

**Learn More: Award
Acceptance and Conflicts
of Interest**

September 2016

Learning Objectives

- Understand Research Administrations role in verifying that investigators and Northeastern University have complied with the awarding agency's requirements related to conflicts of interests, including financial conflicts of interest.
- Understand the process used by RA to verify COI/fCOI requirements at JIT or award acceptance; and
- How you can help facilitate the process.

Institutional Certifications and Assurances

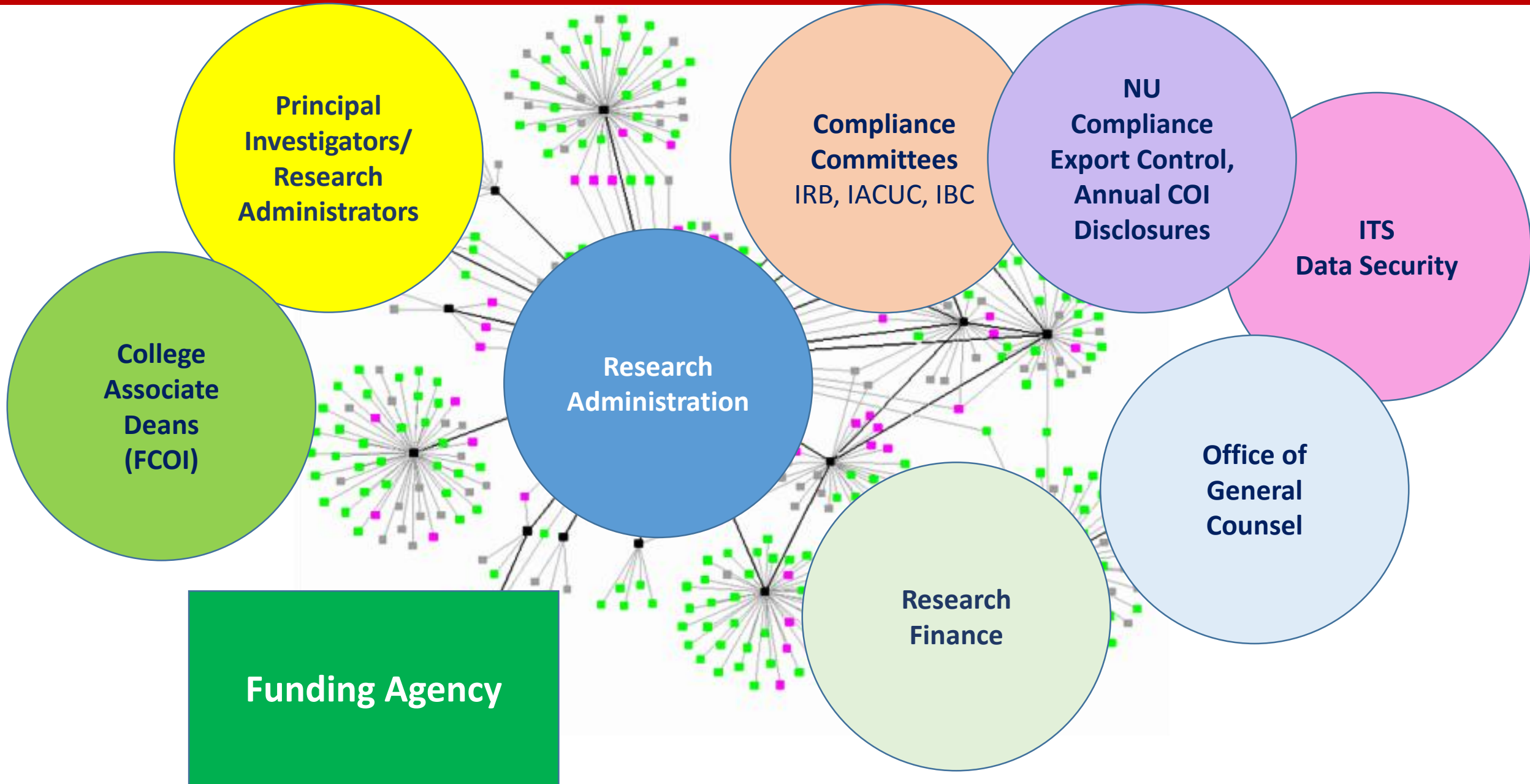
- **Northeastern University, as a grantee, provides at the time of proposal submission and throughout the life-cycle of an award certification and assurances that it is in full compliance with all relevant laws, rules and regulations.**
- **How each grantee implements its research management responsibilities varies but all grantees should include documented practices that address specific regulatory requirements.**
- **Some regulations required that the grantee monitor the covered activity; monitoring involves verification and tracking of compliance with a specific term or condition of the award.**

