

Classification No.: 3120.5

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POLICY AND PROCEDURES FOR ADDRESSING RESEARCH MISCONDUCT

1. PURPOSE

On December 6, 2000, the Executive Office of the President issued the government-wide Federal Policy on Research Misconduct, hereinafter referred to as "the Federal Policy." The Federal Policy applies to all Federally funded and all Federally conducted research as well as to all proposals submitted to Federal agencies for research funding. The Federal Policy requires all Federal agencies that conduct or support research to implement the Federal Policy by December 6, 2001. This Order implements the Federal Policy at EPA.

EPA obtains or funds research by three methods: i) research that is conducted by EPA employees; ii) research that is procured through contracts; and iii) research that is supported through assistance agreements. This Order is consistent with the Federal Policy that addresses only fabrication, falsification, or plagiarism in research misconduct and does not supersede EPA or institutional policies or procedures for addressing other forms of misconduct.

2. <u>AUTHORITY</u>

The authority for this Order is the Federal Policy on Research Misconduct, 65 Federal Register (FR) 76260 (December 6, 2000). (http://www.ostp.gov/html/001207_3.html)

3. APPLICABILITY

This Order applies to all research conducted, sponsored or funded, in whole or in part, by EPA and to research proposals submitted to EPA. It thus applies to research conducted by EPA, conducted or managed for EPA by contractors, and funded by EPA and performed at research institutions, including universities and industrial facilities. These three, together, are referred to hereinafter as "research institutions".

4. <u>EFFECTIVE DATE</u>

This Order is effective upon issuance.

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DEFINITIONS [As defined in the Federal Policy]

A. Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results [65 FR 76262. I], or ordering, advising or suggesting that subordinates engage in research misconduct.

- B. 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, and research involving human subjects or animals. [65 FR 76262. I, footnote 2]
- C. <u>Fabrication</u> is making up data or results and recording or reporting them. [65 FR 76262. I]
- D. <u>Falsification</u> 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. [65 FR 76262. I]
- E. <u>Plagiarism</u> is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. [65 FR 76262. I]
- F. Research misconduct does not include honest error or differences of opinion. [65 FR 76262. I]
- G. 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 the Federal policy. [65 FR 76262 III footnote 4]

6. FINDINGS OF RESEARCH MISCONDUCT

The Federal policy states that a finding of research misconduct requires that:

- A. There be a significant departure from accepted practice of the relevant research community; and
- B. The misconduct be committed intentionally, or knowingly, or recklessly; and

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C. The allegation be proven by a preponderance of the evidence. [65 FR 76262. II]

7. WHEN THE OIG MUST BE NOTIFIED IMMEDIATELY

In accordance with this policy the EPA Office of Inspector General (OIG) must be notified immediately by all subject to this policy of any allegation of research misconduct that involves the following:

- A. Public health or safety is at risk.
- B. Agency resources or interests are threatened.
- C. Circumstances where research activities should be suspended.
- D. There is a reasonable indication of possible violations of civil or criminal law.
- E. Federal action is required to protect the interests of those involved in the investigation.
- F. The research entity believes that 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.
- G. Circumstances where the research community or public should be informed. [65 FR 76263. III]

Situations that do not involve these factors, i.e. factors A through G above, are subject to Section 9 below.

8. OIG PROCEDURES FOR INVESTIGATING RESEARCH MISCONDUCT

- A. Upon receipt of an allegation of research misconduct, the OIG may:
 - i) conduct an OIG investigation;
 - ii) oversee the investigation being conducted by the research entity;
 - iii) allow the research entity to conduct an investigation and request a copy of the report be sent to the OIG or to another Agency office;
 - iv) take other appropriate action.

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B. The OIG will report the results of investigations it conducts or oversees to the appropriate Agency official for a determination of appropriate actions, unless the misconduct investigated is criminal, in which case the OIG will refer the matter to the Department of Justice, pursuant to the Inspector General Act. [EPA Manual 6500]

9. POLICY

EPA and research entities are partners who share responsibility for the research process. While EPA retains the ultimate oversight authority for EPA-supported research, research entities bear primary responsibility for prevention and detection of research misconduct. This includes the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in their entities. [65 FR 76263. III]

