



**Office of the Under Secretary of Defense
(Personnel and Readiness)**

Research Regulatory Oversight Office

**Research Integrity and Misconduct
Operating Instruction**

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1. INTRODUCTION

The Under Secretary of Defense for Personnel and Readiness (USD(P&R)) is charged with ensuring and promoting research integrity, as defined by Federal policy and regulations, and Department of Defense Instructions (DoDIs). The Research Regulatory Oversight Office, also referred to as the Component Headquarters (CHQ), of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)) oversees this process.

2. PURPOSE

This Operating Instruction (OI) describes how the CHQ will implement and comply with the “Federal Policy on Research Misconduct” (reference a) and the Department of Defense Instruction 3210.7, (reference b).

3. APPLICABILITY AND SCOPE

This OI applies to all research, as defined by DoDI 3210.7 (reference b), and other activities that involve such research, even in part, regardless of whether the research is otherwise subject to Federal regulation, if:

- a. The research is supported (e.g., contract or grant) by the Office of the USD(P&R) (OUSD(P&R)), or
- b. The research is conducted under the direction of any employee or agent of the OUSD(P&R), or
- c. The research is conducted using any property or facility of the OUSD(P&R).

This OI applies to the OUSD(P&R) in its entirety, to include its Field Activities and Organizations, and is not restricted by budget activity, program title, or funding source. This OI is *not* applicable to any entity outside the authority, direction, and control of the USD(P&R).

4. AUTHORITY AND DELEGATION

The USD(P&R), as the head of a DoD Component, has delegated the authority in DoDI 3210.7 to the Assistant Secretary of Defense for Health Affairs (ASD(HA)) (reference c) who has further delegated that authority to the Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight (DASD(HRP&O)) (reference d).

5. RESPONSIBILITIES

5.1. DASD(HRP&O)

The responsibilities of the DASD(HRP&O) include, but are not limited to, the following:

1. Promoting the OUSD(P&R) Research Integrity and Misconduct (RIM) Program.
2. Establishing and overseeing OUSD(P&R) procedures for research integrity and misconduct.
3. Promoting policies and procedures that are parallel with other components under the Office of the Secretary of Defense (OSD), including the Service Components.
4. Ensuring OUSD(P&R) institutions comply with applicable research integrity and misconduct rules, regulations, and policies (reference a - b).
5. Representing the OUSD(P&R) RIM program on committees established by the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)) in relation to research integrity and misconduct.
6. Appointing and providing members to DoD committees when requested by ASD(R&E) in accordance with DoDI 3210.7 (reference b).
7. Appointing and overseeing a government appointee a civilian or uniformed appointee as the OUSD(P&R) RIM Program Director.
8. Adjudicating allegations of research misconduct, when applicable, involving intramural or extramural research conducted or supported by OUSD(P&R) institutions to determine when such allegations should be forwarded to another office for resolution (e.g., the OSD, the Office of the Inspector General, or ASD(R&E)).
9. Reporting research misconduct to ASD(R&E) in accordance with DoDI 3210.7 (reference b), Enclosure E3.1.11.
10. Establishing, maintaining, and properly resourcing the CHQ RIM oversight office in a manner that facilitates efficient and effective operations.

5.2. OUSD(P&R) Research Integrity and Misconduct Program Director

The Program Director is the subject matter expert directly responsible to the DASD(HRP&O) for the OUSD(P&R) RIM program. The responsibilities of the RIM Program Director include, but are not limited to, the following:

1. Assisting the DASD(HRP&O) with the implementation of this OI.
2. Providing support and expertise to the DASD(HRP&O) regarding research integrity and misconduct for research conducted or supported by OUSD(P&R) institutions.
3. Managing the CHQ-level RIM oversight office and the day-to-day implementation and operation of the OUSD(P&R) RIM Program.
4. Serving as the subject matter expert for this OI.
5. Serving as the point of contact and coordinating CHQ-level processes and procedures related to research misconduct.
6. Recommending adequate and appropriate staffing for the CHQ to the DASD(HRP&O).
7. Developing procedures to implement policies for the OUSD(P&R) RIM Program.
8. Monitoring and adjudicating, if required, allegations of research misconduct and assure resolution at the appropriate level.

