

Research Ethics and Compliance

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Integrity: a Partnership in Compliance with Rules and Expectations



Integrity

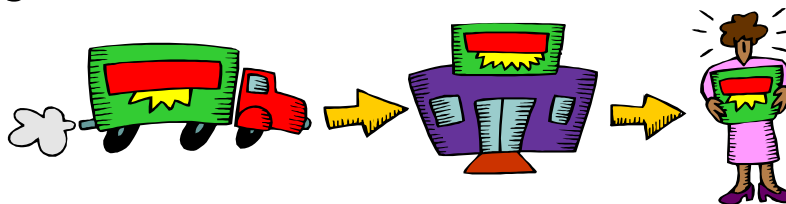
- The right thing, at the right time, and in the right way.
- A sound, complete **system**

System

- **Partnerships** of regularly interacting or inter-dependent groups forming a unified whole

Partnership

- The government, institutions, and research community



The Partnership

- **The Agency** (National Science Foundation)
 - OIG
 - Program Officers
 - Grants Officers
- **Institution Officials**
 - Administrative
 - Financial
 - Education
- **Researcher**
 - Students
 - Colleagues
 - Postdocs
 - Administration





Agency Commitment (NSF's)

- Clear articulation of rules/expectations
- Timely notification
- Responsiveness
- Limit bureaucracy
- Coordination between agencies
- Balance compliance, institution responsibility and latitude, reduction of bureaucracy
- Numerous opportunities for funding (CAREER, REU, Fellowships, SGER, etc)



NSF's Office of Inspector General

- ◆ Provide leadership, coordination and recommend policies to:
 - ✓ Prevent and detect fraud, waste, abuse
 - ✓ Promote economy, efficiency, effectiveness
 - ✓ Independence from agency management
 - ✓ Jurisdiction (NSF activities, programs operations)
 - ✓ Our staff : administrators, attorneys, auditors, criminal investigators, and scientists

Fancy words for ensuring integrity in NSF's programs and operations



Jurisdiction

- Each of the 57 statutory OIGs only have jurisdiction over the programs and operations of the federal agency with which it is associated.
- Similarly, ORI, as an entity within HHS, only has jurisdiction over research misconduct issues related to HHS



Institutional Commitment

- Overall
 - A financial and administrative system to manage projects and staff
 - Create an environment in which employees can operate with integrity

- Proposal
 - Certification to comply with terms and conditions

- Award
 - Full responsibility for conduct of project (e.g. Article 1, GC-1)
 - Responsibility for administrative, financial, and research management and oversight



NSF's Requirements

- The **awardee has full responsibility** for the conduct of the project or activity supported under this award and for adherence to the award conditions. Although the awardee is encouraged to seek the advice and opinion of NSF on special problems that may arise, such advice does not diminish the awardee's responsibility **for making sound scientific and administrative judgements** and should not imply that the responsibility for operating decisions has shifted to NSF.
- By accepting this award, the awardee agrees to **comply with the applicable Federal requirements** for grants and cooperative agreements and to the **prudent management** of all expenditure and actions affecting the award.

Reference: NSF's Grant General Conditions, Article 1.



Researcher Commitment

- **Overall -- Uphold ethics and standards of community**

- Proposal
 - Develop a proposal that responds to the review criteria
 1. Intellectual Merit of Proposal
 2. Broader Impacts of Activity
 - Know and adhere to the rules

- Award
 - Conduct the funded activity
 - Know the rules
 - Keep in touch with agency personnel
 - Ensure compliance and education of staff, students



Common Concerns

- How do I keep ethics and integrity in the spotlight when competing for finances and staff?
- How do I get management's attention when there are so many other issues also begging for attention?



References

- <http://oig.hhs.gov/fraud/complianceguidance.html>
- <http://www.ussc.gov/2003guid/CHAP8.pdf>
- <http://www.ussc.gov/corp/Murphy1.pdf>
- http://www.usdoj.gov/dag/cftf/corporate_guidelines.html
- Grant, G. Odell, G., and Forrester, R; Creating Effective Research Compliance Programs in Academic Institutions; **Academic Medicine**, Vol 74, No. 9, September 1999, p. 951.



