

Wednesday, December 15, 2004

Part VI

Department of Labor

Office of the Secretary

Research Misconduct; Statement of Policy; Technical Correction; Notice

DEPARTMENT OF LABOR

Office of the Secretary

Research Misconduct; Statement of Policy; Technical Correction

AGENCY: Office of the Secretary, Labor. **ACTION:** Statement of policy on research misconduct; technical correction.

SUMMARY: On Friday, September 12, 2003 (Federal Register/Vol. 68, No. 177) USDOL published its policies implementing the Federal Policy on Research Misconduct issued by the Executive Office of the President's Office of Science and Technology on December 6, 2000. Following public comment, and in order to eliminate a possible ambiguity in the USDOL policy statement, the USDOL hereby publishes this technical correction to its policy statement on research misconduct. Though this technical correction changes only two words in the September 12, 2003 USDOL policy statement on research misconduct, the USDOL is hereby publishing the entire USDOL Policy statement.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: The Office of Science and Technology Policy issued a final Federal research misconduct policy on December 6, 2000 in 65 FR 76260–76264 (the "Federal Policy"). The Federal Policy consists of a definition of research misconduct and basic guidelines to help Federal agencies and Federally funded research institutions respond to allegations of research misconduct.

The U.S. Department of Labor (USDOL) is publishing its policies on research misconduct fully consistent with the Federal Policy. This is a policy statement intended as a guide to USDOL managers and supervisors. It is not intended to provide any binding requirements on Department of Labor agencies, officials, or the public. It is not intended to create or recognize any legally enforceable right in any person. We refer to the USDOL policy as the "USDOL Policy."

The Federal Policy provides a uniform Federal definition of research misconduct. It defines research misconduct as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or reporting research results. The Federal Policy also defines "fabrication," "falsification," and "plagiarism." The USDOL Policy adopts the definition of research

misconduct set forth in the Federal Policy.

Consistent with the Federal Policy, USDOL officials should, as appropriate, seek to protect research misconduct investigative and adjudicative files from mandatory disclosure under the Freedom of Information Act, where permitted by law and regulation.

The Department of Labor Manual Series (DLMS) 8, Audits and Investigations, Chapter 700—Incident Reporting and Whistleblower Protection, establishes USDOL procedures and assigns responsibility for reporting and investigating allegations of wrongdoing that would include allegations of research misconduct. The USDOL Policy presented below does not supersede DLMS 8, Chapter 700, but is designed to provide supplementary policies for research misconduct issues.

Authority: 5 U.S.C. 301 and Federal Register/Vol. 65 No. 235, December 6, 2000, Notification of Final Policy, Executive Office of the President, Office of Science and Technology Policy.

Definitions

(1) The "Federal Policy" means the Federal research misconduct policy issued by the Office of Science and Technology Policy on December 6, 2000 in 65 FR 76260–76264.

(2) "Research misconduct" means conduct which a preponderance of the evidence demonstrates to be a significant departure from accepted practices and intentional, knowing, or reckless fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or reporting research results. Research misconduct does not include honest error or differences of opinion.

(a) "Fabrication" means making up data or results and recording or reporting them.

(b) "Falsification" means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research record is not accurately represented in the research record.

(c) "Plagiarism" means the appropriation of another person's ideas, processes, results or words without giving appropriate credit.

(3) "USDOL" means the United States Department of Labor as an entity, or to any agency of the United States Department of Labor acting under the authority of the United States Department of Labor, with the exception of the Office of Inspector General of the United States Department of Labor.

(4) "Appropriate USDOL Agency" means the USDOL agency that has

supported or contracted for the research that involves an allegation of research misconduct.

(5) "OIG" means the Office of Inspector General of the United States

Department of Labor.

(6) "Agency Head" (AH) means the director of a USDOL agency that has the authority to or has been delegated the authority to commit USDOL support for research or to purchase research services or products for the USDOL or one of its agencies.

(7) "Awardee Institution" means an institution or organization that has received research support from a USDOL agency or that has received a contract or grant to provide research services or products to a USDOL agency.

(8) "The USDOL Policy" means the policy and procedures issued by the USDOL to deal with allegations of research misconduct involving research supported by or contracted for by a USDOL agency.

General Policies

(1) USDOL agencies support research activities through grants or other agreements to provide research support. USDOL agencies also purchase research services and products through contracts and purchase orders.

