

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;
- 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 an 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.

Q6. What are some examples of a financial conflict of interest?

A6 – 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.

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

A8 - Payments from subsidiary companies and contractors should be reported as coming from the parent company. For example, if “Company A” hires a contractor to run a conference, and the honorarium check comes from the meeting organizers, the money should still be attributed to the “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, otherwise payments should be reported as coming from the parent company.

Q9. How should I report payments from companies that operate as subsidiaries?

A9 - 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.

Q10. Do I need to report personal payments from the federal government? From DUAP or the PDC?

A10 - 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).

Q11. 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?

A11 - If the entity making payments to the faculty or staff member has very little 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.

Q12. What are some examples of a conflict of commitment?

A12 – 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 440 hours per year for full-time employees).

Q13. How are the COI disclosure forms reviewed?

A13 - 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.

Q14. What is a conflict management plan?

A14 - 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
- Other information as needed.

Q15. What is the threshold for when management plans will be necessary?

A15 - Personal payments of \geq \$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 (with submitted manuscripts), and to audiences for verbal presentations.

Q16. What are the financial thresholds when management plans begin to restrict what I can do?

A16 - Payments of \geq \$25,000/year from an external entity means there will be a rebuttable presumption the employee 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 requires 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 (with 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 that individual cannot be Principal Investigator on a grant or contract related to the company's products or intellectual property.

Q17. How does Duke assess royalties as significant financial interests?

A17 - 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 transfers some portion of the royalties to the faculty member). On one level, 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.

Q18. How does Duke handle equity in publicly-traded companies?

A18 - Faculty members with fair market equity holdings \geq \$5,000 in a publically-traded company are subject to the same rules if they had 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 publically-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.

Q19. What if a company compensates me in equity instead of payments?

A19 - 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.

Q20. How does Duke treat equity in privately-held companies?

A20 - 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.

Q21. How does Duke consider stock options?

A21 - 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 COI Office 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.

Q22. Do I need to report patents and intellectual property? The Office of Licensing and Ventures knows about them.

A22 - 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 reporting this information on the annual COI Reporting Form.

Q23. How does Duke evaluate SBIR/STTRs?

A23 - Because the SBIR/STTR grants create complex relationships, a separate policy has been created. Please see the SBIR/STTR policy when considering an application for either of these grant categories.

Q24. Are disclosure forms kept confidential?

A24 - 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.

Q25. What gifts are acceptable, or are they all banned?

A25 – 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.

Q26. What are examples of permissible gifts?

A26 - 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.

Q27. What are examples of gifts that are not allowed?

A27 –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.

Q28. Does the gift prohibition include the payment of travel expenses related to vendor advisory boards?

A28 – 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.

Q29. 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?

A29 - 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.

Q30. Who should I contact with other questions?

A30 - 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: admincoi@dm.duke.edu

Web site: <http://medschool.duke.edu/research/research-integrity-office>