9. Maintaining records of HQ-level actions and activities as required by law and regulation.
10. Overseeing and monitoring OUSD(P&R) institutional RIM programs.
11. Assisting OUSD(P&R) institutions with establishing and maintaining research integrity and misconduct programs.
12. Issuing routine guidance and procedures to OUSD(P&R) institutions on research integrity programs.
13. Establishing and conducting research integrity training for OUSD(P&R) personnel commensurate to their roles in research.
14. Monitoring education and training related to OUSD(P&R) research integrity and misconduct.

5.3. Institution Leader

The Institution Leader is a senior person with the authority to commit the institution to comply with Federal, DoD, and OUSD(P&R) requirements. The Institution Leader is responsible for maintaining the institution's RIM program in accordance with DoDI 3210.7. The OUSD(P&R) Institution Leader's responsibilities include:

1. Establishing and maintaining a RIM program within his/her institution.
2. Ensuring initial and ongoing research integrity training for individuals involved in the conduct of research.
3. Evaluating and acting on allegations of research misconduct, as outlined in DoDI 3210.7 (reference b).
4. Providing resources needed to ensure compliance with DoDI 3210.7 (reference b) and this OI.
5. Establishing procedures for conducting inquiries and investigations of misconduct in accordance with DoDI 3210.7 (reference b).
6. Promoting research integrity through educational activities.
7. Ensuring initial and ongoing research integrity and misconduct education and training for all personnel involved in the conduct of research.
8. Establishing procedures to evaluate and improve the institution's RIM program.
9. Maintaining records, files, and correspondence related to research misconduct in accordance with this OI.
10. Designating an individual(s) to be the institution's Research Integrity Officer (RIO).

5.4. Research Integrity Officer

The RIO is the subject matter expert directly responsible to the Institution Leader for matters associated with research integrity and misconduct. OUSD(P&R) policy requires an RIO at each institution conducting research. Institution Leaders must appoint RIOs. A RIO must be sufficiently qualified through experience, expertise, and training to carry out the duties and responsibilities outlined below, and must be sufficiently removed from the research to avoid the appearance of a conflict of interest and undue influence. The responsibilities of the RIO include:

1. Developing and coordinating research integrity initiatives within his/her institution.
2. Conducting inquiries and participating in investigations of research misconduct allegations.

3. Providing guidance to Institution Leaders on matters of research integrity and misconduct.
4. Serving as the institutional point of contact for the OUSD(P&R) RIM Program Director for routine matters.
5. Acting as a non-voting member on misconduct investigation committees.

6. POLICIES AND PROCEDURES

6.1. Research Integrity

Research integrity will be promoted with institutional commitments to providing an environment that fosters researchers to operate in congruence with the highest ethical and scientific standards.

6.1.1. RIO Network

RIOs from each OUSD(P&R) institution engaged in research will comprise a formal network that will support all institutions under the purview of the USD(P&R). This RIO network (RION) will provide an environment of support and education among OUSD(P&R) RIOs. The RION will be headed by the OUSD(P&R) RIM Program Director, with the support of CHQ staff members. This network will share best practices and new concepts in promoting research integrity, and will communicate strategic initiatives related to the OUSD(P&R) RIM program.

6.1.2. Education and Training

Institutions under the purview of the USD(P&R) have a triennial research integrity and misconduct training requirement for all individuals engaged in activities, including conducting, reviewing, and overseeing research. This requirement applies to the researchers and other individuals involved in activities related to research. Each institution is responsible for ensuring training resources are available to researchers in order to promote integrity internalization.

1. **Initial Training:** RIOs and research personnel are required to complete initial research integrity and misconduct training. The initial training must be completed through the Collaborative Institutional Training Initiative (CITI) Responsible Conduct of Research course and is valid for three years.
2. **Interim Training:** RIOs and research personnel should take interim training in the intervening years between the CITI training. Each institution is responsible for providing opportunities for interim training.
3. **Triennial Training:** Every three (3) years, RIOs and all research personnel must be re-certified their research integrity and misconduct training. The CITI on-line research integrity training program satisfies this requirement (as described above).
4. **Institution Leaders and other institution executives** have the option of receiving a personal briefing by their RIOs or the CHQ.

