Research Administrators Meeting

MARCH 12, 2026

Wake Forest University School of Medicine

ADVOCATEHEALTH

Agenda

- **Compliance and Integrity**
  - Cedron Williams
- **Research Integrity, Security, and Regulatory Affairs Office**
  - Asif Mahi
- **Pre-Award Announcements**
  - Debbie Sanabria
- **Enterprise Resources**
  - Penny Gatsis

March 12, 2026

Research Administrators Meeting

Cedron N. Williams, Director of Research Compliance
Mary Truell, Director of Research Conflicts of Interest

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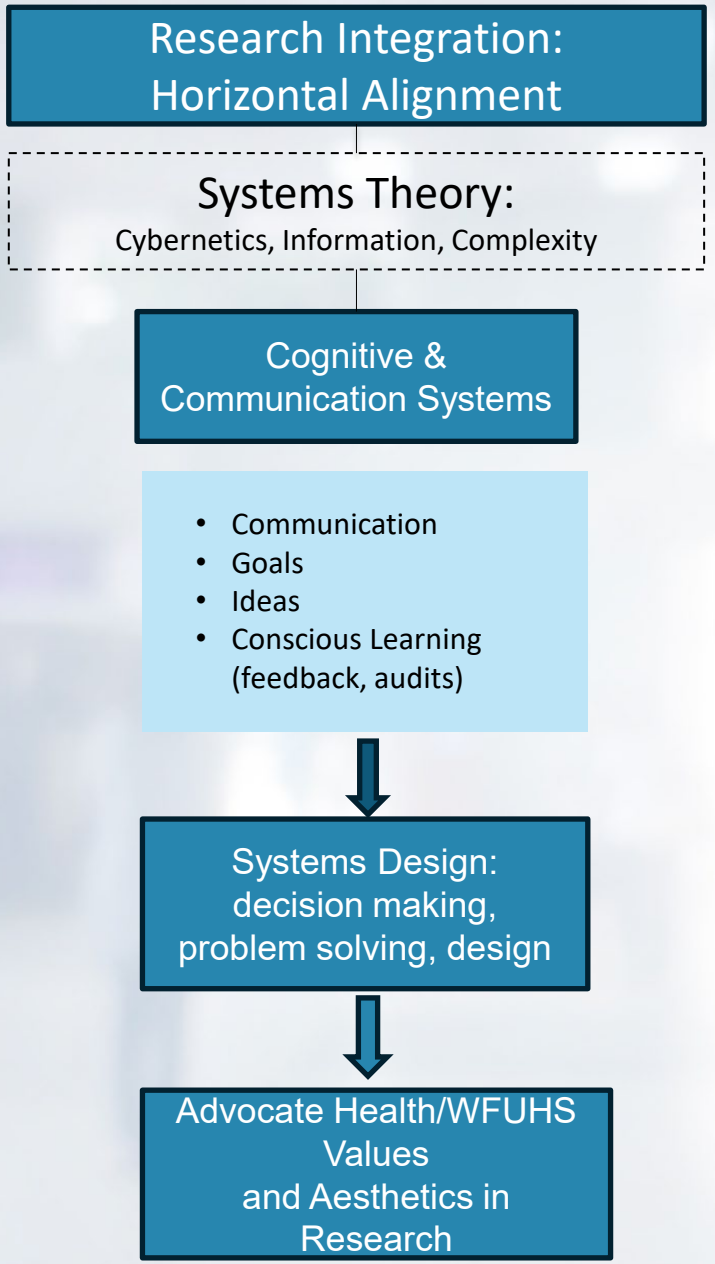
GOALS

- Research Compliance Committee Update
- OIG Mock Audit: Case Analysis
- Conflict of Interest Updates

PHASE TWO FOCAL POINTS FOR RESEARCH ADMINISTRATORS



CASE: New York Medical College (Report number: A-04-20-03583)

This OIG audit was part of a series of audits of institutions of higher education

Posted on OIG website May 14, 2024

- New York Medical College Claimed Unallowable Grant Costs and Did Not Meet Certain Financial Conflict of Interest Requirements (A-04-20-03583)
- New York Medical College Claimed Unallowable Grant Costs and Did Not Meet Certain Financial Conflict of Interest Requirements, A-04-20-03583

Wake Forest University School of Medicine

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OIG's Audit Objectives

Determine whether the College:

(1) managed NIH awards in accordance with Federal and award requirements and

(2) had policies and procedures in place that were designed to meet Federal Conflict of Interest (FCOI) requirements for training and monitoring.

