

Johns Hopkins University Policy on Conflict of Interest and Conflict of Commitment
Frequently Asked Questions

I. General

1. Who is governed by the JHU Policy on Conflict of Interest and Conflict of Commitment (“Policy”)?

All faculty and staff are subject to the Policy. Part-time faculty and part-time staff generally will not be covered by the Policy when they are not acting in their University capacity. Students are subject to the Policy when they (i) are paid or otherwise supported by the University for work or effort (excluding all forms of financial aid); (ii) use, control, or assign to others the use of University facilities and resources; (iii) participate or engage in research under the direction of JHU faculty or staff; or (iv) teach at the University.

2. What is a Conflict of Interest?

The term Conflict of Interest is defined in the Policy. Generally speaking, a Conflict of Interest is a personal non-JHU activity or personal financial interest that is related to your JHU responsibilities and could compromise or appear to compromise the integrity or objectivity of your JHU-related decision making. The perception of a Conflict of Interest is as concerning as an actual Conflict of Interest. This means that a Conflict of Interest may exist whether or not one’s actions are contrary to the University’s interests.

Example 1:

A faculty member establishes a startup company that is related to her JHU research. She is a partial owner of the startup company. Because the startup is in a scientific field related to the faculty member’s JHU research, the faculty member now has a financial interest that could appear to compromise her objectivity in conducting JHU research in that field.

Example 2:

A staff member with procurement responsibilities for JHU has an ownership interest in a construction company that specializes in building highly technical facilities for scientific laboratories. The staff member’s ownership interest is related to his JHU responsibilities and thus could appear to compromise his ability to objectively select the most appropriate vendor for JHU construction projects.

3. What is a conflict of commitment?

The term Conflict of Commitment is defined in the Policy. Generally speaking, a Conflict of Commitment is a non-JHU activity that may interfere with your JHU responsibilities.

Example 1:

A full-time staff member also does bookkeeping work for his wife’s small business. If the bookkeeping work takes so much time that it prevents the staff member from devoting his full professional efforts to JHU, the staff member will have a Conflict of Commitment.

Example 2:

A full-time faculty member begins teaching a course at Loyola University Maryland that is very similar to a course she teaches to JHU students. Because the faculty member is expected to devote all of her professional teaching energies to JHU, her teaching at Loyola has created a Conflict of Commitment.

4. Can staff engage in activity that creates a Conflict of Interest or Conflict of Commitment?

Generally, no. As set forth in the Policy, full-time staff are expected to devote their primary work effort to the University and are prohibited from engaging in Outside Activities (including personal involvement in a faculty startup) that create a Conflict of Interest or Conflict of Commitment with their JHU work.

5. I am a faculty member. How do I seek approval to engage in an Outside Activity that is related to my JHU responsibilities?

Full-time and salaried part-time faculty are required to disclose all proposed Outside Activities and Financial Interests—terms that are defined in the Policy—through eDisclose. The appropriate administrative office will review the proposed Outside Activity or Financial Interest for potential Conflict of Interest and compliance with related divisional policies.

II. Faculty Research

1. I am a faculty member. Am I allowed to serve as principal investigator (PI) on research in which I have a Conflict of Interest?

It depends. For non-human subjects research, in the majority of cases, a conflicted faculty member will be able to serve as PI, provided that the faculty member accepts and complies with the management plan that is issued by the relevant Dean's office to address the conflict of interest, and in particular to protect the integrity of the research and the interests of any students, trainees, and junior faculty who are also involved with the research.

For human-subjects research, service as PI on a protocol is prohibited if a faculty member has any of the following financial interests that are related to the proposed research:

- a. Fees, honoraria, gifts, or in kind compensation (or entitlement to the same), whether for consulting, lecturing, or any other purpose, that are related to the research and exceed \$25,000 in the aggregate in any twelve month period;
- b. Equity interest of any amount (including ownership interests, options, and warrants) in a private entity (or entitlement to the same);
- c. Equity interest (including ownership interests, options, and warrants) in a publicly-traded entity that exceeds \$25,000 in value as determined through reference to current prices (this does not include diversified mutual funds or similar instruments in which the shareholder has no control over the equities held by the fund);

- d. Service as an officer, director, or in any other fiduciary role in a company that has an interest in the outcome of the research.

