Learn More: Award Acceptance & Congruence Reviews

September 2016

Learning Objectives

- **Understand Research Administrations role in coordinating with the respective internal regulatory offices;**
- **Understand what compliance areas require RA's verification 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.

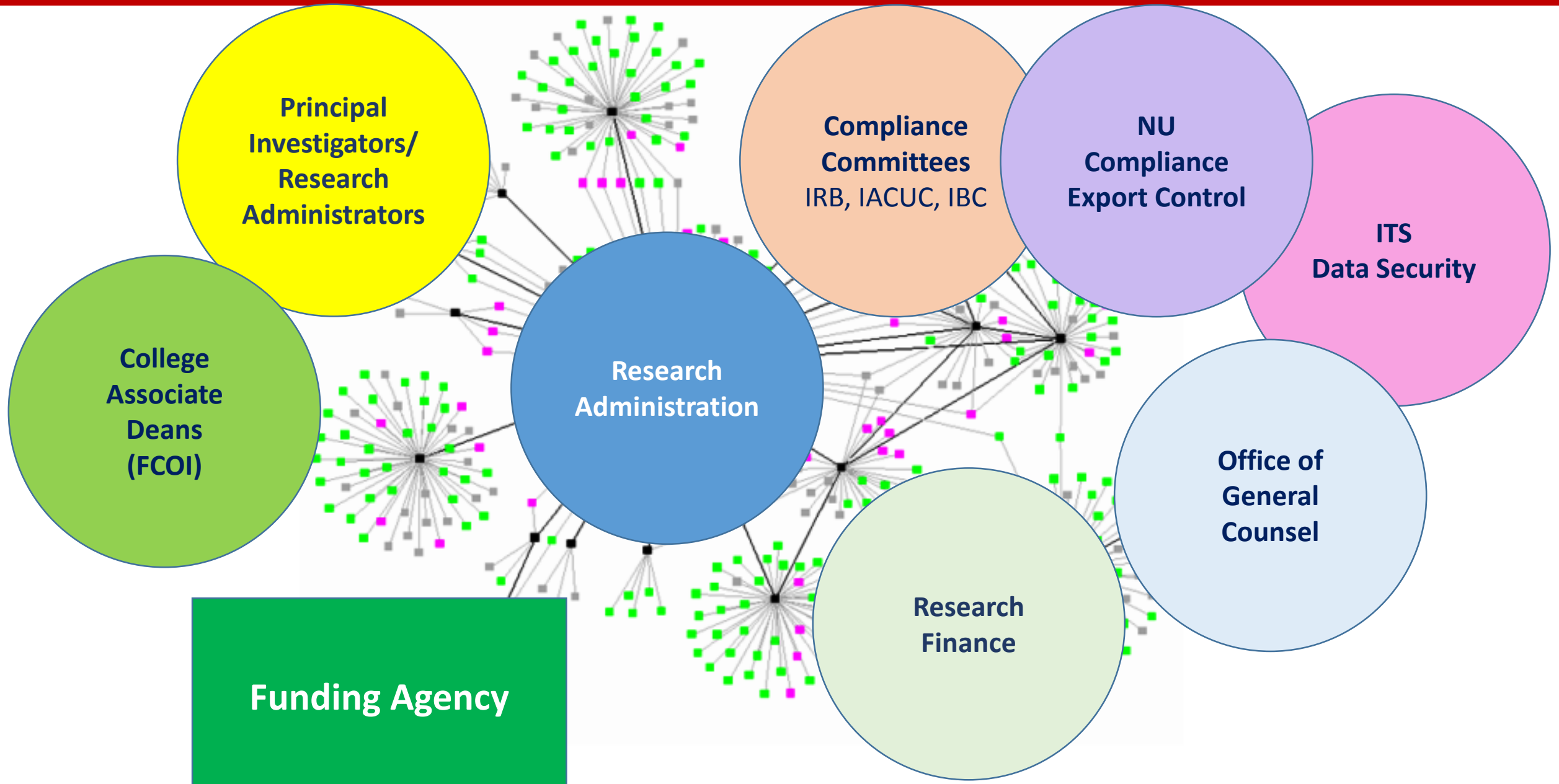
- How each grantee implements its research management responsibilities varies but all grantees should include documented practices that address specific regulatory requirements.

- 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.

