

Federal Research Misconduct Policy

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OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Executive Office of the President; Federal Policy on Research
Misconduct; Preamble for Research Misconduct Policy
AGENCY: Office of Science and Technology Policy.
ACTION: Notification of Final Policy.

SUMMARY: The Office of Science and Technology Policy (OSTP) published a request for public comment on a proposed Federal research misconduct policy in the October 14, 1999 Federal Register (pp. 55722-55725). OSTP received 237 sets of comments before the public comment period closed on December 13, 1999. After consideration of the public comments, the policy was revised and has now been finalized. This notice provides background information about the development of the policy, explains how the policy has been modified, and discusses plans for its implementation.

EFFECTIVE DATE: December 6, 2000.

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SUPPLEMENTARY INFORMATION: Advances in science, engineering, and all fields of research depend on the reliability of the research record, as do the benefits associated with them in areas such as health and national security. Sustained public trust in the research enterprise also requires confidence in the research record and in the processes involved in its ongoing development. For these reasons, and in the interest of achieving greater uniformity in Federal policies in this area, the National Science and Technology Council (NSTC) initiated discussions in April 1996 on the development of a research misconduct policy. The Office of Science and Technology Policy (OSTP) provided leadership and coordination. The NSTC approved the proposed draft policy in May 1999, clearing the way for the October 14, 1999 Federal Register notice. Public comments in response to that notice have been reviewed. The purpose of this notice is to provide information about the policy as it has now been finalized.

This policy applies to federally-funded research and proposals submitted to Federal agencies for research funding. It thus applies to research conducted by the Federal agencies, conducted or managed for the Federal government by contractors, or supported by the Federal government and performed at research institutions, including universities and industry.

The policy establishes the scope of the Federal government's interest in the accuracy and reliability of the research record and the processes involved in its development. It consists of a definition of research misconduct and basic guidelines for the response of Federal agencies and research institutions to allegations of research misconduct.

The Federal agencies that conduct or support research will implement this policy within one year of the date of publication of this notice. An NSTC interagency research misconduct policy implementation group has been established to help achieve uniformity across the Federal agencies in implementation of the research misconduct policy. In some cases, this may require agencies to amend or replace extant regulations addressing research misconduct. In other cases, agencies may need to put new regulations in place or implement the policy through administrative mechanisms.

The policy addresses research misconduct. It does not supersede government or institutional policies or procedures for addressing other forms of misconduct, such as the unethical treatment of human research subjects or mistreatment of laboratory animals used in research, nor does it supersede criminal or other civil law. Agencies and institutions may address these other issues as authorized by law and as appropriate to their missions and objectives.

Summary of Comments

The Office of Science and Technology Policy received 237 comments on the proposed Federal Research Misconduct Policy. Letters were signed by individuals, and by representatives of universities, university associations, Federal agencies, and private entities. Comments are available for review. Comments that resulted in a modification of the policy are summarized below. A section that

addresses other questions raised by the comments follows the summary of modifications.

Uniform Federal Policy

Issue: Many comments recommended various mechanisms to ensure uniform implementation of this policy.

Response: An NSTC research misconduct policy implementation group has been formed to foster uniformity among the agencies in their implementation of the policy.

Section I: Research Misconduct Defined

Issue: A number of comments suggested that the definition of fabrication be modified to read as follows: "Fabrication is making up data or results and recording or reporting them." (Italicized words are suggested addition.) This change is to clarify that the raw data collected or generated in the research process can be fabricated just as can the results of the research.

Response: This change was accepted.

Issue: A number of commenters interpreted the definition of plagiarism to imply that using material gathered during the peer review process was acceptable as long as it is cited.

Response: The policy is intended to address the problem of reviewers who take material from the peer review process and use it without attribution. This constitutes plagiarism. We have deleted the phrase "including those obtained through confidential review of others' research proposals and manuscripts" to avoid any appearance of condoning a breach of confidentiality in the peer review process.

Issue: Despite general support for the rationale for the phrase "does not include honest error or honest differences of opinion," several comments requested various clarifications.