In addition, service as PI of more than minimal risk human subjects research (as determined by the relevant IRB) is prohibited if the faculty member is an inventor of licensed intellectual property.

Service as PI of human subjects research may be prohibited in other situations as well, if the relevant Dean or COI committee determines that the conflict cannot be managed sufficiently to allow the faculty member to serve as PI. Additionally, the IRB will need to approve any participation of a conflicted faculty member on human subjects research, including any proposal for a conflicted faculty member to serve as PI.

Faculty members with conflicts of interest who are serving as PIs of approved, active human subjects research protocols at the time the revised policy takes effect may continue to serve as PI for the duration of the study even if such service would not be allowed under the revised policy, provided that the faculty member is in compliance with the applicable COI management plan.

2. I am a faculty member. Am I allowed to hold the IND or IDE for research in which I have a Conflict of Interest?

As with service as PI, faculty may not hold the IND or IDE for FDA-covered research if the faculty member holds any of the following financial interests that are related to the FDA-covered research:

- a. Fees, honoraria, gifts, or in kind compensation (or entitlement to the same), whether for consulting, lecturing, or any other purpose, that are related to the research and exceed \$25,000 in the aggregate in any twelve month period;
- b. Equity interest of any amount (including ownership interests, options, and warrants) in a private entity (or entitlement to the same);
- c. Equity interest (including ownership interests, options, and warrants) in a publicly-traded entity that exceeds \$25,000 in value as determined through reference to current prices (this does not include diversified mutual funds or similar instruments in which the shareholder has no control over the equities held by the fund);
- d. Service as an officer, director, or in any other fiduciary role in a company that has an interest in the outcome of the research.

In addition, faculty may not be PI or hold the IND or IDE for FDA-covered research if they are inventors of intellectual property--whether licensed or unlicensed--that comprises the clinical investigational product to be studied in the FDA-regulated research.

Faculty currently serving as PI or holding the IND or IDE for ongoing FDA-covered research when such service would be prohibited under the new policy shall be allowed to continue such service for the duration of ongoing protocols only, provided that the faculty member is in compliance with the applicable COI management plan. No new protocols may be instituted under that existing IND or IDE,

however. Instead, a new IND or IDE should be filed with a non-conflicted faculty member as sponsor-investigator.

III. Faculty Startups

1. Are faculty members allowed to form startup companies?

Yes. Provided that they disclose their proposed startup activity in eDisclose before it begins and receive approval from the relevant Dean's Office, faculty members may form startup companies that are related to their areas of JHU research.

2. Are faculty members allowed to serve as officers of startup companies?

Yes, for a limited period of time. Provided that faculty members disclose their proposed service as an officer (e.g., president, chief executive officer, chief scientific officer, chief technology officer) in eDisclose and receive approval from the relevant Dean's Office in advance (and subject to any conditions resulting from a review of potential conflict of interest with research), and provided time commitment associated with the service is approved by the faculty member's department director or chair, they may serve as an officer of a startup company for a period of two years, as further described in the Policy. Upon conclusion of the two year period, it is expected that faculty will either cease their work as an officer of the startup company or take a formal leave of absence from the University to devote their full-time effort to the startup.

For faculty who received approval to serve as officers of startup companies before January 1, 2021—the date of implementation of the Policy—unless otherwise limited by a management plan, they may continue serving as an officer of the startup for two years from the date of Policy implementation (i.e., until January 1, 2023).

3. May faculty hire their students, postdocs, or trainees to work at their startup?

No. Faculty may not hire or otherwise request or require that JHU students, postdocs, or trainees work for or at their startup company in any capacity. JHU students, postdocs, and trainees are not allowed to be employed in a part-time or full-time capacity at faculty startups. This is true regardless of whether or not a student, postdoc, or trainee genuinely wants to work at a faculty startup. Upon graduation or completion of their training and separation from JHU, students, postdocs, and trainees may join faculty startup companies.