Advocate Health's Mock (tentative) Audit Scope and Performance

- Advocate Health Auditors may review Advocate Health/WFUHS policies and procedures to determine whether the research enterprise maintains adequate financial controls in place during the audit period to ensure the allowability of costs in accordance with Federal and award requirements.
- Advocate Health Internal Audit Service team may randomly or select specific awards and transactions
- Advocate Health Internal Audit Service team may test the allowability of costs to determine whether they were reasonable, allocable, consistent, and conformed to any limitations or exclusions.

FEDERAL REQUIREMENTS—COST TRANSFERS

Cost transfers to NIH awards by recipients must be supported by documentation that fully explains how the error occurred and a certification of the correctness of the new charge by a responsible organizational official.

An explanation merely stating that the transfer was made "to correct error" or "to transfer to correct project" is not sufficient. Transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are not allowable (NIHGPS, 7.5, "Cost Transfers, Overruns, and Accelerated and Delayed Expenditures," 2019).

FEDERAL REQUIREMENTS—TRAVEL EXPENSES

Travel expenses for employees of the recipient organization are governed by the recipient's travel policies, consistently applied regardless of the source of funds. In all cases, travel costs are limited to those allowed by formally established organizational policy and, in the case of air travel, the lowest reasonable commercial airfares must be used.

Commercial recipients' allowable travel costs may not exceed those established by the FTR, issued by GSA, including the Maximum per diem and subsistence rates prescribed in those regulations.

FEDERAL REQUIREMENTS—FINANCIAL CONFLICT OF INTEREST

The FCOI regulations at 42 CFR § 50.603 define a "financial interest" to mean "anything of monetary value, whether or not the value is readily ascertainable," and a "significant financial interest" to be any financial interest of the investigator, the investigator's spouse, and the investigator's dependent children that reasonably appears to be related to the investigator's "institutional responsibilities."

A minimum threshold of $5,000 for disclosure generally applies to most types of financial interests or to the total combined value of the financial interests. Intellectual property rights and interests (e.g., patents and copyrights), on receipt of an unspecified amount, may constitute a significant financial interest.

The FCOI regulations at 42 CFR § 50.604 provide explanations of responsibilities of institutions regarding investigator FCOIs

Recommendations to Research Administrators

- Protect your electronic access to enterprise and government systems
- Investigators and Key personnel should personally sign AND date all COI disclosures. (NO spending on awards without the completion of COI disclosures)
- Administrators should enter costs on awards in a timely fashion
- Provide evidence and documentation for costs transfers to confirm reasonability and allowability
- Have regularly conversations with Investigators about Time and Effort to assure the correctness of effort certifications

Newly Aligned Clinical Research SOPs

- Adverse Events, Serious Adverse Events and Unanticipated Problems
- Essential Records
- Federal Inspection, Regulatory, Sponsor, and Internal Audits Policy
- Informed Consent Policy
- Subject Screening and Enrollment Policy
- IRB Submissions Policy
- SOP on Standard Operating Procedures
- Facilitated review and implementation of 3 OnCore SOPs

Achievements to Date

- A 16-member committee has been established with members from all divisions and representation for numerous service lines.
- A formal submission, review and status-tracking process has been developed.
  - Ability to identify harmonization needs, regional requirements, and ensure proper ownership alignment
- SOP Committee Webpage has been created for committee members to submit, track, and edit SOPs, as well as access minutes and agendas.
- A process has been developed and implemented to identify and consolidate legacy policies.
- Updated CTSI Regulatory >Policies Webpage
- Creation of an SOP Reminder section in the Research Rundown Newsletter

Goals in 2026

- Continue to harmonize enterprise level clinical research SOPs.
  - Aiming to have 50% of all division-duplicate SOPs harmonized by Q4 of 2026
- Maintain a centralized, high quality clinical research SOP library in PolicyTech.
  - Moving towards PolicyTech alignment in Q3 of 2026
- Implement a structured workflow for introduction of **new** enterprise-wide clinical research SOPs.
- Strengthen communication and dissemination of SOP updates.

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2025 Confirmed Dates for Exe RCC Meetings

The 2025 Executive Research Compliance Committee Meetings are aligned to the Enterprise Compliance Department's central schedule:

Q2 2026 Pending

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Research Security Training

M. ASIF MAHI, MSL, LL.B

MANAGER, EXPORT CONTROLS AND INTERNATIONAL RESEARCH COLLABORATION

EXPORT COMPLIANCE PROFESSIONAL (ECOP®) - EAR/ITAR

RESEARCH INTEGRITY, SECURITY, AND REGULATORY AFFAIRS OFFICE

3/12/2026

Wake Forest University
School of Medicine

The academic core of Atrium Health

Today's Focus: Refresher and Compliance Update

Brief recap

- Why is Research Security training required?
- What is Research Security?
- What do we aim to achieve?

FAQs

Federal Research Security Training deadline

Why is Research Security Training Required?