6.2. Research Misconduct

Research misconduct, as defined in DoDI 3210.7 (reference b), is fabrication, falsification or plagiarism in proposing, performing, or reviewing research or in reporting research results. The act must be committed intentionally, knowingly, or recklessly and must be a significant departure from standard practices of the research community per the Federal Policy on Research Misconduct (reference a). Research misconduct does not include honest error or differences of opinion.

6.2.1. Institutional Requirements

OUSD(P&R) institutions shall have standard operating procedures (SOPs) for evaluating, reviewing, and responding to internal allegations of research misconduct, and for reporting to the CHQ.

Institutions must provide the CHQ a copy of these research misconduct implementing procedures for approval.

6.2.2. Procedures for Intramural Research Misconduct Cases

Process for cases of alleged misconduct:

1. Report the allegation to the appropriate officials.
2. Conduct an inquiry into whether the allegation meets the definition of misconduct.
3. Conduct a formal investigation to determine if evidence supports a ruling that misconduct occurred.
4. Adjudicate the ruling and propose corrective actions.
5. Provide an opportunity for appeal.

If at any point it is found that any of the following situations apply to a case of alleged misconduct, the CHQ must be notified within 1 business day and provided an explanation of the circumstances within 2 weeks:

1. Public health or safety is at risk
2. The institution's resources or interests are threatened or at risk
3. Research activities are to be suspended because of the inquiry into or investigation of the allegation
4. There is a possible violation of civil or criminal law
5. Action to protect the interest of those involved in the inquiry into or investigation of the allegation is required from CHQ
6. A premature public disclosure of the inquiry or investigation of the allegation may compromise the process
7. The research community or public should be informed

The CHQ will determine if the cases warrant CHQ-level investigation of the incidents. The CHQ reserves the right to conduct all phases of the investigation in instances for which there is evidence of systemic issues with the institution. If so, then CHQ will provide a written notice along with an explanation to the institution as to why the allegation is to be handled at a higher

level. The CHQ will provide a report to the Institution Leader and RIO at the end of the investigation. All requirements in the following sections will apply to CHQ-level investigations.

Information related to a case of misconduct is exempt from the Freedom of Information Act (reference e) while the case is open and being evaluated, unless laws or regulations say otherwise. Information, including identifiable information, must remain confidential and must be revealed only on a need-to-know basis. All information and procedures related to a misconduct case must be in compliance with the Freedom of Information Act (FOIA) (reference e) and the Privacy Act (reference f).

6.2.2.1. Reporting Allegations

Individuals aware of or who suspect potential research misconduct must report the situation to the institution's RIO immediately. Individuals considering reporting a potential misconduct case may consult with the RIO prior to formally reporting misconduct.

Individuals can report potential misconduct directly to the CHQ. If an allegation is made directly to the CHQ, the CHQ will determine whether the inquiry should be handled at the institution or by the CHQ.

The identity of the person making the allegation shall remain confidential and absent from any reports or correspondence. Only the RIO and the investigation committee involved with managing an allegation should know the source of the allegation.

Any individuals reporting research misconduct must be protected from retaliation in accordance with the "Whistleblower Protection Act of 1989" (reference g), the "Whistleblower Protection Enhancement Act of 2012" (reference h), DoD Directive (DoDD) 7050.06 (reference i), "Intelligence Community Whistleblower Protection Act of 1998" (reference j) and "Contractor Employees: Protection from Reprisal for Disclosure of Certain Information" (reference k).