(2) USDOL should take appropriate action against individuals or institutions upon a finding that research misconduct has occurred while conducting or performing research that has been supported by a USDOL agency or that has been contracted for by a USDOL

agency

(3) Allegations of research misconduct against employees of USDOL while in the performance of their official duties are covered by existing laws, rules, regulations and Departmental policy relating to misconduct of its employees, and not by "The USDOL Policy," but in cases involving alleged research misconduct against DOL employees while in the performance of their official duties, DOL officials should apply these laws, rules, regulations and Departmental policy in a manner consistent with the "Federal Policy."

(4) USDOL officials should issue a

(4) USDOL officials should issue a finding of research misconduct only after a careful inquiry and investigation by (a) an awardee institution, (b) by another Federal agency, (c) by the OIG, or (d) by the Appropriate USDOL Agency. An inquiry consists of preliminary information-gathering and preliminary fact-finding to determine whether an allegation or apparent instance of research misconduct has substance and if an investigation is warranted. An investigation should ordinarily be undertaken if the inquiry

determines the allegation or apparent instance of research misconduct has substance. An investigation is a formal development, examination and evaluation of a factual record to determine whether research misconduct has taken place, to assess its extent and consequences, and to evaluate appropriate action.

Pending Proposals and Awards

- (1) Upon learning of alleged research misconduct the appropriate USDOL Agency should take steps to identify potentially implicated awards or proposals and, when appropriate, should ensure that program, grant, and contract officers handling them are informed.
- (2) Neither a suspicion nor allegation of research misconduct nor a pending inquiry or investigation will normally delay review of proposals. Not informing reviewers or panelists of allegations or of ongoing inquiries or investigations will avoid inappropriate influence on their reviews. However, if allegations, inquiries, or investigations have been rumored or publicized, the responsible Agency Head, after consultations with the USDOL Office of Solicitor and the appropriate USDOL contract and grant officers, should consider appropriate steps to avoid inappropriate influence. They might, for example, defer review, inform reviewers to disregard the matter, or inform reviewers of the status of the matter.

Initial USDOL Handling of Research Misconduct Matters

- (1) Officials should normally report allegations of research misconduct on the part of USDOL employees while in the performance of official duties to the immediate supervisor of the employee(s) against which the misconduct is alleged. These allegations should be handled under existing laws, rules, regulations and USDOL policy relating to misconduct of employees of USDOL. In applying these laws, DOL officials should consider utilizing the definitions of research misconduct adopted by the Federal Policy and should consider approaches to the application of existing laws that maximize consistency with the Federal Policy.
- (2) Individuals or groups of individuals who wish to report allegations of research misconduct involving research supported by or contracted for a USDOL agency should report the allegation in writing either to the Awardee Institution involved or to the Agency Head of the Appropriate USDOL Agency.

(3) The Agency Head should forward reports of research misconduct promptly to the OIG.

(4) After forwarding a report of alleged research misconduct to the OIG, it would contribute to an orderly handling of these matters if the Agency Head would:

(a) Defer further action until informed by the OIG that the OIG will be conducting an investigation of the allegation or until a reasonable time period passes without such a notification (The reasonableness of the time period will depend on the particular circumstances, but agency heads may wish to consider the appropriateness of a 30–90 day period);

(b) If informed that an OIG investigation of the allegation will be conducted, the agency head may wish to defer to the OIG investigation of the allegation by taking no further investigatory action at that time;

(5) If the Agency Head is informed by the OIG that there will be no OIG investigation of the allegation or if a reasonable time period passes since the Agency Head has referred the allegation of research misconduct to the OIG, the Agency Head should consider the

following actions:

(a) If the alleged misconduct is with activities under research support to or contract with an institution or enterprise, inform the awardee institution or enterprise of the alleged research misconduct, decide if the institution or enterprise has the capacity to undertake an inquiry and investigation, and if in the judgment of the Agency Head that capacity exists, request in writing that the institution or enterprise undertake an inquiry and, if warranted, an investigation; should the institution fail to notify the Agency Head within a reasonable time after receiving the written request that it will be undertaking an inquiry, the Agency Head may wish to proceed with its own inquiry and, if warranted, its own investigation. Agency heads may wish to consider a brief waiting period to hear from the institution, for example 30 days. They should attempt to conclude their own inquiries promptly. It will often be possible to conclude an inquiry within 90 days after its initiation and any investigation within 180 days after its initiation. The Agency Head should call upon all necessary assistance and expertise that can be provided by the Office of the Solicitor of the USDOL.