Award Acceptance

Prior to drawing down federal funds, Northeastern University verifies that we comply with the terms & conditions of the award.

While there are general regulations applicable to each award, for example, Uniform Guidance, agency-specific policies and regulations, for example PHS financial conflict of interest reporting requirements.

Northeastern University



INDIVIDUAL FINANCIAL CONFLICTS OF INTERESTS

Funding Agencies require that Institutions (grantees) receiving awards have in place policies and procedures to safeguard the integrity of scientific research. These regulations are designed to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research will be free from bias resulting from an investigator's financial interests.

1995 NSF and NIH joint regulation

2011 PHS, which includes NIH, established more rigorous FCOI regulations.

INDIVIDUAL FINANCIAL CONFLICTS OF INTERESTS

NU's FCOI Policy:

https://www.northeastern.edu/policies/pdfs/Policy_on_Financial_Conflict_of_Interest_Related_to_Research.pdf

File Annual Conflict of Interest and Commitment Disclosures with NU's Department of Compliance:

<http://www.northeastern.edu/compliance/conflict-of-interest-program/>

File Newly Acquired/Discovered with the Office of Research Administration & Finance: Please contact Dana Carroll, AVP RA for more information.

Key Concepts

Institutional Official

Investigator

Significant Financial Interest

Related

Financial Conflict of Interest

Key Concepts

Management Plan

Reporting

Public Access

Retroactive Reviews

PHS Required Training

Northeastern University

	PHS <small>(2012)</small>	NSF <small>(1995)</small>
Applicable	Research Awards	Research & Education Awards
Investigators defined	PI, project director, and any other person, regardless of title or position, <i>who is responsible for the design, conduct, or reporting of research</i> funded by the PHS including collaborators and consultants.	Investigator means the principal investigator, co-principal investigators/co-project directors, and any other person at the organization <i>who is responsible for the design, conduct, or reporting of research or educational activities</i> funded or proposed for funding by NSF.
SFI Threshold includes Family SFIs (spouse & dependent children)	\$5,000 Any equity interest	\$10,000 Equity interests equal or greater than \$10K and 5%
Reimbursed Travel Expenses	If directly paid by or reimbursed to the Investigator by non-federal or non-IHE entity.	No
Scope	Institutional Responsibilities , which includes: research, teaching, and administration.	Research or Educational Activities

	PHS <small>(2012)</small>	NSF <small>(1995)</small>
Relatedness Determination	Institutional Official reviews any external financial interest that would reasonably appear to be related to an individual’s institutional responsibilities (which include activities such as research, teaching, professional practice, institutional committee memberships, service on panels such as Institutional Review Boards or Data Safety and Monitoring Boards, and other administrative activities).	Investigator must disclose any SFI “that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or in entities whose financial interests would reasonably appear to be affected by such activities
Reporting	All FCOI management plans via eRA Commons	To NSF only if conflict is unmanageable
Public Disclosure of FCOI	Within 5 days of Request for Information	None

FEDERAL AGENCIES APPLYING PHS STANDARDS

Administration for Children and Families (ACF)

Agency for Healthcare Research and Quality (AHRQ)

Agency for Toxic Substances and Disease Registry (ATSDR)

Centers for Disease Control and Prevention (CDC)

Food and Drug Administration (FDA)

Health Resources and Services Administration (HRSA)

Indian Health Service (IHS)

National Institutes of Health (NIH)

Office of Global Affairs (OG)

Office of the Assistant Secretary for Health (OASH)

Office of the Assistant Secretary for Planning and Evaluation

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Public Health and Science

Substance Abuse and Mental Health Services Administration (SAMHSA)

