



SRA

A Compliance Approach to Research Integrity

Lee Stokes

Investigative Attorney

**Office of Inspector General, National Science
Foundation**

lstokes@nsf.gov

703-292-5180

Southern Section

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What is a compliance program?

- “ ‘Compliance and ethics program’ means a program designed to prevent and detect criminal conduct” .” http://www.ussc.gov/2004guid/8b2_1.htm
- A compliance program teaches and encourages members of an institution to conform to ethical and legal standards.
- An organized and ongoing effort to ensure that the all levels of an organization complies with applicable rules, regulations and laws.

Partnership

The Agency (National Science Foundation)

- OIG
- Program Officers
- Grants Officers

Institution Officials

- Administrative
- Financial
- Education

Researcher

- Students
- Colleagues
- Postdocs
- Administration





NSF's Commitment

- Clearly articulate rules/expectations
- Make timely notification
- Ensure responsiveness
- Limit bureaucracy
- Coordinate with other agencies
- Balance compliance, institution responsibility and flexibility
- Provide opportunities for funding (CAREER, REU, Fellowships, SGER, etc)

Expectations



- Accurate Certifications to the Federal Government
- Reasonable, allowable, allocable, consistent, verifiable costs
- Conduct the funded work
- Adhere to laws, regulations, and policies
- Make documentable process
- Hire trained responsible individuals
- Rules apply to:
 - Employees as well as
 - Sub-contractors, Suppliers, or Affiliated Researchers
 - International collaborators, SBIRs



NSF's Office of Inspector General

- Provides leadership; coordinates & recommends policies necessary to:
 - Prevent and detect fraud, waste, abuse
 - Promote economy, efficiency, effectiveness
- Independent of NSF Management
- Responsible for ensuring the integrity in NSF's programs and operations
- Jurisdiction: NSF activities, programs & operations
- Staffed by attorneys, auditors, scientists, criminal investigators & administrators



Institutional Commitment

- **Overall**
 - Financial and administrative system to manage projects and staff
 - An environment in which employees can operate with integrity
- **Proposal**
 - Certification to comply with terms and conditions
- **Award**
 - Responsibility for administrative, financial, and research management and oversight (e.g. Article 1, GC-1)



Researcher Commitment

- **Proposal**

- Develop a proposal responding to the review criteria
 - Intellectual Merit of Proposal
 - Broader Impacts of Activity / Education and Training
- Know & adhere to the rules, regulations, and ethics

- **Award**

- Conduct the funded activity
- Know and adhere to rules, regulations and ethics
- Ensure compliance and education of staff, students

Uphold ethics and standards of community

Considerations



- A submission to NSF must be of the **highest level of scholarship; citations, co-authors, data accuracy**
- Proposal should be sound with innovative research
- Ensure the accuracy of NSF submissions / certifications
- Completeness of research oversight approvals (human subject, animal, materials)

Considerations



- Oversight of financial and administrative responsibilities
- Accuracy of Current and Pending Support / Biographical Sketch / Annual and Final Reports
- Ensuring peer review confidentiality
- Compliance with misconduct policies and materials

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.

NSF's Requirements



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.

Key Risk Areas

Strategic / Operational / Reputational

Operational Considerations:

- Administration
- Finance
- Research





Administrative

- Conflict of Interest
- Research Misconduct
- Lobbying
- Patent Disclosure (Bayh-Dole Act)
- Training Requirements
- Original Work
- Current & Pending Support Information
- Time & effort (% to each project)
- 2/9th rule limiting summer salary
- Records Retention
- Equipment use and sale
- Debarment, Drugfree workplace, EEO

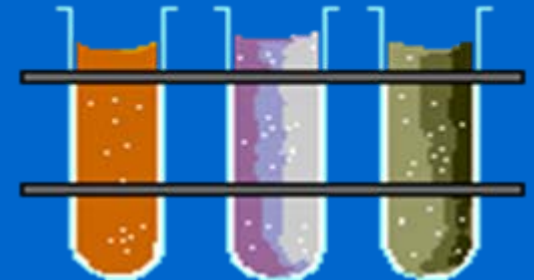


Financial Management

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

Research Management Spotlight

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





Research Management (cont'd)