Response: This phrase is intended to clarify that simple errors or mere differences of judgment or opinion do not constitute research misconduct. The phrase does not create a separate element of proof. Institutions and agencies are not required to disprove possible "honest error or differences of opinion." The phrase has been retained, with the deletion of the second "honest" of the phrase as redundant.

Issue: A number of comments raised questions about what fields of research are included in the definition of research. For example, some readers were unsure about the applicability of [Page 76261] the policy as written to medicine or the social sciences.

Response: The policy applies to research funded by the Federal agencies. In order to be responsive to specific inquiries about what fields of research are covered by the policy, an illustrative, non-exclusive list of selected fields of research is now included in the policy itself.

Section II: Findings of Research Misconduct

Issue: Several comments stressed the need for greater precision in the phrase "significant departure from accepted practices of the scientific community."

Response: This phrase is intended to make it clear that behavior alleged to involve research misconduct should be assessed in the context of community practices, meaning practices that are generally understood by the community but that may not be in a written form. For clarification purposes and in order to be more comprehensive, the term "scientific community" has been modified to read "relevant research community." The policy is not intended to ratify those "accepted practices" but rather to indicate that these may vary among different communities.

Issue: Several comments requested clarification regarding the level of intent that is required to be shown in order to reach a finding of research misconduct.

Response: Under the policy, three elements must be met in order to establish a finding of research misconduct. One of these elements is a showing that the subject had the requisite level of intent to commit the misconduct. The intent element is satisfied by showing that the misconduct was committed "intentionally, or knowingly, or recklessly." Only one of these needs to be demonstrated in order to satisfy this element of a research misconduct finding.

Section III: Responsibilities of Federal Agencies and Research Institutions

Issue: Some comments indicated that this section could be incorrectly construed to require appeal of the agency misconduct finding back to the institution.

Response: The policy has been clarified to affirm that each agency should establish an appeals process for persons found by the agency to have engaged in research misconduct. The subject of the agency finding cannot appeal the agency decision back to the institution, although some institutions do offer an appeal of the institutional finding at the institutional level.

Section IV: Guidelines for Fair and Timely Procedures

Issue: The comments indicated some uncertainty about to whom the actions section applied.

Response: The actions delineated are those that may be taken by the Federal agencies if research misconduct has been shown to have occurred. The section has thus been renamed "Agency Administrative Actions."

Issue: The suggestion was made that publications based on false or fabricated data, or including such data, should be required to be officially withdrawn.

Response: Correction of the research record has been added to the list of possible actions to be taken if a researcher is found to have engaged in research misconduct.

Issue: The suggestion was made that safeguards for informants and subjects of allegations be made more explicit.

Response: More explicit safeguards have been added to the policy for both informants and subjects.

Other Comments

Several comments and clarifications are addressed in the following question and answer format rather than through modification of the policy.

Will agencies be required to announce the details of their implementation plans? Yes. Agencies will announce the details of their implementation plans, including those plans that do not require formal rulemaking.

What types of misconduct are covered by this policy? This policy is limited to addressing misconduct related to the conduct and reporting of research, as distinct from misconduct that occurs in the research setting but that does not affect the integrity of the research record, such as misallocation of funds, sexual harassment, and discrimination. This policy does not limit agencies or research institutions from addressing these other issues under appropriate policies, rules, regulations, or laws. In addition, should the behavior associated with research misconduct also trigger the applicability of other laws (including criminal law) this policy is not intended to limit agencies or research institutions from pursuing these matters under separate authorities.

Does this policy address misrepresentation of a researcher's credentials or publications? Yes, misrepresentation of a researcher's qualifications or ability to perform the research in grant applications or similar submissions may constitute falsification or fabrication in proposing research.

Are authorship disputes covered by this policy? Authorship disputes are not covered by this policy unless they involve plagiarism. Does research misconduct include the mistreatment of human subjects or animals in research? This policy addresses activity that occurs in the course of human subjects or animal research that involves research misconduct as defined by the policy. Thus, falsification, fabrication, or plagiarism that occurs during the course of human or animal research is addressed by this policy. However, other issues concerning the ethical treatment of human or animal subjects are covered under separate procedures and are not affected by this policy.

