

Navigating NSF Regulatory Requirements for Responsible Research

Scott J. Moore, Ph.D., J.D.
Investigative Scientist
National Science Foundation Office of Inspector General
Research Integrity and Administrative Investigations Division

Promoting the Responsible Conduct of Research for College and University Leaders
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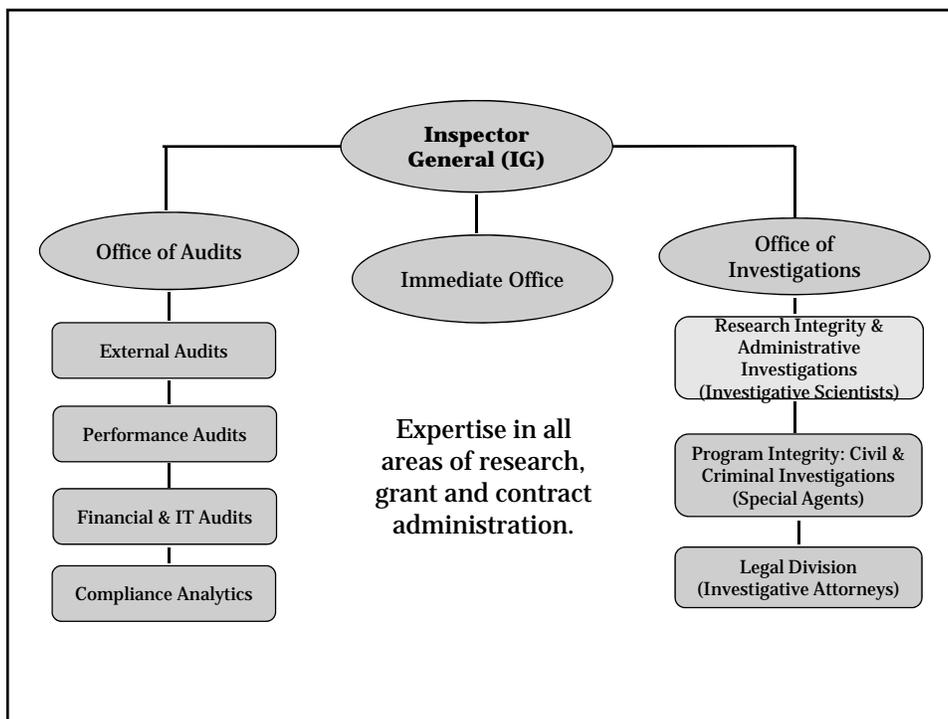
NSF Office of Inspector General (OIG)

- Independent office reporting to the Congress and NSB.
- **Promote economy, efficiency, and effectiveness.**
- **Prevent and detect fraud, waste, and abuse.**
- Accomplishes mission through:
 - Audits
 - Investigations
 - Criminal and Civil (*e.g.*, false claims, false statements, embezzlement).
 - Administrative (*e.g.*, regulatory and policy violations).

**Where does Research Integrity (RI)
and the Responsible Conduct of Research (RCR) fit?**

**NSF delegated the responsibility for investigating research misconduct
in NSF programs to OIG.**

- **Unique among the IG Community**



Both NSF OIG and HHS ORI:

- Assess allegations of research misconduct.
- Oversee institution's investigations, procedures and compliance with federal policies.
- Promote integrity of research.

But there are differences:

NSF OIG

HHS ORI

Independent oversight of NSF's programs and operations.	Oversight of PHS research integrity.
A law enforcement office with subpoena authority and search warrant capability for criminal cases.	Not a law enforcement office.
Can conduct independent investigations without referral to the institution.	Cannot conduct investigations independently.
Make recommendations to NSF for action; NSF Deputy Director adjudicates.	Negotiates Voluntary Exclusions or issues Charge Letters/hearing before Administrative Law Judge.
Reports are available online but are redacted. (Exception: debarred entities are listed in sam.gov)	Summary of findings published in Federal Register with Subject's names listed.
Limited outreach activities. Cannot give grants.	Outreach activities through Division of Education and Integrity, run RIO bootcamps.

Research Integrity Statutes

America COMPETES Act 2007

Mentoring Plans

§7008 “require that all grant applications that include [postdoc funding] include a description of the mentoring activities that will be provided for such individuals . . .” which may include career counseling, proposal preparation, teaching skills, and research ethics.

RCR Training Plans

§7009 “require each institution that applies for financial assistance from the Foundation . . . describe in its grant proposal a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, and postdoctoral researchers participating in the proposed research project”.

Sharing Research Results

§7011 “An investigator supported under a Foundation award, whom the Director determines has failed to comply with the provisions [for data sharing under NSF policy] shall be ineligible for a future award under any Foundation supported program or activity.”

Research Integrity Regulations

Common Rule – Human Subjects – 45 C.F.R. part 690

- Reliance on OHRP Assurance program for IRBs (statutory requirement)
- Must disclose assurance number and approval info during proposal submission.

Research Misconduct Regulation – 45 C.F.R. part 689

- Definitions from OSTP federal-wide policy December 2000.
- Procedural framework similar to HHS ORI with some differences.
 - Timing for referred inquiries and investigations are longer at NSF.
 - No specified statute of limitations at NSF.

