Conducting Research Responsibly

Module Objectives:
- Why is Compliance Important?
- What are the Consequences of Noncompliance?
- Compliance at USF
- Roles and Responsibilities
- Help for Principal Investigators
- Compliance Websites
Why is Compliance Important?

Sponsors want to ensure that:

- Sponsors are **charged fairly** for the costs.
- Investigators are meeting the proposed **effort commitments**.
- Human subjects are **protected**.
- Animal welfare is **respected**.
- The investigators are not influenced by **conflicts of interest**.
- There are **high levels of integrity** with the research.
- **Workplaces are safe** for employees.
What are Consequences of Noncompliance?

- **Heavy fines** for misrepresenting costs, whether intentional or not.
- **Suspension or disqualification** from special privileges or future research funding.
- **Civil and criminal penalties** if convicted of fraud.
- **Loss of public trust** in research conducted by the University.
  - Public relations issues (community, sponsors, students, staff, faculty, etc.).
  - Potential reduction of state funding.
  - **Reduction in donor support** for USF.
Award-Related Settlements:

- $11,500,000 Florida International University, Inflated Research Grant Costs
- $15,000,000 New York University Medical Center, Inflated Research Grant Costs
- $35,000,000 University of Minnesota, Misuse of Federal Grants
- $11,200,000 Stanford University, Inflated Research Grant Costs
- $1,800,000 George Washington University, Misuse of Federal Grants
- $2,600,000 Johns Hopkins University, Effort Reporting
- $3,250,000 Harvard University / BIDMC, Self-Reported Costs
- $3,400,000 University of Alabama Birmingham, False Billing Allegations
- $5,500,000 University of South Florida, Cost Accounting Standards & Effort Reporting
- $5,500,000 Northwestern University, Effort Reporting
- $5,500,000 University of South Florida, Cost Accounting Standards & Effort Reporting
- $3,250,000 Harvard University / BIDMC, Self-Reported Costs

Total settlements: $124,200,000
USF’s guidelines for the Responsible Conduct of Research are based on three important principles:

- The University is obligated to protect and foster the academic freedom and intellectual integrity of all members of the University community in the pursuit of knowledge.

- The University is accountable to sponsors that support the research and scholarship of faculty and must comply with all applicable laws and regulations.

- Each researcher has ultimate responsibility for the accuracy and validity of his/her own work. Each researcher shares this responsibility with colleagues and students with whom he/she establishes collaborative or mentorship relationships.

Refer to: http://www.research.usf.edu/vpfr/policy/respon.htm
Division of Research Integrity and Compliance

Responsible for key research-related assurance and compliance programs required by federal and state agencies and programs for the conduct of research at USF:

- BioSafety Program
- Diving Safety Program
- HIPAA Program
- IACUC – Institutional Animal Care and Use Committee - Comparative Medicine
- IRB - Institutional Review Board
- Research Misconduct
- USF Radiation Safety Program

Refer to: http://www.research.usf.edu/cs/
**USF Regulation and Policy Compliance**

Sponsors may require evidence / certification of University compliance with specific federal and state laws (i.e., Equal Opportunity, Drug Free Work Place). Certifications or any other relevant information may be obtained by contacting the following offices:

- Equal Opportunity: Diversity and Equal Opportunity Office
- Drug Free Workplace: Human Resources, Employee Relations

University regulations, policies and procedures are listed on the General Counsel’s website.

- USF Regulations
- USF Policies and Procedures

Research related policies and procedures are listed on the Research website.

Conflict of Interest policies and procedures, including investigator financial interests in research, are listed on the Conflicts of Interest website.

Additional information including guidelines, forms and institutional data is listed on the Division of Sponsored Research (DSR) website.
Roles and Responsibilities

With the tremendous growth in Research at USF, our continued success is dependent upon understanding the responsibilities associated with our roles.

- Principal Investigator (PI)
- Co-Principal Investigator (Co-PI)
- Department / Center Staff
- Department Chair
- Dean / Director
- Division of Sponsored Research (DSR)
- Research Financial Management (RFM)

Refer to: [http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#PI!A3](http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#PI!A3)
Principal Investigator (PI)

Primary individual in charge of and responsible for activities on a sponsored project

**Responsible for:**

- The overall scientific, fiscal, and administrative conduct of the project.
- Meeting the terms and conditions of the award.
- Representing the project to the sponsor.

Refer to: [http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#PI!A3](http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#PI!A3)
Principal Investigator (PI) continued

Other responsibilities include:

• Developing and submitting the research proposal.
• Participating in awareness and certification programs required by the University.
• Adhering to all regulatory requirements.
• Disclosing all related financial interests and informing other key personnel of their obligation to do so.
• Obtaining necessary reviews & approvals.
• Managing the award budget (reviewing monthly financial reports and ledgers to monitor encumbrances and expenditures, and initiating budget transfer requests as appropriate).
• Complying with USF effort reporting & outside activity policies.
• Retaining the scientific data garnered from the research project.