Why doesn't the policy provide immunity for research misconduct investigative committees? Providing immunity to research misconduct investigative committees and other participants in institutional and agency research misconduct proceedings would require significant statutory or regulatory initiatives which will be explored separately from this policy.

Aren't there circumstances when omission of data or results is appropriate? A number of commenters suggested that there are circumstances when it may be appropriate to omit data in reporting research results. It is not the intent of this policy to call accepted practices into question. However, the omission of data is considered falsification when it misleads the reader about the results of the research.

Does this policy supersede institutional policies regarding research misconduct? Non-federal research institutions have authority to establish policies for research and employee misconduct that serve their own institutional purposes. However, the Federal research misconduct policy (as implemented by the agencies) provides the relevant guidance to institutions for purposes of Federal action. Does this policy supersede other agency policies, procedures, rules, and regulations? Agencies must comply with all relevant Federal personnel policies and laws in responding to allegations of research misconduct. However, personnel actions may not adequately protect the public from the consequences of falsified, fabricated or plagiarized research. For example, Federal personnel

policies may permit termination of an employee who commits research misconduct, but may not address the problem of research misconduct or seek to prevent it from recurring. The administrative actions available under the Federal research misconduct policy, such as debarment from federal funding, supervision and certification of research, and correction [[Page 76262]] of the literature, are designed to specifically address the problems raised by research misconduct.

Must all three elements in the Finding of Research Misconduct section be present for there to be a finding of research misconduct? Yes.

Who makes the final determination about whether or not there is a finding of research misconduct? The Federal agency will make the final decision about whether to make an agency finding of research misconduct. However, within its own internal jurisdiction, a non-Federal research institution may establish policies and take actions as appropriate to its needs and as consistent with other relevant laws. Shouldn't the burden of proof be more stringent, e.g., require "clear and convincing evidence" to support a finding of research misconduct? While much is at stake for a researcher accused of research misconduct, even more is at stake for the public when a researcher commits research misconduct. Since "preponderance of the evidence" is the uniform standard of proof for establishing culpability in most civil fraud cases and many federal administrative proceedings, including debarment, there is no basis for raising the bar for proof in misconduct cases which have such a potentially broad public impact. It is recognized that non-Federal research institutions have the discretion to apply a higher standard of proof in their internal misconduct proceedings. However, when their standard differs from that of the Federal government, research institutions must report their findings to the appropriate Federal agency under the applicable Federal government standard, i.e., preponderance.

Why don't the Federal agencies conduct all inquiries and investigations? Research institutions are much closer to what is going on in their own institutions and are in a better position to conduct inquiries and investigations than are the Federal agencies. While the Federal agencies could have taken on the task of investigating all allegations of research misconduct, or established a separate agency for this purpose, this would have involved a substantial new Federal bureaucracy, which is not thought desirable. An agency may take steps, as appropriate, should a research institution demonstrate a lack of commitment to the policy's guidelines.

How will a lead agency be identified? If more than one Federal agency has jurisdiction over allegations of research misconduct, those agencies should work together to designate a lead agency. What criteria will be used for selecting the research institution that will handle the response to the allegation of research misconduct? In most cases, agencies will rely on the researcher's home institution to respond to allegations of research misconduct. However, in cases where the subject has switched institutions, it may be more appropriate for the institution where the alleged research misconduct occurred to respond to the allegation. The institution where the questioned research was conducted may have better access to the evidence and witnesses and therefore will have the capability to undertake a more efficient and thorough response.

Shouldn't the policy be more explicit about time lines for a response to allegations of misconduct? In establishing reasonable time lines the Federal agencies must balance the interests of concluding the process expeditiously while ensuring it has been conducted fairly and thoroughly. This will allow flexibility for the research institutions while at the same time ensuring that the process does not extend for an unreasonably long period. Research institutions should have the option to request reasonable extensions of agency timelines in individual cases.

What can informants or subjects of allegations expect with regard to confidentiality? The policy strives for confidentiality for all involved to the extent consistent with a fair and thorough process and as allowed by law, including applicable Federal and state freedom of information and privacy laws.

