be indicated by being named as key personnel or receiving salary from effort on an externally funded project that had financial activity within the preceding twelve months.

Disclosure is accomplished by submitting the interactive, online reporting form. Covered Individuals required to provide an annual disclosure form must include all Outside Interests for themselves and their Immediate Family as well as other information required under law and the Policy.

On an annual basis, the Duke Office of Scientific Integrity Conflict of Interest (DOSI-COI) will distribute an announcement that the disclosure form is available for completion. Email reminders are sent as a courtesy to Covered Individuals who have not completed the disclosure form. Not receiving an email reminder does not eliminate or alter a Covered Individual’s requirement to complete the disclosure form.

A Covered Individual is responsible for updating their disclosure form within 30 calendar days of discovering, acquiring or establishing any new Outside Interest (*e.g.*, through purchase, marriage, or inheritance) or changes in any existing Outside Interest.

In addition to annual disclosure, any Covered Individual performing externally funded research must disclose Outside Interests at the time of proposal and at the time of award. This disclosure is done through electronic attestation, the annual COI disclosure form, and communication with DOSI-COI.

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During the proposal attestation process, Covered Individuals who have an investigator role of PI, co-PI, or PI-Fellow are instructed to verify their COI disclosures and required to attest that they will work with DOSI-COI to address any potential COIs. Key personnel receive instruction about disclosing to DOSI-COI, but are not required to attest.

During the award attestation process, Covered Individuals who are listed on the notice of award are required to disclose any Outside Interests. Any Outside Interests disclosed during award attestation are reviewed by DOSI-COI. DOSI-COI reviews the COI disclosure form for all Investigators at the time of award. Awards will not be released until DOSI-COI has cleared the award, which indicates either 1) no FCOIs exist, 2) any FCOIs are appropriately managed and reported as per sponsor requirements.

**3. Review of Disclosure Forms and Attestations**

For PHS funded research, DOSI-COI carries out reviews to determine if a disclosed Outside Interest is a significant financial interest (SFI). An SFI is a financial interest that reasonably appears to be related to the Covered Individual's Institutional Responsibilities and meets certain criteria. For PHS sponsored research, those criteria include, but are not limited to:

- i. Any remuneration received (e.g., consulting fees, lecture payments, paid authorship or honoraria), the total value of which in the 12 months preceding the disclosure and as of the date of disclosure is \$5,000 or more;
- ii. Equity interests (e.g., equity, stocks, stock options, or other ownership interests). For publicly traded entities, the equity interest must be \$5,000 or more, and for a privately held entity, there is no financial threshold;
- iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of external income related to such rights and interests; and
- iv. Any reimbursed or sponsored travel related to the Covered Individual's Institutional Responsibilities.
  - This disclosure requirement does not apply to travel that is reimbursed or sponsored by:
    - a U.S Federal, state, or local government agency,
    - a U.S. institution of higher education as defined at 20 U.S.C. 1001(a),
    - a U.S. academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

For research that is not PHS funded, the monetary thresholds listed above to determine an SFI may be greater, or there may be additional or different criteria for the determination of an SFI.

The term SFI does *not* include:

- i. Ownership of shares in a mutual funds;

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- ii. Salary or other remuneration received from Duke;
- iii. Private Diagnostic Clinic distributions;
- iv. Income from seminars, lectures, or teaching engagements sponsored by U.S. Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education;
- v. Income from service on advisory committees or review panels for U.S. federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. based institution of higher education. Reporting *is* necessary when a foundation is supported by industry;
- vi. Payments made to Duke by an outside organization; and
- vii. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Individual does not directly control the investment decisions.

If an SFI exists, and the Covered Individual is engaged in research at Duke, DOSI-COI and/or the University Conflict of Interest Committee (COIC) will review the SFI to determine if it is related to the Covered Individual's research. An SFI is related to research when DOSI-COI and/or the COIC determine that the SFI could be affected by the research or is in an entity whose financial interests could be affected by the research.

If the SFI is determined to be related to the research, an FCOI may exist. An FCOI exists when DOSI-COI and/or the COIC reasonably determine that the SFI could directly and significantly affect the design, conduct, or reporting of the research.

