TABLE OF CONTENTS
A. Purpose and Scope
B. Definitions
C. Training Requirements
D. Investigator’s Disclosure Requirements
E. Subrecipients and Other Collaborators
F. Review of Disclosure Forms
G. Designation of Institutional Official for Conflict of Interest
H. Conflict of Interest Committee
I. Management Plans for Financial Conflicts of Interest
J. Reporting of Financial Conflicts of Interest to PHS Awarding Components
K. Monitoring
L. Retrospective Review and Mitigation Reports
M. Recordkeeping
N. Non-compliance / Sanctions
O. Appeal of a Conflict of Interest Committee Decision
P. Public Accessibility of FCOI Policy and FCOI Information
Q. Requirements for Reporting and Managing Financial Conflicts of Interest in Research Funded by the National Science Foundation
R. Requirements for Reporting and Managing Financial Conflicts of Interest in Research Under the FAR
S. Consulting and Commercial Research Relationships
T. Student Involvement in Faculty's Outside Professional Activities
U. Frequently Asked Questions
A. Purpose and Scope

Duke University (Duke) issues this document to implement 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”). A copy of the Policy is attached in Appendix A.

This document applies to all individuals (faculty and non-faculty) under the following criteria:

i. Contribute to the design, conduct or reporting of research regardless of funding source;
ii. Teach; or
iii. Make or otherwise influence purchasing or contracting decisions.

The Policy and these implementation guidelines address personal rather than institutional conflicts of interest.

Effective interaction between Duke 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 the Policy and this document is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct or reporting of sponsored research will be biased by any conflicting financial interest, including research funded under Public Health Services (PHS) grants, PHS cooperative agreements, PHS contracts, National Science Foundation, and any other funding source.

Under the Policy and law, Duke has the responsibility to identify and manage any conflict 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 Duke, through procedures described below, reasonably determines that a significant financial interest could affect the design, conduct, or reporting of research.

Duke will maintain an up-to-date, written, enforced policy on financial conflict of interest that complies with regulations and requirements related to conflict of interest and make such policy available via a publicly accessible website. These guidelines 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.

This document sets forth interpretations of the Policy that apply to individual conflicts of interest, and describes the procedures established for the evaluation and management of real or perceived conflicts or potential conflicts of interest. In the event that a conflict arises between the Policy and this document, the provision of the Policy shall govern. Where a regulation or requirement of the funding agency or sponsor conflict with the Policy or this document, those of the funding agency or sponsor will take precedence, unless the regulation or requirement is less restrictive than Duke’s more stringent standard.

B. Definitions

“Financial Conflict of Interest” (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.
“Financial Interest” means 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:

i. Payment for service (e.g., a consulting fee, lecture payment, or honorarium), except as otherwise excluded by law or the Policy;

ii. A gift (e.g., money, hospitality, or a physical item);

iii. An equity interest (e.g., stock, stock option, security, or other ownership interest);

iv. An intellectual property right (e.g., a patent, copyright, or royalty from such right); and

v. 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, such a situation is considered a financial interest.

The term Financial Interest does not include:

i. Ownership of shares in a mutual fund;

ii. Salary or other remuneration from Duke or another accredited institution of higher education;

iii. Salary or other remuneration from the U.S. Department of Veterans Affairs or another federal, state, or local government entity; and

iv. A distribution from Private Diagnostic Clinic, PLLC.

“Individual” means an Investigator, project director, co-Investigator, and any other person regardless of title (and her/his immediate family) who is responsible for the design, conduct, or reporting of research, regardless of funding source; teach; or make or otherwise influence purchasing or contracting decisions. 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 or received.

“Immediate family” means spouse or spousal equivalent and dependent children.

“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 the principal investigator and any other Individual regardless of title or position who has responsibilities 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 financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

“PHS Awarding Component” means the organizational unit of the PHS (Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH)) that funds the research subject to 42 CFR 50, subpart F and 45 CFR, part 94. A list of the applicable entities is attached hereto as Appendix #.

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

“Small Business Innovation Research” (SBIR) 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 reauthorized, and includes the Small Business Technology Transfer (STTR) program, which was established by Public Law 102-564, as amended and
reauthorized.