Should the policy punish informants who act in bad faith or individuals who harass informants? The principal aim of this policy is to communicate to the research community those behaviors that constitute research misconduct and to take actions where research misconduct is found to have occurred. As employers and managers of the research, non-Federal research institutions may adopt policies to address the consequences of false, malicious, or capricious allegations and to respond to retaliation against informants. Agencies may also address this issue in their implementation of this policy.

How should the "seriousness" of the research misconduct be evaluated and how will this relate to any actions taken? In determining what action to take, agencies should fully consider the level of intent of the misconduct, the consequences of the behavior, and other aggravating and mitigating factors.

Next Steps

The Federal agencies have up to one year from the date of publication of this notice to implement the policy. An interagency implementation group has been established under the auspices of the National Science and Technology Council to assist agencies in their implementation process and to strive for the highest level of uniformity possible and as appropriate in their implementation plans.

I. Research Misconduct Defined

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 issuance of this 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.

Research, as used herein, 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.

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.

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.

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.

II. Findings of Research Misconduct

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.

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III. Responsibilities of Federal Agencies and Research Institutions

Agencies and research institutions are partners who share responsibility for the research process. Federal agencies have ultimate oversight authority for Federally funded research, but research institutions bear primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with their own institution.

The term "research institutions" is defined to include all organizations using Federal funds for research, including, for example, colleges and universities, intramural Federal research laboratories, Federally funded research and development centers, national user facilities, industrial laboratories, or other research institutes. Independent researchers and small research institutions are covered by this policy.

Agency Policies and Procedures. Agency policies and procedures with regard to intramural as well as extramural programs must conform to the policy described in this document. Agency Referral to Research Institution. In most cases, agencies will rely on the researcher's home institution to make the initial response to allegations of research misconduct. Agencies will usually refer allegations of research misconduct made directly to them to the appropriate research institution. However, at any time, the Federal agency may proceed with its own inquiry or investigation. Circumstances in which agencies may elect not to defer to the research institution include, but are not limited to, the following: the agency determines the institution is not prepared to handle the allegation in a manner consistent with this policy; agency involvement is needed to protect the public interest, including public health and safety; the allegation involves an entity of sufficiently small size (or an individual) that it cannot reasonably conduct the investigation itself. Multiple Phases of the Response to an Allegation of Research Misconduct. A response to an allegation of research misconduct will usually consist of several phases, including: (1) an inquiry--the assessment of whether the allegation has substance and if an investigation is warranted; (2) an investigation--the formal development of a factual record, and the examination of that record leading to dismissal of the case or to a recommendation for a finding of research misconduct or other appropriate remedies; (3) adjudication--during which recommendations are reviewed and appropriate corrective actions determined.

Agency Follow-up to Institutional Action. After reviewing the record of the investigation, the institution's recommendations to the

institution's adjudicating official, and any corrective actions taken by the research institution, the agency will take additional oversight or investigative steps if necessary. Upon completion of its review, the agency will take appropriate administrative action in accordance with applicable laws, regulations, or policies. When the agency has made a final determination, it will notify the subject of the allegation of the outcome and inform the institution regarding its disposition of the case. The agency finding of research misconduct and agency administrative actions can be appealed pursuant to the agency's applicable procedures.

Separation of Phases. Adjudication is separated organizationally from inquiry and investigation. Likewise, appeals are separated organizationally from inquiry and investigation.

Institutional Notification of the Agency. Research institutions will notify the funding agency (or agencies in some cases) of an allegation of research misconduct if (1) the allegation involves Federally funded research (or an application for Federal funding) and meets the Federal definition of research misconduct given above, and (2) if the institution's inquiry into the allegation determines there is sufficient evidence to proceed to an investigation. When an investigation is complete, the research institution will forward to the agency a copy of the evidentiary record, the investigative report, recommendations made to the institution's adjudicating official, and the subject's written response to the recommendations (if any). When a research institution completes the adjudication phase, it will forward the adjudicating official's decision and notify the agency of any corrective actions taken or planned.

