

Conflict of Interest/Conflict of Commitment

Frequently Asked Questions

Revised 9/4/2020

1. Can you provide a summary of changes related to the COI policy?

Yes, effective June 1, 2020, Duke University will implement a revised Policy on Faculty Conflicts of Interest and Conflict of Commitment in Research (formerly the Individual Conflict of Interest Policy).

The revised policy will encompass the Institution's positions and guidelines for community members engaged in research and outside activities, including start-up companies and relationships with non-faculty individuals. Individuals who are required to complete the Conflict of Interest Disclosures should review the revised policy to ensure awareness and compliance with updated Institutional directives.

The following is a summary of changes which may affect the reporting and management of outside activities for individuals required to complete annual financial conflict of interest disclosures:

- Conflict of Commitment: The policy includes definitions, expectations and processes for regular and non-regular rank faculty to meet standards set in the Faculty Handbook, 5.2.2.2 Conflict of Commitment. Individuals should review to determine what and how to disclose, discuss and manage potential conflicts of commitments with their supervisors.
- Conflict of Interest for Faculty involved in Start-Ups: Appendix A formalizes Institutional guidance on managing faculty's involvement with and actions on behalf of start-ups with which they may be involved.
- Relationships with non-faculty members: Appendix B formalizes Institutional guidance of relationships between faculty and non-faculty members in outside activities.
- Dispute Resolution: Defining pathways for dispute resolution of Conflict of Interest management plans and potential violations of management plans and/or the Policy. Includes potential outcomes and steps the Institution may take in response to inquiries and/or violations.

The newly **revised policy does not change the requirements for individuals to annually disclose conflicts of interest, or to amend their disclosure within 30 days of a change.** Additionally, it reaffirms the Institution's commitment to management of potential conflicts of interest and adherence with relevant sponsor policies.

2. What is the main purpose of the policy?

To maintain the integrity of Duke University, its personnel, and the public's interest as it relates to conflicts of interest and conflicts of commitment in research.

3. To whom does the policy apply?

The policy applies to regular-rank tenure and non-tenure track faculty members. These faculty members will hold one of the following titles: unmodified professor, associate professor and assistant professor; unique named titles associated with named chairs; and approved non-tenure track titles including professor of the practice, clinical professor, research professor, lecturer and medical instructor (and associate/assistant professors of the same categories).

Furthermore, the policy also applies to: 1) individuals granted Principal Investigator status and 2) those individuals employed by the University and providing material benefits to externally funded research projects. This will be indicated by being named a key personnel or receiving salary from effort on a U.S. federal, state or local government funded project that had financial activity within the preceding twelve months.

4. What are the financial thresholds that define conflicts of interest?

“Significant Financial Interest” is defined by federal and state statutes as: 1) anything of monetary value, including but not limited to, salary or other payments for services (e.g. consulting fees or honoraria) that exceed \$5,000, 2) equity interest (e.g. stock options, stocks, or other ownership interests) of > 5%, and 3) intellectual property rights, (patents, copyrights, etc.).

5. What are some examples of potential conflicts of interest?

- Using University resources in activities that may lead to financial gain for the faculty member (or their immediate family).
- Using University resources to benefit an external entity
- Using the name of the University in promoting activities that may lead to financial gain for the faculty member (or their immediate family).
- Interacting with students in external as well as internal roles. e.g., seeing students as clients or patients, employing students for non-University work.
- Engaging in research in which a faculty member (or their immediate family) has a financial interest, including interests in a start-up company and/or interests related to licensed intellectual property.
- Having a relationship or affiliation between the faculty and the source of information or materials.
- Competing with the University for clients, contracts, etc.
- Financial involvement of a faculty member (or their immediate family) with an outside organization, or holding a position in an outside organization.
- Having an external interest that could be implicated in internal University decisions. e.g., contracts, hiring, research, or in giving advice.
- Payments from outside entities or stock interests greater than \$5,000.

6. What needs to be reported on the disclosure form?

- Payments for services (consulting, lectures, advisory board payments, or honoraria);
- Equity interests, i.e. stocks, stock options, and other ownership interests; **
- Intellectual property rights (e.g., licenses and royalties);
- Donations (monetary, unrestricted funds, in-kind designated for research)
- Relationships and activities with foreign institutions and funding agencies
- All external professional activities.

Federally funded Individuals are also required to disclose items such as sponsored or reimbursed travel and/or gifts and gratuities. These disclosures should be made using appropriate mechanisms and in accordance with relevant university policies.

**Some publicly traded stock must be disclosed, but only in specific circumstances. – Do you own now, or expect to own in the next 12 months, more than \$5,000 in stock, in a PUBLICALLY HELD ORGANIZATION that provides funds to Duke in support of your Institutional Responsibilities (e.g. teaching, research, committee, or other administrative responsibilities)? Do not include investments where you do not directly influence investment decisions, such as mutual funds and retirement accounts. Do include stock/options, warrants and other existing ownership interests.

