FREQUENTLY ASKED QUESTIONS

COMPLYING WITH THE FINANCIAL CONFLICT OF INTEREST POLICY
AND OTHER ETHICAL STANDARDS

Q1. To whom does the disclosure process apply?

A1 – The disclosure process applies to the following individuals employed by the University or Health System:

- The President, Duke senior officers, and trustees;
- Any faculty member (regular and non-regular rank), post-doctoral fellow, graduate and undergraduate student, and other individual who is listed as “key personnel” or acts as an “investigator” on research. An investigator is anyone who contributes to the design, conduct, analysis, or reporting of results of research;
- Any individual paid using funds from a externally funded grant (e.g., an NIH, NSF, state, or Department of Defense grant);
- Certain individuals involved in making or advising on purchasing decisions;
- Certain individuals who are engaged in the selection, purchase, or prescription of medications, devices, or services for patient care;
- Certain individuals who are involved in hiring, evaluating, and managing employees at Duke; and
- Certain individuals who provide expert advice or otherwise exercise independent discretion in performing his/her duties.

Q2. As part of this policy, what am I being asked to do?

A2 - You are being asked to do two things:

- First, to comply with the Financial Conflict of Interest Policy (Policy) and other ethical standards of institutional importance to the University or Health System (e.g., conflict of commitment, nepotism, and gift prohibition).
- Second, to submit an annual conflict of interest disclosure form and to update your responses over the course of the year within 30 days of a reportable change. Examples of a reportable change include acquiring or discovering (e.g. through purchase, marriage, inheritance) a new financial interest, including but not limited to an outside position, equity in a business, and royalties or honoraria, or employing a member of your family.

Q3. How will the Policy and ethical standards be interpreted and implemented?

A3 - The Policy will be interpreted and implemented to accomplish its purposes: that is, to protect the integrity of the University and Health System and the individuals covered by the Policy. In this regard, it is important to remember that an essential aspect of any conflict of interest policy is to prevent even the perception of a conflict, because the integrity of the University and Health System can be compromised by even the appearance of a conflict of interest. In other words, how would the transaction or behavior in question appear to the public if it were published on the front page of the local newspaper, or can the action be explained to a
trustee, parent or student as in the best interests of the University?

Q4. How are family members of an employee covered and why?

A4 – Family members are covered in two different ways:

- For financial conflict of interest, federal rules require the individual to report his/her own financial interests and those of any immediate family member, which is defined to include a spouse, spousal equivalent, and/or dependent children. Under these rules, the concern is that the family members’ financial interests can affect an individual’s decisions related to objectivity in research, clinical care, teaching, and other institutional responsibilities.

- For nepotism, i.e., decisions affecting the employment of relatives, “family” is broader and includes a spouse, spousal equivalent, children, parents, brothers, sisters, step-parents, step-children, and step-brothers or sisters, and other persons living in the same household as that individual. There is a concern when an employee hires or has direct or indirect supervision of a family member, or where the employee can influence employment decisions affecting the employment of the family member, i.e., hiring, firing, setting hours and wages, evaluations, promotion, etc.

Q5. What disclosures are required?

A5 - The disclosure form includes questions that try to identify relationships, primarily financial, that might affect your work for Duke. Examples of areas that might be affected include how you conduct research, teach, or provide patient care. Another example is purchasing or recommending items on Duke’s behalf. While many faculty and staff do not have all of these duties, most have at least one. The disclosure form specifically requires providing information related to the following areas:

- General information about your position at Duke;
- Whether you or a family member have a financial interest (as described below) that is related to or overlaps with your responsibilities on behalf of Duke or with a company that does business with Duke;
- Whether you or a family member serve on an outside entity’s board as a director, trustee, advisor, etc., or have a position with fiduciary obligations, including as an president, vice-president, treasurer, secretary, or other officer position;
- Whether you are listed as an owner, inventor, contributor, or co-owner on any licensed or optioned intellectual property, including patents, provisional patents, copyrights, or trademarks;
- Whether you are involved in any research that assesses a company's product, service, or intellectual property (e.g., something that could evolve into a product or new use for an existing product - whether or not you have any other relationship with the company or its competitors);
- Whether you provide any advice to investors, including a hedge fund, venture capital firm, brokerage house, investment advisor, hedge fund manager, etc.;
- Whether you have funding from an SBIR or STTR, i.e., types of federal awards provided directly to small businesses;
- Whether any intermediary company receives money on your behalf, e.g., a consulting group that receives payment for your work (in which case you will be asked to identify
the original funding entity);

- Whether you employ or supervise a member of your family; and
- Whether you engaged in government relations activities that Duke must account for and report as lobbying activities to comply with federal (e.g., IRS) and state law.