(b) If the alleged misconduct is with activities under research support to an individual or group of individuals, the Agency Head should consider proceeding with its own inquiry and, if warranted, its own investigation after

informing each of the individuals of the alleged research misconduct. It may often be possible to complete any inquiry within 90 days after its initiation and any investigation within 180 days after its initiation. The Agency Head should call upon all necessary assistance and expertise that can be provided by the Office of the Solicitor of the USDOL.

Roles of Awardee Institutions

USDOL supports research activities in various ways, including the award of grants, contracts, purchase orders, or other agreements to provide support. Grants that include support for research activities are made to institutions, usually to universities and research institutes, and not directly to individuals. Similarly, most contracts for research services and products, including purchase orders, are entered into with institutions, including universities, research institutes, and business enterprises, rather than directly with individuals. In some cases, the USDOL will enter into a contract with or will provide support for research directly to an individual or to a group of individuals.

When the grant or contract or support of research is awarded directly to an individual or group of individuals rather than to an institution or enterprise there will be no role for such

an institution or enterprise.

When the grant or contract or support of research is awarded to an institution

or business enterprise.

(1) The awardee institution or enterprise may often be willing to bear primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of alleged research misconduct. If in the judgment of the Appropriate USDOL Agency, the awardee institution or enterprise has the capacity to conduct an inquiry, investigation, and adjudication, the appropriate USDOL Agency may want to rely on the awardee institution or enterprise to promptly:

(a) Initiate an inquiry into any suspected or alleged research

misconduct;

(b) Conduct a subsequent investigation, if warranted;

(c) Take action necessary to ensure the integrity of research, the rights and interests of research subjects and the public, and the observance of legal requirements or responsibilities; and

(d) Provide appropriate safeguards for subjects of allegations as well as

informants.

(2) If an institution or enterprise wishes the Appropriate USDOL Agency

to defer independent inquiry or investigation, it may eliminate the need for such inquiry or investigation by:

(a) Completing any inquiry and deciding whether an investigation is warranted promptly, so that the USDOL Agency can be satisfied that the public interest will be served. Completion within 90 days would be preferable. If completion of an inquiry is delayed, but the institution wishes USDOL deferral to continue, the Appropriate USDOL Agency may want to ask the institution to provide periodic status reports.

(b) Informing the Appropriate USDOL Agency if an initial inquiry supports a

formal investigation.

(c) Keeping the Appropriate USDOL Agency informed during such an

investigation.

- (d) Completing any investigation and reaching a disposition within a reasonable time, preferably within 180 days of the initiation of the investigation. If completion of an investigation is delayed, but the institution wishes USDOL deferral to continue, the Appropriate USDOL Agency may ask the institution to submit periodic status reports.
- (e) Providing the appropriate USDOL Agency with the final report from any

investigation.

- (3) USDOL believes it is in the public interest that if during an investigation into research misconduct, any individuals or groups of individuals become aware of any of the following they should follow the guidelines in the Federal Policy:
 - (a) Public health or safety is at risk;(b) USDOL's resources, reputation, or

other interests need protecting;
(c) There is reasonable indication

- (c) There is reasonable indication of possible violations of civil or criminal law;
- (d) Research activities should be suspended;
- (e) Federal action may be needed to protect the interests of a subject of the investigation or of others potentially affected; or

(f) The scientific community or the public should be informed.

(4) To facilitate awareness of the USDOL Policy among contract and grant research recipients, Agency Heads should consider working with their contract and grant officers to insert language into contract and grant documents that makes Awardee institutions aware of the USDOL Policy and of the Federal Policy. For example, the language could include informational references to the Federal Policy as stated in the Federal Register Vol. 65. No. 235, December 6, 2000 and to the Department of Labor Manual Series (DLMS) Chapter 800.

Investigations

- (1) When an awardee institution or the OIG or a Federal agency other than the Appropriate USDOL Agency, has promptly initiated its own inquiry and investigation, the Appropriate USDOL Agency may wish to defer its own inquiry or investigation until it receives the results of that external inquiry and investigation. If the Appropriate USDOL Agency does not receive the results of the external inquiry within what it believes to be a reasonable time, the Appropriate USDOL Agency should proceed with its own inquiry and, if warranted, its own investigation. It will often be appropriate for the Agency to proceed with its own inquiry if it does not receive the results of the external inquiry within 90 days and to proceed with its own investigation if it does not receive the results of an external investigation within 180 days.
- (2) If the Appropriate USDOL Agency decides to initiate an investigation, it should be conducted with fairness. Among the fair procedures that agencies should consider are giving prompt written notice to the individual or institutions to be investigated where such notice would not prejudice the investigation or relate to a criminal investigation that is underway or under active consideration. Where notice is delayed, agencies should consider the need to give the notice as soon as it will no longer prejudice the investigation or contravene requirements of law or Federal law-enforcement policies.
- (3) If a criminal investigation by the Department of Justice, the Federal Bureau of Investigation, or another Federal agency is underway or under active consideration by these agencies, the Appropriate USDOL Agency should decide what information, if any, may be disclosed to the subject of the investigation or to other USDOL employees.
- (4) Ån investigation by the Appropriate USDOL Agency may include:
- (a) Review of award files, reports, and other documents already readily available at USDOL or in the public domain;
- (b) Review of procedures or methods and inspection of data, laboratory materials, and records at awardee institutions;
- (c) Interviews with subjects or witnesses:
- (d) Review of any documents or other evidence provided by or properly obtainable from parties, witnesses, or other sources;
- (e) Cooperation with other Federal agencies; and

