

## ***Northwestern University Policy on Conflict of Interest & Conflict of Commitment Frequently Asked Questions (FAQ)***

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Below is a list of questions, categorized by type, with regards to the core Northwestern University Policy on Conflict of Interest and its supporting policies.

A list of Additional FAQ's for supporting policies can be found at:

- [Feinberg: Disclosure and Professional Integrity Policy](#)

For access to the FAQ provided by the National Institutes of Health, which directly cites the new federal regulation for Public Health Service (PHS) funding, please go to:

- [NIH Financial Conflict of Interest Frequently Asked Questions](#)

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## Policy Questions

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### *What is the new definition of Investigator?*

"The project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposed for such funding, which may include, for example, collaborators or consultants."

### *Who does this regulation apply to?*

If you meet the definition of an "Investigator," the regulation applies to you.

This may include, but is not limited to:

- Faculty
- Staff
- Post-Doctoral Fellows
- Students
- Graduate Students
- Consultants
- Collaborators

The Principal Investigator (PI) ultimately determines and is responsible for identifying investigators on the project. In addition, if you receive compensation from a faculty company or have PHS funding in your name (not from a training grant), you will need to complete the financial disclosure. Please review the policy on Conflict of Interest and Conflict of Commitment as well as the Policy on Conflict of Interest in Research for details.

### *What is a Significant Financial Interest? What information do I have to disclose?*

Any Significant Financial Interests (SFI), which means an external financial interest consisting of one or more of the following interests of an Investigator (and those of the Investigator's spouse and dependent children), when combined for the 12 months preceding the disclosure date, from a single entity:

Nature of SFI	Threshold	Excluded (Do not Disclose)
Compensation and/or other payments for service	Exceeds \$5,000*	Compensation received less than \$5,000, as well as any compensation received for lectures, seminars, teaching engagements, or service on advisory committees or review panels relating to federal, state, or local government agencies, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is

		affiliated with an institution of higher education, and compensation received from NU funds.
<b>Equity interests in a publicly-traded entity</b>	Exceeds \$5,000*	Interests in publically-traded entities valued at less than \$5,000 as well as interests in any entity through personal retirement accounts and mutual funds
<b>Equity interests in a non-publicly-traded entity</b>	0	Interests in any entity through personal retirement accounts and mutual funds
<b>Intellectual property rights and interests upon receipt of income related to such rights and interests</b>	0	Royalties received from NU funds, and unlicensed intellectual property that does not generate income
<b>Sponsored or reimbursed travel</b> <i>Applies to PHS-funded researchers only: Investigators who have <u>any</u> PHS funding or any funding from agencies following PHS COI regulations must disclose any reimbursed or sponsored travel</i>	Exceeds \$5,000 from a single entity	Travel administered through NU funds, and travel reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

\* Investigators whose primary appointment is in the Feinberg School of Medicine (FSM) are subject to a zero dollar reporting threshold, meaning that regardless of the thresholds identified above, FSM faculty must report any remuneration greater than zero.

*Do the new regulations only apply to those investigators with NIH or PHS funding?*

Northwestern's COI Policy and procedures apply to research funded by:

- PHS
- NSF
- Agencies specifically following PHS COI requirements
- Industry-sponsored clinical trials
- Other sponsors with COI requirements

[Click here](#) for more information.

*Is it just Northwestern University that has to comply with these regulations?*

No. All institutions that accept PHS funding must comply with the new regulations. It will be a common practice for all institutions to implement the same guidelines and processes. In the future, we expect more agencies and sponsors to be following the new federal regulations.

*What actions will be taken in the event that an Investigator fails to comply with Northwestern's Policy on Conflict of Interest and Conflict of Commitment or management plan?*

When an Investigator fails to comply with the 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.

## Process & Procedures

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### *Which offices within Northwestern are involved in administering the regulation?*

Northwestern is obligated to administer the policy to all Investigators as long as it meets all requirements of the regulation. The offices and committees involved are:

- Northwestern University Conflict of Interest Office (NUCOI)
- School Conflict of Interest Committees
- Conflict of Interest Oversight Committee (COIOC)
- Staff Conflict of Interest Committee
- Office for Sponsored Research (OSR)
- Accounting Services for Research and Sponsored Programs (ASRSP)

### *How does the proposal process work now?*

After a proposal is entered into InfoEd, e-mails will be triggered in an overnight process to Investigators who have no research COI disclosure on file in FASIS, alerting them to complete their disclosure, as well as to complete training if not already completed.

### *Will this new process hold up my grant submission?*

If no COI disclosure is on file for an Investigator named on a research proposal funded by agencies subject to NU's COI requirements, the proposal may not be submitted. It is the responsibility of the Investigator to complete the online training COI disclosure in a timely matter.