#### **4. Sponsored/Reimbursed Travel for PHS funded Investigators**

Investigators with research sponsored by PHS are required to disclose certain information about sponsored or reimbursed travel taken in the preceding 12 months, if the Investigator and the travel meet the following criteria:

**Requirements.** Requirements for reporting reimbursed or sponsored travel are as follow:

- i. The Investigator is paid for research that is PHS funded;
- ii. The travel is reimbursed or sponsored by an entity external to Duke; and
- iii. The travel is related to the Investigator's Institutional Responsibilities.

**Exceptions.** Investigators do **not** have to report travel if it is reimbursed/sponsored by any of the following:

- i. A U.S. based institution of higher education (as defined in 20 U.S.C. § 1001(a));
- ii. A U.S. federal, state or local government agency;

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- iii. An U.S. based academic teaching hospital; a medical center; or
- iv. A research institute that is affiliated with a U.S. based institution of higher education.

Travel that qualifies for reporting, must be submitted through the reporting system at [https://radapps.duke.edu/sponsored\\_travel](https://radapps.duke.edu/sponsored_travel) within 30 days of travel and include the following information:

- i. The identity of the sponsor/organizer (if the sponsor is a company but they are working through a marketing company, report the primary sponsor of the trip rather than the intermediary);
- ii. The purpose of the trip (speaking, consulting, meetings, etc.);
- iii. The destination for the trip; and
- iv. The duration of the travel, specifically the departure and return dates.

DOSI-COI will determine if further information is needed, including a determination or disclosure of monetary value.

For more information about sponsored travel, please refer to <https://dosi.duke.edu/conflict-interest/sponsored-travel-reporting-form>

## **5. Management Plans**

Management plans are documents issued to Covered Individuals that outline requirements that are necessary to mitigate potential bias in research. They detail the conditions or restrictions imposed upon the Covered Individual in the conduct of the research or in the relationship with the external entity. Management plans are issued for FCOIs and may be issued for SFIs that are related to Duke research but not determined to be an FCOI. Each management plan is relationship-specific, and a Covered Individual may have more than one management plan, depending on their relationships.

Management plans are typically developed through collaboration between DOSI-COI and the Conflict of Interest Committee (COIC).

Complex FCOIs require careful consideration by DOSI-COI and/or the COIC. After confirming the accuracy and completeness of the disclosure form and possibly obtaining additional information from the Covered Individual, the DOSI-COI and/or the COIC will develop a custom management plan to manage, reduce, or eliminate the FCOI.

Examples of management elements include, but are not limited to:

- i. Public disclosure of the FCOI (e.g., when presenting or publishing the research results);
- ii. For research projects involving human subjects, disclosure of the FCOI to the IRB and directly to participants and potential participants;
- iii. Appointment of an independent monitor capable of taking measures to protect the

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design, conduct, and reporting of the research against bias;

- iv. Modification of the research plan;
- v. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- vi. Reduction or elimination of the financial interest (e.g., sale of an equity) that creates the FCOI; or
- vii. Severance of the relationship that creates the FCOI.

DOSI-COI will issue FCOI management plans, and monitor compliance with management plans.

Pursuant to rules issued by PHS, NSF, and other sponsors, a management plan for an FCOI must be in place before the agency's funds are released to the Investigator for carrying out sponsored research.

**6. Reporting of Financial Conflicts of Interest (FCOI) to PHS Awarding Components**

For PHS funded research projects, prior to the expenditure of funds, Duke will provide the sponsor a report of any FCOI determinations related to that funded research.

During the period of the award, Duke will report within 60 days any FCOI identified by a new Investigator, or subsequent to the initial disclosure by an existing Investigator.

At least annually (at the same time as when Duke is required to submit an annual progress report, multi-year progress report, if applicable or at time of extension) DOSI-COI will report the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.

Federal reports shall include sufficient information to enable the PHS awarding component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- (i) Project number;
- (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (iii) Name of the Investigator with the financial conflict of interest;
- (iv) Name of the entity with which the Investigator has a financial conflict of interest;
- (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (vi) Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000),

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or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;

(vii) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and

(viii) A description of the key elements of the Institution's management plan, including:

- (A) Role and principal duties of the conflicted Investigator in the research project;
- (B) Conditions of the management plan;
- (C) How the management plan is designed to safeguard objectivity in the research project;
- (D) Confirmation of the Investigator's agreement to the management plan;
- (E) How the management plan will be monitored to ensure Investigator compliance; and
- (F) Other information as needed.