A. Research Misconduct and EPA Employees

i. Reporting

- a) EPA employees must promptly report allegations of research misconduct by EPA personnel to their supervisors or, if necessary, directly to the Office of Inspector General (OIG) as required by EPA Ethics Advisory 91-7 and EPA Manual 6500, Chapter 3, Section 2.b.
- b) All EPA employees who become aware of alleged research misconduct from or by research institutions, e.g., assistance agreement recipients and contractors or their employees, must promptly report such allegations to the OIG, whether or not the external entity conducts its own inquiry.
- c) Only OIG employees are authorized to conduct research misconduct investigations not conducted by an institution. No other employees who receive an allegation of misconduct are authorized to independently conduct research misconduct inquiries or investigations without the permission of the OIG. In the event that a grievance is filed involving any aspect of the alleged research misconduct, the OIG and the servicing Human Resources component and/or the deciding official will work cooperatively in responding to the grievance.

ii. Procedures

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For EPA employees who are subjects of allegations, due process safeguards come into effect if and when the Agency decides to take action on an OIG report. For these safeguards, see Sections 9(A)(iv)(a) and (b) below.

a) <u>Safeguards for Informants.</u> Section 7(b) of the Inspector General Act, 5 U.S.C. app. 3, as amended, provides:

"The Inspector General shall not, after receipt of a complaint or information from an employee, disclose the identity of the employee without the consent of the employee, unless the Inspector General determines such disclosure is unavoidable during the course of the investigation."

b) <u>Safeguards for Whistleblowers.</u> Section 7(c) of the Inspector General Act, 5 U.S.C. app. 3, as amended, provides:

"Any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority, take or threaten to take any action against any employee as a reprisal for making a complaint or disclosing information to an Inspector General, unless the complaint was made or the information disclosed with the knowledge that it was false or with wilful disregard for its truth or falsity."

c) Safeguards for Subjects of Allegations.

For EPA employees, the safeguards for employees occur after the OIG has done its investigation and submitted its report to EPA management for adjudication. For these safeguards, see 9(A)(iv)(a) and (b) below.

iii. Investigations

The Office of Inspector General conducts and supervises investigations pursuant to all relevant Federal laws, rules, regulations, the President's Council on Integrity and Efficiency (PCIE) Quality Standards for Investigations (http://ignet.gov/pande/standards/invstds.pdf) and the OIG Office of Investigations Policy Manual.

iv. Adjudication

a) In deciding what administrative actions are appropriate, the Agency should consider the seriousness of the misconduct, including, but not

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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, entities, or the public welfare. [65 FR 76264. V]

b) For EPA employees, administrative actions must comply with EPA Order 3120.1, Conduct and Discipline Manual and any applicable collective bargaining agreements. In addition, EPA will take appropriate steps to correct the research record.

B. Research Misconduct by Contractors

i. Reporting

a) Contractors are responsible for reporting allegations of research misconduct occurring in research either directly or indirectly under their control. In accordance with the terms and conditions of their contracts with EPA, contractors and contractor employees must report allegations of research misconduct to the appropriate EPA Contracting Officer or Contracting Officer's Technical Representative (COTR), who will report these allegations to the OIG. (See Sections 7 and 9.A.i.b above.).

ii. Procedures

All investigations and adjudications of research misconduct conducted by research institutions should include the following fair and timely procedures:

- a) Safeguards for Informants. Safeguards 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. [65 FR 76263. IV]
- b) <u>Safeguards for Subjects of Allegations</u>. Safeguards for subjects of allegations give individuals the confidence that their rights are

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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. 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). [65 FR 76263. IV]

iii. Investigations

- a) Objectivity and Expertise. The selection of individuals to review allegations and conduct investigations who have appropriate expertise and have no unresolved conflicts of interest, helps to ensure fairness throughout all phases of the process. [65 FR 76263. IV]
- b) <u>Timeliness.</u> Reasonable time limits for the conduct of the inquiry, investigation, adjudication, and appeal phases (if any), with allowances for extensions when appropriate, provide confidence that the process will be well managed. [65 FR 76263. IV]
- c) 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. To the extent permitted by law and regulation, 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. [65 FR 76364. IV]
- d) Upon receipt of an allegation of research misconduct, a contractor may initiate an inquiry to determine whether there is sufficient evidence to proceed to an investigation. If, for whatever reason, the contractor cannot or believes it should not conduct the inquiry, the contractor must report it immediately to the Contracting Officer, COTR, and the OIG. [65 FR 76263. III]
- e) When the investigation is complete, the contractor will forward to the OIG a copy of the evidentiary record, the investigative report, recommendations made to the contractor's adjudicating official, and