NON-FEDERAL FUNDING AGENCIES APPLYING PHS STANDARDS

Alliance for Lupus Research (ALR)

Alpha-1 Foundation

American Asthma Foundation

American Cancer Society (ACS)

American Heart Association (AHA)

American Lung Association (ALA)

Arthritis Foundation (AF)

CurePSP

Juvenile Diabetes Research Foundation (JDRF)

Lupus Foundation of America (LFA)

Patient-Centered Outcomes Research Institute (PCORI)

Susan G. Komen for the Cure

CITI Training – FCOI mini (PHS) course

All PHS funded investigators are required to taking the required PHS FCOI training prior to undertaking PHS-funded research and every 4 years thereafter.

NU's PHS FCOI Training is via CITI

<https://www.citiprogram.org/>



FCOI

Role	Responsibility
Principal Investigator	Identify individuals on the project who are “responsible for the design, conduct or reporting of research”.
Investigators	File disclosures prior to applying for grant funding, annually thereafter and within 30 days of acquiring or discovering new SFIs. If applicable, take PHS FCOI training via CITI. Cooperate with IO in the review of SFIs and development of any management plans. Compliance with respective management plans and NU’s policies on Conflicts of Commitment, Interest and agency-specific FCOI regulations.
NU Compliance Department	Receives annual COI disclosures
Research Administration	Receives on-going, ad-hoc disclosures, coordinates reviews with respective Institutional Officials and verifies that funding-agency specific FCOI regulations are met prior to the expenditure of awarding agency funds.
Institutional Official (College Dean or designee)	Reviews investigators’ SFIs and specific applications to determine if an FCOI exists, prepares required management plans, monitors compliance with plans.

FINANCIAL CONFLICTS OF INTEREST

- ✓ Investigators
- ✓ Collaborating Investigators
 - Subrecipient Investigators
 - Individual Consultants
- ✓ No expenditure of grant funds until reviewed and/or, as applicable, reported.

FCOI Certification Form

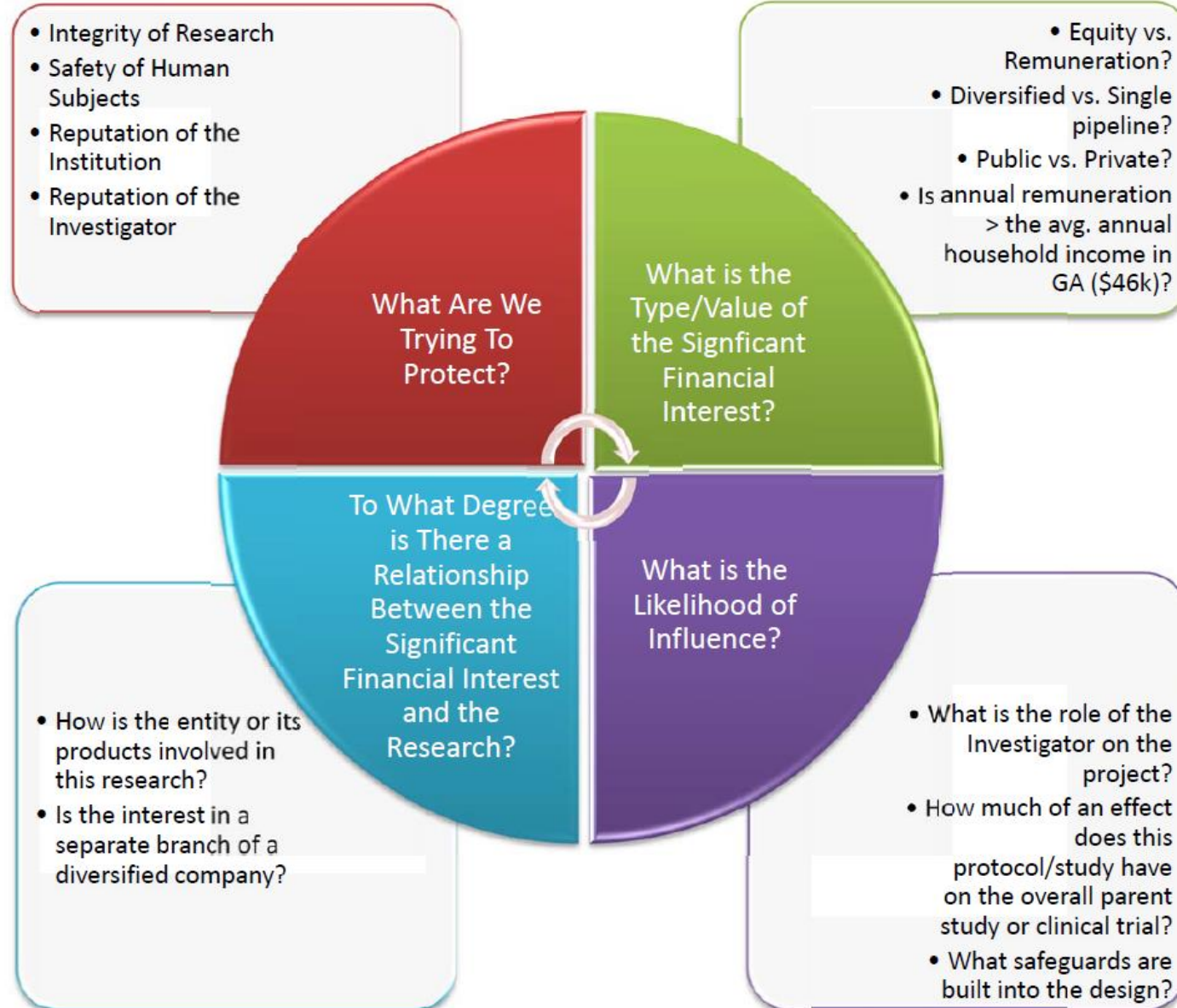
Project Information	
Coeus IP#	Grant #
Project Title	
Funding Agency	
<input type="checkbox"/> Pass Through	<input type="checkbox"/> Prime Source of Funding