For research supported by other sponsors, Duke will report as required by those sponsors, law, or the Policy, as applicable.

## **7. Monitoring**

All management plans will be acknowledged by the Covered Individual, tracked, and monitored at least on an annual basis.

Standard monitoring will involve review of the management plan at the next annual reporting or whenever a Covered Individual updates a disclosure. Monitoring will determine whether the relationship between the FCOI and Institutional Responsibilities has changed or is expected to change, and whether the management plan should be updated based on new information disclosed by the covered Individual, policy, law, or standards established by the COIC. Higher risk management plans may require more frequent monitoring.

The initial monitoring is done by DOSI-COI. If no changes are needed to the management plan, it will remain in effect. If changes are required, DOSI-COI will identify needed changes in consultation with, or based on past recommendations by, the COIC. The Covered Individual will be required to acknowledge the new management. The COIC will review any management plan changes via consent agenda at convened meetings.

Ongoing monitoring of a management plan is required until the elimination of the FCOI and/or the research project ends.

## **8. Retrospective Review and Mitigation Reports in PHS funded research**

Pursuant to PHS rules, whenever an SFI is not disclosed or reviewed in a timely manner or a Covered Individual fails to comply with a management plan, Duke will, within 60 days,

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determine if the SFI is related to PHS funded research and, if so, whether an FCOI exists. If an FCOI exists the DOSI-COI will, within 120 days, perform a retrospective review to determine if the PHS-funded research conducted during the period of noncompliance was biased in the design, conduct, or reporting of such research.

Duke will document the retrospective review, which will include at least the following key elements:

- i. Project number;
- ii. Project title;
- iii. Project Director/Principal Investigator (PD/PI) or contact PD/PI if a multiple PD/PI model is used;
- iv. Name of the Investigator with the FCOI;
- v. Name of the entity with which the Investigator has an FCOI;
- vi. Reason(s) for the retrospective review;
- vii. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- viii. Findings of the review; and
- ix. Conclusions of the review.

Based on the results of the retrospective review, if appropriate, DOSI-COI shall update any previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

If bias is found, Duke will notify the applicable PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report will include, at a minimum, the key elements documented in the retrospective review above, a description of the impact of the bias on the research project, and Duke's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, Duke will submit FCOI reports annually as prescribed by the regulation.

For research supported by other sponsors, Duke will report as required by those sponsors, law, or the Policy, as applicable.

**9. Subrecipients and Other Collaborators**

For PHS, NSF, and other applicable federally-funded research, Duke will incorporate in a written agreement with any subrecipient terms that establish whether the Policy or the subrecipient's COI policy will apply to subrecipient's Investigator, and will include time periods to meet disclosure and/or COI reporting requirements. If the subrecipient's Investigator will comply with the subrecipient's COI policy, the subrecipient must certify as part of the

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agreement with Duke that its COI policy complies with the applicable federal regulation(s).

If the subrecipient cannot provide such a certification, the agreement between Duke and the subrecipient will state that subrecipient Investigator is subject to the Policy, which will apply to research activities that are directly related to the subrecipient's work for Duke.

Duke will use the Policy if Duke will be a subrecipient to another entity on a PHS, NSF or other award, and the prime grantee/contractor asks whether Duke will use the prime recipient/contractor's policy.

**10. Recordkeeping**

Duke will maintain records of all disclosures and all actions taken by Duke with respect to each disclosure as follows: (1) in the case of grants or cooperative agreements, for at least three years from the date of submission of the final expenditures report, or where applicable, from other dates specified in 45 CFR 75.361 for different situations; and (2) in the case of research contracts, for three years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7.

**11. Training Requirements**

Per PHS regulations, Duke will require that each Covered Individual engaged in PHS funded research complete COI training:

- i. Prior to engaging in research related to any PHS funded project;
- ii. At least every four years; and
- iii. Immediately when any of the following circumstances apply: (A) Duke revises the Policy in a manner that affects the Investigator; (B) when an Investigator is new to Duke; or (C) when Duke finds an Investigator is not in compliance with the Policy or management plan.