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the subject's written response to the recommendations (if any). [65 FR 76263. III]

f) Whether or not a contractor initiates an inquiry or investigation, the OIG may conduct an independent investigation of the matter, or may intervene at any time during a contractor's inquiry or investigation to conduct its own investigation. If the OIG initiates an investigation, the contractor must immediately suspend its investigative work. [EPA Manual 6500]

iv. Adjudication

- a) When the contractor completes the adjudication phase, the contractor will forward the adjudicating official's decision and notify the OIG and the Contracting Officer or COTR of any corrective actions taken or planned. [65 FR 76263. III]
- b) After reviewing the record of inquiry or investigation, the contractor's recommendations, if any, and any corrective action taken by the contractor, the cognizant EPA official may:
 - α) request that the contractor conduct an additional investigation;
 - β) request the OIG to conduct an investigation;
 - γ) take administrative action, as appropriate.
- c) When the Agency has made a final determination, it will notify the subject of the allegation of the outcome and inform the contractor regarding the Agency's disposition of the case, unless, for law enforcement reasons, the OIG recommends otherwise. [65 FR 76263. III]
- d) Agency Administrative Actions

Administrative actions available include, but are not limited to, appropriate steps to correct the research record; the imposition of special certification or assurance requirements to reprimand; the imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of the contract; suspension or termination of an active contract; or suspension and debarment in accordance with applicable government-wide rules on

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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 Non-procurement Programs maintained by the U.S. General Services Administration.

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, entities, or the public welfare. [65 FR 76264. V]

C. Recipients of Assistance Agreements (hereinafter referred to as recipients)

i. Reporting

- a) Recipients must immediately notify the EPA project officer who will then inform the OIG if, at any time, an allegation falls into one of the categories listed in Section 7 above.
- b) Recipients must report non-Section7 allegations to the OIG when they have conducted an inquiry and determined that there is sufficient evidence to proceed with an investigation. [65 FR 76263. III]

ii. Procedures

All investigations and adjudications of research misconduct conducted by research institutions should include the following fair and timely procedures:

a) Safeguards for Informants. Safeguards 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. [65 FR 76263. IV]

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b) <u>Safeguards for Subjects of Allegations</u>. Safeguards for subjects of allegations 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). [65 FR 76263. IV]

iii. Investigations

- a) Objectivity and Expertise. The selection of individuals to review allegations and conduct investigations who have appropriate expertise and have no unresolved conflicts of interest, helps to ensure fairness throughout all phases of the process. [65 FR 76263. IV]
- b) <u>Timeliness.</u> Reasonable time limits for the conduct of the inquiry, investigation, adjudication, and appeal phases (if any), with allowances for extensions when appropriate, provide confidence that the process will be well managed. [65 FR 76263. IV]
- c) 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. To the extent permitted by law and regulation, 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. [65 FR 76364. IV]
- d) Upon receipt of an allegation of research misconduct, a recipient may initiate an inquiry to determine whether there is sufficient evidence to proceed to an investigation. If, for whatever reason, the recipient cannot or believes it should not conduct the inquiry, the recipient must report it immediately. [65 FR 76263. III]
- e) When the investigation is complete, the recipient will forward to the OIG a copy of the evidentiary record, the investigative report, recommendations made to the recipient's adjudicating official, and the

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subject's written response to the recommendations (if any). [65 FR 76263. III]

f) Whether or not a recipient initiates an inquiry or investigation, the OIG may conduct an independent investigation of the matter, or may intervene at any time during a recipient's inquiry or investigation to conduct its own investigation. If the OIG initiates an investigation, the recipient must immediately suspend its investigative work. [EPA Manual 6500]

iv. Adjudication

- a) When the recipient completes the adjudication phase, it will forward the adjudicating official's decision and notify the OIG and the responsible EPA grants official of any corrective actions taken or planned. [65 FR 76263. III]
- b) After reviewing the record of inquiry or investigation, the recipient's recommendations, if any, and any corrective action taken by the recipient, the cognizant EPA official may:
 - α) request that the recipient conduct an additional investigation;
 - β) request the OIG to conduct an investigation;
 - γ) take administrative action, as appropriate. [40 CFR 30.61, 30.62, and 31.43]
- c) When the Agency has made a final determination, it will notify the subject of the allegation of the outcome and inform the recipient regarding the Agency's disposition of the case, unless, for law enforcement reasons, the OIG recommends otherwise. [65 FR 76263.III]
- d) Agency Administrative Actions

<u>Possible Administrative Actions.</u> Administrative actions available include, but are not limited to, appropriate steps to correct the research record; the imposition of special certification or assurance requirements to reprimand; the imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of the assistance agreement; suspension,

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termination or other action regarding an active assistance agreement pursuant to 40 CFR 30.61, 30.62, and 31.43; 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 Non-procurement Programs maintained by the U.S. General Services Administration.

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, entities, or the public welfare. [65 FR 76264. V]