

CAYUSE: Outside Interests (OI) Conflict of Interest @ CCNY

PRESENTED BY
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DIRECTOR, RESEARCH COMPLIANCE AND ETHICS

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Key Conflict of Interest Terms

- **Research:** A systematic experiment, study, evaluation, demonstration or survey, in any academic field, designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, causes, functions or effects
- > **Sponsored Projects**: Project activities that include research, creative activity, and training. It includes instruction or service undertaken within or on behalf of the University pursuant to funding or other support from an external source.
- Investigator: The project director, principal investigator, co-principal investigator, students, and any other person, regardless of title of position, who is responsible for the design, conduct, or reporting of a University Sponsored Project, which may include, for example, collaborators or consultants, whether or not such individual is employed by the University or the Research Foundation.



Key Conflict of Interest Terms con't

- Institutional Responsibilities: An investigator's professional responsibilities on behalf of the University, performed in the course of and within the scope of the Investigator's appointment or employment by the University, which may include, for example, activities such as research, research consultation, teaching, professional practice, institutional administration, committee memberships, and service on panels such as Institutional Review Boards, Institutional Animal Care and Use Committees or Institutional Biosafety Committees
- **Conflicts of Interest:** A conflict of interest exists when two or more contradictory interests relate to an activity by an individual or an institution. The conflict lies in the situation, not in any behavior or lack of behavior of the individual. That means that a conflict of interest is not intrinsically a bad thing. (Office of Research Integrity)
- College Conflicts Officer Appointed by the College President, the CCO is responsible for receiving and reviewing all Financial Disclosure Forms from Investigators at the College. The CCO determines whether or not any disclosed Significant Financial Interest is related to the proposed Sponsored Project, and if so, whether or not a Financial Conflict of Interest exists and if so, whether a Significant Financial Interest is related to the Sponsored Project. The CCO assists in the implementation and monitoring of any management and oversight plans developed by the Conflicts Committee



CUNY's Conflict of Interest (COI) Policy

CUNY's Conflict of Interest policy and procedures are designed to ensure, to the extent possible, that any financial interests and/or conflicts of commitment are managed in a manner that prevents bias in the design, conduct, reporting, or regulatory review of research.

https://www.cuny.edu/research/research-compliance/conflict-of-interest/

Purpose in Sponsored Projects

* To promote integrity by establishing standards and procedures to ensure, to the extent possible, that any Significant Financial Interest (as defined in Section 8.19) that could directly and significantly affect the design, conduct or reporting of a Sponsored Project at the University (each, a "Financial Conflict") does not bias the design, conduct or reporting of the Sponsored Project.



CUNY's Conflict of Interest (COI) Policy

Each College within CUNY appoints a College Conflicts Officer (CCO) who is appointed by the President or their designee, and serve as the first level of review. CCNY's CCO works collaboratively with our Office of Research Compliance and Ethics (RCE) and CUNY Office of Research staff, to implement CUNY COI Policy, for promoting the need to disclose significant financial interests to faculty and staff at their College, and for reviewing all disclosures in accordance to this policy.

- Conflicts related to the Researcher's commitment should be disclosed to the Research Integrity Officer (RIO).
- ✓ Conflicts related to research involving human subjects should be disclosed to the Human Research Protection Program (HRPP);
- Conflicts related to research involving animal subjects should be disclosed to the Institutional Animal Care and Use Committee (IACUC).

CCNY's CCO

Dr. Maria Lima, Medical Professor, Molecular Cellular and Biomedical Sciences Associate Dean for Research/Chief Research Officer mlima@med.cuny.edu



Conflict of Interest (COI) Review Process

A Significant Financial Interest (SFI) is determined when:

One or more of the following financial interests of an Investigator (and the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities

Equity Ownership and Intellectual Property (CALCIP) Disclosure

Each CUNY investigator who has become aware of a Company's acquisition or intention to acquire ownership of or a license to investigator developed, created or discovered intellectual property must also complete the CUNY Acquisition of or License to CUNY Intellectual Property Form (CALCIP)

Currently, researchers are expected to disclose any Financial Conflicts of Interest (FCOI) using the significant interest financial disclosure and supplement forms. Completed and signed PDF forms are then returned to the Office of Research Compliance and Ethics(RCE) via email.



