



Department of Defense

INSTRUCTION

NUMBER 3210.7
May 14, 2004

USD(AT&L)

SUBJECT: Research Integrity and Misconduct

- References: (a) DoD Directive 3216.2, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," March 25, 2002
- (b) Federal Register, Volume 65, page 76262, December 6, 2000, "Federal Policy on Research Misconduct" current edition
 - (c) Title 32, Code of Federal Regulations, Part 22, "DoD Grant and Agreement Regulations (DoDGARs)," current edition
 - (d) Title 48, Code of Federal Regulations, Chapter 2, "Defense Federal Acquisition Regulation Supplement (DFARS)," current edition
 - (e) through (g), see enclosure 1

1. PURPOSE

This Instruction supplements the policy established by paragraph 4.8. of reference (a) and implements subparagraph 5.1.5. of reference (a) by specifying detailed procedures and standards for the Department of Defense for the prevention of research misconduct. This Instruction is consistent with the "Federal Policy on Research Misconduct" (reference (b)), which calls upon those Federal Agencies that support or conduct research on an intramural or extramural basis to issue policies and procedures that conform to the Federal policy.

2. APPLICABILITY AND SCOPE

This Instruction applies to:

2.1. The Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Defense Agencies, the DoD Field Activities and all other organizational entities in the Department of Defense (hereafter referred to collectively as "the DoD Components").

2.2. All allegations of research misconduct (as defined in enclosure 2) by performers or reviewers of research (also as defined in enclosure 2) or advanced technology development activities that use DoD resources, including:

2.2.1. Civilian and military employees of the DoD Components;

2.2.2. Employees of non-Federal entities that receive DoD funding through procurement contracts, grants, cooperative agreements, or other funding instruments, under the terms of those instruments;

2.2.3. Individual consultants, under the terms of their appointments; and

2.2.4. Individuals other than DoD employees participating in research activities conducted by the DoD Components or under their auspices, including proposal reviewers not covered under subparagraphs 2.2.2. or 2.2.3., individuals under special personnel appointments, and visiting scientists, under the terms of the instruments that establish their relationship with the Department of Defense.

3. DEFINITIONS

Terms used in this Instruction are defined in enclosure 2.

4. POLICY

Consistent with the objective of reference (b) to ensure public trust in the research enterprise, the DoD Components shall promote the integrity of research conducted under their purview. The DoD Components shall establish procedures to foster integrity in research activities and to respond to allegations of research misconduct consistent with applicable laws and regulations.

5. PROCEDURES

Guidance for implementation of this Instruction by the DoD Components is provided in enclosure 3. The guidance addresses requirements that pertain to research institutions in general, as well as specific requirements for intramural research institutions. Enclosure 4 specifies the requirements to be implemented in the DoD Grant and Agreement Regulations and the Defense Federal Acquisition Regulation Supplement (references (c) and (d)) for inclusion in applicable contracts, other acquisition instruments, grants, and agreements.

6. RESPONSIBILITIES

6.1. The Director, Defense Research and Engineering (DDR&E), under the Under Secretary of Defense (Acquisition, Technology, and Logistics) (USD(AT&L)):

6.1.1. Shall amend reference (c) to implement the requirements of this Instruction for extramural research institutions. Amendments to reference (c) shall be proposed in the Federal Register for public comment within 270 days of the effective date of this Instruction.

6.1.2. Shall be the central point of contact within the Department of Defense for policy matters relating to research misconduct and interpretation of this Instruction.

6.1.3. Shall act as the principal DoD liaison with Federal Agencies outside the Department of Defense on matters pertaining to research misconduct.

6.1.4. Shall establish a committee consisting of representatives from the DoD Components to assist in the implementation and maintenance of this Instruction.

6.1.5. May issue DoD instructions or other guidance necessary to implement this Instruction.

6.1.6. May grant exceptions to requirements of this Instruction, if they are consistent with law and justified by special circumstances.

6.1.7. May specify periodic or ad hoc reporting requirements, including any required to obtain information to respond to inquiries by the Office of Science and Technology Policy.