“Significant Financial Interest” (SFI) means receiving anything of monetary value whether or not the value is readily ascertainable, that reasonably appears to be related to the Individual’s institutional responsibilities, including, but not limited to:

i. Payments for services (e.g., consulting fees, lecture payments, paid authorship or honoraria);
ii. Equity interests (e.g., stocks, stock options, or other ownership interests); and
iii. Intellectual property rights and interests (e.g., patents, copyrights, and royalties from such rights).

The term does not include:

i. Ownership of shares in a mutual funds;
ii. Salary or other remuneration received from Duke;
iii. Private Diagnostic Clinic distributions;
iv. Income from seminars, lectures, or teaching engagements sponsored by 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 an Institution of higher education;
v. Income from service on advisory committees or review panels for 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 an Institution of higher education (e.g., NIH). 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 made in these vehicles.

C. Training Requirements

Duke will require that each Individual complete FCOI 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 the Duke; or (C) when Duke finds an Investigator is not in compliance with the Policy or management plan.

D. Disclosure Requirements

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, and who make or otherwise influence purchasing or contracting decisions at Duke. These include:

i. Paid faculty;
ii. Individuals with a financial conflict of interest identified in the previous year;
iii. Investigators and other Individuals identified on federal and private grants, collaborative agreements, and contracts who are involved in the design, conduct, or reporting of research;
iv. Investigators and other Individuals identified on IRB applications who are involved in the design, conduct, or reporting of research;
v. Individuals with intellectual property (IP) managed by Duke;
vi. Individuals with significant administrative responsibilities that include procurement activities; and
vii. Other Individuals or categories of individuals that may be designated by the Conflict of Interest Committee.
Individuals required to provide an annual disclosure form must include all significant financial interests of \( \geq 5,000 \) for themselves and their immediate family as well as other information required under law and Duke policy.

The Office of Research Support will distribute an announcement of the need to complete the annual reporting form on at date to be set by the Conflict of Interest Committee.

Disclosure is accomplished by Individuals completing the interactive, online reporting form through the Internet. Individuals unable to access the online reporting form must contact the Office of Research Support to make alternate arrangements to disclose.

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.

Updating the annual disclosures:

- Each Individual is responsible for maintaining a current, accurate reporting form with the Office of Research Support;
- At the time of application for PHS-funded research;
- An Individual is responsible for updating her/his reporting form within 30 calendar days of discovering, acquiring or establishing any new significant financial interest (e.g. through purchase, marriage, or inheritance) or changes in any existing significant financial interest that might reasonably be related to their research efforts, Institutional Responsibilities, or other basis for reporting.

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 all sponsored or reimbursed travel taken on or after August 24, 2012, but only if the investigator and the travel both meet certain criteria (listed below).

The following requirements must be met for reporting reimbursed or sponsored travel:

- The Investigator is paid for research that is sponsored/funded by the PHS (see Appendix B);
- The travel is reimbursed or sponsored by some external entity (see exceptions below); and
- The sponsored travel is related to your institutional responsibilities to Duke (e.g. as a physician scientist, you're being sponsored to speak about your science, as opposed to being sponsored to speak on unrelated topic, like a hobby).

Investigators do not have to report travel if it is reimbursed or sponsored by any of the following:

- an Institution of higher education (as defined in 20 U.S.C. § 1001(a));
- a federal, state or local government agency;
- an academic teaching hospital; a medical center; or
- a research institute that is affiliated with an institution of higher education.

Otherwise, travel supported by all other sponsors must be reported, including foundations, professional associations, societies, professional boards, corporations, etc.

If the travel qualifies for reporting (i.e. is sponsored and is related to professional responsibilities), using the Duke Sponsored Travel Disclosures web site, located at https://adgapps.duhs.duke.edu/phs_travel you must report the following:

- 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 date you left and the date you returned.

E. **Subrecipients and Other Collaborators**

Where Duke carries out PHS and NSF-funded research through a subrecipient, including a subgrantee, contractor, subcontractor, or collaborator, Duke will take reasonable steps to ensure that each Investigator complies with the applicable regulation. As required, Duke will incorporate in 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, and will include time periods to meet disclosure and/or FCOI reporting requirements. 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 applicable requirement.