SFI Disclosure Forms (Current method)

INITIAL Non-PHS FORM

CUNY Significant Financial Interest (SFI) Disclosure Form For Sponsored Projects <u>NOT</u> Funded by the Public Health Service to be completed by each investigator on the project				
Name of Investigator ¹ :				
Role of Investigator (project director / PI / co-PI / consultant / etc.):				
Phone: Email:				
Phone: Email:				
CIDIV C. II /C't f.D d.				
CUNY College/Site of Research:				
Title of Sponsored Project ² :				
The or sponsored Project .				
n. h. a				
Funding Source:				
Disclosure submission for:				
☐ New funding proposal or application				
☐ Annual progress report				
☐ Material change in a previously disclosed SFI				
☐ Discovery or acquisition of a new SFI				
☐ New investigator joining an ongoing sponsored project at CUNY				
Please indicate whether you, your spouse, or your dependent children have any of the	following financial			
interests that may reasonably be related to your institutional responsibilities ³ :	ionowing innancial			
Please note that this form must be completed by all individuals responsible for the d	lesign, conduct, or			
reporting of sponsored project.				
	Yes□			
A total of salary, any other payment for services (for example, consulting fees or	No □			
honoraria), and royalties expected to be received in the next 12 months that	NO 🗆			
Investigator: The project director, principal investigator, co-principal investigators, and any other person, regardless of tit	d			
	de of position, who is responsible sultants, whether or not such			

onsibilities: An investigator's professional responsibilities on behalf of the University, performed in the course of and within the scope of continuent or employment by the University, which may include, for example, activities such as research, research constitution, teaching institutional administration, committee memberships, and service on panels such as Institutional Review Boards, Institutional Animal

gnatu	re Date	
you lonflict green	responded "yes" to any of the questions above, you must also complete a CUI to Supplement Form. If Form, and the Supplement Form if required, shoul Conflicts Officer, with a copy to your Grants Officer. The supplement Form of the Information it seeks, please refer to of interest web site or contact your College Conflicts Officer. The supplement Form of the Information it seeks, please refer to of interest web site or contact your College Conflicts Officer. The above statements are complete, true and accurate. It will submit an updated Form annually, prior to submission of annual progress re days of any material change to the above-disclosed Significant Financial Interest. It will comply with all applicable regulations, CUNY policies, sponsor requirement and oversight plans issued by CUNY.	the sponsored projects ports; and also within 30 est(s) or discovering or
	Do you teach, supervise, or otherwise have control over any student or postdoctoral associate at CUNY who might be involved in work for any corporation, partnership, or other legal entity (excluding entities controlled by the U.S. government, the State or City of New York, or CUNY) in or from which you have a financial interest described in any of Items 1 or 2 above?	Yes□ No □
	If you are responsible for developing, discovering, or creating CUNY-owned intellectual property, are you aware of the acquisition or intention to acquire ownership of, or a license to, that intellectual property by any corporation, partnership, or other legal entity (excluding entities controlled by the U.S. government, the State or City of New York, or CUNY) in or from which you have a financial interest described in any of Items 1 or 2 above? NOTE: If you answered "Yes" to this question you must also complete the CUNY Acquisition of or License to CUNY Intellectual Property (CALCIP) form and submit it to your College Conflicts Officer and the Director of the CUNY Technology Commercialization Office (TCO).	Yes□ No □ N/A □
	Intellectual property rights and interests (for example, patents, copyrights). Unself ONLY:	No □
	An equity interest (for example, stocks, stock options, or other ownership interests) in any single entity that, when aggregated for you, your spouse, and your dependent children, exceeds \$10,000 in value, as determined through reference to public prices or other reasonable measures of fair market value, AMD represents more than a five percent (5%) ownership interest in the entity.	Yes□ No □ Yes□
	exceeds \$10,000, when aggregated for you, your spouse, and your dependent children, excluding any salary, royalties, or other remuneration from CUNY and income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities or from service on advisory committees or review panels for such entities.	