6.2.2.2. Inquiry

Inquiries should be conducted by the RIO to determine if there is merit behind the allegation and whether the allegation meets the definition of misconduct. An inquiry must be completed within 30 calendar days of receipt of an allegation. If an extension to this timeframe is required, the RIO must submit an extension request outlining the reason for the extension to the Institution Leader for approval. The RIO will create a report that outlines the inquiry along with his/her determination as to whether and why the allegation is of substance or not. The report should go to the Institution Leader for final determination as to whether a formal investigation will be opened. Both the inquiry report and the Institution Leader's decision must be forwarded to the OUSD(P&R) RIM Program Director within 2 business days. The Institution Leader must notify the individual against whom the allegation has been made in writing within 14 calendar days of the determination. A copy of this correspondence must be sent to the OUSD(P&R) RIM Program Director. The report should include:

- Description of the allegation
- Methods and procedures used to gather the information and evaluate allegation
- Outcome of the inquiry

- Findings and supportive evidence, if any
- Copies of extension requests, if any
- Any supporting documents

In cases that are determined to be without merit, the matter should be closed and records retained in accordance with the approved National Archives and Records Administration (NARA) records disposition schedule.

If the RIO has a conflict of interest that precludes him/her from leading the inquiry in an unbiased manner, the RIO should forward the case to the Institution Leader, copying the CHQ, who will identify another individual with the appropriate expertise to lead the inquiry. If the allegation is forwarded to CHQ or CHQ exercises its authority to conduct the review, then the DASD(HRP&O) will determine who will conduct the investigation and may use any available resources, including the Office of the Inspector General, legal counsel, or expert consultants.

The CHQ will handle allegations and any proceedings moving forward (i.e., investigation and appeals) in the following instances:

- The institution cannot handle the case in a thorough and unbiased manner
- It is in the public's interest for the CHQ to handle the case
- The institution is not of sufficient size to be able to respond to or handle the case

If the allegation falls within the scope of Enclosure E3.1.9.6 of DoDI 3210.7 (reference b), the allegation should be forwarded to CHQ within 1 business day. The CHQ will make a determination as to who should handle the allegation.

6.2.2.3. Investigation

If the allegation of research misconduct is found to have merit, then a formal investigation should be opened within 30 calendar days after the report is submitted. The Institution Leader should charge a committee to conduct the investigation. The Institution Leader and RIO should work together to appoint 3-5 individuals to sit on this committee. Members of the investigation committee should not have any conflict of interest with the investigation or the alleged research misconduct case. They must have sufficient expertise and training to be able to understand the circumstances of the alleged research misconduct and be able to make an independent determination regarding any wrongdoing. The RIO can be involved with this committee as a non-voting, ex-officio member.

Investigations must be completed and a report sent to the Institution Leader and RIO within 120 calendar days of its initiation. If an extension to this timeframe is required, the committee must submit an extension request outlining the reason for the extension to the Institution Leader for approval.

The report should include:

- Description of the allegation
- Methods and procedures used to gather the information and evaluate allegation
- Outcome of the investigation

- Findings and supportive evidence, if any
- Degree of seriousness of the allegation
- For determinations of research misconduct, recommendations for personnel actions under applicable law and regulations, including DoDI 1400.25 (reference l) for civilian personnel and 10 U.S.C. Chapter 47 (reference m) for military personnel

After the case is closed, the records will be maintained in accordance with NARA approved records disposition schedules.

The Institution Leader should forward this report to the OUSD(P&R) RIM Program Director within 2 business days of receipt and before the case moves to adjudication. The Institution Leader should notify the individual against whom the allegation has been made in writing within 14 calendar days of receiving the committee's report. This correspondence should include a redacted copy of the committee's report, with all names and potentially identifying information removed, and appeal options.

After the case is closed, the records will be maintained in accordance with NARA-approved records disposition schedules.

6.2.2.4. Adjudication

Adjudication is to be handled at the Institution Leader level, when possible, with the assistance of the RIO, if necessary, and General Counsel. The CHQ reserves the right to be the adjudicating authority in instances outlined in Section 5.b.2 and 5.b.2.2 of this OI.

The CHQ, in consultation with General Counsel, and any other applicable civilian or military consultants must approve action plans and remedies resulting from an investigation. The CHQ will inform the DASD(HRP&O) and assist him/her in reporting the outcome to ASD(R&E).