6.1.8. Shall coordinate with the Director of Defense Procurement and Acquisition Policy (DDPAP) in matters relating to contracts and other acquisition instruments.

6.1.9. In coordination with the DDPAP, shall propose changes to reference (d) to implement the requirements of this Instruction for contracts and other transactions with extramural research institutions for presentation to the Defense Acquisition Regulation Council. Changes to reference (d) shall be proposed in the Federal Register for public comment within 270 days of the effective date of this Instruction.

6.2. The Heads of the DoD Components shall:

6.2.1. Develop, issue, and monitor implementing policies and procedures to ensure compliance with this Instruction and applicable DoDGARs and DFARS requirements (references (c) and (d)).

6.2.2. Ensure that authorities and responsibilities under this Instruction are delegated to levels of command or authority that allow responses to allegations of research misconduct to be handled at an appropriate organizational level consistent with the requirements of this Instruction.

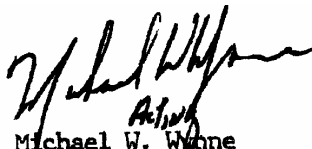
6.2.3. For allegations of research misconduct that involve more than one DoD Component or a DoD Component(s) and a non-DoD Federal entity, jointly determine and assign executive responsibility for compliance.

6.2.4. Maintain adequate documentation of all responses to allegations of research misconduct conducted by a headquarters-level DoD Component or by an intramural research institution.

6.2.5. Establish procedures to ensure timely response to DDR&E reporting requirements.

7. EFFECTIVE DATE

This Instruction is effective immediately.



Michael W. Wynne
Acting Under Secretary of Defense
for Acquisition, Technology, and
Logistics

Enclosures - 4

- E1. References, continued
- E2. Definitions
- E3. Requirements for DoD Components' Research Misconduct Procedures
- E4. Requirements for Extramural Research Institutions

E1. ENCLOSURE 1

REFERENCES, continued

- (e) Section 2409 of title 10, United States Code, "Contractor Employees: Protection from Reprisal for Disclosure of Certain Information"
- (f) Section 552 of title 5, United States Code, "Freedom of Information Act"
- (g) Section 552a of title 5, United States Code, "Privacy Act"

E2. ENCLOSURE 2

DEFINITIONS

E2.1.1. Adjudication. The stage in the response to an allegation of research misconduct when the outcome of the investigation is reviewed, and appropriate corrective actions, if any, are determined. Corrective actions generally will be administrative in nature (e.g., termination of an award(s), debarment, special approvals, or correction of the research record); however if there is an indication of violation of civil or criminal statutes, civil or criminal sanctions may be pursued.

E2.1.2. Fabrication. Making up data or results and recording or reporting them.

E2.1.3. Falsification. 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.

E2.1.4. Finding of Research Misconduct. The conclusion proven by a preponderance of the evidence that there was research misconduct and that such misconduct represented a significant departure from accepted practices of the relevant research community and has been committed intentionally, knowingly, or recklessly.

E2.1.5. Inquiry. The stage in the response to an allegation of research misconduct when an assessment is made to determine whether the allegation has substance and an investigation is warranted.

E2.1.6. Investigation. The stage in the response to an allegation of research misconduct when the factual record is formally developed and examined to determine whether to dismiss the case, recommend for a finding of research misconduct, and/or take other appropriate remedies.

E2.1.7. Plagiarism. The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

E2.1.8. Research. 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, physical sciences, social sciences, statistics, and research involving human subjects or animals regardless of the funding appropriation used to support it.

E2.1.9. Research Institution. All organizations using DoD resources (including funds, personnel, equipment, facilities, and other resources) for research. Research institutions include, but are not limited to, DoD intramural research laboratories, federally funded research and development centers affiliated with the Department of Defense, colleges and universities, national user facilities, industrial laboratories, and other research institutes, centers, or organizations.

E2.1.10. Research Misconduct. Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

E2.1.11. Research Record. The record of data or results that embodies the facts resulting from scientific inquiry. It includes, but is not limited to, research proposals, laboratory records, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles, whether in physical or electronic form.