SUPPLEMENT Non-PHS FORM

Sponsored Projects <u>NOT</u> Funded by the Public Health Service	e	Please provide requested details regarding your positive responses made on the CUNY Significant
	_	Financial Interest Disclosure Form and, if necessary, use additional Supplement Forms:
Name of Investigator:	- 1	 A total of salary, any other payment for services (for example, consulting fees or honoraria), and royalties expected to be received in the next 12 months that exceeds \$10,000, when aggregated for you, your spouse, and your dependent children, excluding any remuneration from CUNY and income from engagements sponsored by public or nonprofit entities or from service on advisory
Role of Investigator (project director / P1 / co-P1 / consultant / etc.):		committees or review panels for such entities:
CUNY College/Site of Research:		i) Name of person or persons (and relationship to self) to whom the salary or payment is expected to be made:
Title of Sponsored Project:		Name of entity:
Funding Source:		Nature of salary, payment for other services, or royalties (description of work performed for remuneration):
Does this project involve human subject research? Yes \square No \square	_	
	- 1	Amount of salary, payment for other services, or royalties expected to be received in the next 12 months:
	- 1	Relationship to your institutional responsibilities:
	- 1	ii) Name of person or persons (and relationship to self) to whom the salary or payment is expected to be made:
	- 1	Name of entity:
	- 1	Nature of salary, payment for other services, or royalties:
	- 1	Amount of salary, payment for other services, or royalties expected to be received in the next 12 months:
	- 1	Relationship to your institutional responsibilities:
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SFI Disclosure Forms (Current method)

INITIAL PUBLIC HEALTH SERVICES FORM

CUNY Significant Financial Interest (SFI) Disclosure Form For Sponsored Projects NOT Funded by the Public Health Service

Name of Investigators: ¶ Role of Investigator (project director / PI / co-PI / consultant / etc.): CUNY College/Site of Research: → Title of Sponsored Project: Disclosure submission for: ☐ New funding proposal or application¶ ☐ Annual progress report ☐ Material change in a previously disclosed SFI¶ ☐ Discovery or acquisition of a new SFI 1 ☐ New investigator joining an ongoing sponsored project at CUNY¶ Please indicate whether you, your spouse, or your dependent children have any of the following financialinterests that may reasonably be related to your institutional responsibilities: Please note that this form must be completed by all individuals responsible for the design, conduct, or reporting of sponsored project. 1.- A total of salary, any other payment for services (for example, consulting fees or honoraria), and royalties expected to be received in the next 12 months that nvestigator: The project director, principal investigator, co-principal investigators, and any other person, regardless of title of position, who is responsible the design, conduct, or reporting of a University Sponsored Project, which may include, for example, collaborators or consultants, whether or not such dividual se employed by the University or the Research Foundation. | rsity pursuant to funding or other support from an External Sponsor.

titional Responsibilities: An investigator's professional responsibilities on behalf of the University, performed in the course of and within the scope of signator's appointment or employment by the University which may include, for example, activities such as research, research consultation, teaching, anal practice, institutional administration, committee memberships, and service or panels such as institutional Review Boards, institutional Anticipies and analysis of the property of the pr

. With respect to any publicly traded entity, a total of (a) salary and any payment for services not otherwise identified as a salary (for example, consulting fees, honoraria, paid authorship) received from the entity in the past 12 months AND (b) the value of any equity interest in the entity (including any stock, stock option, or other ownership interest), as determined through reference to public prices or other reasonable measures of fair market value as of the date of this disclosure, in excess of \$5,000. 2. With respect to any non-publicly traded entity, a total of salary and any payment for services not otherwise identified as a salary (for example, consulting fees, honoraria, paid authorship) received from the entity in the past 12 months in excess of \$5,000. With respect to any non-publicly traded entity, any equity interest in the Yes□ entity (including any stock, stock option, or other ownership interest), No \square regardless of value. Intellectual property rights and interests (for example, patents and copyrights).