### When do I have to disclose?

You must make an initial research COI disclosure in the FASIS system subsequent to 8/24/12, and continuously update it throughout the year within 30 days of discovering, acquiring, and/or receiving a new SFI. Additionally, a research COI disclosure must be made at least annually.

### *Is there a different conflict of interest form for the Department of Defense, Department of Energy, etc.?*

It is reasonable to occasionally expect to see a solicitation that requires disclosure. It is typical that these agencies ask the institution to accept the responsibility of acquiring and reporting this information as appropriate. In this case, the individuals listed on the project will need to fill out the research grant disclosure according to the system prompts in FASIS.

### *If a PI has a joint appointment, who is responsible for the PI completing their disclosure for initial review?*

It is the responsibility of the home department. Home department means the primary academic appointment or primary appointment with the Northwestern University.

### *Is it the responsibility of the administrators to make sure Investigators update their information?*

No. It is the responsibility of the Investigator to update his/her information and disclose based on the requirements put forth by the policy. Administrators in the community insure the policy is communicated so that Investigators understand their roles and responsibilities.

### *Do I have to go through this process every time an award comes in or grant gets renewed?*

No. If you have completed an initial research COI disclosure in the FASIS COI system subsequent to August 24, 2012, and have no new SFIs to report, there is no need to submit a new COI disclosure prior to proposal submissions solely to acknowledge no change. This does require that as new SFIs occur throughout the year, you disclose them within 30 days.

### *Will the Office for Sponsored Research (OSR) check if the disclosure has been completed?*

Yes. OSR will verify that each Investigator listed on a proposal has completed training and disclosure prior to submitting an application to an external sponsor for funding.

### *Do we ask consultants or persons outside the institution if they have an existing COI policy at their institution?*

Yes, if they do not have a current COI policy in place they must follow the Northwestern policy. Please click [here](#) for subrecipient information.

## Training Requirements

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### *When can training be done?*

It can be completed at any time online: <https://nupa.northwestern.edu>

### *Does the regulation require Investigator training?*

Yes. All Investigators, including subrecipient Investigator(s), must complete training prior to engaging in research and at least every four years, and immediately under the designated circumstances:

- Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds that an Investigator is not in compliance with the Institution's Financial Conflict of Interest policy or management plan.

### *Do we have to attend training?*

Training consists of reading and attesting to having read a PDF document within the FASIS system.

*I am a Lurie employee and have gone through the NIH FCOI training through our system. Does this training suffice for my NWU training?*

No. Although both trainings may cover similar material, it is required to complete the training if you meet the definition of Investigator on the Northwestern side of research project, as defined by the Northwestern University policy. If you are a subrecipient at Lurie's through a subcontract from NU to Lurie, you are covered under Lurie's COI policy and process and do not have to complete the NU COI training and disclosure.

## **FASIS System Questions**

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*How do I access the Sponsored Research COI Disclosure Questionnaire?*

Through the Self Service Portal at: <http://nupa.northwestern.edu>.

If you have never used the Self Service portal it may take some time the first time you log-in to download all the information. Once you have signed into the portal:

1. Click "Conflict of Interest" under "My Role" on the left-side navigation
2. Under "COI Training & Disclosures" select "COI Training for Research".
3. Open and read the PDF document
4. Close the PDF document & Click "Attest" to having read and understood the contents
5. Once the Attest link has been clicked, click the link that will appear on the bottom left-side to access to the COI Disclosure.
6. Select the box "Initial Disclosure"
7. Select the "Continue" button that will appear on the bottom right side and answer the COI disclosure questions
8. Review your answers.
9. Click "Sign"
10. Click "Submit"

Here is a link for instructions on deleting cookies in case you receive an error message:  
<http://www.it.northwestern.edu/security/browser-management/>

*I've already done my initial disclosure. I'm submitting a new proposal in a week. Do I need to do anything?*

No, unless you have a new SFI to disclose. If you have no new SFIs to disclose, no COI disclosure is necessary relative to the new proposal submission.

*I've already done my initial disclosure and have a new SFI. How do I update my disclosure?*

Follow the instructions below to update your disclosure:

1. Click the following link and sign-in with your NetID & Password: [Conflict of Interest Portal](#)
2. On the left-hand side of the screen, under "My Role," select "Conflict of Interest"
3. Select "COI Disclosure for Research"
4. Check your reason for disclosure
5. Answer the COI disclosure questions
6. **Click "Sign" and "Submit"**

*I have equity in a non-publically traded company that currently has no value (\$0). Will the system allow me to disclose this?*

Yes. Please indicate zero (\$0) as the dollar amount and provide a comment further describing the involvement or reason for no value.

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