Other Reasons to Notify the Agency. At any time during an inquiry or investigation, the institution will immediately notify the Federal agency if public health or safety is at risk; if agency resources or interests are threatened; if research activities should be suspended; if there is reasonable indication of possible violations of civil or criminal law; if Federal action is required to protect the interests of those involved in the investigation; if the research institution believes the inquiry or investigation may be made public prematurely so that appropriate steps can be taken to safeguard evidence and protect the rights of those involved; or if the research community or public should be informed.

When More Than One Agency is Involved. A lead agency should be designated to coordinate responses to allegations of research misconduct when more than one agency is involved in funding activities relevant to the allegation. Each agency may implement administrative actions in accordance with applicable laws, regulations, policies, or contractual procedures.

IV. Guidelines for Fair and Timely Procedures

The following guidelines are provided to assist agencies and research institutions in developing fair and timely procedures for responding to allegations of research misconduct. They are designed to provide safeguards for subjects of allegations as well as for informants. Fair and timely procedures include the following: **Safeguards for Informants.** Safeguards for informants give individuals the confidence that they can bring allegations of research misconduct made in good faith to the attention of appropriate authorities or serve as informants to an inquiry or an investigation without suffering retribution. Safeguards include protection against retaliation for informants who make good faith allegations, fair and objective procedures for the examination and resolution of allegations of research misconduct, and diligence in protecting the positions and reputations of those persons who make allegations of research misconduct in good faith.

Safeguards for Subjects of Allegations. Safeguards for subjects give individuals the confidence that their rights are protected and that the mere filing of an allegation of research misconduct against them will not bring their research to a halt or be the basis for other disciplinary or adverse action absent other compelling reasons. Other safeguards include timely written notification of subjects regarding substantive allegations made against them; a description of all such allegations; reasonable access to the data and other evidence supporting the allegations; and the opportunity to respond to allegations, the supporting evidence and the proposed findings of research misconduct (if any).

Objectivity and Expertise. The selection of individuals to review allegations and conduct investigations who have appropriate expertise and have no unresolved conflicts of interests help to ensure fairness throughout all phases of the process. **Timeliness.** Reasonable time limits for the conduct of the inquiry, investigation, adjudication, and appeal [[Page 76264]] phases (if any), with allowances for extensions where appropriate, provide confidence that the process will be well managed. **Confidentiality During the Inquiry, Investigation, and Decision-Making Processes.** To the extent possible consistent with a fair and thorough investigation and as allowed by law, knowledge about the identity of subjects and informants is limited to those who need to know. Records maintained by the agency during the course of responding to an allegation of research misconduct are exempt from disclosure under the Freedom of Information Act to the extent permitted by law and regulation.

V. Agency Administrative Actions

Seriousness of the Misconduct. In deciding what administrative actions are appropriate, the agency should consider the seriousness of the misconduct, including, but not limited to, the degree to which the misconduct was knowing, intentional, or reckless; was an isolated event or part of a pattern; or had significant impact on the research record, research subjects, other researchers, institutions, or the public welfare.

Possible Administrative Actions. Administrative actions available include, but are not limited to, appropriate steps to correct the research record; letters of reprimand; the imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of an award; suspension or termination of an active award; or suspension and debarment in accordance with applicable government-wide rules on suspension and debarment. In the event of suspension or debarment, the information is made publicly available through the List of Parties Excluded from Federal Procurement and Nonprocurement Programs maintained by the U.S. General Services Administration. With respect to administrative actions imposed upon government employees, the agencies must comply with all relevant federal personnel policies and laws.

In Case of Criminal or Civil Fraud Violations. If the funding agency believes that criminal or civil fraud violations may have occurred, the agency shall promptly refer the matter to the Department of Justice, the Inspector General for the agency, or other appropriate investigative body.

VI. Roles of Other Organizations

This Federal policy does not limit the authority of research institutions, or other entities, to promulgate additional research misconduct policies or guidelines or more specific ethical guidance.

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Assistant Director for Budget and Administration, Office of Science and
Technology Policy.

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