5.	If you are responsible for developing, discovering, or creating CUNY-owned intellectual property, are you aware of the acquisition or intention to acquire ownership of, or a license to, that intellectual property by any corporation, partnership, or other legal entity (excluding entities controlled by the U.S. government, the State or City of New York, or CUNY) in or from which you have a financial interest described in any of Items 1, 2, or 3 above? NOTE: If you answered "Yes" to this question you must also complete the CUNY Acquisition of r License to CUNY Intellectual Property (CALCIP) form and submit it to your College Conflicts Officer and the Director of the CUNY Technology Commercialization Office (TCO).	Yes□ No □ N/A□
6.	Do you teach, supervise, or otherwise have control over any student or postdoctoral associate at CUNY who might be involved in work for any corporation, partnership, or other legal entity (excluding entities controlled by the U.S. government, the State or City of New York, or CUNY) in or from which you have a financial interest described in any of Items 1, 2, or 3 above?	Yes□ No □
7.	Any reimbursed or sponsored travel (i.e. travel paid on your behalf and not reimbursed to you so that the exact monetary value may not be readily available), related to your institutional responsibilities. EXCLUSIONS: This does NOT apply to travel reimbursed or sponsored by a United States 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.	Yes□ No □

If you responded "yes" to any of the questions above, you must also complete a CUNY Significant Financial Interest Supplement Form. This Form and the Supplement Form, if required, should be submitted to your College Conflicts Officer, with a copy to your Grants Officer.

If you have any questions about this Form or the information it seeks, please refer to the sponsored projects conflict of interest web site or contact your College Conflicts Officer.

Last Updated: May 2020

SUPPLEMENT PHS FORM

CUNY Significant Financial Interest Supplement Form

tor PHS Funded Sponsored Projects
irector / PI / co-PI / consultant / etc.):→ ¶
ed Project: → → ¶
→ ¶
an subject research? Yes⊕ No⊕¶
,
e Form and, if necessary, use additional Supplement Forms: → ¶ or other services (for example, consulting fees, honoraria, paid authorship
traded entity in the past 12 months: 1
is (and relationship to self) to whom the salary or payment was made:¶
entity:¶
ent for other services, or royalties (description of work performed for
ent received: ¶
utional responsibilities: "

1.	Salary and any payment for other services (for example, consulting fees, honoraria, paid authorsh received from a publicly traded entity in the past 12 months:
	Name of person or persons (and relationship to self) to whom the salary or payment was made:
	Name of publicly traded entity:
	Nature of salary, payment for other services, or royalties (description of work performed remuneration):
	Amount of salary or payment received:
	Relationship to your institutional responsibilities:
2.	Equity interest (including any stock, stock option, or other ownership interest) in a publicly trac entity:
	Name of person or persons (and relationship to self) who hold(s) the equity interest:
	Name of publicly traded entity:
	Type of equity interest:
	Current value of equity interest:
	Relationship to your institutional responsibilities:

Last Updated: May 2020



PHS Funding Requirements

PHS Agencies

- Agency for Toxic Substances & Disease Registry (ATSDR)
- Center for Disease Control & Prevention (CDC)
- Food & Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Office of the Assistant Secretary for Preparedness and Response (ASPR), including Biomedical Advanced Research and Development Authority (BARDA)
- Office of Global Affairs (OGA)
- Substance Abuse & Mental Health Services Administration (SAMHSA)