Research Integrity Policies

NSF requirements handled often through policy and incorporation in the grant terms.

Primary resource is the

Proposal & Award Policies & Procedures Guide (PAPPG)

<http://www.nsf.gov/pubs/policydocs/pappguide/nsf16001/>

Includes:

the Grant Proposal Guide (GPG)

the Award Administration Guide (formerly the Grant Policy Manual)

Research Misconduct (RM)

- Dec 2000, OSTP (Office of Science and Technology Policy) published a final federal policy with a uniform definition of research misconduct.
- NSF adopted the policy and finalized its regulation April 17, 2002.
- RM means “fabrication, falsification, or plagiarism in proposing or performing research funded by NSF, reviewing research proposals submitted to NSF, or in reporting research results funded by NSF.”
45 C.F.R. 689.1(a)

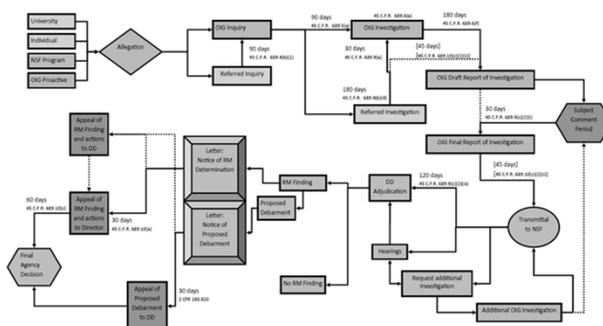
Research Misconduct

- ***Does not*** include mistakes or honest error or differences of opinion.
- “Awardee institutions bear primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of the alleged research misconduct.” 45 C.F.R. 689.4(a)
- “Inform OIG immediately if an initial inquiry supports a formal investigation.” 45 C.F.R. 689.4(b)(2) - also required by the grant terms
- If warranted, OIG conducts additional investigation activities and in a report, makes recommendations to the NSF Deputy Director, who adjudicates.
- For a formal RM finding, the preponderance of the evidence must support the act by the subject at a threshold level of intent.

Research Misconduct Process

Referrals

Referral Letters & Committee Briefings



Research Misconduct: The Act

- **Fabrication** means making up data or results and recording or reporting them.
- **Falsification** means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- **Plagiarism** means the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Note:

Plagiarism is different from copyright infringement.
Must be a “significant departure from the accepted practices of the relevant research community.”
No requirement for intent to deceive in the act definitions.

“Research Record”

Defined in OSTP footnote 3, 65 FR 76262)

“the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.”

Generally this may be interpreted to include:

- data in the least processed form possible.
- data and analysis for the specific results published, and often the excluded data.

Research Misconduct: Intent

For a finding of research misconduct the act must have been committed “intentionally, knowingly or recklessly [and not merely carelessly].”

45 C.F.R. 689.2(c)(2)

???

A federal research misconduct finding generally has a legal consequence subject to legal review by a Federal District Court.

Institutions may potentially be reviewed by state or local courts.

Careless, reckless, knowing, and intentional (purposeful/willful) have been defined through common law over several hundred years. These are the definitions the court will likely use to review the case.

definitions already exist in law

Black’s Law Dictionary definitions for the levels of intent are generalized over jurisdictions and provide a starting point for the assessment.

Research Misconduct: Intent

Careless	Reckless	Knowing	Intentional
No Finding	Finding of Research Misconduct		
Reasonable Person Standard		Individual Standard	

Research Misconduct: Framework for Assessing Intent

Careless: The subject did not exercise the care that a reasonable person similarly situated would have exercised under the circumstances.

Reckless: The subject did not exercise the care a reasonable person similarly situated would have exercised under the circumstances, and did so with a conscious awareness of, or indifference to, the risk of adverse consequences of his actions and the potential resulting harm.

Knowing: The subject had an awareness or understanding of his actions. The subject acted consciously or deliberately.

Intentional: The subject acted with a specific purpose in mind (i.e., purposeful or willful but not necessarily premeditated).

***CAUTION: Consult with your legal counsel
for interpretations appropriate to your venue.***

Research Misconduct: Crafting Protective Actions

For NSF final actions (45 C.F.R. Part 689.3) are dependent on:

1. How serious the misconduct was;
2. The degree to which the misconduct was knowing, intentional, or reckless;
3. Whether it was an isolated event or part of a pattern;
4. Whether it had a significant impact on the research record, research subjects, other researchers, institutions or the public welfare; and
5. Other relevant circumstances.

When Institutions are deciding final actions, are they considering these factors?

OIG needs to know what factors are considered.

Research Misconduct: Assessing the Institution Report

OIG reviews the institutional investigation to assess for

Accuracy

Completeness

Reasonable Procedures

NSF OIG
Research Integrity and Administrative Investigations Division

Jim Kroll, Director
Aaron Manka, Scott Moore, Aliza Sacknovitz
Rachel Allbritten, Erik Runko, Cynthia Davis, Valerie Hillgren

Contact Information

www.nsf.gov/oig	4201 Wilson Boulevard
Hotline: 1-800-428-2189	Suite II-705
E-mail: oig@nsf.gov	Arlington, VA 22230
Fax: (703) 292-9158	ATTN: OIG HOTLINE