E3. ENCLOSURE 3

REQUIREMENTS FOR DoD COMPONENTS' RESEARCH MISCONDUCT PROCEDURES

E3.1.1. The DoD Components shall adopt implementing procedures that recognize the role of the research institution in ensuring that research is conducted under the highest ethical standards and in reviewing allegations of research misconduct. A copy of the implementing instructions (and any subsequent modifications) shall be provided to the DDR&E.

E3.1.2. The authority to review and act on allegations of research misconduct by DoD employees or others working in DoD facilities (other than contractor employees or consultants) shall be placed at the lowest possible organizational level that allows an independent, unbiased, and equitable process. However, implementing procedures may retain for the headquarters-level of the DoD Component (parent command) the right to exercise authorities that otherwise would be delegated to intramural research institutions.

E3.1.3. The DoD Components shall designate in their implementing procedures responsible individuals and the process for reviewing and responding to research misconduct-related information and documentation submitted by research institutions.

E3.1.4. Implementing procedures shall minimize disruption to research in process unless the research misconduct could result in a threat to public health or safety.

E3.1.5. The DoD Components may use their existing procedures for intramural research institutions as long as they comply with the minimum requirements of this Instruction. Nothing in this Instruction is intended to supersede current civilian or military personnel management authorities.

E3.1.6. For extramural research institutions, the DoD Components may continue to follow existing requirements until they are superseded by changes to references (c) and (d), as applicable. The DoD Components may not adopt new or changed research integrity/research misconduct policies for extramural institutions in advance of final changes to references (c) and (d).

E3.1.7. The DoD Components may use any available resources to respond to allegations of misconduct, including their Office of the Inspector General, legal counsel, and expert consultants.

E3.1.8. The DoD Components may develop alternate or additional procedures to address allegations of research misconduct that arise under classified research as long as they comply with the minimum requirements of this Instruction and references (c) and (d), as applicable.

E3.1.9. At a minimum, the DoD Components' procedures implementing this Instruction for intramural research institutions shall include the following:

E3.1.9.1. Responsibilities for handling each phase of the response to an allegation of research misconduct: inquiry, investigation, and adjudication. These responsibilities shall be assigned to organizations and officials that understand the research and the research environment, can ensure objectivity, can provide due process, and reach a timely resolution. The responsibilities for adjudication shall be separate from those for inquiry and investigation, but they can be assigned to an individual higher in the chain of command or to a part of the research institution other than that which conducted the inquiry and investigation.

E3.1.9.2. Procedures for handling allegations of research misconduct made directly to the headquarters level of the DoD Component (instead of the research institution).

E3.1.9.3. The circumstances, if any, under which the headquarters level of the DoD Component may respond directly to an allegation (other than exercise of the authority provided in paragraph E3.1.2.). These include, but are not limited to, a determination that the research institution is unable to conduct a thorough and unbiased inquiry and investigation; a determination that it is in the public interest for the parent command to conduct the inquiry and investigation; or a determination that the allegation involves a small organization or an individual that cannot reasonably be expected to respond.

E3.1.9.4. Responsibilities for, and the form and timing of, notifying an individual that an allegation of research misconduct involving him or her has been made and its disposition.

E3.1.9.5. A requirement to provide the report of the inquiry to a designated official in the DoD Component after completion of the inquiry phase, if the individual's commander (military personnel) or supervisor or commander (civilian) determines there is sufficient evidence to proceed to an investigation.

E3.1.9.6. A requirement that the research institution immediately notify the headquarters level of the DoD Component and provide an explanation of the circumstances if:

E3.1.9.6.1. The public health or safety is at risk.

E3.1.9.6.2. The research institution's resources or interests are threatened or at risk.

E3.1.9.6.3. Research activities are to be suspended because of the inquiry into or investigation of the allegation.

E3.1.9.6.4. There is a possible violation of civil or criminal law.

E3.1.9.6.5. Action to protect the interests of those involved in the inquiry into or investigation of the allegation is required from the parent command.