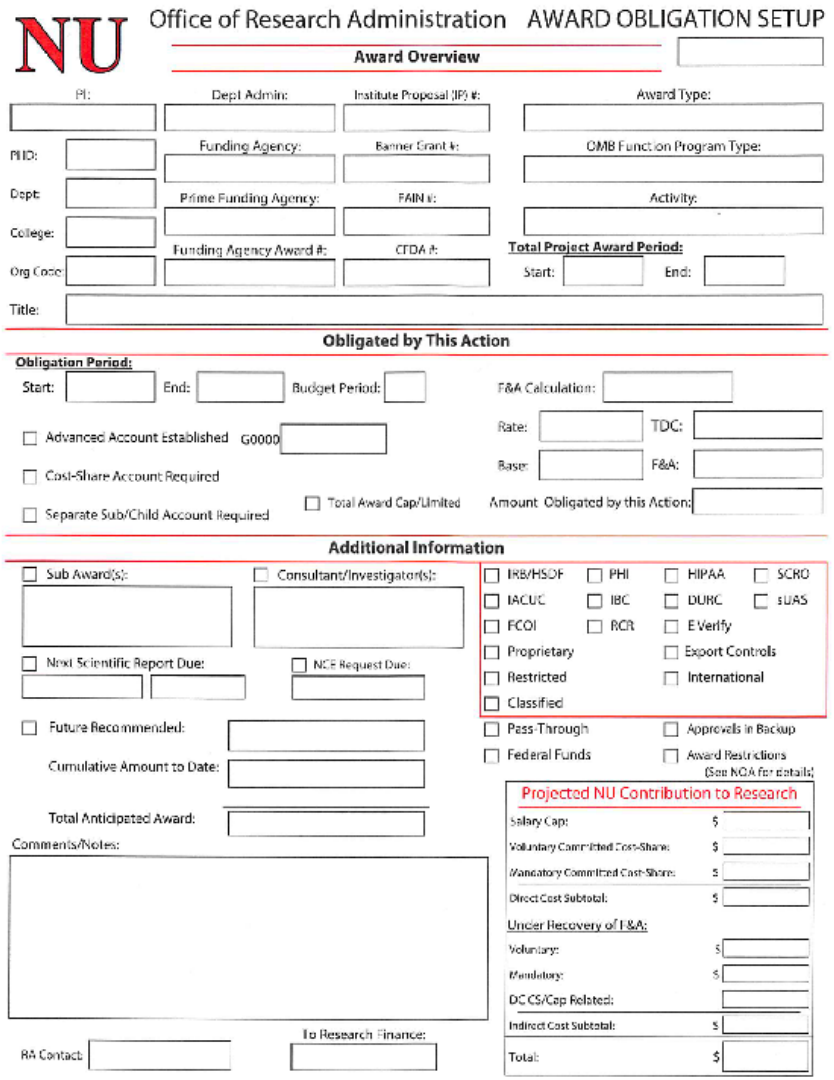
Award Acceptance

Prior to drawing down federal funds, Northeastern University verifies that we are 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.


Principal Investigators/ Research Administrators
Compliance Committees
IRB, IACUC, IBC
NU Compliance Export Control
ITS Data Security
College Associate Deans (FCOI)
Research Administration
Office of General Counsel
Research Finance
Funding Agency

Award Acceptance Checklist (aka Setup Form)



NU Office of Research Administration AWARD OBLIGATION SETUP

Award Overview

PI: | Dept Admin: | Institute Proposal (IP) #: | Award Type:

PIID: | Funding Agency: | Banner Grant #: | OMB Function Program Type:

Dept: | Prime Funding Agency: | FAIN #: | Activity:

College: | Funding Agency Award #: | CFDA #: | **Total Project Award Period:** Start: End:

Org Code:

Title:

Obligated by This Action

Obligation Period: Start: End: Budget Period:

F&A Calculation: Rate: TDC: Base: F&A:

☐ Advanced Account Established G0000

☐ Cost-Share Account Required

☐ Separate Sub/Child Account Required

☐ Total Award Cap/Limited

Amount Obligated by this Action:

Additional Information

☐ Sub Award(s): ☐ Consultant/Investigator(s):

☐ Next Scientific Report Due: ☐ NCE Request Due:

☐ Future Recommended:

Cumulative Amount to Date:

Total Anticipated Award:

Comments/Notes:

RA Contact: To Research Finance:

☐ IRB/HSDF ☐ PHI ☐ HIPAA ☐ SCRO

☐ IACUC ☐ IBC ☐ DURC ☐ sUAS

☐ FCOI ☐ RCR ☐ E-Verify

☐ Proprietary ☐ Export Controls

☐ Restricted ☐ International

☐ Classified

☐ Pass-Through ☐ Approvals in Backup

☐ Federal Funds ☐ Award Restrictions (See NOA for details)