Investigators		
Name	Role	Signature
	Principal Investigator	

Outside Collaborators or Consultants who meet the PHS Definition of Investigator (responsible for design, conduct or reporting of research)				
Name	Role	Institution	PHS Compliance Policy	
			Yes	No
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>

Compliance Notes:

Training Verification SFI/FCOI Verification





COMPLIANCE MONITORING

Verification and Tracking

- ✓ Training (PHS FCOI)
- ✓ Filing Disclosures
 - Annual
 - Within 30 days of newly acquired or discovered
- ✓ Eliminate, Mitigate, Manage SFIs
- ✓ Reporting
- ✓ Retroactive Reviews



Institutional Officials

- Review:
 - ✓ Proposal
 - ✓ SFI Disclosures
- Determine Relatedness
- Determine if Related SFI constitute an FCOI
- Prepare Management Plans for FCOIs

Individual Financial Conflict of Interest – Institutional Official Determination Form

Project Information

Institute Proposal No.: _____ Award No.: _____

Project Title: _____

Applicable fCOI Standard: NSF PHS DOD Other: _____

Investigators				
Name	Role	SFI Disclosed? (Yes/No)	SFI constitutes FCOI? (Yes/No)	If applicable, date of PHS training:
	Principal Investigator/ Project Director			
	NU Investigator			
	NU Investigator			
	NU Investigator			
	NU Investigator			
	External Investigator			
	External Investigator			

Certification

I have reviewed the attached application against the above referenced disclosure(s) and certify that:

- There are no Financial Conflicts Interest associated with this award; or
- An FOCI exists and the corresponding Management Plan is attached; or
- There is a Financial Conflict of Interest(s) that cannot be managed.

Associate Dean for Research

Printed Name: _____

Date: _____

CONFLICTS OF INTEREST – PROCUREMENT

§ 200.112 Conflict of interest.

The Federal awarding agency must establish conflict of interest policies for Federal awards. The non-Federal entity must disclose in writing any potential conflict of interest to the Federal awarding agency or pass-through entity in accordance with applicable Federal awarding agency policy

For more information please contact Research Administration via ORAF@northeastern.edu or 617-373-5600.

<http://www.northeastern.edu/research/raf/fcoi/>

Thank you.