Source: <u>US DHHS Organizational Chart</u>



PHS Funding Requirements Con't

Procedures for complying with PHS Requirements

- Revised regulations issued by The Department of Health and Human Services (HHS) issued in regards to Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought in 2011.
- Applicable to all PHS authorized research, including, Research grants, Co-op agreements, Career Development and Center grants, fellowship and Infrastructure awards, Institutional training grant, Program project, Research resources award, Conference grants, Minority Biomedical Research Support, Subrecipients, subgrantees & collaborators.
- Not applicable to Phase I Small Business Innovation Research (SBIR) or Small Business Technology Transfer (SBTT) applications
- Publicly traded entity In 12 months if total of salary and any payment for services received from the entity, <u>AND</u> value of any equity interest in the entity exceeds \$5,000. Same threshold for Non-Public Traded entity, however either salary **OR** Equity Interest exceeds \$5,000
- Upon income received for Intellectual Property or Rights
- The occurrence of any reimbursed travel or sponsored travel



PHS Funding Requirements Con't

Training Requirements for Recipients of PHS Funding

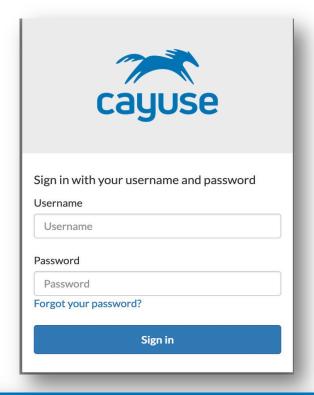
- The Collaborative Institutional Training Initiative (CITI Program) training in Conflicts of Interest is required of all Investigators PRIOR to engaging in research related to any PHS-funded grant or cooperative agreement.
- Additionally, the CCO may require other individuals at CCNY to complete this on-line training. Individual training requirements may be based on such considerations as the nature of an existing conflict; non-compliance with the CUNY Conflict of Interest Policy or other CUNY policies; non-compliance with a conflict of interest (COI) management plan; or non-compliance with applicable laws and regulations or sponsor requirements.
- Training is valid for four years. Detailed requirements and instructions are available at:

http://www.cuny.edu/research/research-compliance/training-education/citi-training



Introducing Outside Interest (OI)

OI is an online platform where CCNY Researchers, using their Single Sign-On (SSO) credentials, can securely submit their Significant Conflict of Interest Financial Disclosures for review by the Conflicts Of Interest Committee.







Submitting COI Financial Disclosures

- Submit your new COI Financial Disclosure Form at the time of the Annual Campaign and when submitting a new proposal with the Office of Grants and Sponsored Programs (GSP).
- The Annual Campaign is conducted at the beginning of the calendar year
 - Emails for the Annual Campaign will be sent to Researchers.
 - They notify Researchers of the annual period and the task to complete the Annual Disclosure.
- Click on the link to the OI portal during the campaign period and complete Annual Disclosures for both Public Health Services (PHS) and Non-PHS research.



ANNUAL DISCLOSURE

The Annual Disclosure is the master form where all relationships with any external organization are captured. It must be updated yearly and whenever there is a change in relationship. The Annual Disclosure must be updated prior to completing the Research-Based Disclosure.

