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Internal Monitoring: Identify Potential Issues in Research Programs Early and Often

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OBJECTIVES

IDENTIFY THE DIFFERENCE BETWEEN AUDIT AND INTERNAL MONITORING

DEFINE THE GOALS FOR INTERNAL MONITORING IN RESEARCH ADMINISTRATION

KNOWLEDGE OF CORRECTIVE ACTION PLANS – DEVELOPING AND FOLLOWING THROUGH

AUDIT VS INTERNAL MONITORING

AUDIT

- INDEPENDENT OVERSIGHT
  - External groups (e.g., FDA, NIH, OIG, USDA, etc.)
  - Internal oversight units/boards not directly associated with a department (e.g., Compliance Offices, Grants and Accounting, IRB, IACUC, etc.)
- CAN RESULT IN PUNITIVE ACTIONS PRONE TO SANCTIONS, PENALTIES, ETC.

INTERNAL MONITORING

- INTERNAL OVERSIGHT
  - Staff within department (e.g., Compliance Officer, Compliance Manager, Finance Director, etc.).
  - Institutional groups with direct association with department (e.g., Quality and Education teams)
  - Internal Audits
- EDUCATION AND REVISION OF PROCESS
- COULD RESULT IN REPORTING AND PUNITIVE MEASURES

GOALS OF AN INTERNAL MONITORING PROGRAM

- IDENTIFY ISSUES EARLY
- MAINTAIN COMPLIANCE WITH REGULATION, LAW, AND INSTITUTIONAL POLICY
- STREAMLINE PROCESSES
- EDUCATION OF STAFF AND INSTITUTIONAL OFFICIALS

INTERNAL CONTROLS

§200.1 Definitions- Internal controls

Internal controls means a process, implemented by a non-Federal entity, designed to provide reasonable assurance regarding the achievement of objectives in the following categories:

(a) Effectiveness and efficiency of operations;

(b) Reliability of reporting for internal and external use; and

(c) Compliance with applicable laws and regulations.

