

LEARN MORE: Research Compliance Monitoring

NU-RES
April 2020



Northeastern University

**Principal
Investigators/
Research
Administrators**

**Compliance
Committees
IRB, IACUC,
IBC**

**NU
Compliance
Export
Control,
Annual COI
Disclosures**

**ITS
Data Security**

**College
Associate
Deans
(FCOI)**

**NU-RES
Administration
Compliance
Finance**

**Office of
General
Counsel**

**Funding Agencies
Sponsors**

Institutional Certifications and Assurances

- Northeastern University, as a grantee, provides at the time of proposal submission and throughout the life-cycle of an award certifications 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 research activity; monitoring involves verification and tracking of compliance with a specific term or condition of the award.

Learning Objectives

- Understand the Office of the Inspector General's role in conducting audits, preventing fraud, waste and abuse; and reporting findings and recommendations to their respective federal agencies and Congress.
- Understand your and NU-RES' role in verifying that investigators and Northeastern have complied with the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (more commonly known as UG or Uniform Guidance) and non-financial regulations (e.g., OLAW, 45 CFR 46, Biosafety, Export Controls, etc.)
- Understand your role in monitoring awards to prevent fraud, waste and abuse;
- Identify the various institutional offices responsible for non-financial regulatory oversight;
- Understand the consequences of failure to properly monitor awards.

Harvard University Agrees To Pay \$1.3 Million To Settle Government Grant Allegations



April 27, 2020

By [Derek J. Anderson](#)



KEY CONCEPTS

Financial:

- Fraud
- Waste
- Abuse

Non-Financial:

- Protection Against Harm

KEY CONCEPTS

- **Monitoring = Verification & Tracking**
- **Contemporaneous Documentation @ the Business Level**
- **Consequences: Administrative, Civil, Criminal**

MAJOR AREAS OF CONCERN

Area	Issue	Responsible Party	Institutional Oversight	Verification Tracking	Regulations	NU
Financial	Non-allowable Expenditures	PI/College	NU-RES Finance	Financial Reports, T&E Certifications	Uniform Guidance 2 CFR 200 et.seq. and/or FAR	Certification
COVID-19 Financial Impacts	Allowability of award expenditures during an Emergency when personnel are idle or the expense was incurred but the event did not occur (e.g., travel,).	PI/College	NU-RES Finance	Documentation of expenditure and explanation of specific COVID-19 impact	OMB/Agency specific guidance	Certification

MAJOR AREAS OF CONCERN

Area	Issue	Responsible Party	Institutional Oversight	Verification Tracking	Regulations	NU
Conflicts of Interest						
COI: Objectivity in Research	Research findings and results may be biased by an investigator's financial interest in the research outcomes.	PI/College	NU-RES Compliance	PHS Financial Conflict of Interest Management Plans	PHS	Certification
COI: Financial Conflicts	Investigators or Project Personnel will improperly financially benefit from the award.	PI/College	University Compliance and Procurement	Northeastern's CMAP	Agency-Specific	Certification

MAJOR AREAS OF CONCERN

Area	Issue	Responsible Party	Institutional Oversight	Verification Tracking	Regulations	NU
Conflicts of Interest						
COI: Organizational Conflicts	Northeastern will improperly benefit from an award	Provost's Office	Center for Research Innovation (CRI) and NU-RES Compliance	Documentation of the University's interests in or relationships with other entities that may interfere with impartial performance or give the University unfair advantage.	Agency specific requirements	Certification

MAJOR AREAS OF CONCERN

Area	Issue	Responsible Party	Institutional Oversight	Verification Tracking	Regulations	NU
Animals	Humane Use and Care for Animals Used in Testing, Research & Training	PI/Project Personnel	NU-RES Compliance: Department of Laboratory Animal Medicine (DLAM) and Institutional Animal Care and Use Committee (IACUC)	Congruence between an approved IACUC proposal & the research activity	OLAW	Assurance

MAJOR AREAS OF CONCERN

Area	Issue	Responsible Party	Institutional Oversight	Verification Tracking	Regulations	NU
Non-Financial						
BioSafety	Lab Safety <ul style="list-style-type: none"> • Personnel • Environment 	PI/Project Personnel	Environmental Health & Safety (EHS) and the Institutional Biosafety Committee (IBC)	EH&S and/or the IBC reviews research activities to identify hazards (chemicals, materials, waste); regulatory registration requirements, select agents, and dual-use research concerns.	Local, state and federal	Certifications

MAJOR AREAS OF CONCERN

Area	Issue	Responsible Party	Institutional Oversight	Verification Tracking	Regulations	NU
Non-Financial						
Human Subjects	Protecting study subjects in research projects, privacy re: personally identifiable data	PI/Project Personnel	NU-RES Compliance – Office of Human Subject Research Protections	IRB’s certification that it has reviewed the research activity. <ul style="list-style-type: none"> Human Subjects Determination Form Exempt Studies Self-Determination Form IRB Protocol or Reliance Agreement 	45 CFR 46 (aka the Common Rule)	Assurance
Stem Cells <ul style="list-style-type: none"> hESC Non-Human Stem Cells 			NU-RES Compliance Stem Cell Review Oversight (IRB and/or IBC)	Review of research activity against applicable protocols.	State and Federal	Certification

MAJOR AREAS OF CONCERN

Area	Issue	Responsible Party	Institutional Oversight	Verification Tracking	Regulations	NU
Non-Financial						
Export Controls	Protect controlled technologies	PI/Project Personnel	NU-RES Compliance –	NU-RES Compliance reviews all research activity that is not governed by the Fundament Research Exclusion (FRE) and issues a Technology Control Plan (TCP)	EAR, ITAR, OFAC	Certification
Restricted Party Screening	Preventing engagement with individuals who may be disbarred or otherwise prevented from receiving federal funds	College/NU-RES and/or University Compliance	NU-RES Compliance	For Research & Sponsored Activities NU-RES documents in the other party's profile.	Federal	Certification

BEST PRACTICES

Review Compliance Requirements/Checklists

General

Eligibility

Duplicate Funding

Matching Funds

Misrepresentations

Financial

Allowability

Allocability

Non-Financial

Failure to obtain required approvals and/or training;

Failure to disclose or report.

For more information please see
<https://research.northeastern.edu/nu-res/>

NU-RES COVID-19 Updates

NU-RES

At Northeastern University, our culture is built on innovation, and shaping solutions for our challenges. The growth and success of the university's research program presented an opportunity to reorganize research services to align processes and capacity with the scale of the enterprise.



Or contact NU-RES@northeastern.edu