

The Third Annual Medical Research Summit

The Leading Forum on the Law, Regulation and Ethics of Medical Research in the United States



Concurrent Session III
March 6, 2003

**3.05 Investigating Allegations of
Scientific Misconduct and the
False Claims Act**

Edwin Rauzi
Davis Wright Tremaine
Seattle, WA



**U.S. Department of Health and Human Services
Public Health Service
Grant Application (PHS 398)**

Instructions for PHS 398
Rev. 05/2001

Form Approved Through 05/2004
OMB No. 0925-0001

"This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into.

Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure."

Standard Form LLL, "Disclosure of Lobbying Activities," its instructions, and continuation sheet are available from GrantsInfo, National Institutes of Health, e-mail: GrantsInfo@nih.gov, (301) 435-0714.

NONDELINQUENCY ON FEDERAL DEBT

The Federal Debt Collection Procedure Act, 28 U.S.C. 3201 (e), provides that an organization or individual that is indebted to the United States, and has a judgment lien filed against it, is ineligible to receive a Federal grant. NIH cannot award a grant unless the authorized organizational official of the applicant organization (or individual in the case of an individual National Research Service Award) certifies, by means of his/her signature on the application, that the organization is not delinquent in repaying any Federal debt. If the applicant discloses delinquency on a debt owed to the Federal Government, NIH may not award the grant until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed.

RESEARCH MISCONDUCT

Each institution that receives or applies for a research, research training, or research-related grant or cooperative agreement under the Public Health Service Act must certify that the institution has established administrative policies as required by (1) 42 CFR Part 50, Subpart A, "Responsibilities for PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science" and (2) 42 CFR 94, "Public Health Service Standards for the Protection of Research Misconduct Whistleblowers" (effective on the date set forth in the final rule.)

The signature of the official signing for the applicant organization on the Face Page of the application serves as certification that:

1. The institution will comply with the requirements of the PHS regulations for dealing with reporting possible scientific misconduct under 42 CFR Part 50, Subpart A, and for protecting research misconduct whistleblowers under 42 CFR Part 94;
2. The institution has established policies and procedures incorporating the provisions set forth in 42 CFR Part 50, Subpart A, and 42 CFR Part 94;
3. The institution will provide its policies and procedures to the Office of Research Integrity upon request; and
4. The institution will submit an Annual Report on Possible Research Misconduct (Form 6349). A copy of Form 6349, covering the previous year, will be automatically sent to all PHS awardees by the Office of Research Integrity each January.

"Misconduct in Science" and "Research Misconduct" are defined by the Public Health Service as "fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretation or judgments of data."

For further information, please contact:

Office of Research Integrity
Division of Education and Integrity
Rockwall II, Suite 700
5515 Security Lane
Rockville, MD 20852,
Phone: (301) 443-5300
Fax: (301) 594-0042 or (301) 445-5351.

ASSURANCE OF COMPLIANCE (CIVIL RIGHTS, HANDICAPPED INDIVIDUALS, SEX DISCRIMINATION, AGE DISCRIMINATION)


Before a grant award can be made, a domestic applicant organization must certify that it has

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

FORM APPROVED: OMB No. 0937-0198; Expires: 12/31/02
See Statement of Burden on Reverse

ANNUAL REPORT ON
POSSIBLE RESEARCH MISCONDUCT

Period Covered by this Report
January 1, 2001 to December 31, 2001

Please make any mailing changes in the space to the right: 

INSTITUTIONAL OFFICIAL'S NAME

INSTITUTIONAL OFFICIAL'S TITLE

NAME OF INSTITUTION

MAILING ADDRESS OF INSTITUTIONAL OFFICIAL

Place mailing label here.

Section I. Administrative Policy

Each institution which receives or applies for a PHS research, research-training or research-related grant or cooperative agreement must have established an administrative policy for responding to allegations of research misconduct that complies with the PHS regulation (42 CFR Part 50, Subpart A) and certify that it will comply with that policy. This regulation does not cover regulated research under the jurisdiction of the Food and Drug Administration (FDA).

• Has your institution established the administrative policy for responding to allegations of research misconduct required by the PHS regulation?

☐ Yes ☐ No

Section II. Types of Misconduct Activity Related to PHS Applications and Awards

A. ☐ **PLEASE CHECK THE BOX** (to the left) if your institution has **NOT** received any allegations or conducted any inquiries or investigations of allegations during the reporting period that (1) fall under the PHS definition of research misconduct and (2) involve receipt of or requests for PHS funding, then complete Section III. Otherwise, please complete Section II.

B. Please provide the requested information for each incident of alleged misconduct that involved a request for or receipt of PHS funds that fell within the PHS definition of research misconduct. Please note that, in accordance with section 50.103(d)(4), all investigations are to be reported to the Office of Research Integrity (ORI) before or immediately upon commencement of the investigation.