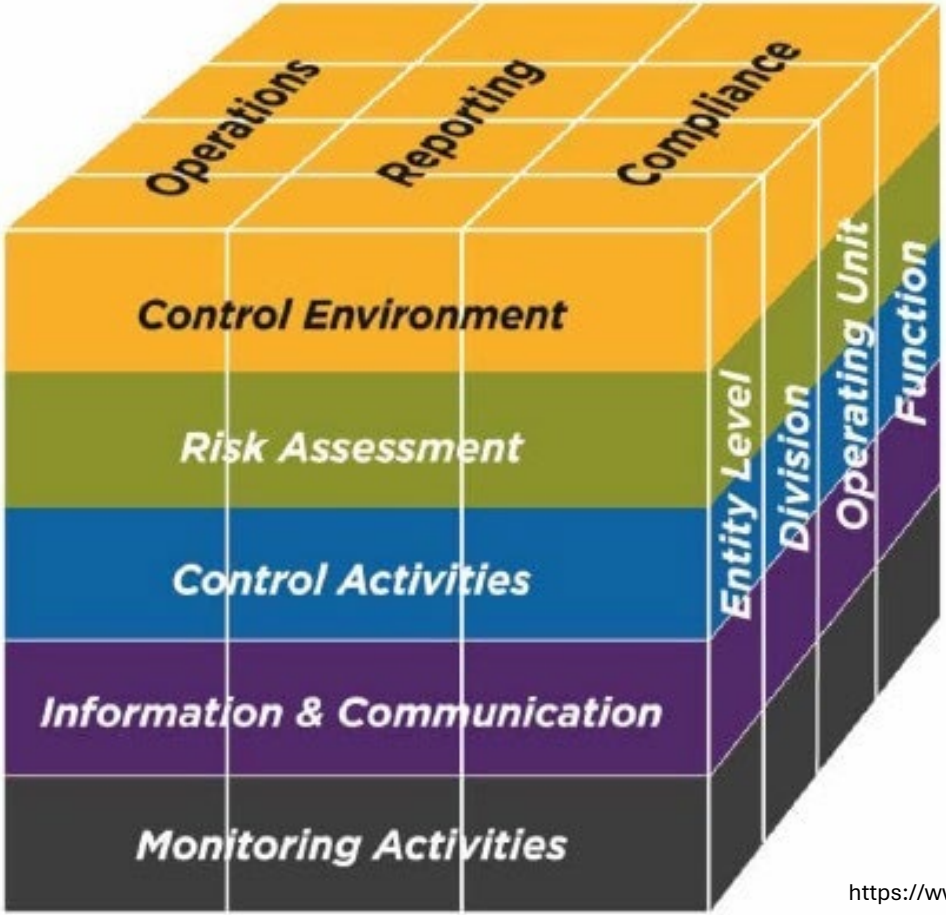
§200.303 Internal controls

The non-Federal entity must:

- (a) **Establish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award**. These internal controls should be in compliance with guidance in "Standards for Internal Control in the Federal Government" issued by the Comptroller General of the United States or the "Internal Control Integrated Framework", issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).
  - (b) **Comply with Federal statutes, regulations, and the terms and conditions of the Federal awards.**
  - (c) Evaluate and monitor the non-Federal entity's compliance with statutes, regulations and the terms and conditions of Federal awards.
  - (d) Take prompt action when instances of noncompliance are identified including noncompliance identified in audit findings.
  - (e) Take reasonable measures to safeguard protected personally identifiable information and other information the Federal awarding agency or pass-through entity designates as sensitive or the non-Federal entity considers sensitive consistent with applicable Federal, state, local, and tribal laws regarding privacy and obligations of confidentiality.

COSO Framework for Internal Controls

- **Historical Background**: Committee of Sponsoring Organizations of the Treadway Commission (COSO) was established in 1985 by five private-sector organizations to combat fraudulent financial reporting. It aimed to create a unified framework for internal controls across industries.
- **Adoption by the Federal Government**: The U.S. federal government adopted the COSO Framework to strengthen internal controls in public sectors, using it as a foundation for developing federal audit guidelines, such as the "Green Book" for auditing internal controls in federal programs.
- Three Objectives: The COSO Framework helps organizations achieve three objectives: Operations (effectiveness and efficiency), Reporting (reliability of reporting), and Compliance (adherence to laws and regulations). These guide the overall purpose of internal controls.
- **Five Key Components**: The framework focuses on five elements: Control Environment, Risk Assessment, Control Activities, Information & Communication, and Monitoring.
- **Purpose**: It helps organizations ensure compliance with regulations, mitigate risks, and promote operational efficiency.
- **Widely Used**: COSO is a global standard, enhancing governance, accountability, and risk management in both financial and non-financial operations.



COSO FRAMEWORK

https://www.coso.org/SitePages/Home.aspx

ESTABLISHING A COMPLIANCE MINDSET

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Financial and Administrative Compliance is.....

- Compliance with certifications and assurances
- Expenditure of funds according to laws, regulations, policies, procedures, and award terms and conditions
- The effective management of public funds to maximize research outcomes
- The avoidance of fraud, institutional mismanagement, and poor management of sponsored funds

How do We Show Compliance?

- Source Documents/Documentation
- Business Systems and Business Rules
- Sound Professional Judgment and Competence
- Ongoing professional development and training

Source Documents/ Documentation

Include those original documents providing evidence that transactions have occurred.

Examples:

purchase orders	payroll time records	equipment orders	contracts

Such records also include the general ledger and subsidiary records or equivalent.

Alternative Documentation

Federal agency officials and auditors have the discretion to use ***their*** professional judgment to accept alternative documentation in certain instances as full or partial evidence that a transaction occurred, should source documentation be lost or otherwise unavailable.

For example, calendar or journal entries may be considered alternative documentation, if time and effort records are not available.