7. Do I have to disclose information about my immediate family?

Yes. You will be asked to disclose the outside interests of your spouse or domestic partner and your dependent children that relate to your institutional responsibilities at the University.

8. Do I have to report information about work I do on behalf of the University for or with outside entities?

No. You do not need to disclose work you perform for an entity outside of the University if you performed the work as part of your University responsibilities. If the contract underlying your services is an agreement between the entity and the University that was negotiated by the Office of Research Contracts, you **do not** need to disclose it.

9. Do I need to disclose personal consulting services I perform for for-profit companies, even if I did not get paid or receive direct payment for the services (e.g. the company made a gift to my department instead of paying me)?

Yes. You must report all of your outside activities, even if you did not receive payment for them. Report any activities, relationships or interests that you have that were not coordinated or negotiated by Duke.

10. Do I need to disclose personal consulting services I perform for non-profit companies, such as service on committees or governing boards of professional organizations, even if I am not paid for these activities?

Yes. Even if you did not get paid, all consulting services you provide for non-profit organizations must be disclosed if they relate to your individual responsibilities at the University.

11. What could be excluded from reporting on the disclosure form?

- Ownership of a share in a mutual fund
- Salary or other remuneration from Duke or another accredited U.S. institution of higher education
- Salary or other remuneration from the U.S. Department of Veterans Affairs or another U.S. federal, state, or local government entity
- A distribution from Private Diagnostic Clinic, PLLC or the Duke University Health System
- Book Royalties

12. Do I have to disclose non-professional activities?

In general, you do not have to disclose activities that are not related to your University responsibilities unless the time devoted to them interferes with your obligations as a University employee.

13. Do I need to disclose income/dividends from investments in IRAs and diversified mutual funds?

No, these do not need to be disclosed.

14. What federal government work do I need to disclose?

You **do not** need to report work you perform on grant or other panels evaluating applications for research funding from the United States government (e.g., from NIH, NSF, NASA, etc.).

You should disclose work that you performed or expect to perform for the US federal government that give, or could be perceived to give, the University an unfair competitive advantage in securing or that could bias judgment on a government contract. Consider services you performed as an employee, independent contractor, or consultant for the federal government or for any other entity.

Organizational Conflicts of Interest (OCIs) can result when the nature of the work someone at the University performs for the federal government creates an actual or potential conflict of interest for the University on a future Federal award. OCIs can occur when someone at the University prepares or writes specifications for federal funding opportunities, has access to non-public information that provides a competitive advantage, or when someone is evaluating or assessing any work performed by others at the University.

15. What is the main difference between conflict of interest and conflict of commitment?

A conflict of interest may arise when a faculty member's relationship with an outside entity might appear to bias that individual's judgment in performing his or her professional responsibilities at the University. A conflict of commitment may arise when a faculty member engages in external activities or assumes external commitments that might appear to compromise their ability to fulfill the responsibilities of their University obligations.

16. What limits are imposed for a faculty members outside activities?

At no time should any outside activity, with or without compensation, exceed the four (4) days per month standard, for full-time faculty, averaged over an annual period of service based on term of appointment. Exceptions to this policy may be granted by the dean, director or designee where conditions such as reduced effort allow for increased outside activity without creating a conflict of commitment. The University has established four days per month as the outer limit for faculty members' outside activity.

17. Can faculty use university's resources for their outside activities?

No, outside activities may not involve the use of University facilities, materials, services, personnel, or information without prior University approval and a written agreement between all parties.

18. Can faculty members include Duke as a party into their personal contracts for an outside professional activity?

No, faculty member should not include Duke as a party for their personal contracts. Negotiation of the terms of the contract or agreement is the responsibility of the faculty member. The faculty member should ensure the terms of any such agreement, including confidentiality and intellectual property terms, are consistent with his/her obligations under applicable Duke policies. Research in Duke facilities must not be conducted under such personal contracts or agreements.

19. If it is determined that I have a conflict of interest or conflict of commitment, how will it be managed?

Each person's situation is different. Conflicts are managed on a case-by-case basis to ensure that the unique needs of the individual and the University are met.

20. What is the main goal of a COI/COC Management plan?

Management plans are intended to mitigate the potential bias of an apparent or potential conflict to preserve the integrity of the research.

21. What are some examples of strategies that help with addressing bias from a potential or apparent conflict of interest?