Projected NU Contribution to Research

Salary Cap:	$
Voluntary Committed Cost-Share:	$
Mandatory Committed Cost-Share:	$
Direct Cost Subtotal:	$
Under Recovery of F&A:	
Voluntary:	$
Mandatory:	$
DC CS/Cap Related:	
Indirect Cost Subtotal:	$
Total:	$

Acceptance and Compliance Monitoring SOPs

Verification and Tracking

- ✓ IRB/IACUC/IBC Certifications
- ✓ Conflicts of Interest
- ✓ Responsible Conduct of Research
- ✓ Terms & Conditions

Human Subjects Research

- ✓ Institutional Review Board (IRB)
- ✓ Protected Health Information (PHI)/HIPAA
- ✓ Federal Wide Assurance
- ✓ IRB Certification & Human Subjects Training
- ✓ Special Agency Requirements (e.g., DOD)

HUMAN SUBJECTS RESEARCH

OMB No. 0990-0263
Approved for use through March 31, 2018

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[ ] ORIGINAL [ ] CONTINUATION [ ] EXEMPTION	[ ] GRANT [ ] CONTRACT [ ] FELLOWSHIP [ ] COOPERATIVE AGREEMENT [ ] OTHER:_____	
4. Title of Application or Activity		5. Name of Principal Investigator, Program Director, Fellow, or Other

6. Assurance Status of this Project *(Respond to one of the following)*

[ ] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No._____, the expiration date_____ IRB Registration No. _____

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____*(if applicable)*

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[ ] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [ ] Full IRB Review on (date of IRB meeting) _____ or [ ] Expedited Review on (date)
[ ] If less than one year approval, provide expiration date _____
[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution
11. Phone No. *(with area code)* 12. Fax No. *(with area code)* 13. Email:	
14. Name of Official	15. Title
16. Signature	17. Date

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7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[ ] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [ ] Full IRB Review on (date of IRB meeting) _____ or
[ ] Expedited Review on (date)
[ ] If less than one year approval, provide expiration date
_____
[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

ANIMALS

- ✓ Institutional Animal Care and Use Committee (IACUC)
- ✓ Animal Welfare Assurance
- ✓ IACUC Verification of Congruence
- ✓ Training

ANIMALS

Notification of NU-IACUC PROTOCOL APPROVAL

Protocol #: 16-0308R

To: Dr. Jonghan Kim
From: Sean Sullivan, NU-IACUC Coordinator
Date: March 21, 2016

Title of Protocol: **Effect of Maternal Exposure to Metals on Developmental Toxicity**

Funding Agency: Northeastern University Undergraduate Provost's Award, Northeastern University Start-Up Fund
Species / Number: Mouse/101
Approval Date: March 11, 2016
Expiration Date: March 1, 2019
Annual Updates Due by: March 1, 2017 & March 1, 2018
Hazardous Materials: Cadmium Chloride

This protocol has been approved by the NU-IACUC for a period of three years and is subject to submission of Annual Protocol Information Update Form. A reminder and the form will be sent to you three months prior to the annual expiration date.

The procedures approved in this protocol have not been compared with the Vertebrate Animal Section (VAS) of a supporting grant.

This program is fully accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International. The OLAW Assurance number is: A-3155.

DLAM is at your service – please call anytime during normal business hours should you have any questions or concerns.

The Principal Investigator is responsible for the following:

1. Changes to this protocol must be submitted the NU-IACUC prior to their initiation.
2. Compliance with all NU-IACUC, DLAM, & OEHS Policies.
3. Submission of Annual Protocol Update Form for review and approval.
4. If applicable, submission to NIH/funding agency of any changes in the protocol that are not described in the grant.

The NU-IACUC can and will terminate projects that are not in compliance with these requirements. Please contact Sean Sullivan at x 3958 for any questions.

Best wishes with your research.

Notification of NU-IACUC PROTOCOL APPROVAL

Protocol #: 16-0305 R

To: Dr. Jonghan Kim
From: Sean Sullivan, NU-IACUC Coordinator
Date: March 14, 2016

Title of Protocol: **Pharmacokinetics and Therapeutic Efficacy of Nanomedicine in Iron Overload Disorders**

Funding Agency: B-BIC Pilot Grant
Species / Number: Mouse/300; Rat/150
Approval Date: March 14, 2016
Expiration Date: March 1, 2019
Annual Updates Due by: March 1, 2017 & March 1, 2018
Hazardous Materials: n/a

This protocol been approved by the NU-IACUC for a period of three years and is subject to submission of Annual Protocol Information Update Form. A reminder and the form will be sent to you three months prior to the annual expiration date.

