

**POLICY ON FACULTY CONFLICTS OF INTEREST AND
CONFLICTS OF COMMITMENT IN RESEARCH**

Effective June 1, 2020

Executive Summary

Duke University is committed to maintaining a collaborative, productive environment for Duke faculty and staff so that they may carry out the University's mission of advancing knowledge, including accelerating the translation of novel research ideas into practice. This includes the encouragement of outside activities and relationships with third parties that further the work and research of Duke faculty. While these relationships are inevitable in a university setting, they also give rise to the possibility of conflicts of interests and 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.

Duke University faculty have an obligation to disclose conflicts of interest and conflicts of commitment to University officials so that potential conflicts of interest or commitment can be evaluated and managed by the Duke Office of Scientific Integrity – Conflict of Interest Office (DOSI-COI). University officials may be engaged if the need for eliminating the conflict arises. The management and/or elimination of conflicts of interest and conflicts of commitment allows the University to maintain the integrity of the institution, its personnel, and the public's interest.

This 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.

- I. Guiding Principles
 - a. Conflict of Interest

For an interest to be considered in conflict with those of the professional responsibilities of the faculty, it would have the real or apparent ability to directly and significantly affect either the design, conduct or reporting of funded research, or the performance of duties and responsibilities on behalf of Duke. A financial conflict of interest may exist in educational, purchasing and research settings. Examples of conflicts include, but are not limited to, the following:

- 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.

Note: the acceptance of gifts is governed by a separate policy.

b. Conflict of Commitment

Duke faculty members owe their primary professional commitment to the University, and faculty members should devote the commensurate time and mental energies to the education, research and service programs of the institution. The specific responsibilities and professional activities that constitute an appropriate primary commitment will differ across schools and departments, but they should be based on the expectations specified in the faculty member's initial offer or reappointment letter and the awareness of the departmental chair, dean or appropriate faculty leader.

Regular rank faculty have an obligation to meet the University's expectations for teaching, research, service, and faculty governance.

Even where obligations to the University are met, a faculty member may not engage in activities that compete with the University or that otherwise diminish or undermine the University's mission. It is inappropriate for faculty, without prior approval from his or her supervisor, to divert to other entities or

institutions opportunities for research, education, clinical care or financial support which otherwise might flow to the University.

For **other faculty**, who may hold titles such as lecturers or clinical professor, the University has the expectation that these individuals will meet the commitments commensurate with their appointments and as specified in their initial offer and/or re-appointment letter.

Regardless of title, any faculty member's outside engagements must not detract from the performance of University duties or responsibilities nor should faculty engage in undisclosed external professional activities.

Faculty members should disclose, and have a supervisor and/or other appropriate university official review at least annually (typically during the faculty member's annual review). The disclosures should be comprised of non-Duke activities within a faculty member's area of professional and/or academic expertise, whether paid or unpaid, and whether for profit, not-for-profit, or non-profit. In reviewing the disclosures, supervisors should consider the faculty member's comprehensive commitments and obligations at the University and their ability to meet commitments.

Note: 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, as stated in Section 5.2.2.4 of the Faculty Handbook.

II. Disclosure of Outside Activities

University and federal regulations require an annual conflict of interest disclosure form for faculty members and individuals to whom this policy applies (see Executive Summary). These individuals should also report any changes to relationships as they arise or within thirty (30) days of a change, by updating their disclosure form.

The information reported may be compared to information provided by companies, federal agencies or other sources. Duke reserves the right to request additional information, as deemed necessary.

When preparing his/her disclosure form, individuals should include the following items:

- 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.

Individuals are not required to disclose the following:

- 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

The annual disclosure process includes institutional training regarding the reporting requirements and regulations related to COI.