**Q6. What is an example of a financial interest?**

Payments from an outside entity (from a pharmaceutical company, for example) or anything of actual or potential monetary value owned by the employee or family member can be a relevant financial interest. Duke cares about these financial interests when they are related to the employee’s duties and responsibilities at Duke, including the following:

- Payments for services, including honoraria, consulting fees, lecture payments, etc. that are not otherwise excluded under the Policy (because it comes from a university, hospital, etc. See A5);
- A right of ownership in intellectual property (copyright, patent, trademark);
- Equity ownership (stock, stock option, security, or other ownership interest); and
- Any other interest that Duke determines qualifies as a financial interest.

To clarify what is meant by “related to the employee’s duties and responsibilities at Duke,” these duties and responsibilities include activities like research, teaching, clinical care, and administrative activities (like purchasing). We exclude hobbies or professional activities that do not relate to your work at Duke. For example, if an English professor was also a professional antique automobile appraiser, the appraising would not be related to her role as an English professor.

**Q7. Are there examples of financial interests that are exempt from the Conflict of Interest review process?**

A7 - The following do not constitute financial interests of concern to this policy:

- Ownership of a share or shares in a mutual fund that the individual does not directly control;
- Salary or other payment from Duke or another U.S. institute of higher education, from hospitals, from research institutes, or from a branch of government, including federal, state, or local; and
- Payments from the Duke Private Diagnostic Clinic, PLLC are also considered exempt.

**Q8. What are some examples of a financial conflict of interest?**

A8 – A financial conflict of interest may exist when there is a financial interest that has the potential to directly and significantly affect the design, conduct or reporting of funded research, or the performance of duties and responsibilities on behalf of Duke. Some examples include:

- A financial interest that affects the investigator’s objectivity such that the design, conduct, and reporting of research performed is not free from bias;
- A financial interest that affects the care provided to a patient. For example, a decision to provide one treatment over another because the individual has a consulting contract with the company that manufactures the first treatment;
• A financial interest that affects the purchase of items like equipment, supplies, and services. For example, ownership by an administrator or a family member in a vendor or potential vendor that does or may do business with the University or Health System when the administrator has some control over the decision or recommendation of purchases from vendors offering the same services or products; and
• A financial interest that affects what information the individual decides to include in an article or presentation.

Q9. What are some examples of a conflict of commitment?

A9 – A conflict of commitment can exist when a non-Duke obligation prevents an individual from spending the time required for his/her full-time commitment to the University or Health System. Some examples include:

• Membership by an individual on multiple scientific advisory or corporate boards, including committees, that could take that individual away from his/her job at the University or Health System to the extent that the employee's full-time job obligations to the University or Health System are not met;
• Employment by another entity that is intended to be part-time, but that interferes with full-time duties at the University or Health System even if unrelated to the missions of Duke (i.e., part-time real estate agent or owner/manager in a start-up company); and
• For faculty, the fundamental rule is that consulting should be limited to 1 day per week (a maximum of 44 days/year for full-time employees). Within the School of Medicine, this is interpreted to mean 10 hours per week.

Q9. Am I required to complete a training program?

A9 – It depends. If you are an “investigator” on a U.S. Public Health System (i.e., NIH, FDA, SAMHSA, etc.) funded award (i.e., you are responsible for the design, conduct, or reporting of the research), then “YES” the federal rules require you to complete training prior to engaging in PHS-funded research and at least every four years, and immediately under the designated circumstances:

• You are new to Duke and qualify as an investigator;
• You are found not to be in compliance with the Policy or your management plan; and
• Duke changes the Policy in a manner that affects Investigator requirements

The required training program is available to all persons in a leadership role on sponsored projects or programs, i.e. principal investigators, project leaders, core leaders, project directors, co-principal investigators, and PI fellows.

The link to the training program is found here: http://finance.duke.edu/research/training/index.php?crs=307&trn=26

Other training programs are also available at Duke.

Q10. What is sponsored/reimbursed travel and do I have to report it?

A10 – Under PHS regulations, investigators who are planning to participate in funded research must disclose their reimbursed or sponsored travel related to their institutional responsibilities
over the previous twelve-month period to Duke no later than the time of application for funded research. They must also submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

Campus currently only requires reporting if PHS (or a component agency) is the sponsor. The School of Medicine/Health System requires reporting of all sponsored/reimbursed travel, regardless of the sponsor.

You can report the sponsored or reimbursed travel at the following link: https://radapps.duke.edu/phs_travel

You can learn more about this reporting requirement at the following links:
- https://ors.duke.edu/phs-reimbursed-sponsored-travel

Q11. How are the COI disclosure forms reviewed?

A11 - The forms are reviewed initially by Duke’s Research Integrity Office (School of Medicine/Health System/Staff) and Office of Research Support (Campus) to determine if there are any relationships over pre-defined thresholds, like the NIH standard of a financial interest of $5,000 or more, for board memberships with for profit companies, and other key issues. If there are none, the form will be cleared as not posing a potential or actual issue. Sometimes, the information submitted is incomplete or needs more information, and the COI review staff will ask you to supplement or clarify your answer. Issues that reach thresholds of possible conflicts are reviewed by staff and in many cases then evaluated by one of the four COI committees (Administrative, Duke Medicine, Campus, and Institutional) to decide if a conflict requires management. If the committee determines that management is needed, either the compliance staff or a committee member will contact you to develop a plan appropriately tailored to the conflict. You will be required to sign the management plan and confirm that it is still applicable and remains in effect each year thereafter.