Refer to: http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#PIIA3
Co-Principal Investigator (Co-PI)

Responsible for the administrative, fiscal and scientific conduct of the project.

- May be granted spending authority on the award.
- Must fulfill the same obligations as the Principal Investigator for his/her section of the project.

Refer to: http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#CoP1A3
Department / Center Staff

- Attend educational and training programs.
- Assist PIs in the development of research proposals and budgets.
- **Assist PIs with completion of all USF required forms and compliance requirements.**
- Assist PIs in the interpretation and application of rules, policies, and procedures.
- Assist PIs with personnel appointments and processing award-related expenditures.
- **Prepare, process, and manage documents and provide information for recording program income and cost sharing.**
- Review monthly financial reports to help monitor encumbrances and expenditures, and make adjustments where necessary.

Refer to: [http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#AdminStaff!A3](http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#AdminStaff!A3)
• Provide information to Research Financial Management (RFM) or the USF Research Foundation to resolve discrepancies.

• Review and prepare effort reports for certification.

• Provide information to Research Financial Management (RFM) for invoicing and verification for financial reporting.

• Maintain documentation for all expenditures.

Refer to: [http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#AdminStaffA3](http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#AdminStaffA3)
Department Chair

- **Ensures that faculty and staff receive training** on the policies and procedures for the proper management of contract and grant proposals, awards and reporting.

- **Facilitates the work/obligations of faculty** who serve as PIs.

- **Makes available staff and infrastructure** to ensure the appropriate conduct of research.

- **Verifies** PI eligibility and the appropriateness of the proposed project.

- **Ensures unit/departmental compliance with regulations pertaining to human and animal subjects.**

Refer to: [http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#UnitHead!A3](http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#UnitHead!A3)
Dean / Director

- With the Department Chair, ensures that faculty and staff understand the policies and procedures for the proper management of contract and grant proposals, awards and reporting.

- **Reviews the proposal** in a timely manner to ensure the following:
  - The PI has obtained the appropriate signatures on the Internal Form.
  - The PI is eligible and qualified.
  - College goals and University objectives are met in the proposal.

- Approves internal and external sources of matching funds/cost sharing.

- Ensures that faculty and staff have the opportunity for relevant training.

- Reviews and approves the use and transfer of any research equipment.

Division of Sponsored Research (DSR)

- Helps PIs prepare proposals.
- Ensures compliance requirements are met.
- Verifies proposal budgets are accurate and comply with university and sponsor standards.
- Gets the proposal OUT THE DOOR (submits proposals to sponsors) on time.
- Negotiates and accepts awards on behalf of USF.
- Reviews and negotiates contracts.
- Prepares research subcontracts.
- Serves as liaison to sponsor regarding extensions, change of PI, change of work scope, budget transfers, revised budgets.
- Provides information and training programs to support researchers and increase participation in research and creative activities.

Refer to: [http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#DSRIA3](http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#DSRIA3)
Research Financial Management (RFM)

- Assists PIs and staff with compliance and financial issues.
- Activates new sponsored projects/accounts.
- Oversees cost sharing/matching reporting.
- Coordinates federal effort reporting.
- Monitors program income.
- Processes all project budget transfers.
- Reviews and approves all award related cost transfers.
- Prepares and submits invoices and financial reports.
- Establishes Research Initiatives (for F&A rebates, fixed priced residuals and Internal Awards) and convenience account funds.
- Coordinates award closeouts.
- Coordinates sponsor audits of projects.

Refer to: [http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#RFM!A3](http://www.research.usf.edu/files/training/ResearchRoles&Responsibilities.xls#RFM!A3)
Help for Principal Investigators

Help is available!

The following provide help with compliance issues:

- Dean, Department Chair & Administrative Staff
- College Research Administrators Network
- Division of Sponsored Research (DSR)
- Division of Research Integrity and Compliance
- University Services
- Research Financial Management (RFM)
- University Audit and Compliance
- USF General Counsel
Compliance Websites

- Division of Sponsored Research:
  - [http://www.research.usf.edu/sr/](http://www.research.usf.edu/sr/)
- Division of Research Integrity and Compliance:
  - [http://www.research.usf.edu/cs/](http://www.research.usf.edu/cs/)
- Conflicts of Interest:
  - [http://health.usf.edu/research/compliance/coi_general.htm](http://health.usf.edu/research/compliance/coi_general.htm)
- University Policies:
  - [http://www.usf.edu/OGCWeb/policies/](http://www.usf.edu/OGCWeb/policies/)
- University Regulations:
  - [http://www.usf.edu/OGCWeb/Regulations/](http://www.usf.edu/OGCWeb/Regulations/)
- USF Research Policies and Procedures:
  - [http://www.research.usf.edu/misc/rrpp.htm](http://www.research.usf.edu/misc/rrpp.htm)