**12. Noncompliance / Sanctions**

The following items in the non-exclusive list may be grounds for a finding of noncompliance and possible sanction against a Covered Individual:

- i. Not complying with the terms of the Policy;
- ii. Not submitting a truthful and timely disclosure form;
- iii. Failing to fulfill training requirements;
- iv. Failing to update a disclosure form when a new Outside Interest is obtained;
- v. Failing to cooperate with or otherwise respond to requests for additional information from DOSI-COI or the COIC, other designated officials at Duke, or a sponsor; or
- vi. Failing to comply with the elements of an FCOI management plan.



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DOSI-COI and/or the COIC will review the matter and communicate with the Covered Individual to determine if noncompliance has occurred. If it is determined that noncompliance has occurred, the following is a non-exclusive list of means by which the noncompliance may be resolved:

- i. Request that a disclosure form be completed, updated, amended, etc.;
- ii. Provide the Covered Individual with another opportunity to respond to requests for information or collaboration;
- iii. Recommend a delay or cessation of disbursement of the Covered Individual's grant funding;
- iv. Conduct a review in compliance with applicable regulations and report the matter to the funding agency, as appropriate;
- v. Submit notice of noncompliance to other Duke offices and officials, as appropriate; or
- vi. Refer the case to the appropriate Duke official or committee for action as appropriate under Duke policies or standards.

In any case in which the HHS determines that a PHS-funded research 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 an FCOI that was not managed or reported by Duke as required by the PHS regulation, Duke will require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and request an addendum to previously published presentations.

**13. Public Accessibility of COI Policy and FCOI Information**

For PHS funded research, Duke will make information available concerning identified FCOIs by senior/key personnel by a written response to any requestor within five business days of a request made to dosicoi@duke.edu. This information will include:

- i. The name of the Investigator;
- ii. The Investigator's title and role with respect to the research project;
- iii. The name of the entity in which the SFI is held;
- iv. The nature of the SFI, and
- v. The approximate dollar value of the SFI or a statement that the interest is one whose value cannot be readily determined through reference to public process or other reasonable measures of fair market value.

In situations where Duke is working with a subrecipient, the institution whose policy the subrecipient is following will be responsible for providing COI information upon request.

**14. National Science Foundation Specific Issues**

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For research funded or proposed for funding by the National Science Foundation (NSF), the term “investigator” means the Investigator, and any other Individual at Duke who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.

Duke will report conflicts in accord with the NSF policy, i.e. when they are not manageable or as required by NSF requirements.

**15. Definitions**

**“Financial Conflict of Interest” or “FCOI”** means an Outside Interest that is related to an Individual’s Institutional Responsibilities, and which could or may appear to directly and significantly affect the design, conduct, or reporting of research.

**“HHS”** means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

**“Immediate family”** means a spouse, domestic partner and dependent children.

**“Covered Individual”** means:

- i. Regular-rank tenure and non-tenure track faculty members.
- ii. Individuals granted Principal Investigator status and those individuals employed by the University and providing material benefits to externally funded research projects. This will be indicated by being named as key personnel or receiving salary from effort on an externally funded project that had financial activity within the preceding twelve months.

**“Institutional Responsibilities”** means an Individual’s professional responsibilities on behalf of Duke, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

**“Investigator”** means an Individual regardless of title or position who has responsibility for the design, conduct, or reporting of research, including, as applicable a consultant or collaborator, and includes the Investigators’ Immediate Family.

**“Manage”** means taking action to address a COI/FCOI, which can include reducing or eliminating the COI/FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

**“Outside Interests”** means any financial interests and other personal interests or relationships with an external entity that are related to a Covered Individual’s Institutional Responsibilities.

**“PD/PI”** means a project director or principal investigator of a research project; the PD/PI is included in the definitions of senior/key personnel and Investigator.

**“PHS”** means the Public Health Service of the U.S. Department of Health and Human Services,

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and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

**“PHS Awarding Component”** means the organizational unit of the PHS.

**“Research”** means a systematic investigation, study, experiment or project intended to develop or contribute to generalizable knowledge.

**“Senior/key personnel”** means the PD/PI and any other person identified as senior/key personnel in a proposal, progress report, or any other report submitted to the PHS or other relevant agency.

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