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), or NSF requirements. With respect to grants or cooperative agreements, this arrangement should be defined in a formal written agreement with each consortium participant.

If Duke will be a subrecipient to another entity on a PHS 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. The answer is always that Duke uses its own FCOI policy. Duke does not agree to use or follow any other entity’s FCOI policy, forms, or procedures.

F. **Review of Disclosure Forms**

Disclosure forms are analyzed by the Office of Research Support staff to determine if disclosed SFIs are related to the disclosing Individual’s research and, if related, whether the SFI is a FCOI. The Office of Research Support will develop and maintain standard operating procedures (SOPs), approved by the Conflict of Interest Committee, on how disclosures and management plans are processed, routed, analyzed, classified, reviewed and monitored.

G. **Designation of Institutional Official for Conflict of Interest**

The Provost shall designate an institutional official for conflict of interest (IO-COI). The IO-COI provides expertise, leadership and consultation on issues related to FCOI. Consistent with the Policy and regulations the IO-COI shall:

i. Solicit and review disclosures of SFI;
ii. Determine whether disclosures are related to the disclosing Individual’s Institutional Responsibilities, and if so whether the SFI is a FCOI;
iii. Take actions to manage a FCOI;
iv. Monitor compliance with management plans;
v. Manage noncompliance with the Policy, this document, regulations, policy, etc.;
vi. Provide initial and ongoing reports as required by sponsors and regulations;
vii. Maintain records relating to all disclosures of SFIs and the review and response to such disclosures consistent with regulations
viii. Serve as chair of the Conflict of Interest Committee

H. **The Conflict of Interest Committee**

1. **Charge to the Committee**
The Campus Conflict of Interest Committee is responsible for the review and management of reported or otherwise identified potential conflicts of interest regarding individuals with a primary appointment in one of the Campus\(^1\) schools, centers, or institutions of Duke University.

The Committee's primary function is to protect the integrity of Duke's research and education missions, as well as the integrity of the organization and the individual.

Where management of a potential conflict of interest is required, the Committee works with the Duke individual involved to consider all facts available to it and develop a management plan. Once developed, all management plans will be acknowledged by the individual, tracked over time, and monitored.

2. **Composition of the Committee**

The Committee will consist of Voting Members drawn from regular-rank faculty and Ex-Officio members, typically non-voting, drawn from administrative positions at Duke.

The Committee will be chaired by the Vice Provost for Research and will consist of as many Voting Members as deemed necessary by the Provost.

Diversity of academic disciplines within the voting membership of the Committee will be a priority. Ex-Officio members will typically be recruited from the following areas:

i. School of Medicine Conflict of Interest Committee – will be granted voting privileges if regular-rank faculty member,

ii. Office of Research Support, including the Office of Human Protections Administration,

iii. Office of University Counsel,

iv. Institutional Ethics and Compliance, Office of Internal Audits,

v. Office of Licensing and Ventures.

3. **Appointment to the Committee**

Voting Members of the Campus COI Committee are appointed by the Provost from a list of regular-rank faculty members put forward by the Vice Provost for Research. All appointments must also have the approval of the Executive Committee of the Academic Council (ECAC).

Ex-Officio members of the Committee serve at the pleasure of the Chair as a resource to aid the review and discussion of matters before the Committee.

4. **Meetings**

The Committee will schedule meetings on at least a bimonthly basis, typically on the second Wednesday of a month, at dates, times, and places specified by the Chair.

A quorum will consist of at least 4 voting members of the Committee. Members of the Committee may participate in a meeting of the Committee by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other. Participation in a meeting pursuant to this provision shall constitute presence in person for purposes of quorum and approval of a matter voted upon.

5. **Terms on the Committee**

Voting members of the Committee are asked to serve 2-3 years on the Committee.

6. **Vacancies on the Committee**

\(^1\) Campus includes Arts and Sciences and Trinity College, The Fuqua School of Business, Divinity School, School of Law, Nicholas School of the Environment and Earth Sciences, Pratt School of Engineering, and Sanford School of Public Policy.
An unscheduled vacancy of a voting member of the Committee will be filled by the Provost within two scheduled meetings.

7. **Voting**
   The voting members of the Committee will, providing a quorum is present, vote on all matters brought before the Committee. A simple majority of the voting members present is required for a motion to be approved.