The procedures approved in this protocol have been compared with the Vertebrate Animal Section (VAS) of the supporting grant and have been found to be congruent. Additionally, the PI has resolved all discrepancies between the two.

This program is fully accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International. The OLAW Assurance number is: A-3155.

DLAM is at your service – please call anytime during normal business hours should you have any questions or concerns.

The Principal Investigator is responsible for the following:

1. Changes to this protocol must be submitted the NU-IACUC prior to their initiation.
2. Compliance with all NU-IACUC, DLAM, & EHS Policies.
3. Submission of Annual Protocol Update Form for review and approval.
4. Submission to funding agency of any changes in the protocol that are not described in the grant.

The NU-IACUC can and will terminate projects that are not in compliance with these requirements. Please contact Sean Sullivan at x 3958 for any questions.

Best wishes with your research.

BIOSAFETY

Registration of Biohazards amd Recombinant DNA Research

All biological research must be conducted using accepted biological safety practices and in full compliance with university policies and all applicable federal rules and regulations. Research projects involving recombinant DNA, pathogens of humans, livestock animals, plants, and biological toxins must be registered and reviewed by our Institutional Biosafety Committee (IBC).

Recombinant DNA is defined as the joining of natural or synthetic DNA segments to DNA molecules that can replicate in a living cell. Recombinant DNA research is the use of recombinant DNA for any purpose, including transgenic plants and animals.

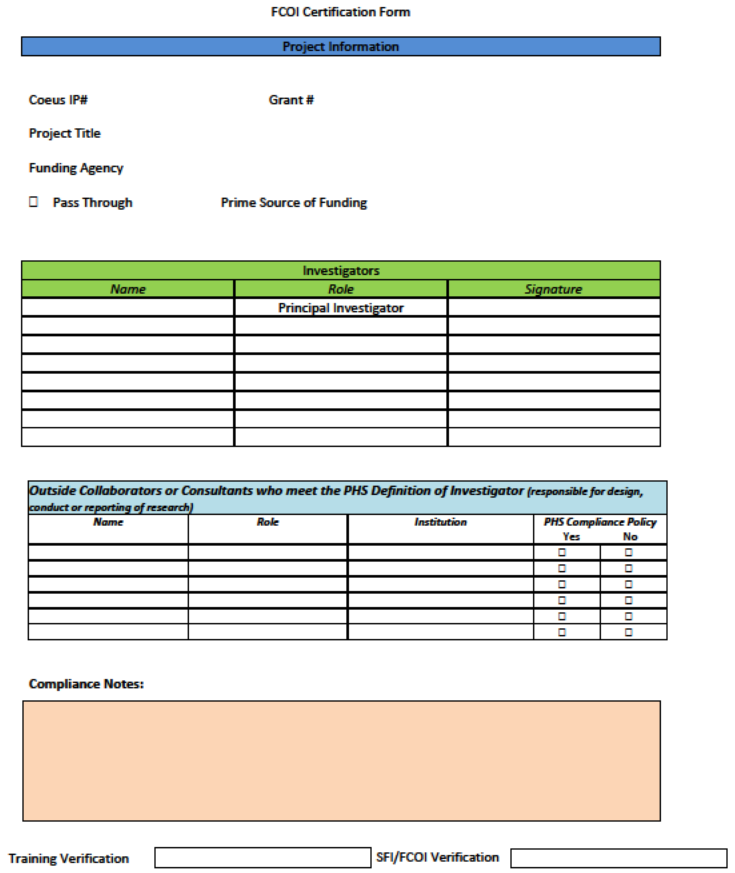
Conflicts of Interest

§ 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

Financial Conflicts of Interest

- ✓ Investigators
- ✓ Subrecipients
- ✓ No expenditure of grant funds until reported via eRA Commons



FCOI Certification Form

Project Information

Coeus IP# Grant #

Project Title

Funding Agency

☐ Pass Through 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
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Compliance Notes:

Training Verification SFI/FCOI Verification

PHS Policy

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)

Responsible Conduct of Research

NSF and NIH

Students/Postdocs

CITI

NSF Award Compliance Training

Training will begin in October 2016