- Change or absence of PI
- Current & Pending Support Information
- Duplicate Proposal submission to NSF & other agencies
- Progress and final reports
- Bioterrorism preparedness & Response Act of 2002 (agents, toxins, human animal or plant)
- Enhanced Border Security Act (registration)



Background on the Sentencing Guidelines

- The Organizational Sentencing Guidelines (OSG) were created, and later amended, by the United States Sentencing Commission, an independent Federal Agency.
- The OSG are designed to create punishment guidelines for organizations convicted of Federal crimes.



Definition of Organization

- "Organization" means "a person other than an individual." 18 U.S.C. § 18.
- The term includes corporations, partnerships, associations, joint-stock companies, unions, trusts, pension funds, unincorporated organizations, governments and political subdivisions thereof, and non-profit organizations. (see §8A1.1. (1))

Why do you care about these OSGs?

- Criminal liability can attach to an organization whenever an employee of the organization commits an act within the apparent scope of his or her employment, **even if the employee acted directly contrary to company policy and instructions.**

- An entire organization, despite its best efforts to prevent wrongdoing in its ranks, can still be **held criminally liable for any of its employees' illegal actions** (see <http://www.ussc.gov/TRAINING/corcover04.pdf>)



Silver Lining

Implementation of an **effective** compliance and ethical plan can reduce the potential fine by up to **95%**



But:

What are the elements of an effective compliance plan?

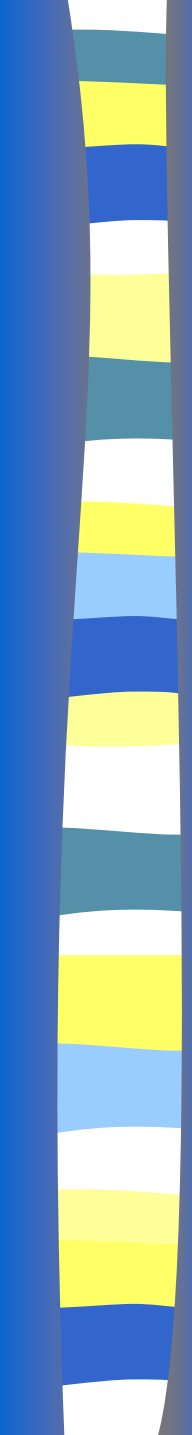


Institutional Compliance

7 Elements

- 1) Standards and procedures to prevent and detect criminal conduct
- 2) Organizations governing authority should know of plan or program and exercise oversight of the program
- 3) Reasonable effort/ due diligence when hiring personnel with substantial authority
- 4) Provide training at all levels and periodic updates on compliance and ethics

Institutional Compliance

- 
- 5) Employ auditing and monitoring systems designed to detect criminal behavior and periodically evaluate both the effectiveness of the systems and of the compliance/ethics programs as a whole
 - 6) Enforce compliance standards through incentive and disciplinary actions and provide non-retaliatory internal reporting systems.
 - 7) Reasonable steps to respond to and prevent further similar offenses upon detection of a violation.

Oversight and Monitoring

Balance compliance, awardee responsibility with 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)
- Proactive reviews from investigations (OIG)



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





Specific Risk Areas

- Parking Charges
- Double Charging
- Questionable PI Effort Allocations
- Unspent Grant Funds
- Staffing too thin
- Lack of training
- Lack of independent or oversight
- Absence of UP-TO-DATE policies and procedures? (COI)

Tailor YOUR program to reduce YOUR risk

Consequences of Significant Errors

- Special Oversight/Review Status
- Administrative Sanctions
- Suspension or Termination of Awards
- Civil/Criminal Violations
- Suspension/Debarment/Exclusion
- Corrective Action Plans
- Compliance Plans
- Fines, Penalties
- Exceptional Status



May apply to either awardee or PI

Penalties

- \$15 M; overcharging IDC
- \$30 M, exceptional status and oversight program; misuse of federal grants
- \$12 M; overbilling
- \$650,000; research fraud and abuse
- \$.5M; Sexual harassment
- \$1.2M inflated research grant costs
- \$150,000 and 5-year compliance program, misuse of federal funds