III. Disclosures regarding Conflict of commitment

Per University and sponsor requirements, faculty members must be able to demonstrate a lack of real or apparent conflicts of commitment when engaging in research. Information regarding conflicts of commitment may be requested for completion of Other Support, Current & Pending, or other sponsor forms, or no less than an annual review with a faculty member's direct supervisor (may be as a part of the official performance review). When compiling a list of real or potential conflicts of commitment, an individual should consider the following:

- A managerial role at a startup company that has received Series A investment. Duke faculty may hold managerial roles (*i.e.*, C-level positions, membership on the Board of Directors, or the equivalent) in a startup company only while the company is privately held and prior to receiving Series A investment. After that time, the Duke faculty member may serve only in advisory or consultant positions and may no longer hold a managerial position with the startup company. Please see Appendix A, Conflict of Interest Considerations for Faculty Involved with Startups.
- Relationships with individuals for whom the faculty has a supervisory role as a part of their responsibilities for Duke. Please see Appendix B, Guidelines for Faculty/Non-Faculty Outside Relationships.
- Outside professional activities involving a company in which the Duke faculty member has equity, intellectual property interests, a leadership role, or other significant interest must also meet the requirements of all other applicable Duke University policies, including but not limited to University-Industry Guidelines, Intellectual Property, Conflict of Interest, and SBIR-STTR.

Furthermore, individuals should be aware of the following conditions:

- 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.

- If a faculty member is identified (by themselves or others) with their Duke title or affiliation for purposes related to outside activities, the faculty member must take care to indicate that their comments and actions are purely personal, neither part of their Duke responsibilities nor done on Duke's behalf. If public materials, such as advertisements, promotional material, solicitations, websites, blogs, emails and/or social media posts, are prepared it should also include noting that titles and affiliations are provided for identification purposes only and that any views expressed by the individual are his or hers alone.
- Any personal contract or other agreement entered into by the faculty member for outside professional activities will not include Duke as a party, and 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.

IV. Evaluation and Management of Potential Conflicts of Interest and Commitment

The DOSI-COI Office is responsible for overseeing the evaluation and management of disclosed potential conflicts for regular rank faculty and those to whom this policy applies (See Executive Summary). Upon disclosure of a potential conflict of interest, DOSI-COI officials will evaluate the extent of the potential conflict to determine whether management is required.

Upon evaluation, DOSI-COI may determine that one or more of the following actions is appropriate:

- Further consultation with central administration to help determine how to respond to and manage a given disclosure. In these instances, DOSI-COI will engage the necessary central administration office, as appropriate.
- No further action is necessary. In these instances, DOSI-COI may determine it is sufficient to document the relationship, but take no action to manage the relationship.
- Issuing a cautionary memo. These memos may be sent in situations where there is a disclosed relationship that, at present, does not require a formal management plan.
- Develop and implement a conflict management plan that attempts to mitigate the potential bias from the real or apparent conflict. The plan may include, but is not limited to:
 - 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

In determining the appropriate actions, DOSI-COI will make decisions in order to best strengthen the institution's commitment to the rigor and reproducibility of research conducted using University resources and personnel.

V. Dispute Resolution

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.

VI. Documentation and Record Retention

DOSI-COI will maintain institutional records of actions (including no further action) taken in response to disclosures. Records are made available as deemed institutionally appropriate and required by federal regulations. This will in part assist University officials in responding to disclosures in an equitable manner.

If the disclosures involve externally-funded research, DOSI-COI will communicate and provide information as required with the appropriate sponsors, per their guidelines and reporting instructions.

VII. Violations

Failure to comply with this policy may lead to disciplinary action, up to and including termination of appointment in accordance with applicable disciplinary procedures. Possible violations that may lead to disciplinary action include, but are not limited to, the following:

- failure to fully disclose a potential conflict;
- failure to fully comply with a required conflict management plan; and
- failure to respond to inquiries made by DOSI-COI.

Potential violations may be submitted to the DOSI-COI office by emailing dosicoi@duke.edu. In consultation with leadership, DOSI-COI will refer the potential violation to a relevant University committee or Official, such as the Incident Response and Issue Resolution Committee (for cases involving Sponsored Research), the Research Misconduct Officer, the Chief Audit, Risk, & Compliance Officer, etc. These committees/officials will conduct an assessment of the potential violations, per their operating procedures, taking into consideration any mitigating circumstances.

The results of the assessment will be submitted to the Dean, Director or appropriate designee for action, which should be consistent with University policy. If the faculty wishes to dispute any decision or action, they may notify their Dean, Director or appropriate designee for escalation to the Vice President for Research.

VIII. Exceptions

Exceptions to these policies will not be granted without the existence of compelling circumstances. Faculty members are responsible for presenting information that would substantiate a claim of compelling circumstances; and the DOSI-COI office is responsible for reviewing and processing these claims. Further review or resolution of disputes should be carried out in the manner of violation disputes.