   The Chair of the Committee will abstain from voting with the exception of casting a tie-breaking vote.

8. **Minutes**
   Each meeting will be recorded by an audio device for the sole purpose of drafting minutes. Once the minutes have been compiled and the official minutes have been approved by the Committee the recording and all previous drafts of the minutes will be destroyed.

   To protect the confidentiality of the meetings and shield Committee Members, individual comments made by Committee Members will be attributed to “Committee Member” in the minutes.

   The drafting of the minutes will be the responsibility of the Committee Coordinator.

9. **Conflict of Interest within the Committee**
   If a member of the Committee has a personal interest in the outcome or a conflict of interest regarding an individual or a matter brought before the Committee, that member will disclose the relationship or conflict to the Committee as a whole. The conflicted member, if he or she chooses, may remain in the meeting to provide important information for the discussion of situation but must recuse him/herself for the vote regarding the matter.

   FCOI involving human subjects will be referred to the School of Medicine Conflict of Interest Committee.

1. **Management Plans for Financial Conflicts of Interest**
   According to federal rules, any FCOIs in NSF and PHS-funded research must be managed prior to expenditure of any federal funds.

   Simple financial conflicts of interest are managed by issuing a standard management plan to the Individual with the FCOI. A standard management plan will require that the Individual take certain steps, which may include but are not limited to one or more of the following: (1) follow-up with the IRB, IACUC, and/or Office of Research Support (ORS); and (2) disclosure of the conflict to potential research participants, academic journals and manuscript reviewers, audiences of conferences and seminars, and sponsors; (3) recusal from directly influencing purchasing decisions. Standard management plans, which are issued by the Office of Research Support, are reported and reviewed by the Conflict of Interest Committee at convened meetings, usually monthly. The Conflict of Interest Committee may accept or modify these plans, as necessary.

   Complex FCOIs 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.

   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. Examples of conditions or restrictions that might be imposed to manage FCOI 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 design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
   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 interest); or
   vii. Severance of the relationship that creates the FCOI.

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, i.e. whether it “directly and significantly affect the design, conduct, or reporting of the PHS-sponsored research.”

J. **Reporting of Financial Conflicts of Interest to PHS Awarding Components**

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 Policy and this document.

During the period of the award, Duke will report within 60 days any FCOI identified by a new Investigator, or subsequent to the initial FCOI report by an existing Investigator. When the grantee submits his/her annual progress report or at the time of extension, Duke will report the status of any FCOI and any changes in management plans to the PHS Awarding Component. 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) to provide the status of the FCOI ad any changes to the management plan, if applicable, until the completion of the project. The content and format of reports will be consistent with regulations.

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

K. **Monitoring**

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, ORS, School Administration and others with a clear need to know. Each management plan is conflict-specific, and an Individual may have more than one FCOI and more than one management plan.

Standard monitoring will involve review of the instituted management plan at the next annual reporting or whenever an Individual updates his/her report. Monitoring of the management plan will determine whether the relationship between the FCOI and Institutional Responsibilities (e.g. sponsored research) has changed or is expected to change, and whether to update the management plan based on new information from the Individual, Policy, law, or standards established by the Committee.

The initial monitoring is done by the Assistant Director of Compliance in the Office of Research Support. 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 the FCOI is simple or complex and follow the corresponding process for new FCOI. The Committee may require a project specific monitoring process when it believes such a plan is warranted.
Ongoing monitoring of a management is required until the termination of the FCOI, which may include the completion of the research project, and reporting of results in publications and presentations, termination of rights in IP, sale or trade of the financial interest, etc.

L. Retrospective Review and Mitigation Reports

Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including failure by the Individual to disclose a Significant Financial Interest that is determined by the Institution to constitute a FCOI; failure by the Duke to review or manage such a FCOI; or failure by the Individual to comply with a management plan, then Duke will, within 120 days of its determination of noncompliance, complete a “retrospective review” of the Individual’s activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the 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 a 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.

If bias is found, Duke will notify the 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.

M. Recordkeeping

Duke will maintain records of all financial disclosures and all actions taken by Duke with respect to each FCOI as follows:

i. 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 74.53(b) for different situations;
ii. 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.

