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 Duke Financial Conflict of Interest adopted by the Board of Trustees of Duke University in May 2011 (the “Policy”), and these guidelines 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 by grants, cooperative agreements, contracts by the Public Health Services (PHS), National Science Foundation (NSF), etc.

A copy of the Policy is available on the following links:
- ORS Web site: https://ors.duke.edu/conflict-interest
- Faculty Handbook: https://provost.duke.edu/faculty-resources/faculty-handbook/

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

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

2. Disclosure Process
All Individuals who have a primary appointment in one of the following must submit an annual disclosure form:

- Arts and Sciences and Trinity College
- The Fuqua School of Business
- Divinity School
- School of Law
- Nicholas School of the Environment
- Sanford School of Public Policy, or
- Pratt School of Engineering

Disclosure is accomplished by submitting the interactive, online reporting form through the Internet. Individuals required to provide an annual disclosure form must include all Significant Financial Interests (SFIs) for themselves and their immediate family as well as other information required under law and the Policy.

The Office of Research Support (ORS) will distribute an announcement that the disclosure form is available for completion. Email reminders are sent as a courtesy to Individuals who have not completed the disclosure form. Not receiving an email reminder does not eliminate or alter an Individual’s requirement to complete the annual disclosure form.
An Individual is responsible for updating her/his disclosure 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 SFI.

3. Review of Disclosure Forms

The Provost designated the Vice Provost for Research as an institutional official for COI. On behalf of the Vice Provost for Research, ORS carries out reviews to determine if disclosed SFIs relate to the Individual’s institutional responsibilities and if so, whether the SFI is a FCOI. In addition, ORS will do the following:

i. Take actions to manage a FCOI;
ii. Monitor compliance with management plans;
iii. Manage noncompliance with the Policy, this document, regulations, policy, etc.;
iv. Provide initial and ongoing reports as required by sponsors and regulations; and
v. Maintain records relating to all disclosures of SFIs and the review and response to such disclosures consistent with regulations.

ORS develops and maintains standard operating procedures (SOPs), approved by the Campus Conflict of Interest Committee (Campus Committee), on how disclosures and management plans are processed, routed, analyzed, classified, reviewed and monitored.

4. Management Plans

Each management plan is conflict-specific, and an Individual may have more than one Financial Conflict of Interest (FCOI) and more than one management plan.

In most cases, an Individual with a FCOI must receive a management plan. Pursuant to rules issued by PHS, NSF, and other sponsors, the management plan must be in place before the agency’s funds are released to the Investigator for carrying our sponsored research.

Simple FCOIs are managed by issuing a standard management plan to the Individual. 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 Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB), and/or ORS; and (2) disclosure of the conflict to potential research participants, academic journals and manuscript reviewers, audiences of conferences and seminars, and sponsors; (3) and, recusal from directly influencing purchasing decisions. Standard management plans, which are issued by ORS, and are reported and reviewed by the Campus Committee at convened meetings. The Campus Committee may accept or modify these plans, as necessary.

Complex FCOIs require careful consideration by the Campus Committee. After confirming the accuracy and completeness of the reporting form and possibly obtaining additional information from the Individual, the Campus 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 entity. Examples of terms and conditions 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;

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); or

vii. Severance of the relationship that creates the FCOI.

A 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.”

5. Reporting of Financial Conflicts of Interest to PHS Awarding Components

For PHS and other applicable-funded research projects, prior to the expenditure of funds, Duke will provide the sponsor 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, rules, 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 and 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.
6. Monitoring

All management plans will be acknowledged by the 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 an Individual updates his/her report. Monitoring 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 Campus Committee.

The initial monitoring is done by ORS. If no changes are needed the plan will remain in effect. If changes are required, ORS will recommend changes and update the Campus Committee. The Campus 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.

7. Retrospective Review and Mitigation Reports

Pursuant to PHS’ rules, whenever a FCOI is not identified or managed in a timely manner, Duke will, within 120 days of its determination of noncompliance, complete a “retrospective review” of the Investigator’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.