Business Systems

SYSTEM BUSINESS RULES

SUPPORT FINANCIAL AND ADMINISTRATIVE COMPLIANCE.

ENFORCE FEDERAL AND UNIVERSITY POLICIES AND PROCEDURES.

ARE INTEGRAL TO A INSTITUTIONS INTERNAL CONTROL STRUCTURE.

Professional Judgment and Competence

Key Elements:

- **Education & Training**: General, specialized, and continuous education builds the foundation of knowledge and skills.
- **Experience**: Practical, on-the-job learning and continuous improvement through peer and management feedback.
- **Ongoing Development**: Competence is not solely defined by years of experience but by relevant activities and growth.
- **Commitment to Learning**: Maintaining proficiency through lifelong learning is crucial for effective professional judgment.
- **Risk Management**: Effective professional judgment involves using risk assessment and mitigation strategies to ensure compliance.

Major Risk Areas

Allowability and Cost Allocation Methods

- benefit to project
- end of award

Subrecipient Monitoring

Travel

- unreasonable/unallowable

Poor internal controls

Separation of duty/signature authority

Lack of policies and procedures

Inadequate documentation

Compliance Solutions and Strategies

Internal and external training
Seek assistance from sponsor
Stay current with issues
Create guidelines
Enhance Internal controls
Readily available list of relevant policies
Reconcile accounts consistently
Document inconsistencies (internally)
Understand limitations
Written Procedures
Utilize Graduate and undergraduate students
Consultants
Internal Audit
Leverage or form Oversight Committees

FALSE CLAIMS ACT

False Claims Act (FCA)

What Is It?

Established during the Civil War to combat fraud against the government

Allows whistleblowers to report fraudulent activities (qui tam suits)

Why It Is Important:

As grantees, we attest to the government that our organizations can comply with all terms and conditions of the award

There does not need to be an intent to defraud the government

How It Can Cost Us:

Damages (Including treble damages)

Penalties

Institutional Reputation

Increased Administrative Burden

AREAS OF COMPLIANCE IN RESEARCH ADMINISTRATION

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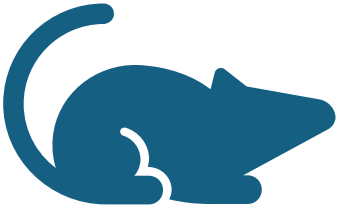


ANIMAL RESEARCH

- **PURPOSE OF INTERNAL MONITORING**
  - HUMANE TREATMENT OF ANIMALS IN RESEARCH
  - LABORATORY STANDARDS
  - COMPLETE AND ACCURATE DATA TO SUPPORT RESEARCH IN HUMANS

HUMAN SUBJECTS

The purpose of monitoring is to ensure:

- *Human subject protection: The rights and well-being of human subjects are protected.*
- ***Reliability of trial results**: The reported trial data are accurate, complete, and verifiable from the source documents.*
- *Compliance with the current Institutional Review Board (IRB) approved protocol/amendment(s), with International Council for Harmonization (ICH) Good Clinical Practice (GCP), and with applicable regulatory requirements.*

The sponsor of a clinical research study is responsible for quality assurance throughout all stages of the trial process by ensuring trials are adequately monitored.

University of Utah Office of Quality Compliance: https://qualitycompliance.research.utah.edu/sop-library/uu-sop-15.php#:~:text=Internal%20monitoring%20is%20primarily%20utilized,may%20benefit%20from%20internal%20review. (emphasis added)

CONFLICT OF INTEREST

FINANCIAL

Federal, state, and local thresholds apply

Management and monitoring

COMMITMENT

Time and effort

Recording and certifying

ORGANIZATIONAL

Consideration of any institutional conflicts

Management and monitoring

Emerging Compliance Area: Research Security

Research Security Framework

Conflict of Interest and Conflict of Commitment

Cybersecurity

Federal Disclosures

Export Controls

Foreign Travel

Foreign Visitors

Intellectual Property

Research Security Training

Considerations

How is your organization staying abreast of federal laws and agency requirements?