E3.1.9.6.6. A premature public disclosure of the inquiry into or investigation of the allegation may compromise the process; or

E3.1.9.6.7. The research community or public should be informed.

E3.1.9.7. The notice and accompanying explanation provided by the intramural research institution (pursuant to subparagraph E3.1.9.6.) shall be used by the headquarters level of the DoD Component to determine whether it or the research institution shall respond directly to the allegation (if that right is reserved as provided under paragraph E3.1.2.).

E3.1.9.8. In any instance where the authority to adjudicate the findings is not delegated to the intramural research institution, a requirement that, after completing the investigation, the research institution report the outcome of the investigation to the same individual as under subparagraph E3.1.9.5. The report shall include a copy of the evidentiary record, the investigative report, and any other materials that bear on the allegation. If adjudicated by the research institution, a requirement that the research institution report the outcome of the adjudication to this individual. The report shall include a summary of the findings and any action taken.

E3.1.9.9. Required documentation for each phase of the response to an allegation of misconduct and requirements related to document retention, storage, handling, and dissemination (see subparagraph E3.1.9.12. for requirements for confidentiality). At a minimum, the documentation should include the allegation; the methods and procedures used to gather the information and evaluate the allegation; the outcome of the investigation (including the findings and supporting evidence), if any; and, for findings of research misconduct, any recommended or imposed institutional sanctions, and any recommended corrective actions.

E3.1.9.10. Procedures to protect the rights of those who make allegations of research misconduct to promote a climate where the informant does not fear retribution (for example, section 2409 of title 10, United States Code, "Contractor Employees: Protection from Reprisal for Disclosure of Certain Information" (reference (e))). Protections for those alleging research misconduct should include protection

against retaliation or harm to their positions or reputations for making a good faith allegation and fair and objective procedures for the examination and resolution of allegations.

E3.1.9.11. Procedures to protect the rights of those who are alleged to have engaged in research misconduct in order to instill confidence that individuals shall be treated in an impartial and professional manner. Protections for subjects of allegations of research misconduct should include providing them a description of substantial allegations made against them; giving them reasonable access to the data and other supporting evidence related to the allegation; and affording them the opportunity to respond to the allegation, the evidence, and the findings.

E3.1.9.12. Procedures intended to ensure 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, the procedures shall limit knowledge about the identity of subjects and informants to those who "need to know." The procedures shall be in compliance with the Freedom of Information Act and the Privacy Act (references (f) and (g)).

E3.1.9.13. Time frames for completing each phase of the response to an allegation of research misconduct.

E3.1.9.14. Types of remedies available.

E3.1.9.15. Available appeal rights. The authority to which an appeal may be made must not be an office or individual directly involved in the inquiry, investigation, or adjudication of an allegation of research misconduct. "Office" means that organizational component with formal responsibility for one or more phases of the response to an allegation of research misconduct. The organizational level may be defined by the DoD Component as long as there is an adequate separation of responsibilities and there is no appearance of bias, inequity, or conflict of interest.

E3.1.9.16. If authority to respond to an allegation of research misconduct is delegated to a research institution, a requirement that a copy of the research institution's implementing procedures be provided to the headquarters level of the DoD Component.

E3.1.10. Relationship to Other Requirements. Some of the research covered by this Instruction also may be subject to regulations of other governmental agencies (e.g., a DoD research institution that receives funding under a grant from another Federal Agency). Research covered under this Instruction that also is subject to requirements of other Agencies or funding sources must be conducted in compliance with all applicable requirements.

E3.1.11. Non-compliance. Instances of any DoD Component or intramural research institution failing to comply with the requirements of this Instruction shall be referred for resolution to a management level that is at least one level above where the non-compliance is alleged to have occurred. DoD Components shall provide the DDR&E reports of all actions taken under this paragraph. Issues related to non-compliance by extramural research institutions with requirements related to research integrity and misconduct shall be addressed, as provided in enclosure 4, paragraph E4.1.10., and implemented in references (c) and (d).