- **Federal Regulatory Requirement**
  - NSPM-33 (2021)
  - CHIPS & Science Act (2022)
  - Guidelines for Research Security Programs at Covered Institutions' (2024)
- **Required**
  - "*Key personnel*" on federal awards.
    - Instances where Common Forms SciENcv Bio-sketch is collected.
  - Key personnel can appear in the form of:
    - Principal Investigator (PI)
    - Co-Investigator (Co-I)
    - Mentors / Co-Mentors
    - Other Significant Contributors (OSC) or
    - Consultant
    - Residents & Fellows (Clinical and/or Research)

What is Research Security?

- **Safeguarding the Research Enterprise**
- **Focused on four key areas**
  - ❑ International travel security
  - ❑ Export Control training
  - ❑ Cybersecurity
  - ❑ Research Security training
- **Collective responsibility**
  - ❑ Working together to achieve a common goal of compliance.

Compliance = Continued Funding

- **Compliant**
  - Federal regulations
  - Agency-specific rules
    - Common requirements (Ex.: NIH, NSF, DoD)
      - Disclosure of all sources of support and affiliations
      - Prohibition on ‘Malign Foreign Talent Recruitment Programs’
      - Mandatory Research Security training
      - Institutional Research Security programs
      - Data security and management
  - Institutional certification

- **Non-compliance**
  - Risks funding loss for PI and Institution.

- **Workday**
  - Automatic assignment
    - Currently 3000+ Faculty enrolled
  - Annual requirement
  - Self-enrollment
    - Resident & Fellows (Clinical and/or Research)
    - Department Managers, Administrators, and staff can enroll

Frequently Asked Questions (FAQs)

1. How do I access the module?

- Employees (Workday): https://wd5.myworkday.com/aah/learning/course/7054eb1a841010309c85504c65e80000
- Non-employees (Articulate): https://360.articulate.com/review/content/48ab57d8-eabf-48ea-9baf-2f0cf2d2596b/review

2. Do I need to take this module? *Yes*

- '*Key Personnel*' as indicated in slide #3.
- "…*seeking or receiving Federal research and development funding*…"
- Faculty appointments

3. I'm emeritus/adjunct, do I need to take this module?

- Yes, if named on application as Key Personnel

4. How do I manage the logistics of this training at the department level?

- Localized approach
  - Example: Begin to collect the Research Security Training certificate of completion.

Federal Deadline

- **Research Security Training Requirements for NIH**
  - ❑ NOT-OD-26-017 | Effective: May 25, 2026

Purpose

This notice notifies the extramural community of the NIH implementation of the Research Security Training (RST) requirements outlined in the CHIPS and Science Act of 2022 (P.L. 117-167).

In accordance with Section 10634 of Act, each covered individual (for NIH this is defined as senior/key personnel) listed on an NIH grant application must certify that they have completed RST within 12 months of the date of application submission. NIH does not collect Current and Pending (Other) Support at the time of application based on our Just-in-Time policy. Therefore, NIH will collect the individual certification at the time of the application submission, through the Biographical Sketch in SciENcv.

The Act also requires applicant institutions to certify that each covered individual who is employed by the institution and listed on the application has completed RST. The Authorized Organization Representative (AOR), via their signature on the face page of the application, will certify the applicant institution's compliance with this requirement.

Applicants and recipients may utilize any training that addresses cybersecurity, international collaboration, foreign interference, and rules for proper use of funds, disclosure, conflict of commitment, and conflict of interest. NSF, in partnership with the National Institutes of Health (NIH), the Department of Energy (DOE) and the Department of Defense (DOD), have provided four online RST modules as a resource to the extramural community. Subsequently, the SECURE Center developed an updated and condensed version of the four modules. The condensed RST module is designed to meet the government-wide RST requirement in Section 10634 of the CHIPS and Science Act of 2022 (42 U.S.C. § 19234). To that end, NIH also recognizes completion of the condensed module as compliant with the respective RST requirements.

Effective Date: At this time, the research security training requirement is optional. Completion of RST and the individual and institutional certifications will be effective for applications submitted for due dates on or after May 25, 2026.

Contact Info.

- **M. Asif Mahi**
  - Mohammad.mahi@advocatehealth.org
- **Research Security website**
  - https://ctsi.wakehealth.edu/regulatory/research-security
- **Research Security Policy (Enterprise)**
  - Available within PolicyTech https://atrium.policytech.com/dotNet/documents/?docid=136335&app=pt&source=browse
  - PDF copy will also be made available with this presentation

Pre-Award Announcements

Research Security Training Certificate

- **Benefits of Department Collection of RST Certificates:**
  - Challenge for Department leaders to know if faculty have completed the training.
    - Workday Research Security Training provides individuals with a dated certificate of completion.
    - As RST certificates are collected, departments can create their own tracking lists.
    - Departments can confirm that Senior Key Personnel Certificate Form attestations are accurate.
  - Department Administrators will be prepared for NOT-OD-26-017, upcoming attestation changes with Common Forms Bio-sketch.