Let's Talk About

- Managing the Process
- Cost Sharing
- Program Income
- Effort Reporting
- Subrecipient Monitoring
- Participant Support
- Signature Responsibilities

Managing Integrity in the Award and Proposal System



Division of Sponsored Research
Proposal Review and Certification Form

For DSR use only.
Date Received:
Due Date:
Postmark Receipt
ID#:

PROJECT TYPE

Competitive Renewal Continuation New Proposal Pharmaceutical Contract Supplemental Request

Account Number, if continuation: | Date Proposal Submitted to Sponsor: | Previous Proposal Number, if any:

INVESTIGATORS

PI Name | PI SSN | PI Phone | PI Fax | PI E-mail Address

Department Receiving Credit for Award: | PI's Mail Point:

Other Contact (not PI): | Contact's Phone: | Contact's Fax: | Contact E-mail Address:

Co-PI Name | Co-PI Phone | Co-PI Fax | Co-PI E-mail Address

(For additional Co-PIs, attach an additional sheet. List employees only.)

SPONSOR

Sponsor/Agency Name:

Agency Program:

Sponsor Contact: | Title:

Address: | State: | Zip:

City: | State: | Zip:

Phone: | Fax: | E-Mail:

Funding Source: Federal Funded State Funded Local Government For-Profit Corporation

Nonprofit Organization Non-University Related Other

Project Title:

*Note: For projects requiring IRB or IACUC approval, the project title entered here must be the same as what appears on your IRB or IACUC application.

INITIAL BUDGET PERIOD | PROJECT PERIOD | UNIVERSITY COMMITMENT

From: 08/01/00 To: 07/31/01 | From: 08/01/00 To: 07/31/03 | Tuition: Graduate Assistant stipends/salaries are requested. Yes No. If yes, tuition and fees should also be requested. If yes, and tuition/fees not requested, please explain:

Direct Costs: | Direct Costs:

Indirect Costs: | Indirect Costs:

Total Costs: | Total Costs: | Additional Compensation/Overload? Yes No

Indirect Costs: | Indirect Costs: | Will this project generate subcontracts? Yes No

Full Federal Indirect Costs? Yes No. If no, state reason: | Type: Research Training Other

Program requirement (14% maximum)

Additional Space and/or Facility Requirements for this Project? Yes No. If yes, please describe:

Full Federal Indirect Costs? Yes No. If no, state reason:

Program requirement (14% maximum)

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Full Federal Indirect Costs? Yes No. If no, state reason:

Program requirement (14% maximum)

Additional Space and/or Facility Requirements for this Project? Yes No. If yes, please describe:

FOR FEDERAL AND FEDERAL FLOW-THROUGH AWARDS ONLY:

Yes No Budget request includes salary for clerical and administrative staff, postage, local telephone service, office supplies, general purpose software, subscriptions, and/or memberships. If yes, you must include special justification in budget narrative in order to comply with federal cost accounting standards (OMB Circular A-21).

Cost-Sharing

Cost-Sharing? Yes No Required: % or Voluntary: %

First-Year Commitments:	Department	College/Area	DSR	Total
Salary & Fringe Ben.	\$	\$	\$	\$
OCO	\$	\$	\$	\$
Expense	\$	\$	\$	\$
Indirect Costs	\$	\$	\$	\$
Total	\$	\$	\$	\$

Approvals

Biohazards | Radioactive Materials | Human Subjects | Laboratory Animals

Recombinant DNA Yes No Yes No Yes No

Infectious Agents Yes No Yes No Yes No

Toxins Yes No Yes No Yes No

Status: NO COMPLIANCE Expedited Expedited Expedited

Approval Date: | Approval Date: | Approval Date: | Will data support an FDA submission? Yes No

Number: | Number: | IRB No.: | IACUC No.:

Conflict of Interest Certification

Do any participating faculty, staff, or students (or their spouses or dependent children) have any financial interest such as royalty, equity, or any other payments (e.g., consulting, salary, etc.) in the sponsor or other entities having a financial interest in intellectual property, products or services that are the subject of the proposed research? Yes No If yes, provide a completed Financial Interest Disclosure form to your chairperson. Financial Interest Disclosure forms can be obtained from DSR or under Conflict of Interest (... 309) at <http://www.research.edu/vp/irpgo.htm>.