Adjudication should be finalized 30 calendar days after the investigation has been completed. A report of the adjudication shall be completed and sent to the RIO, OUSD(P&R) RIM Program Director, the individual against whom the allegation was made, and any other authorities or offices involved with the adjudication phase. The individual who made the complaint may receive a copy of the report, but FOIA (reference e) standards must be applied to the information contained in the report. If the Institution Leader is not the adjudication authority, then the Institution Leader must receive a copy of the adjudication report. The report should include:

- A summary of findings
- Actions or remedies taken
- Appeal options
- Institution impact, if feasible
- Impact for future research, if feasible

The institution should have procedures in place to continue remedies should the individuals related to the case move or transfer to other institutions.

6.2.2.5. Appeal

Appeals of the outcome of the investigation must be submitted in writing within 30 calendar days of receiving the investigation outcome report. The appeal must provide additional evidence that supports the grounds for appeal.

When the institution conducts the investigation and adjudication, the CHQ will be the appeals official. The DASD(HRP&O) will be the appeals official in cases where CHQ handled the investigation and adjudication. The appeals official must review all documents and evidence related to the case. If evidence shows that the appeal has merit, then a new investigation committee should be formed and the investigation should be re-opened. Individuals from the previous committee cannot serve on this new committee.

A final decision regarding the appeal should be completed by the appeals official within 45 calendar days of receipt of the appeals request. The decision shall be provided in writing to the respondent, the RIO, the new investigation committee, and the CHQ (if not the appeal official). If the decision is to overturn the findings of the original committee's research misconduct investigation, the institution must make every effort to restore the respondent's reputation.

As with other phases of the research misconduct investigations, the records related to appeals will be maintained in accordance with NARA-approved records disposition schedules.

6.2.2.6. Interim Actions

Interim actions may be required during any of the aforementioned procedures to mitigate issues or risks. Authority to execute any interim actions is reserved for the Institution Leader. Any interim actions should be warranted based on the best interest of all involved parties and the institution. General Counsel and human resources should be consulted prior to implementing any interim actions.

6.2.2.7. Non-Compliance

Institutions that fail to comply with Federal Policy on Research Misconduct (reference a) and this OI will be subject to corrective action by the CHQ. Reports related to institutional non-compliance will be provided to ASD(R&E).

6.2.3. Research Misconduct Requirements for Extramural Research

Non-DoD institutions receiving DoD funding to conduct research must have policies and procedures in place that meet the requirements specified in Enclosure 4 of DoDI 3210.7 (reference b). These policies and procedures do not need to be submitted to the DoD awarding activity, but they should be available upon request.

The CHQ shall receive copies of all reports and outcomes of the misconduct allegation that fall under Defense Federal Acquisition Regulation Supplement (DFARS) (reference n) and DoD Grants and Agreements Regulations (reference o). The CHQ must also be notified as soon as it

is determined that the misconduct case falls within the boundaries of requirement Enclosure E4.1.6 of DoDI 3210.7 (reference b).

If at any point it is found that any of the following situations apply to a case of alleged misconduct, the CHQ must be notified within 1 business day and provided an explanation of the circumstances within 14 calendar days:

- Public health or safety is at risk
- The institution's resources or interests are threatened or at risk
- Research activities are to be suspended because of the inquiry into or investigation of the allegation
- There is a possible violation of civil or criminal law
- Action to protect the interest of those involved in the inquiry into or investigation of the allegation is required from the CHQ
- A premature public disclosure of the inquiry or investigation of the allegation may compromise the process
- The broader research community or public should be informed

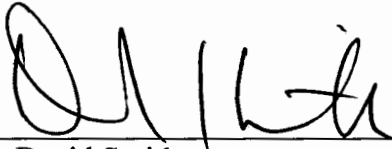
The extramural research institution is responsible for responding to allegations of research misconduct. However, the DoD awarding activity may respond to the allegation if:

1. The research institution is unable to conduct a thorough and unbiased inquiry and investigation;
2. It is in the public interest for the Department of Defense to conduct the inquiry and investigation; or
3. The allegation involves a small organization or an individual that cannot reasonably be expected to respond.

If the DoD handles the allegation, the procedures in Section 6.2.2 above would apply.