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  - **Subrecipients:**
    - **Incoming Sub-awards:**
      - Primary subrecipient sponsors may request a copy of the RST certificate.
    - **Out-going Sub-awards:**
      - Departments/OSP will need a copy of RST certificate of completion as confirmation.

Frequently Asked Questions (FAQ's) Pt. 1

1. **Are departmental staff required to take Research Security Training?**
   - Staff are encouraged to complete RST. Individuals may self enroll, and managers have the option to assign the training.
   - Completing RST supports career development and grant administration knowledge.

2. **Do non-research Program Directors have to complete Research Security Training?**
   - All senior key personnel noted on a federally funded proposal are required to complete RST.

3. **Do all proposals require completion of Research Security Training?**
   - It will depend on where the money (funding source) is coming from.
     - If federally funded, RST is required.
     - If not federally funded, RST is not required. Please review the sponsor guidelines accordingly.

Frequently Asked Questions (FAQ's) Pt. 2

4. **As RST certificates are collected, how can I best keep track?**
   - It is recommended for the department to maintain an Excel spreadsheet to track all collected certificates.

5. **I've previously completed RST and did not print a certificate. How do I print proof of completion?**
   - Please see the following Workday proof of completion steps. A PDF copy of the document will also be sent to the RA listserv along with this presentation.

6. **Where can I go to find the latest information and guidance on Common Forms: Biographical Sketch and Current and Pending (Other) Support?**
   - NIH has updated their FAQ website page. Frequently Asked Questions (FAQs) | Grants & Funding. Additional questions will display either NEW or UPDATED next to it.

Enterprise Resources

Research Resources for Study Teams

Stay informed on all things research administration. Please bookmark the following enterprise resource site:

- Research Resources for Study Teams – Centralized access to IRB, OCR, OSP, CRU, PolicyTech Job Aids, Encompass Tip Sheets for Research, SCaRF, and Phlebotomy Training resources. Accessible by all enterprise teammates.
    - Within the OSP section, we have centralized access to all existing SharePoint resource pages:
        - Huron Grants and Agreements Training Videos
        - OSP Forms and Templates
        - OSP Minute: Institutional reference guides, tip sheets, and work-flow grids
        - Research Administrators Meetings: Power Point slides and meeting recordings
        - OSP External Training Resources: Externally hosted research administration training, webinars, online courses, and sponsor resources

Implementation of New Federal Initiatives and Policies

Stay informed on changes in policies and procedures taking place within federally sponsored research. Below is a selection of websites and resources:

- CTSI Research Rundown: Subscribe to our research-focused Monday newsletter
- WFUSM Response to Federal Action: A SharePoint site dedicated to coordinating and managing the Wake Forest University School of Medicine's responses to federal legislative, regulatory, and administrative actions.
- Report Your Grant Status Updates & Submit Questions: If your research project has experienced changes or disruptions, please complete this form.
- NIH Implementation of New Initiatives and Policies: Centralized information about the status of changes impacting NIH grants process and plans for implementing new initiatives and policies.
- Notices of NIH Policy Changes: Centralized site containing all NIH policy notices. Subscribe to receive notices each week.

Connect with OSP

When unsure of who to contact in OSP, please refer to the following mailboxes:

OSP Section	Subject Area	Email Address
Pre-Award	Huron Proposal Submissions (Federal, State, Foundation)	awards@wfusm.edu
Post-Award	▪ Working with Project Financial Information (CORE Connect) ▪ Post Award Management Topics (Set-Up to Closeout) ▪ Compliance Questions	postaward@wfusm.edu
Post-Award – Cash Team	Cash postings/applications	ospcashahwfb@advocatehealth.org
Contracts - General	Huron Agreements	osp_contracts@wfusm.edu
Contracts - Subawards	Huron Agreements – Subawards	subawards@wfusm.edu
Systems and Reporting	▪ Huron Technical Assistance ▪ Huron Employee Certification Compliance (ECC) ▪ Huron Reporting	▪ Technical Assistance: ryan.favreau@advocatehealth.org or john.dohnal@advocatehealth.org ▪ ECC: effortreportingahwfb@advocatehealth.org ▪ Reporting: nicholas.lindsay@advocatehealth.org

Connect and learn from our teams during weekly Research Administration Virtual Office Hours

To see which OSP specialists are assigned to your department please consult the OSP Departmental Assignments list.

Please join us for the next Research Administrators Meeting:

Thursday, May 14, 2026

10:00 – 11:00 am

We welcome your input and feedback.

To request future topics/speakers or to be added the Research Administration listserv please email penny.gatsis@advocatehealth.org