If yes: (1) Does/will any equity interest exceed \$10,000 in current value or exceed 1% ownership interest, or (2) do/will aggregate annual payments for royalty and other payments (e.g., consulting, salary, etc.) exceed \$10,000? Yes No

UNIVERSITY ENDORSEMENTS: The attached project has been examined by the officials whose signatures appear below. The principal academic review of the project is the responsibility of the Department (Center/Institute) and College. These signatures indicate that the signers are familiar with the project and are satisfied with and responsible for all commitments in the project as they relate to their areas (space/personnel/financial/etc).

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Principal Investigator	Date	Chairperson	Date	Dean	Date
-----	-----	-----	-----	-----	-----
Co-Principal Investigator	Date	Chairperson	Date	Dean	Date
-----	-----	-----	-----	-----	-----
Co-Principal Investigator	Date	Chairperson	Date	Dean	Date
-----	-----	-----	-----	-----	-----
Co-Principal Investigator	Date	Chairperson	Date	Dean	Date
-----	-----	-----	-----	-----	-----

(For additional Co-PIs, attach an additional sheet. For employees only.)

Clinics or Affiliates:	Pharmaceutical Study:	Cancer Center:
-----	-----	-----
Authorized Official	Date	Vice President, Medical Affairs
-----	-----	Date
-----	-----	Director, Research Admin.
-----	-----	Date

Electronic or Paper Format
Ensure coordinated reviews and approvals



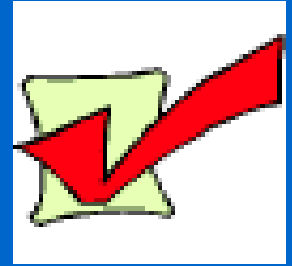
Issues and Information

- Internal Proposal Review and Sign off
- Award Performance and Financial Monitoring
- Key Documents and Information
 - Circulars, Regulations, Policies
 - GC-1, FDP, Special Conditions
 - Grant Proposal Guide
 - Grant Policy Manual
 - Specific Announcement or Solicitation Guidance
 - Program Officer, Grants Administrator
 - NSF Web site www.nsf.gov

Cost Sharing and Program Income



Allowable Cost Sharing



- Verifiable.
- A specific contribution for only one federally-assisted project.
- Necessary and reasonable for project objectives.
- Allowable under the applicable cost principles.
- May not be paid by the federal government under another award, except where authorized.
- Provided for in the budget (NSF's line "M").

Program Income



- Program income means **gross income** earned by the awardee that is directly generated by a supported activity or earned as a result of the award
- Must be received or accrued during the period of the award and added to the funds committed to the project by NSF and used to further project objectives
- Conference grants have no time limit on income and income is used to offset NSF contribution



Case: Program Income

Allegation:

PI of an NSF conference grant failed to properly account for program income, improperly spent NSF funds and violated COI rules.

Process

- University had audited the award prior to telling OIG.
- After reviewing the University's internal audit report, we conducted an independent investigative financial review of the grant.



Facts after University's audit

PI awarded a sub-contract to a company owned by the PI and his wife to: coordinate the conference, receive registration fees (**program income**) and pay certain expenses not covered by the grant.

The University had no knowledge of the Sub-K until afterward – the account was overdrawn which triggered an internal audit.

PI did not report the program income to NSF or the University.



Facts after University's Audit

Through a settlement, the PI agreed to pay \$22,453.65 to the University.

The COI violation also may have violated state COI and other laws and was turned over to state law enforcement officials.



Facts after OIG audit and investigation

- Based on our review, \$124,955 was received in program income of which we questioned \$87,302.
- Payments to the company were questioned as were alcoholic beverages, gifts and other entertainment expenses.
- The University agreed with most of our findings and returned \$63,652 to NSF.