IX. Policy Revision

The deans or department directors (or their designees) will review all action taken under this policy on an annual basis. As a result of these reviews, they will present any recommendations for adjustment or increased education to the University's Executive Research Oversight Committee.

The DOSI-COI office, in conjunction with the COI committee, will review the policy on a bi-annual basis.

This policy refers to Sections 5.2.2.2 -5.2.2.4 of the Faculty Handbook.

This policy is intended to be consistent with federal and state law. Where there is a discrepancy, the applicable federal or state law or rule of the funding agency will take precedence, unless the law or rule is less restrictive than Duke's more stringent standard.

Additional information for faculty involved with Duke startup companies

In situations where a faculty member or other investigator has a significant role or interest in a start-up company that is also engaged in research with the University, consideration is given on a case-by-case basis as to whether or not the investigator may be involved in the University research activity involving the same company.

Duke faculty with a significant role or interest in a startup company must:

- Separate and clearly distinguish on-going University research and education from work being conducted at the company. This should be documented in writing at least annually and reviewed by the Department Chair and/or Dean.
- Limit work for the company so that it does not exceed the four (4) days per month standard, for full-time faculty, averaged over an annual period of service based on term of appointment, as

Duke faculty with a significant role or interest in a startup company must NOT:

- Negotiate with the University on behalf of the company.
- Receive monetary gifts for research or sponsored research funding from the company without prior University review and a written agreement between the University and the company.
- Involve company personnel in University research without prior written agreement between the University and the company.
- Supervise individuals at the startup who are non-faculty members of the Duke community and with whom the faculty member has a position of influence over at Duke, without prior review and approval by appropriate University official (see Appendix B, Guidelines for Faculty/Non-Faculty Outside Relationships)
- Use University resources or facilities for company purposes without prior written agreement between the University and the company.
- Undertake human subjects research for the company at the University as PI/protocol director or supervise faculty who are PI/protocol directors for such human subject research without prior review/approval of the University.

Exceptions to these policies will not be granted without the existence of compelling circumstances. Faculty members are responsible for presenting information that would substantiate a claim of compelling circumstances; and the DOSI-COI office is responsible for reviewing and processing these claims.

Appendix B, Guidelines for Faculty/Non-Faculty Outside Relationships

The academic environment also encourages mentor/mentee relationships between faculty and non-faculty individuals (including undergraduate, graduate, and masters' students, along with doctoral candidates and postdoctoral appointees as well as graduate medical trainees). These relationships provide incalculable benefits, but when a faculty/non-faculty relationship extends to an outside activity, the following guidelines and principles may govern interactions:

1. Quite often, financial relationships between faculty members and students take place within the context of a start-up company founded by the faculty member, although other types of relationships are possible (e.g., where the faculty member and the student consult for another entity). In general, although the institution does not actively monitor these relationships, the assumption is that a full-time postdoctoral appointee or other post-secondary student with a stipend is receiving a living wage which is sufficient to allow them to focus on their prescribed research/work, and taking on part-time projects for a faculty member is inconsistent with those assumptions.
2. A Duke faculty member may not supervise or directly employ (i.e., hire) any non-faculty member of the Duke community for an outside professional activity if that Duke faculty member is also in a supervisory role for the individual as part of their primary commitment. Supervisory roles include, but are not limited to, student advisor, faculty mentor, member of dissertation committee, principal investigator, attending clinician, program/center/institutional director, and/or departmental/divisional leader.
3. All outside professional activities that may involve a non-faculty member of the Duke community working with and/or reporting to the Duke faculty member as part of their primary commitment requires review and approval by:
 - a. the appropriate Dean(s), including of the graduate or undergraduate school as applicable if the non-faculty member is in a student/trainee role.
 - b. the department chair, if the non-faculty member is an employee of the University.

An independent ombudsperson will be made available to the non-faculty member if the circumstances necessitate or the Dean/Department Chair or individual make such a request.

4. No Duke faculty member should engage in behavior that would appear to require, coerce, or otherwise pressure a non-faculty individual to work with them in any outside professional activity; this restriction applies to individuals even if there is no direct reporting relationship to the faculty member in question.