PLEASE NOTE: For each incident of alleged research misconduct resulting in an allegation, inquiry, and/or investigation at your institution: (1) provide the ORI case number, if assigned; (2) check the type of activity (allegation, inquiry, and/or investigation -- may include more than one activity type for each reported incident); and (3) check the type of misconduct involved with each activity (may include more than one type of misconduct). Attach a separate sheet if additional space or clarification is required.

Do **NOT** include any alleged fiscal misconduct, human or animal subject abuses, conflicts of interest, or violations of FDA regulated research.

1. Activity continued into 2001:

Incident Number	ORI Case Number, if assigned	Type of Activity	Type of Misconduct			
			Fabrication	Falsification	Plagiarism	Other Serious Deviations
1. _____		<input type="checkbox"/> Inquiry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/> Investigation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. _____		<input type="checkbox"/> Inquiry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/> Investigation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. _____		<input type="checkbox"/> Inquiry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/> Investigation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Continued on back

Section II. (Continued)

B. (Continued)

2. Activity begun in 2001:

Incident Number	ORI Case Number, if assigned	Type of Activity	Type of Misconduct			
			Fabrication	Falsification	Plagiarism	Other Serious Deviations
1. _____	<input type="checkbox"/>	Allegation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	Inquiry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	Investigation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. _____	<input type="checkbox"/>	Allegation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	Inquiry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	Investigation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. _____	<input type="checkbox"/>	Allegation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	Inquiry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	Investigation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

C. Did your institution determine that any of the allegations received in 2001 were made in bad faith? ☐ Yes ☐ No

If so, how many allegations were determined to have been made in bad faith? _____

What actions, if any, did your institution take against the whistleblower(s)?

Allegation 1: _____

Allegation 2: _____

Section III. Certification

Official Certifying for Institution:

NAME OF OFFICIAL (Please type)	TITLE
SIGNATURE	DATE
TELEPHONE NUMBER ()	FAX NUMBER ()

E-MAIL ADDRESS OF OFFICIAL:

STATEMENT OF BURDEN

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Reports Clearance Officer, PHS, Hubert H. Humphrey Building, Room 503-H, 200 Independence Avenue, S.W., Washington, D.C. 20201 (Attn: PRA) and to: Office of Management and Budget, Paperwork Reduction Project (0937-0198) Washington, D.C. 20502. *Please do not return this form to either of these addresses.*

RETURN THIS FORM TO:

Assurance Program
Office of Research Integrity
5515 Security Lane, Suite 700
Rockville, MD 20852

Phone: (301) 443-5300
FAX: (301) 594-0042
E-Mail: JBUTLER@OSOPHS.DHHS.GOV

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The “New” Federal definition of Scientific Misconduct is not yet effective

Please note that PHS funded institutions should continue to apply the current PHS regulations, "Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science," 42 CFR Part 50, Subpart A, originally issued in 1989, until HHS formally implements the new Federal definition and policy through revised regulations.

42 CFR § 50.101 (Scope)

**The regulations apply to each entity that
applies for**

a research,

research training, or

**research-related grant or cooperative
agreement**

under the Public Health Service (PHS) Act.

42 CFR § 50.101 (Content)

The regulations require each entity to establish--

uniform policies and procedures
for investigating and reporting
instances of alleged or apparent
misconduct

42 CFR § 50.101 (Limits)

The regulations do not supersede
procedures for resolving

fiscal improprieties,
issues concerning the ethical
treatment of human or animal
subjects, or
criminal matters.

42 CFR § 50.101 (Duties)

An applicant or recipient institution
shall make an annual submission to the
Office of Scientific Integrity

(1) The institution's assurance shall
be updated annually

(2) An institution shall submit, along
with its annual assurance, information
on allegations, inquiries, and
investigations

(Current definition) Misconduct or Misconduct in Science

fabrication,

falsification

plagiarism, or

other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research.

The Alternate Characterization

[Scientific Misconduct] does not include--

(1) honest error or

(2) honest differences in
interpretations or
judgments
of data.

Assurances

- Each institution that applies for or receives assistance for biomedical or behavioral research must have an assurance that it

(1) Has established an administrative process for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored research conducted at the applicant institution or sponsored by the applicant; and

(2) Will comply with its own administrative process and the regulations.

An institution will be in compliance with its assurance if it:

- (1) Establishes, keeps current, and upon request provides authorized Departmental officials the policies and procedures required by the regulations.
- (2) Informs its scientific and administrative staff of the policies and procedures and the importance of complying with those policies and procedures.

An institution will be in compliance with its assurance if it:

- (3) Takes immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged.
- (4) Informs, in accordance with this subpart, and cooperates with the OSI with regard to each investigation of possible misconduct.