Afterword

The University both surveyed PI's and independently reviewed NSF grants to determine if there was any potential for generating program income or participant support.

The university put together a task force to develop a series of training modules. Completion of the modules is required by all new PI's and current faculty.



Afterword

- Because of this case, we conducted a proactive review of 71 awards which had generated close to \$1 million in conference fees.
- We continue to work with the institutions to resolve the issues. To date we have recouped \$68,826.13 that was inappropriately used.



What we found in other cases

- Unreported income
- Spouses hired
- Liquor
- Unnecessary/Unrelated items
- Federal employees travel funded
- Grantee's employees
- Excessive travel

Effort Reporting





Basics:

Total compensation is reasonable and is not included as indirect costs

Academic Year Salaries are based on regular compensation

Outside Academic Year Salary may not exceed the base salary divided by the number of months in the period for which the base salary is paid.

Summer Salary may not exceed two-ninths of the academic year salary aggregated over all NSF awards



Basics: (Cont'd)

- **Extra Compensation Above Base Salary** only for education projects where specifically approved by NSF.
- **Sabbatical Leave Salary** must be approved by NSF and be
 - proportional to the service rendered;
 - in accordance with established institutional sabbatical policies
 - may not exceed the individual's base salary



Effort Reporting Red Flags

- Current and Pending Support
- Summer Salary
- No one can work more than 100% of their time
- Must be after the fact certification
- Two signatures (individual and reviewer)
- No whiteout



Case: Effort Reporting

Allegations

- PI of an NSF grant had improperly charged approximately \$18,000 in labor and other indirect cost to the NSF grant.
- On at least two occasions, the PI billed NSF for work done for his private company.
- The lab was financially mismanaged with an operating deficit of \$1.5 million



OIG investigation

We asked that the University conduct an audit of the labor cost associated with the NSF grant at issue.

The audit report identified \$95,606 in labor and associated indirect charges were inappropriately charged to the NSF grant account due to poor financial management of the lab.

No intent or purposeful wrongdoing occurred.



Results

- The University returned \$95,606.
- Because the statute of limitation had run with regard to any criminal charges and there was no evidence of intentional wrongdoing, we closed the case.



Silver Lining

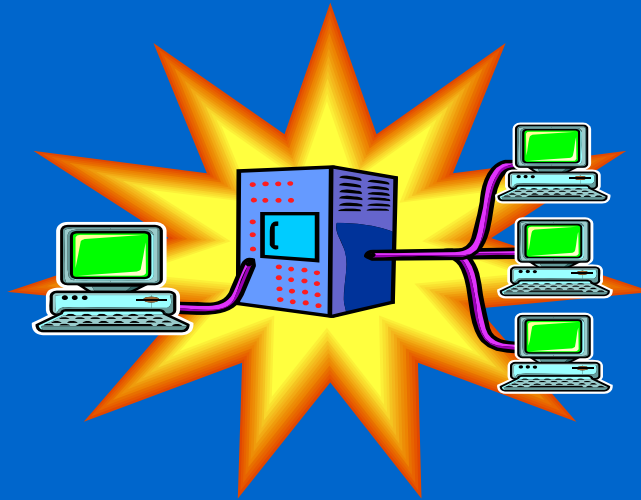
- Prior to our involvement with this issue, the University had hired a CPA to oversee the lab's funds, because they were concerned about the internal controls.
- When we came to the University with the allegation, the internal audit reviewed the numbers and agreed that something was wrong.



Another issue

- This is really an unmanaged COI in disguise. The University made the lab staff and PI track their time hourly, but did not audit the department.
- The way the internal auditors discovered that something was wrong was by looking at the timecards. The timecards did not match the movement of funds.