Q12. What is a conflict management plan?

A12 - A conflict management plan documents your role at Duke and the fact that your financial interest results in a conflict, and it contains the terms for managing issues going forward. Management plans are common and required by regulators and sponsors. Provided below is a summary of terms that may be included in a management plan:

- Public disclosure of the financial interest, e.g., when publishing or presenting the results of the research, to the Institutional Review Board(s) or directly to participants in a clinical trial;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias;
- Changing personnel or responsibilities, or removing personnel from all or some part of the project;
- Reducing or eliminating the financial interest (e.g., sale of an equity interest);
- Severing of relationships that create financial conflicts;
- Confirming the employee’s agreement to the management plan;
- Describing how the plan will be monitored to ensure compliance; and
Q13. Are disclosure forms kept confidential?

A13 - Yes. Disclosure forms are kept confidential except where a disclosure is required by law or for an administrative purpose. Examples of an administrative purpose include a review by a conflict of interest committee or by grant administrators where a potential conflict relates to the grant. Sometimes, a sponsor requires notice that a conflict is being managed and, as part of this, requires a description or summary of the management plan.

Q14. What gifts are acceptable, or are they all banned?

A14 – That depends on where you work at Duke. Campus-based employees are prohibited from accepting material gifts, favors, or hospitality that might influence or appear to influence their decision making or compromise their judgment in actions, i.e., anything having a fair market value of $25 or more.

Duke Medicine employees and medical staff should refer to the DUHS Gifts and Courtesies Policy (see http://intranet.dukemedicine.org/compliance/default.aspx) that generally prohibits acceptance of any gifts, except patient gifts reasonable in value under certain circumstances, medical models for patient education and medication samples within outpatient clinics. Under special circumstances, certain staff may, upon advanced approval of one’s supervisor, accept gifts that are reasonable in value and are appropriate to accomplish DUHS’s business objectives.

Q15. What are examples of permissible gifts?

A15 - The following is not comprehensive, but provides examples meant to facilitate a better understanding. For non-Duke Medicine areas, gifts that could be allowed include:

- Accepting a meal from a potential contributor or donor to Duke, when development activities are part of the employee’s job responsibilities;
- Accepting a gift from a current or potential vendor that is unrelated to the employee’s job responsibilities, e.g., for an existing personal relationship.

Q16. What are examples of gifts that are not allowed?

A16 – The following gifts would not be allowed:

- Accepting a gift basket of food / wine even if you intend to share it with all the employees in that division or department;
- Accepting from a vendor representative payment for a dinner attended by the employee;
- Accepting from a vendor tickets to sporting events, concerts, plays and similar events;
- Accepting from a vendor merchandise, such as televisions, watches, etc.;
- Payment from a vendor of expenses to attend a conference;
- Using a vendor representative’s vacation home for free or less than fair market value, (unless the vendor representative is an immediate family member and the home is used for a family gathering); and
- Accepting free clinical supplies, items or equipment that would not be in compliance
with Procurement’s vendor policy.

Q17. **Does the gift prohibition include the payment of travel expenses related to vendor advisory boards?**

A17 – Duke allows companies to hire faculty or employees as consultants. Travel to consulting activities, including scientific advisory boards, may be paid by the company. If the company is a direct vendor to Duke and the employee is asked to serve on an advisory board, the situation must be evaluated and approved by the employee’s supervisor. If it is determined that the board participation is in the best interest of Duke and its constituency, then the expenses related to that service must be paid by Duke.

Q18. **Does the gift prohibition include the payment by a vendor of travel expenses related to a site visit to review vendor’s capabilities to provide goods or services to Duke?**

A18 - Yes. With regard to visits to vendor facilities, if the department administrator in consultation with Procurement determines that it is in the best interest of Duke, then Duke will pay the travel expenses.

Q19. **Who should I contact with other questions?**

A19 - If you have related questions that have not been addressed here, please contact any of the following offices for assistance:

For Campus faculty, students, and other personnel involved in sponsored research
Office of Research Support  
Tel: 919.684-3030 (general) / 919 681-8540 (direct)  
Email: coi-campus@duke.edu  
Web site: http://ors.duke.edu/conflict-interest

For School of Health System and Medicine/Nursing faculty and their staff
Research Integrity Office  
Tel.: 919-684-3121  
Email: dukecoi@dm.duke.edu  
Web site: http://medschool.duke.edu/research/research-integrity-office

For administrators and staff
Research Integrity Office  
Tel.: 919-684-3121  
Email: dukecoi@dm.duke.edu  
Web site: http://medschool.duke.edu/research/research-integrity-office