N. Noncompliance / Sanctions

The following items in the non-exclusive list are grounds for a finding of noncompliance and sanctions:

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 significant financial interest is obtained;
v. Failing to cooperate with or otherwise respond to requests for additional information from the Assistant Director of Compliance, the Conflict of Interest Committee, other designated officials at Duke, or a sponsor; and
vi. Failing to fulfill the terms and conditions of a conflict management plan

Where noncompliance is perceived, the Office of Research Support or Conflict of Interest Committee will review the matter and communicate with the Individual. The following non-exclusive list of are means by which noncompliance may be resolved:

i. Request that a disclosure form be completed, updated, amended, etc.;
ii. Provide the Individual with another opportunity to respond to requests for information or collaboration;
iii. Recommend a delay or cessation of disbursement of the Individual’s grant funding;
iv. Conduct a retroactive review in compliance with applicable regulations and report the matter to the Conflict of Interest Committee or funding agency, as appropriate
v. Submit notice of noncompliance to any of the following, as appropriate: Chief Compliance Officer, Office of Internal Audits, Dean or chair of the department if the Individual is faculty, supervisor if Individual is non-faculty, Institutional Animal Care and Use Committee (IACUC), Office of Sponsored Programs (OSP), and Institutional Review Board (IRB).
vi. Refer the case to the appropriate Duke official or committee for progressive discipline action as appropriate under Duke policies or standards

Agreements with subrecipients consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated. Similarly, any agreement with a subrecipient organization may be terminated if that organization fails to comply with its obligations under the PHS regulations.

In any case in which the U.S. Department of Health and Human Services 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.

O. Appeal of a Conflict of Interest Committee Decision

If an Individual wishes to appeal the determination of the Committee, the Individual must submit a written appeal detailing the basis for the appeal to the Provost or his/her designee within ten (10) calendar days of receipt of the decision.

The appeal will be reviewed by the Provost. The decision of the Dean is final. The procedure is an exclusive mechanism for resolution of FCOI issues. Other Institutional policies and procedures cannot be invoked in an effort to re-adjudicate the determinations of the Committee or the Dean.

P. Public Accessibility of FCOI Policy and FCOI Information

Duke makes its policy on Financial Conflict of Interest in PHS-Funded Research publicly available via the this web site http://www.provost.duke.edu/pdfs/fhb/FHB_App_O.pdf.

Duke will make information available concerning identified FCOIs by Senior/Key personnel (as identified in the relevant submittal to the PHS-funding unit) by a written response to any requestor within 5 business days of a request made to ors-grant@duke.edu. Duke will update such information as specified by the HHS rules. 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, it is Duke’s responsibility to make FCOI information publicly accessible. However, when the subrecipient Investigator is required to comply with the subrecipient’s FCOI policy, the subrecipient Institution will also make FCOI information publicly accessible. In these situations, Duke can consider including the requirement for the subrecipient Institution to make FCOI information publicly available as part of the subaward agreement.

Q. Requirements for Reporting and Managing Financial Conflicts of Interest in Research Funded by the National Science Foundation

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.

For NSF-funded research, Duke has chosen to apply the definition of “Significant Financial Interest (SFI)” as used in the PHS FCOI regulation, as it relates to remuneration and equity interests in publicly-traded and non-publicly traded entities, and as it relates to intellectual property rights and interests. However, unlike for PHS-funded projects, Duke currently is not requiring Investigators on NSF-funded projects to report reimbursed or sponsored travel. Otherwise, Duke will implement NSF’s requirements as established throughout this document.

R. Requirements for Reporting and Managing Financial Conflicts of Interest in Research Funded Under the Federal Acquisition Regulations

For conflicts of interest related to sponsored research or services provided pursuant to the Federal Acquisition Regulations (FAR), Duke will implement applicable requirements as established throughout the Policy and this document, except those that are not directly required under the FAR.

S. Consulting and Commercial Research Relationships

An Investigator may not participate in sponsored research at Duke involving technology that is owned by or contractually obligated to a business in which the Investigator has a financial interest, or with which the faculty member has a consulting or other commercial research relationship, unless the participation is approved the Committee or its designee.