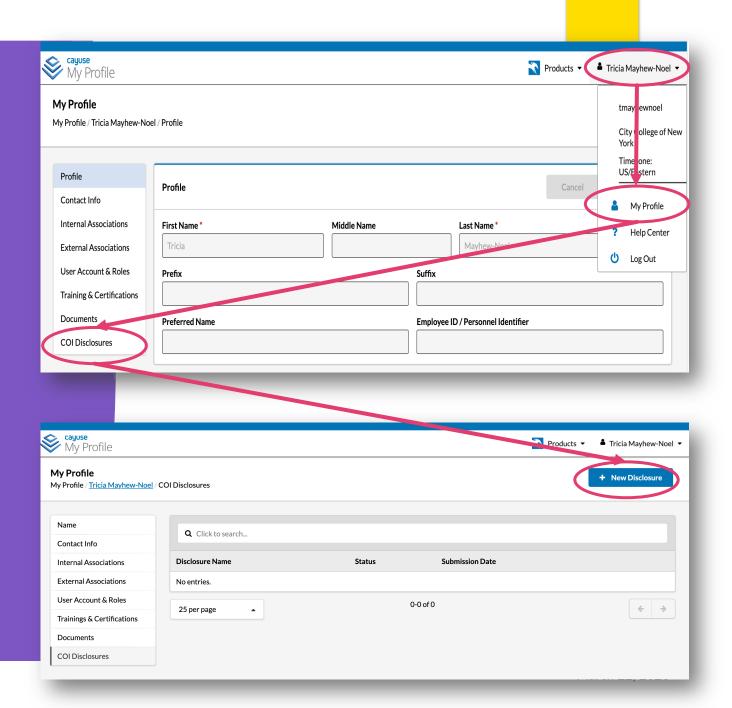
RESEARCH-BASED DISCLOSURE

A Research-Based Disclosure is required when submitting a proposal, with responses specific to the proposed activities of that proposal.



Submitting a New COI Financial Disclosure

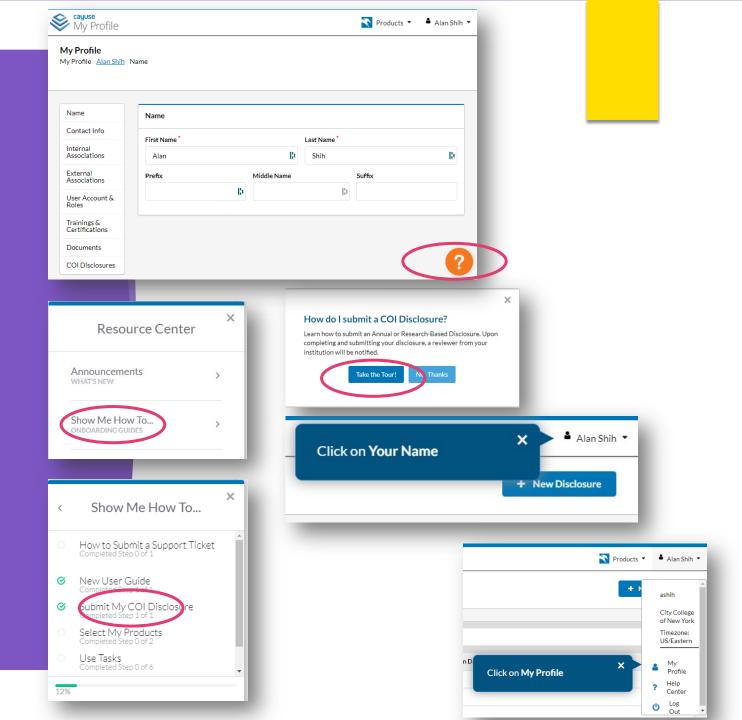
- 1. Go to upper right-hand corner under your name, click on My Profile
- 2. Click on COI Disclosures
- 3. In the upper right-hand corner click + New Disclosure





OI HELP

Click on the Question Mark in the lower right of your screen, and step-by-step instructions will appear to guide you through the process of submitting a new disclosure form.