- (f) Opportunity for the subject of the investigation to be heard.
- (5) The Appropriate USDOL Agency may wish to contract with or invite outside consultants or experts to participate in a USDOL investigation.
- (6) The Appropriate USDOL Agency should make every reasonable effort to complete a USDOL investigation and to report its recommendations, if any, to the Assistant Secretary of Labor for Administration and Management promptly. It will often be possible to complete such investigation within 180 days after initiating it, and, within 60 days after completing the investigation, to submit the investigative report along with a recommended disposition to the Assistant Secretary for Administration and Management.
- (7) The subject of the investigation may wish to hire legal representation to assist in responding to allegations.
- (8) In many cases, Agency Heads will be relying on outside inquiries and investigations, e.g., those being conducted by awardee institutions or by the OIG, or by another federal agency. However, there may be cases when Agency Heads have no alternative but to conduct their own inquiry and, if necessary, their own investigation. One possible way to proceed is to contract out the inquiry and/or investigation to an institution with expertise in research misconduct issues, for example, a large research university or professional organization. Another way would be to proceed with the inquiry and/or investigation using a panel of experts, both internal and external to USDOL to review all documents and interview all participants to the dispute and the allegation and to produce a report. The agency head should call upon whatever assistance can be provided by USDOL contract and grant officers and by the USDOL Office of the Solicitor as it proceeds.

Interim Administrative Actions

(1) After an inquiry or during an external investigation or an investigation by the Appropriate USDOL Agency, the Assistant Secretary of Labor for Administration and Management or other appropriate USDOL official may recommend that interim actions be taken to protect Federal resources or to guard against continuation of any suspected or alleged research misconduct. The Assistant Secretary or other appropriate USDOL official should consider making such recommendation when requested by the Agency Head of the Appropriate USDOL Agency, and should consult with the appropriate USDOL Grant or Contract

Officer and the Office of the Solicitor of the USDOL.

(2) When suspension of a grant or contract or other award is believed to be appropriate, the official responsible for making decisions should be legally authorized to take such actions and should ordinarily be the appropriate USDOL Grant or Contract Officer.

(3) Officials should consider taking such interim actions whenever information developed during an investigation indicates a need to do so. The appropriate Grant or Contract Officer should periodically review such interim actions during an investigation and modify them as warranted. An interested party may wish to request a review or modification by the immediate supervisor of the suspending official.

(4) The suspending official should make, and the Appropriate USDOL Agency should retain, a record of interim actions taken and the reasons for taking them.

Dispositions

(1) Agency heads should carefully consider any report they may receive from (a) an external investigation by an awardee institution or (b) a report from an OIG investigation, or (c) a report from an investigation by another Federal agency, or (d) a report from an investigation conducted by the Appropriate USDOL Agency. It would be appropriate for the Agency Head of the Appropriate USDOL Agency to assess not only the accuracy and completeness of the report, but also whether the investigating entity followed reasonable procedures. The Agency head will ordinarily be able, within 30 days, either to recommend adoption of the findings in whole or in part or to initiate a new investigation. If a new investigation is initiated, it can normally be completed within 90 days of its initiation.

(2) When any satisfactory external investigation or an investigation by the Appropriate USDOL Agency fails to confirm alleged misconduct,

(a) The Appropriate USDOL Agency should notify the subject of the investigation and, if appropriate, those who reported the suspected or alleged misconduct. This notification may include the investigation report.

(b) Any interim administrative restrictions that were imposed should

ordinarily be lifted.

(3) When a satisfactory external investigation or an investigation by the Appropriate USDOL Agency confirms misconduct, the agency head, in consultation with the Office of the Solicitor of USDOL, should recommend

to the Assistant Secretary for Administration and Management an appropriate disposition and any final actions to be taken by USDOL.