Examples of not meeting the timeliness standard include the following:
   i. Failure by the Investigator to disclose a SFI that is determined by Duke to constitute a FCOI;
   ii. Failure by Duke to review or manage such a FCOI; or
   iii. Failure by the Investigator to comply with a management plan.

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 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.

8. 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 FCOI policy will apply to subrecipient’s Investigator, and will include time periods to meet disclosure and/or FCOI reporting requirements. If the subrecipient’s Investigator will 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.

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 for disclosing SFIs 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.

9. Recordkeeping

Duke will maintain records of all financial disclosures and all actions taken by Duke with respect to each FCOI 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 74.53(b) for different situations; and (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.

10. Training Requirements

Per PHS regulations, 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 Duke; or (C) when Duke finds an Investigator is not in compliance with the Policy or management plan.
11. PHS Sponsored/Reimbursed Travel

Investigators with research sponsored by PHS 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 (listed below).

Requirements. Requirements for reporting reimbursed or sponsored travel are as follow:
1. The Investigator is paid for research that is sponsored/funded by the PHS;
2. The travel is reimbursed or sponsored by some external entity; and
3. 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:
1. An institution of higher education (as defined in 20 U.S.C. § 1001(a));
2. A federal, state or local government agency;
3. An academic teaching hospital; a medical center; or
4. A research institute that is affiliated with an institution of higher education.

If the travel qualifies for reporting, the Investigator must use the Duke Sponsored Travel Disclosures web site (https://adgapps.duhs.duke.edu/phs_travel to report the following:
1. 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);
2. The purpose of the trip (speaking, consulting, meetings, etc.);
3. The destination for the trip; and
4. The duration of the travel, specifically the departure and return dates.

12. Noncompliance / Sanctions

The following items in the non-exclusive list are grounds for a finding of noncompliance and possible sanction against an Individual:
1. Not complying with the terms of the Policy;
2. Not submitting a truthful and timely disclosure form;
3. Failing to fulfill training requirements;
4. Failing to update a disclosure form when a new SFI is obtained;
5. Failing to cooperate with or otherwise respond to requests for additional information from the Assistant Director of Compliance, the Campus Committee, other designated officials at Duke, or a sponsor; and
6. Failing to fulfill the terms and conditions of a conflict management plan

Where noncompliance is perceived, ORS or the Campus Committee will review the matter and communicate with the Individual. The following non-exclusive list of are means by which noncompliance may be resolved:
1. Request that a disclosure form be completed, updated, amended, etc.;
2. 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 Campus 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, IACUC, Office of Sponsored Programs (OSP), and IRB.

vi. Refer the case to the appropriate Duke official or committee for action as appropriate under Duke policies or standards

Agreements with subrecipients that either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated.

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 that 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 FCOI Policy and FCOI Information

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 five business days of a request made to ors-grant@duke.edu. Per 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.
14. National Science Foundation Specific Issues

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

15. Federal Acquisition Regulations

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

16. Definitions

“Financial Conflict of Interest” or “FCOI” means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research or otherwise overlaps with an Individual’s institutional responsibilities.

“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.

“Institution” means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS or other sponsored research funding.

“Immediate family” means a spouse and dependent children.

“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, teaches; makes or otherwise influences purchasing or contracting decisions. The term includes anyone who:

i. Has faculty or special PI status;

ii. Is a postdoctoral associate/scholar;

iii. Is listed as “key” or “Investigator” on a sponsored research project, or otherwise contributes to the design, conduct or reporting of research;

iv. Is an exempt employee who received salary support from a government source or a sponsored research project;

v. Teaches; or

vi. Makes or otherwise influences purchasing decisions related to sponsored research.
A person generally qualifies as an Individual if she/he meets at least one of the following:

- has faculty or special PI status;
- is a postdoctoral associate/scholar;
- is listed as “key” or “investigator” in SPS on an active award; or
- is an exempt employee who has received salary support from a government source or from a sponsored research project.

“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 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 FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

“PD/PI” means a project director or principal Investigator of a PHS-funded 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, 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.

“Small Business Innovation Research” or “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” or “SFI” means a financial interest 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), the value of which in the 12 month 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; and

iii. Intellectual property rights and interests (e.g., patents, copyrights, and royalties from such rights).

The term SFI 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.