Subrecipient Monitoring





Basics

- No significant part of the research or substantive effort under an NSF grant may be contracted or transferred without prior NSF authorization.
- The grantee shall submit
 - a clear description of the work to be performed;
 - the basis for selection of the subawardee; and
 - a separate budget for each subaward.
- If NSF approves, award will be amended
- Grantees shall ensure conditions flow down to all subawardees

NSF Expectations

- An effective system for monitoring subrecipients consider:
 - program complexity, dollar amount, percentage passed through
 - subrecipient (contract) vs. vender (purchase order)
 - Nature of deliverable (a thing, research, a service)
 - fixed price vs. cost reimbursement.
 - Type of subawardee
- Technical, Financial, and Compliance reviews
- Comply with applicable A-133 subparts
- Comply with applicable A-110 parts

Participant Support



Know the rules

- Use caution when supporting employees
- Use caution when supporting Federal employees
- Direct costs of stipends, subsistence or travel allowances and registration fees
- Direct costs of dissemination and sharing of research results and publication / distribution of grant materials



Participant Support Costs

- Should not be included in indirect cost calculations
- Should not use for supplies
- Need to be well documented, so keep the paper
- Monitor subcontracts



Cautions:

- Funds may not be used for other purposes without the specific prior written approval of the cognizant NSF
- Awardee must account for participant support costs separately

Signature Responsibilities



Proposal Signatures

- Compliance with award terms and conditions
- Accuracy and completeness of statements
- COI Policy
- Drug-Free Workplace
- Debarment and Suspension
- Lobbying (proposal >\$100,000)
- Certification (18 USC 1001)



Conflict of Interests

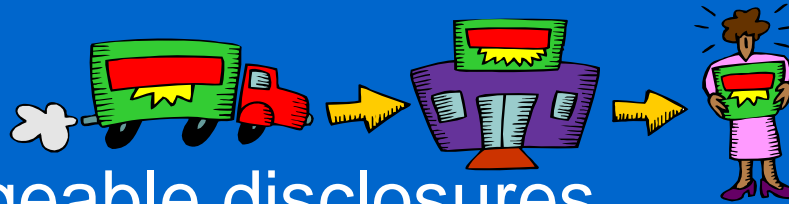
Institutional and Personal

Financial and Commitment



Process managed by Institution

Ensure:



- Knowledgeable disclosures
- Disclosures objectively reviewed by trained staff
- A signature, a date, an approval number, a responsibility warning
- Incorporation with other review procedures
- Disclosure of unmanaged situations to NSF
- Audit for compliance, proactive reviews

Covers SBIRs, commitments other than financial

Acting ethically may require that you
choose among shades of gray



A well-structure compliance program can reduce
your risk and guide your decisions



Case: False Statement and Fraud

Allegations

- Subject's wife owned a private company which had an NSF Small Business Innovation Research (SBIR) Phase I grant.
- Subject, a science professor, used his lab and graduate students to carry out work under the grant.



Facts after OIG Investigation

- No work had been performed under the SBIR Phase I grant.
- Most of the \$99,300 went to pay salary to the subject and his wife or for fictitious expenses.
- The final report submitted by the subject was copied verbatim from one of his student's thesis. Based on the report, NSF awarded the company an SBIR Phase II award. \$99,974 of which had been disbursed.

Result

- We recommended that NSF suspend the Phase II and referred the matter to the United States Department of Justice.
- The Subject repaid \$198,975 and made an unrestricted donation to NSF and was voluntarily excluded from receiving Federal funds for a period of 3 years.
- The Subject plead guilty to 1 count of violating 18 U.S.C. §1001 – false statement and was later sentenced to 5 years probation, \$15,000 fine.

INTEGRITY STARTS WITH YOU!

If you are aware of, or suspect

- research misconduct

- fraud

- waste

- abuse

- Issues of economy or efficiency
or if you just have questions,

Please contact the

NSF Office of Inspector General





Contact Information

Internet: www.nsf.gov/oig/oig.html

E-mail: oig@nsf.gov

Telephone: 703-292-7100 (Lee x5180)

Anonymous: 1-800-428-2189

Write: 4201 Wilson Blvd.
Arlington, VA 22230

References

<http://oig.hhs.gov/fraud/complianceguidance.html>

<http://www.usssc.gov/2003guid/CHAP8.pdf>

<http://www.usssc.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.

Jordan, K.S.; and Murphy, J.E.; Compliance Programs: What the Government Really Wants. Page 121.

<http://www.usssc.gov>