A narrow exception to this rule exists if the student, postdoc, or trainee co-invented the IP around which the startup is founded and co-founds the company with the faculty. In that case, and provided the student, postdoc, or trainee receives appropriate divisional approval, the student, postdoc, or trainee may work for the company.

4. May faculty form startup companies with academic collaborators who happen to be students, postdocs, or trainees?

If an academic project involving faculty, students, postdocs, and/or trainees results in intellectual property that the faculty, student, post-doc, and trainee co-inventors are interested in commercializing

through a startup company, the team members may—upon review and approval by the relevant academic program and divisional bodies—form a startup company. In these cases, special care must be taken to ensure the interests of students, postdocs, and trainees are protected from undue pressure or influence and that the students, postdocs, and trainees continue to place their primary focus on their academic program.

5. Are staff members allowed to form or join faculty startup companies?

No. Staff participation in faculty startups is prohibited when such participation is related to the staff member's JHU responsibilities. The relatedness analysis is broadly interpreted such that it is highly unlikely that any JHU staff member, regardless of their specific responsibilities, will be allowed to join or work for a faculty startup company. In some cases, staff members are inventors of JHU technology that is licensed to startup companies and, as such, are entitled to a share of the licensing revenue. These conditions are outlined in the [JHU Intellectual Property Policy](#).

6. I am a faculty member. May my startup company sponsor non-human subjects research at JHU? May I be PI of that research?

Generally, yes – with limitations. There must be a sponsored research agreement between the company and JHU that is negotiated and executed by a JHU research administration office (ORA or JHURA). The conflicted faculty member may not be involved in that negotiation, and may not execute the agreement on behalf of the startup company.

Upon execution of a sponsored research agreement, and provided that the faculty member(s) participating in the research have timely disclosed their interests through eDisclose and received approval from the relevant Dean's Office before the sponsored research begins, faculty usually may serve as principal investigator on non-human subjects research that is sponsored by their startup company. Any participation in the research as PI or other investigator will be subject to review for conflict of interest and a management plan issued by the relevant Dean's Office. Failure to comply with the applicable management plan may lead to review under professional misconduct procedures.

In certain situations, the Dean's office may determine that the Conflict of Interest cannot be sufficiently managed to allow the startup to sponsor research at JHU. In other situations, the Dean's Office may allow the sponsored research to occur, but may prohibit the conflicted faculty member from serving as PI of the research.

7. What limitations are commonly applied to faculty who desire to conduct non-human subjects university research sponsored by or related to their startup companies?

Although each situation is unique, a common management plan for a faculty member who proposes to conduct research in her JHU lab that is sponsored by or is related to a startup company in which she has a financial interest includes *at least* the following limitations:

- The conflicted faculty member must disclose her financial interest in the sponsor in all publications and other relevant settings, including internal JHU divisional and department meetings.
- The conflicted faculty member must recuse herself from all university decision-making with respect to business negotiations with and decisions about the sponsor, including IP licensing negotiations and procurement negotiations and decisions.

8. I am a faculty member. May my startup sponsor human subjects research at JHU? Can I be PI of that research?

Generally, faculty startups may sponsor human subjects research at JHU. But the conflicted faculty member will not be allowed to serve as PI. Please see Questions II.1 and II.2 of this FAQ for further explanation of the limits on engagement in human subjects research when that research involves a startup company in which faculty hold equity.

9. Can I be a co-investigator of university human subjects research that is sponsored by or related to my startup?

While each specific situation is unique, generally speaking conflicted faculty may be co-investigators on human subjects research protocols. A common management plan for this situation would include at least the following limitations:

- The conflicted faculty member must disclose her financial interest in the sponsor in all publications and other relevant settings, including internal JHU divisional and department meetings.
- The conflicted faculty member must recuse herself from all university decision-making with respect to business negotiations with and decisions about the sponsor, including IP licensing negotiations and procurement negotiations and decisions.
- The conflicted faculty member may not obtain consent from human subjects.