Institutional Compliance

- 7 elements of a good compliance program
 - 1) Reasonable Compliance Standards and Procedures
 - 2) Specific High-level Personnel Responsible
 - 3) Due Care in Assignments with Substantial Discretionary Authority
 - 4) Effective Communication of Standards and Procedures

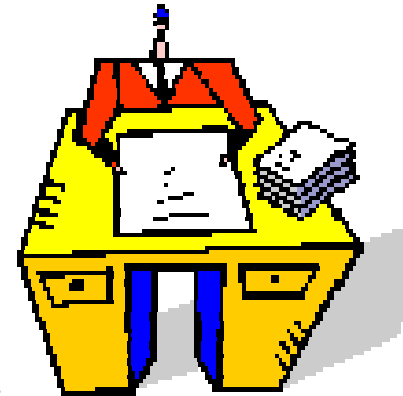


Institutional Compliance

- 5) Establish Monitoring and Auditing Systems and Reporting System (Whistleblowing without fear of Retaliation)
- 6) Consistent Enforcement of Standards through Appropriate Mechanisms (including failure to detect)
- 7) Respond Appropriately to the Offense (reporting to law enforcement, modify program, prevention)

Key Focus Areas

- Administration



- Finance



- Research



Administrative Spotlight

- Conflict of Interest
- Research Misconduct
- Lobbying
- Patent Disclosure (Bayh-Dole Act)
- Training Requirements
- Original Work
- Current and Pending Support Information
 - time and effort (% to each project not > 100%)
 - 2/9th rule limiting summer salary
- Records Retention (financial, research, other)
- Equipment use and sale
- Debarment, Drugfree workplace, EEO



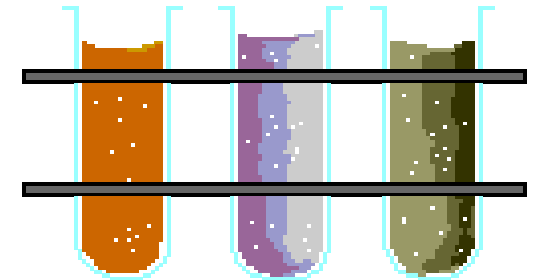
Financial Management Spotlight

- Internal Systems Management
 - In NSF Grant Conditions
 - In OMB Circulars
- Contracts and Subcontracts
- Cost Sharing
- Program Income (research and conference grants)
- Participant Support
- Rebudgeting
- FCTRs/Annual and Final Reports
- Equipment
- Time and Effort Reports



Research Management Spotlight

- Human Subjects Review (IRB)
- Animal Welfare (IACUC)
- Radiation Safety
- Biosafety (Recombinant DNA and other issues)
- Collection Permits
- Variety of Environmental Permits
- Data Sharing, Sample Sharing





Research Management (cont'd)

- Change or Absence of PI
- Current and Pending Support Information Duplicate Proposal Submission to other agencies, to NSF
- Progress and Final Reports
- Bioterrorism preparedness and Response Act of 2002 (Agents, Toxins --- human, animal, or plant)
- Enhanced Border Security Act (student registration)

Oversight and Monitoring

- Balance compliance, awardee responsibility and latitude, reduction of bureaucracy
- Oversight
 - Audits and reviews (A-133, agency, OIG)
 - Inspections or site visits (agency or OIG)
 - Civil and criminal investigations (OIG)
 - Administrative investigations (OIG)
 - Focused reviews from investigations (OIG)



Consequences of Significant Errors

- ✓ Special Oversight/Review Status
- ✓ Administrative Sanctions
- ✓ Suspension or Termination of Awards
- ✓ Civil/Criminal Violations
- ✓ Suspension/Debarment
- ✓ Corrective Action Plans
- ✓ Loss of reputation
- ✓ Confidence in Science

May apply to either awardee or PI





There is a Real Cost for Poor Compliance Programs

- \$30 million and a multi-year compliance plan
- \$15 million for overcharging
- 2 researchers serving jail terms

Education Prevention and Integrity

- Focus on Integrity: People and Attitude
- Integration of Process, Documentation, and Education
- Integrity of system ensuring comprehensive oversight
- Specific oversight programs, responsibilities
 - committees function and are properly convened
 - document work
- Training programs for managers, researchers, support staff, and oversight staff
- Partnership and communication between Awardee research, administrative, compliance staff and Agency






A compliance program that works

- ✓ Know the rules
 - ✓ Rules are NOT static and CHANGE by agency
 - ✓ Review number 1
 - ✓ Train employees
 - ✓ Train the trainer
 - ✓ Support the trainer from the top
 - ✓ Identify compliance personnel (need policies, procedures, reporting, reviewing, enforcement mechanisms, resources, obstacle resolution)
- From industrial perspective: this is a **QUALITY ASSURANCE/QUALITY CONTROL** function

Acting ethically may require that you choose among shades of gray



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