- Disclosing the potential conflict to appropriate sources inside and/or outside the University;
- Modifying or limiting the faculty member's duties to minimize or eliminate the conflict;
- Reducing the faculty member's appointment to accommodate the outside interest or activity;
- Securing the faculty member's agreement to modify or suspend outside activity, use of University resources, or other activities that create the potential conflict;
- Prohibiting certain outside activity as inconsistent with the faculty member's obligations to the University;
- Initiating an oversight plan to mitigate potential bias;
- Other actions or steps, as appropriate

22. My Management Plan says that I may not use University resources for my outside activity, what does that mean?

University resources includes time, funding, facilities, equipment, intellectual property, personnel, materials, or information/data that would not be available to the general public and that you would not be free to disclose to other members of the larger scientific community by publication or presentation. Any consulting agreement that requires you to use University resources, other than incidental use of phone/email/computer, should be restructured as an agreement with the University for your services as a University employee.

23. What is the difference between cautionary memo and management plan?

Cautionary Memos are advisory in nature. They contain a list of reminders that one should be mindful of when maintaining outside relationships. Management plans, on the other hand contain action items that must be adhered to in order to remain in compliance with the COI/COC policy and federal regulations. Both are intended to protect faculty/staff members, as well as the University, from even the appearance of a conflict of interest or commitment.

24. Can faculty members dispute decisions made in response to the disclosure or non-disclosure of a potential conflict of interest or commitment?

Yes, Faculty members may dispute decisions made in response to the disclosure or non-disclosure of a potential conflict of interest or commitment. The recourse for such a dispute is to make a request in writing to the Conflict of Interest Committee at dosicoi@duke.edu. Once a request is received, the DOSI-COI office will issue an email notifying the individual that their case is under review.

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

Payments from subsidiary companies or 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 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.

26. 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 & Johnson) will be treated as one entity (the overarching company - Johnson & Johnson in this case), unless the COI Office specifically concurs that the subsidiary truly operates independently of the holding company.

27. How is a Series A Investment defined for purposes of Section III in the policy?

The first significant venture capital or angel equity investment financing for a startup following a seed round (the traditional definition). Series A Funding does not include funding from federal grants such as STTR/SBIR, funds from "friends and family", or other Duke translational funding sources.

28. 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 all thresholds and is managed accordingly if there is an identified research overlap.

29. How does Duke define a start-up company for purposes of COI?

There could be more than one definition for a start-up. A very broad definition is a privately held company in which a faculty or staff member holds an equity interest.

30. I might receive payment to consult for a start-up company. Do I have to disclose this?

Yes, you must disclose the relationship and you must follow the policy requirements for consulting agreements with industry.

31. How does Duke evaluate SBIR/STTRs?

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.

32. What actions should be taken in the event that an Investigator fails to comply with the Institution's Financial Conflict of Interest policy or management plan? (NIH/PHS)

When an Investigator fails to comply with the Institution's Financial Conflict of Interest policy or the management plan, the Institution shall within 120 days:

- a) complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine any bias in the design, conduct or reporting of research;
- b) document the retrospective review consistent with the regulation; and
- c) document the Institution's determination as to whether any NIH-funded research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with the Institution's Financial Conflict of Interest policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research.

If bias is found, the Institution shall notify the NIH promptly and submit a mitigation report to the NIH that shall address the following:

- impact of the bias on the research project and
- the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, the Institution shall submit FCOI reports annually, in accordance with the regulation. Depending on the nature of the Financial Conflict of Interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the NIH-funded research project between the date that the Financial Conflict of Interest is identified and the completion of the Institution's independent retrospective review, in accordance with 42 CFR 50.605(a)(3) and 42 CFR 50.605(b)(3).

In addition, if the NIH determines that one of its funded clinical research projects 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 a Financial Conflict of Interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Other sponsors or granting agencies determine these sanctions generally on a case-by-case basis. University sanctions can be applied for non-compliance regardless of funding source.

33. Is an Investigator required to disclose all financial interests received from a foreign Institution of higher education or the government of another country?

Yes. In each case when the regulation refers to exclusions of Institutions of higher education as defined in 20 U.S.C. 1001(a) or a federal, state or local government agency, the reference is made to a United States (U.S.) Institution of higher education or a federal, state or local government agency within the U.S.

34. When do I report my reimbursed or sponsored travel?

Investigators must disclose their significant financial interests (SFIs), including reimbursed or sponsored travel, no later than at the time of application over the previous twelve-month period (initial disclosure), which is also the same disclosure requirement that applies to all other SFIs. Travel can be disclosed at:

https://radapps.duke.edu/phs_travel

35. When Federal COI reporting is required, what are we required to report?

This includes but is not necessarily limited to the following:

- Project number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the Financial Conflict of Interest;
- Name of the entity with which the Investigator has a Financial Conflict of Interest;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000- \$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;

A description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research; and A description of the key elements of the Institution's management plan, including:

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

We use the same template for reporting to other agencies unless other guidance is received from the agency.

36. Who should I contact with other questions?

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

For Research related COI: DOSI-COI, Email: dosicoi@duke.edu

For Non-Research related COI: OARC, Email: admincoi@dm.duke.edu