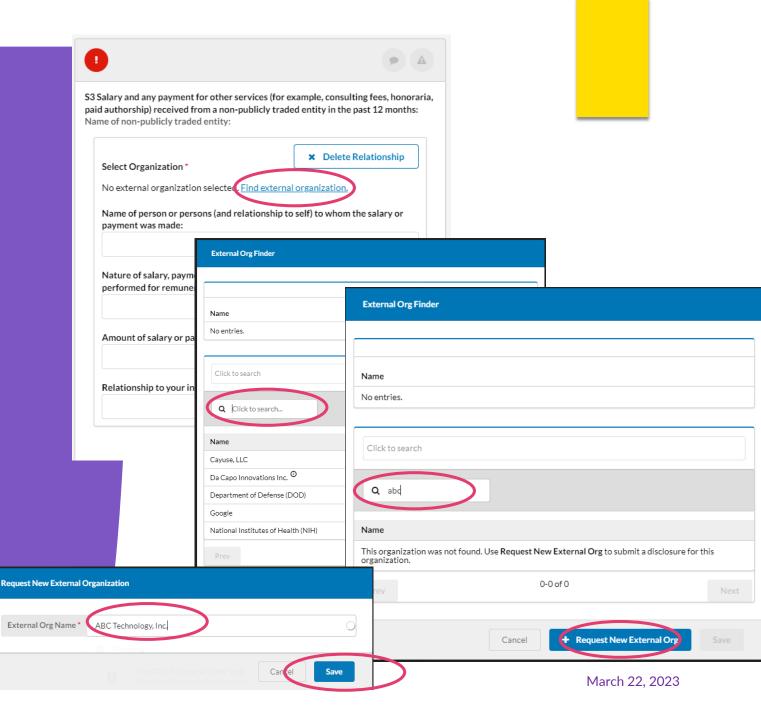
FCOI Responses

When you answered an YES to a question, additional questions would appear dynamically for you to answer.

How to add a new relationship?

You would need to select the entity (external organization) that this potential conflict is associated with

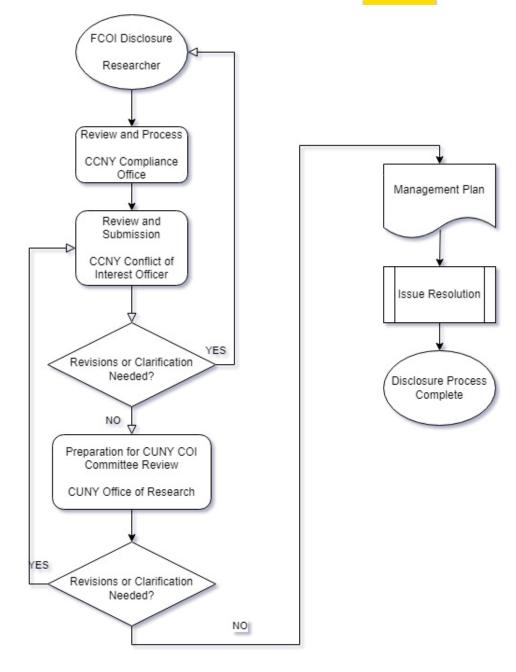
- 1. Search for the External Organization
- 2. If not found, + Request New External Org
- 3. Enter the name and Save





FCOI Workflow

How would a disclosure be reviewed and processed?





Rollout Timeline

FEBRUARY -

Internal testing period by the implementation team

MARCH -

Finalize form design and testing with Vendor

APRIL (early) -

Campus rollout starting with the Division of Science

MAY - JUNE -

Phased-in rollout with the entire campus



Demonstration Notes

The following pages are not to be presented, but a note on the demonstration procedures



- Go to My Profile -> COI Disclosure
- Briefly explain the annual and researchbased disclosures
- Show how the HELP works
- New Disclosure

- Explain Sections
 - PHS vs Non-PHS
 - CALCIP
 - Document Section and when to use it
 - FAQ's purpose
 - Certification
- Explain Question Numbering
 - 1, 2, 3.... vs. NP1, NP2, etc.
 - S1, S2, S3...



- Reporting a relationship that might be of FCOI concern
 - External Org
 - What if you cannot find it on the list?
 - Add new ones

- Document Section
- Being returned -email



Questions?

Contact us at research@ccny.cuny.edu