T. Student Involvement in Faculty's Outside Professional Activities

In furtherance of the University-Industry Guidelines, the Office of Research Support, as delegated by the Committee, must review and approve, in writing any participation by a student in the outside professional activities of an Investigator.

The Assistant Director of Compliance for the Office of Research Support will meet with the student to discuss with him/her issues related to the performance of these activities. After the discussion, the student will have a choice to execute a disclosure affirmation waiver document, to signify her/his understanding of the issues involved, that will also be signed by the Vice Provost for Research, the PI and appropriate chair or director. The arrangement shall not be approved where the quality of the student's education or other Duke interests are in jeopardy, including, but not limited to any potential publication restriction or impediment to completing a thesis, dissertation, post-doctoral program, etc.
A list of the issues to be discussed with the student and a copy of the disclosure affirmation waiver is included as Appendix C.

U. **Frequently Asked Questions**

1. **How should I handle payments from a contractor, for example a medical education company, when I know who the primary sponsor is?**

   Payments from subsidiary companies and contractors should be reported as coming from the parent company. For example, if “Company A” hires a contractor to organize a conference, and the honorarium check comes from the meeting organizers, the money should still be attributed to “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, if the meeting meets the standard for independence (for example, in medicine, continuing medical education certification), the honorarium need not be reported.

2. **How should I report payments from companies that operate as subsidiaries?**

   In general, companies that are owned by larger companies (for example, Janssen and Ortho Biotech are owned by Johnson and Johnson) will be treated as one entity (the overarching company – Johnson and Johnson in this case), unless the COI Office specifically concurs that the subsidiary truly operates independently of the holding company.

3. **I use a local company to track my payments and manage my consulting contracts, and I receive my checks from that company. How should I report those relationships?**

   Payments made to an intermediary business entity for services performed by a faculty member should be reported on the annual COI reporting form attributed to the original sponsor. 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, including the fees deducted for management services.

4. **Do I need to report personal payments from the federal government? From DUAP or the PDC?**

   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).

5. **Do I need to report all my payments from external entities? For example, I own a pizza franchise in Hickory. Do I need to report that?**

   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 institutional responsibilities like research, purchasing, or teaching.

6. **What is the threshold for when management plans will be necessary?**

   Personal payments of ≥$5,000/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 (submitted manuscripts), and to audiences for verbal presentations.

7. **What are the financial thresholds when management plans begin to restrict what I can do?**

Payments of $\geq 25,000/year from an external entity means there will be a rebuttable presumption the Individual 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 (submitted manuscripts), and to audiences for verbal presentations.

Similar rules apply if an individual has any privately traded equity, or any options in a private or public company. In those cases, the same rebuttable presumption is enforced that the individual cannot be Principal Investigator on a grant or contract related to the company’s products or intellectual property.

8. **How does Duke assess royalties as significant financial interests?**

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 hand, 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). It should be noted that Duke does not agree with the Federal rule that royalty payments received through the institution are not reportable as a FCOI. In some cases, the results of research could dramatically affect the size of a royalty stream, and thus to avoid the appearance or reality of a conflict of interest affecting the research results, Duke will manage any research where the COI Committee believes there is the potential for FCOI.

9. **How does Duke handle equity in publicly-traded companies?**

Faculty members with fair market equity holdings $\geq 5,000 in a publicly-traded company are subject to the same rules had they received $\geq 5,000 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 publicly-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. For reporting purposes, the value of a share of publically traded stock will generally be determined on the basis of the stock’s price on the last day of trading in the previous year.

10. **What if a company compensates me in equity instead of payments?**

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.

11. **How does Duke treat equity in privately-held companies?**
   Because it may be difficult to determine fair market value for 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.

12. **How does Duke consider stock 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 Office of Research Support 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.

13. **Do I need to report patents and intellectual property? The Office of Licensing and Ventures knows about them.**
   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. While the OLV may know about intellectual property, given the number of people involved in the management of patents and intellectual property, the need for completeness requires individual reporting.