(a) In cases in which debarment from further contracts or grants is considered by the Appropriate USDOL Agency to be the preferred disposition, the case should be referred to the relevant office of contracts and grants management within the USDOL but:

(i) The debarring official should normally be either the Assistant Secretary of Labor for Administration and Management, or an official designated by the Assistant Secretary.

(ii) Except in unusual circumstances, the investigation report and recommended disposition should be included among the materials that appropriate officials provided to the subject of the investigation as part of the notice of proposed debarment.

(iii) It would be helpful to the subject if the notice of a debarring official's decision would include instructions on

how to pursue any appeal.

(b) In other cases,

(i) Except in unusual circumstances, the investigation report should be provided by the Appropriate USDOL Agency to the subject of the investigation, who should be invited to submit comments or rebuttal within a reasonable time period. Thirty days will ordinarily be a sufficient time period for subjects to submit these comments or rebuttals. Any response should receive full consideration and may lead to revision of the report or of a recommended disposition.

(ii) Normally within 60 days after completion of an investigation by the Appropriate USDOL Agency or the receipt of a report from a satisfactory external investigation, it will be practicable for the Agency Head of the Appropriate USDOL Agency to submit to the Assistant Secretary of Labor for Administration and Management the investigation report, any comments or rebuttal from the subject of the investigation, and a recommended disposition. The recommended disposition may include proposals for any final actions to be taken by USDOL.

(iii) The Assistant Secretary of Labor for Administration and Management should review the investigation report and the recommended disposition. The Assistant Secretary may initiate further hearings or investigation.

Final Actions

(1) In the case of findings of research misconduct involving research supported by the USDOL or one of its agencies, possible final actions to be considered are listed below for guidance purposes and range from minimal restrictions (Group I) to the most severe and restrictive (Group III). They are not mandated, nor exhaustive and do not include possible criminal sanctions.

(a) Group I Actions:

(i) Send a letter of reprimand to the individual or institution.

(ii) Require, as a condition of any future award of a grant or contract or purchase order or other support for research, that for a specified period an individual or institution obtain special prior approval of particular activities from the Assistant Secretary for Administration and Management or the designee of the Assistant Secretary.

(iii) Require, for a specified period, that an institutional official other than those guilty of misconduct certify the accuracy of reports generated under an award or provide assurance of compliance with particular policies, regulations, guidelines, or special terms and conditions.

(b) Group II Actions:

(i) Totally or partially suspend an active award, or restrict for some specified period designated, activities or expenditures under an active award.

(ii) Require special reviews of all requests for funding or support of research from an affected individual or institution, for a specified period, to ensure that steps have been taken to prevent repetition of the misconduct.

(iii) Require a correction to the research record.

(c) Group III Actions:

(i) Terminate an active award or other agreement of support for research.

(ii) Require the return to USDOL of any funds that have been disbursed to the grantee or contractor.

(iii) Prohibit participation of an individual as a USDOL reviewer, advisor, or consultant for a specified period.

(iv) Using prescribed procedures and through the authorized USDOL official, debar or suspend an individual or institution from participation in USDOL contracts or grants or purchase orders or research support for a specified period.

(v) In the event of such debarment or suspension, provide appropriate documentation to the authorized USDOL official setting forth the basis for recommending suspension and/or debarment from government wide federal contracting and/or grant opportunities for a specified period, including placement on the "Excluded Parties Listing Services" maintained by the General Services Administration (GSA) at http://www.epls.gov.

(2) In deciding what final actions are appropriate when misconduct is found, USDOL officials should consider:

- (a) How serious the misconduct was;
- (b) The degree to which the misconduct was knowing, intentional, or reckless;
- (c) Whether it was an isolated event or part of a pattern;
- (d) Whether it had a significant impact on the research record, research subjects, other researchers, institutions or the public welfare; and
 - (e) Other relevant circumstances.

Appeals

- (1) Any adverse action against a grantee or contractor arising from research misconduct or otherwise is subject to applicable DOL procedures, including any appeal/disputes procedures.
- (2) The Secretary of Labor may wish to appoint an uninvolved USDOL officer or employee to review an appeal and make recommendations. The official deciding appeals should inform the

appellant when a final decision has been reached. It will normally be practicable to make an appellate decision within 60 days after receiving the appeal.

Signed at Washington, DC this 9th day of December 2004.

Elaine L. Chao,

Secretary of Labor.

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