Inquiries, Investigations, and Reporting--

Policies and procedures must provide for:

Inquiring immediately into an allegation or other evidence of possible misconduct. An inquiry must be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period.

A written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry.

Inquiries, Investigations, and Reporting--

Policies and procedures must provide for:

- The individual(s) against whom the allegation was made shall be given a copy of the report of inquiry.
- If they comment on that report, their comments may be made part of the record.
- If the inquiry takes longer than 60 days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period.

An inquiry decide only whether an investigation is warranted

- *Inquiry* means information gathering and initial fact finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.
- *Investigation* means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred.

The [New Improved] Federal Policy on Research Misconduct

- Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- No rights, privileges, benefits or obligations are created or abridged by the policy alone. The creation or abridgment of rights, privileges, benefits or obligations, if any, shall occur only upon implementation of this policy by the Federal agencies.

The [New Improved] Federal Policy on Research Misconduct

Research includes all basic, applied, and demonstration research in all fields of

science,
engineering, and
mathematics.

This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or animals.

(Future?) Misconduct

- Fabrication is making up data or results and recording or reporting them.
- Falsification is 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.

(Future?) Misconduct

- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion.

The research record--

is 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.

Adding burden of proof and state of mind

A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community; and
- The misconduct be committed intentionally, or knowingly, or recklessly; and
- The allegation be proven by a preponderance of evidence.

Key differences

Current definition of Scientific Misconduct

other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research.

- *Burden of Proof*
- *State of Mind*

Model Policies and Procedures

The mother lode--

<http://ori.dhhs.gov/html/publications/guidelines.asp>

In both cases, the model documents tend to increase the scope of the researcher's duties (so read them before adopting them verbatim).

The False Claims Act

Where do laws come from?

- The scandal
- The editorial
- “There ought to be a law”
- The Law

Any Person who

knowingly presents

- to an officer or employee of the United States Government
- a false or fraudulent claim for payment or approval; or

Any Person who

knowingly uses

- a false record or
- statement
- to get a false or fraudulent claim paid or approved by the Government

is liable to the U.S. Government for a civil penalty of--

- not less than \$5,000 and not more than \$10,000, *per claim**
- plus 3 times the amount of damages which the Government sustains
- plus attorneys' fees

* this amount is increased by an inflation factor

“knowing” and “knowingly” mean that a person--

has actual knowledge of the information;

acts in deliberate ignorance of the truth or falsity of the information; or

acts in reckless disregard of the truth or falsity of the information,

no proof of specific intent to defraud is required.

The “Pure Heart and Empty Head” Defense

(and why it usually doesn’t work)

What is a “Claim”?

A “claim” includes any request or demand

- whether under a contract or otherwise,
- for money or property which is made to a contractor, grantee, or other recipient
- if the United States Government provides any portion of the money or property which is requested. . .

The concept of a “private attorney general”

A person may bring a civil action

- for the person
- and for the United States Government.
- The action shall be brought in the name of the Government.
- The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

The existence of the lawsuit is, initially, kept secret

A copy of the complaint and the evidence and information the Whistleblower has is given to the Government

The complaint is filed “in camera” and remains under seal for at least 60 days, and is not served on the defendant until the court orders

The Government may elect to intervene and proceed with the action

The existence of the lawsuit may remain a secret for years

The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal

By all accounts, “good cause” for an extension is relatively easy to establish

Even if the government decides the case has no merit, it may not go away

If the Government declines, the person who initiated the action has the authority to pursue the case

If the Government requests (and it always does), it receives copies of all pleadings in the action and copies of deposition transcripts

The court may permit the Government to intervene at a later date

The conscious effort to foster a “bounty hunter” mentality

- If the Government proceeds with the lawsuit, action, the person who brought it to its attention shall receive
 - at least 15 percent
 - but not more than 25 percent
- of the proceeds of the action or settlement of the claim
- depending upon the extent to which the person contributed to the success of the case

If the whistleblower goes it alone, the potential reward is greater

- If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages.
- The amount shall be
 - not less than 25 percent and
 - not more than 30 percent
- of the proceeds of the action or settlement

The “Care and Feeding’ of Whistleblowers

Is a release of claims by a whistleblower enforceable?

What is retaliation?

The two leading cases

- *United States ex rel Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402 (3rd Cir. 1999).
- *United States ex rel. Berge v. Board of Trustees of the Univ. of Ala.*, 104 F.3d 1453, 1457-1459 (4th Cir.), cert. denied, 522 U.S. 916 (1997)

The Bottom Line

- The Assurance is given, at a minimum, once a year.
- For some institutions, the accuracy of the Assurance—with respect to the full range of its components—may be open to question.
- An inaccurate Assurance is susceptible of being characterized as a “knowing use of a false statement in order to get a claim paid.”