14. **How does Duke evaluate SBIR/STTRs?**
   Because the SBIR/STTR grants create complex relationships, a separate policy will be implemented.
APPENDIX A
[PLACEHOLDER FOR DUKE FINANCIAL CONFLICT OF INTEREST POLICY]

APPENDIX B
Organizations that Require Compliance with the U.S. PHS Financial Conflict of Interest Regulations

U.S. Public Health Service includes the following components
  o National Institutes of Health (NIH)
  o Centers for Disease Control and Prevention (CDC)
  o Food and Drug Administration (FDA)
  o Substance Abuse and Mental Health Services Administration (SAMHSA)
  o Office of the Assistant Secretary for Preparedness and Response (ASPR)
  o Office of Global Affairs (OGA)
  o Agency for Toxic Substances and Disease Registry (ATSDR)
  o Health Resources and Services Administration (HRSA)
  o Indian Health Service (IHS)
  o Agency for Healthcare Research and Quality (AHRQ)
  o Office of the Assistant Secretary for Health

Other Agencies/Entities that Reportedly Have Adopted the PHS FCOI Rule
  o Administration on Aging (AoA)
  o Administration for Children and Families (ACF)
  o Alliance for Lupus Research (ALR)
  o American Cancer Society (ACS)
  o American Heart Association (AHA)
  o Arthritis Foundation (AF)
  o California Breast Cancer Research Program (CBCRP)
  o California HIV/AIDS Research Program (CHRP)
  o Juvenile Diabetes Research Foundation (JDRF)
  o Lupus Foundation of America (LFA)
  o Susan G. Komen for the Cure
APPENDIX C

Involvement of Students/Postdoctoral Scholars/Associates in a Faculty Member’s Outside Professional Activities

Potential Benefits
- Educational enrichment through professional/practical application
- Gain professional experience with an outside entity in a field related to your academic interests
- Build up CV
- Enhance faculty recommendation
- Build professional equity
- Earn extra money

Potential Concerns
- Difficult to safeguard the academic relationship
- Blurs faculty-to-student/postdoc relationship
- Harder to compartmentalize
- Complicates the ability to discern a conflict of interest
- More potential to over-commit – “harder to say no”
- Authorship – publication of confidential information or trade secrets

Other Issues for Consideration:
- Tax issues
- Limits imposed as a result of receiving financial aid
- IP rights

For questions or concerns, please contact:
Brian Lowinger, J.D.
Assistant Director for Compliance
Office of Research Support
2200 W. Main Street, Suite 710
Campus Box 104010
Durham, NC 27705-4010
Phone: 919-681-8540
Email: brian.lowinger@duke.edu
Disclosure and Affirmation Waiver

Required Disclosure:
Duke Policy: Faculty Handbook, University-Industry Guidelines
Company:
Faculty Member:
Relationship to Company: Consultant
Duke Student/Postdoctoral Associate/Scholar:

Disclosure:
I, [[PI Name and Title]], hereby disclose my relationship, described above, with [[Company Name]]. It is the intent of me and [[Student Name]] to be engaged in activities at said company as outlined in the attached statement of work. I am requesting approval Duke University for [[Student’s Name]] work described in the attached document.

[[PI Name]].
Duke University

Affirmation:
I, [[Student Name]], hereby affirm that I have been informed of the potential complications that may arise because of my involvement in Professor [[PI’s Last Name]] outside professional activities, in this case [[describe outside activity]] with [[Company]]. I understand that if I have any questions or concerns I may contact the Assistant Director for Compliance, Mr. Brian Lowinger, (919-681-8540 or brian.lowinger@duke.edu) or any of the individuals co-signing this document.

[[Student Name]]
Duke University

The following hereby acknowledge receipt of this disclosure and affirmation and give approval for the involvement of the above listed Duke Student/Postdoctoral Associate/Scholar’s activities regarding the company listed above, and as outlined in the attached statement of work.

[[Name]], [[Title – Director, Chair, Etc.]]
[[Department/Center]]
Duke University

James N. Siedow, Ph.D.
Vice Provost for Research
Duke University
Statement of Work
(To Accompany Disclosure and Affirmation Waiver Regarding the
Involvement of Duke Student/Postdoctoral Associate/Scholar in a
Faculty Member’s External Professional Activities)

Faculty Member: [[Name]] Ph.D.
Company:
Relationship to Company:
Duke Student/Postdoctoral Associate/Scholar: [[Name]]

Statement of Work:

Brief description of outside work inserted and, if applicable, time commitment