E4. ENCLOSURE 4

REQUIREMENTS FOR EXTRAMURAL RESEARCH INSTITUTIONS

E4.1.1. Extramural research institutions must foster an atmosphere conducive to research integrity. They must develop procedures to respond to allegations of research misconduct that ensure:

E4.1.1.1. Appropriate separation of responsibilities for inquiry and investigation, and adjudication. (See paragraph E4.1.3.)

E4.1.1.2. Objectivity.

E4.1.1.3. Due process.

E4.1.1.4. Whistleblower protection.

E4.1.1.5. Confidentiality; and

E4.1.1.6. Timely resolution.

E4.1.2. Extramural research institutions may use existing procedures applicable to all of their federally and non-federally funded activities as long as they meet the requirements specified in this enclosure. These procedures are not required to be submitted to the DoD awarding activity, but must be available for inspection at the research institution.

E4.1.3. Except as provided paragraph E4.1.4., following an allegation of research misconduct made directly to it, whether related to an ongoing award or to a proposal submitted to the Department of Defense for funding consideration, the research institution is responsible for response to the allegation. This includes conducting the inquiry, investigation, and, if applicable, adjudication of the allegation. The responsibilities for adjudication must be separate from those for inquiry and investigation, but they can be assigned to an individual higher in the chain of command or to a part of the research institution other than that which conducted the inquiry and investigation.

E4.1.4. The DoD awarding activity shall refer an allegation of research misconduct made to the Department of Defense to the cognizant extramural research institution for response. However, the DoD awarding activity may respond to an allegation of research misconduct made to it or to the research institution if the awarding activity determines that:

E4.1.4.1. The research institution is unable to conduct a thorough and unbiased inquiry and investigation;

E4.1.4.2. It is in the public interest for the Department of Defense to conduct the inquiry and investigation; or

E4.1.4.3. The allegation involves a small organization or an individual that cannot reasonably be expected to respond.

E4.1.5. After completion of the inquiry phase, the research institution must notify the individual specified in the award of any allegation of research misconduct for which there is sufficient evidence to proceed to an investigation. Each applicable award shall specify the official to whom such notices must be sent.

E4.1.6. The research institution is required to provide immediate notification at any time if:

E4.1.6.1. The public health or safety is at risk.

E4.1.6.2. The research institution's resources or interests are threatened or at risk.

E4.1.6.3. Research activities are to be suspended because of the inquiry into or investigation of the allegation.

E4.1.6.4. There is a possible violation of civil or criminal law.

E4.1.6.5. Action to protect the interests of those involved in the inquiry into or investigation of the allegation is required from the DoD Component.

E4.1.6.6. A premature public disclosure of the inquiry into or investigation of the allegation may compromise the process; or

E4.1.6.7. The broader research community or public should be informed.

E4.1.7. Following completion of the investigation, the research institution must provide a copy of the evidentiary record, the report of the investigation, recommendations made to the institution's adjudicating official, and the written response of the individual that is the subject of the allegation to any recommendations. This information must be provided to (insert name or title of the Contracting Officer (generally the Administrative Contracting Officer), Grants Officer, Agreement Officer, or other designated official).

E4.1.8. The extramural research institution must maintain the following documents related to an allegation of research misconduct:

E4.1.8.1. Written statement of the original allegation.

E4.1.8.2. Formal notification to the subject of the allegation.

E4.1.8.3. Written outcome of the inquiry phase and supporting documentation.

E4.1.8.4. Written report of the investigation, including the evidentiary record and supporting documentation; and

E4.1.8.5. If applicable, statement of recommended corrective actions and any response thereto, including any corrective action plan.

E4.1.9. The documents specified in paragraph E4.1.8. are considered project-related records that must be retained for 3 years after the final decision.

E4.1.10. In the event the extramural institution does not comply with the requirements of the award, the DoD awarding activity may use any available administrative or other appropriate remedy, including the termination of award(s) or suspension and debarment of the institution. The DoD awarding activity also may recommend suspension or debarment of the individual that is the subject of the allegation after a finding of research misconduct.