Who is your primary point of contact/office responsible for overseeing these requirements?

Do you need to update or create new institutional policies and procedures?

What training programs are occurring to help faculty and staff understand their responsibilities?

Acknowledge that requirements will almost certainly cut across institutional departments

- Division of Research
- Provost/Academic Affairs
- General Counsel
- Graduate School
- Information Technology

Recent Research Security FCA Settlements

- DOJ: Stanford FCA Case Involved Failures to Disclose Foreign Support From Seven Countries

Stanford agreed to pay the government $1,938,682, of which $1,334,404.57 is restitution and $604,278 is a penalty, and pledged to work with the NSF to strengthen its disclosure policies.

- Ohio State University Pays Over $875,000 to Resolve Allegations that It Failed to Disclose Professor's Foreign Government Support

The Ohio State University (OSU) paid the government $875,689, stemming from an unidentified OSU investigator with funding from the Army, NASA and NSF from 2012 to 2020.

- Department Of Justice Reaches Million-Dollar Settlement With Van Andel Research Institute To Resolve Allegations Of Undisclosed Foreign Ties To NIH Grants

Van Andel Research Institute agreed to pay $1.1 million to resolve allegations that it violated the False Claims Act by failing to disclose a foreign component of a NIH award and by failing to disclose foreign research support for two researchers who served as PIs of NIH awards.

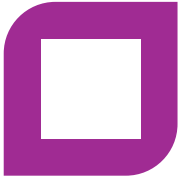
KEYS FOR SUCCESSFUL INTERNAL MONITORING

KEYS TO SUCCESSFUL INTERNAL MONITORING

POLICIES AND PROCEDURES

DOCUMENTATION

REPORTING



LEADERSHIP SUPPORT

CORRECTIVE ACTION PLANS

CORRECTIVE ACTION PLANS

- IDENTIFY ISSUE
- ROOT-CAUSE ANALYSIS
- REPORT IF NECESSARY
- PLAN SOLUTION
- WRITE IT DOWN
- TIMELINE FOR FOLLOW-UP
- DOCUMENT FOLLOW-UP

WHATEVER THE PLAN IS...

FOLLOW IT THROUGH UNTIL ISSUES ARE RESOLVED

2 CFR 200.511 Audit Findings Follow-Up – Corrective Action Plans

- Plans Typically Include
  - Name of the Contact Person Responsible for the CAP
  - What Actions Will Be Taken to Correct Deficiency
  - How Will Progress be Measured
  - What is Your Anticipated Completion Date (Be Realistic)
- Becomes Part of Your Single Audit Submission
- Take The Plan(s) Seriously
- Failure to Adequately Respond Increases Scrutiny and Could Jeopardize Future Funding

RESOURCES

Resources – Regulations/Audit

2 CFR 200 – Uniform Guidance	•(https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title02/2cfr200_main_02.tpl)
Single Audit Compliance Supplement (2023)	•(https://www.whitehouse.gov/wp-content/uploads/2023/05/2023-Compliance-Supplement_PDF_May-2023.pdf)
Federal Acquisition Regulations	•(https://www.ecfr.gov/current/title-48)
Federal Register Register	•(https://www.federalregister.gov/)
COSO Framework	•(https://www.coso.org/Shared%20Documents/COSO-ICIF-11x17-Cube-Graphic.pdf)
All Federal Audits in One Place -Oversight.gov	•(https://www.oversight.gov/

Resources – Office Inspector General

These sites contain audits, work plans, reports to Congress and other useful information. Look for sections entitled "Reports and Publications" or similar names for audits or "Annual Plan" or "Work Plan" for their planned activities.

Defense	http://ww.dodig.mil/
Energy	http://energy.gov/ig/office-inspector-general
HHS	http://oig.hhs.gov/
NASA	https://oig.nasa.gov/
NSF	http://www.nsf.gov/oig/
USDA	http://www.usda.gov/oig/