7. SIGNATURE APPROVAL

As the delegated authority for the USD(P&R)'s Research Integrity and Misconduct Program, I hereby approve this Operating Instruction.

Signature  Date 27 Dec 2016
Dr. David Smith
Deputy Assistant Secretary of Defense
(Force Health Protection and Readiness)

APPENDIX A (References)

- (a) Federal Register, Volume 65, page 76262, December 6, 2000, "Federal Policy on Research Misconduct," current edition
- (b) DoDI 3210.7, "Research Integrity and Misconduct," May 14, 2004
- (c) USD(P&R) memorandum, "Delegation of Authority for Research Integrity and Misconduct," March 16, 2010
- (d) ASD(HA) memorandum, "Delegation of Authority for Research Integrity and Misconduct," August 24, 2015
- (e) Title 5 U.S.C. §552, Freedom of Information Act
- (f) Title 5 U.S.C. §552a, Privacy Act of 1974
- (g) Title 5 U.S.C. §1201 Notes, et seq., Whistleblower Protection Act of 1989
- (h) Title 5 U.S.C. §2302, as amended by the Whistleblower Protection Enhancement Act of 2012
- (i) DoDD 7050.06, "Military Whistleblower Protection," April 17, 2015
- (j) P.L. 105-272, 112 Stat. 2396, Intelligence Community Whistleblower Protection Act of 1998
- (k) Title 10 U.S.C. §2409, Contractor Employees: Protection from Reprisal for Disclosure of Certain Information
- (l) DoDI 1400.25, "DoD Civilian Personnel Management System," May 20, 2012
- (m) Title 10 U.S.C. Chapter 47, Uniformed Code of Military Justice
- (n) 48 CFR 207, 235, and 252, "Defense Federal Acquisition Regulation Supplement; Protection of Human Subjects in Research Projects," July 29, 2009
- (o) 32 CFR 21, "DoD Grant and Agreements Regulations," July 28, 2004

APPENDIX B (Acronyms)

ASD(HA)	Assistant Secretary of Defense for Health Affairs
ASD(R&E)	Assistant Secretary of Defense for Research and Engineering
CHQ	Component Headquarters
CITI	Collaborative Institutional Training Initiative
DASD(HRP&O)	Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight
DoDD	Department of Defense Directive
DoDI	Department of Defense Instruction
FOIA	Freedom of Information Act
NARA	National Archives Records Administration
OI	Operating Instruction
OSD	Office of the Secretary of Defense
OUSD(P&R)	Office of the Under Secretary of Defense for Personnel and Readiness
PL	Public Law
RIM	Research Integrity and Misconduct
RIO	Research Integrity Officer
RION	Research Integrity Officer Network
SOPs	Standard Operating Procedures
USC	United States Code
USD(P&R)	Under Secretary of Defense for Personnel and Readiness

APPENDIX C (Definitions)

Unless otherwise noted, these terms and their definitions are for the purpose of this Operating Instruction.

adjudication. Defined in Enclosure 2 of reference (b).

fabrication. Defined in Enclosure 2 of reference (b).

falsification. Defined in Enclosure 2 of reference (b).

inquiry. Defined in Enclosure 2 of reference (b).

Institution Leader. A senior person with the authority to commit the institution to comply with Federal, DoD, and OUSD(P&R) requirements

investigation. Defined in Enclosure 2 of reference (b).

plagiarism. Defined in Enclosure 2 of reference (b).

Research Integrity Officer Network. A formal network comprised of Research Integrity Officers from each OUSD(P&R) institution engaged in research. This network provides an environment of support and education, best practices and new concepts in promoting research integrity, and will communicate strategic initiatives related to the OUSD(P&R) RIM program.

Research Integrity Officer. The subject matter expert directly responsible to the Institution Leader for matters associated with research integrity and misconduct.

research integrity. The adherence of researchers to ethical and professional research principles and standards, including intellectual honesty, and objective data evaluation and reporting.

research misconduct. Defined in Enclosure 2 of reference (b).

research. Defined in Enclosure 2 of reference (b).