Defense Health Agency

ADMINISTRATIVE INSTRUCTION

NUMBER 3200.02
April 29, 2022
Incorporating Change 1, November 19, 2024

DAD-R&E

SUBJECT: Research Integrity and Misconduct Policy and Procedures

References: See Enclosure 1.

1. PURPOSE. This Defense Health Agency-Administrative Instruction (DHA-AI), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (o), establishes the Defense Health Agency's (DHA) procedures to authorize investigation of alleged research misconduct in Public Health Service (PHS) supported research.

2. APPLICABILITY. Unless superseded by Department of Defense Uniformed Code of Military Justice or Office of Personnel Management investigations, this DHA-AI applies only to PHS supported research conducted in DHA Activities.

3. POLICY IMPLEMENTATION. It is DHA's instruction, pursuant to References (f) through (o), that the DHA's Research Integrity and Misconduct (RIM) Program will, in the case of any PHS supported research being conducted at institutions:

a. Respond to each allegation of research misconduct in a thorough, competent, objective, and fair manner, including taking precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the complainant(s), respondent(s) or witness(es).

b. Foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.

c. Take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses, and committee members, including but not limited to protecting such individuals from retaliation by respondents and/or other institutional members.

d. Maintain, in accordance with Part 93, Paragraph 108 of Reference (g), confidentiality regarding the identity of respondents and complainants in research misconduct proceedings and maintain confidentiality for any records or evidence from which research subjects might be identified.

e. Take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, providing all information, research records, and evidence pertinent to such research misconduct proceedings.

f. Cooperate with the United States Department of Health and Human Services (HHS) during any research misconduct proceeding or compliance review.

g. Assist in administering and enforcing any HHS administrative actions imposed on any agents or employees of DHA Activities arising from research misconduct proceedings.

h. Ensure a current and active Assurance of Compliance is on file to be provided to PHS by the institution(s)' Institutional Official(s) (IO) pursuant to Part 93, Paragraph 301 of Reference (g).

i. Direct any questions to the Director, DHA Office of Research Protections.

4. RESPONSIBILITIES. See Enclosure 2.

5. PROCEDURES. See Enclosure 3 through 4.

6. PROPONENT AND WAIVERS. The proponent of this publication is the Deputy Assistant Director (DAD), Research and Engineering (R&E). When Activities are unable to comply with this publication the activity may request a waiver that must include a justification, to include an analysis of the risk associated with not granting the waiver. The Activity Director or senior leader will submit the waiver request through their supervisory chain to the DAD-R&E to determine if the waiver may be granted by the Director, DHA or other appropriate authority.

7. RELEASABILITY. **Cleared for public release**. This DHA-AI is available on the Internet from the Health.mil site at: https://health.mil/Reference-Center/Policies and is available to authorized users from the DHA SharePoint site at: https://info.health.mil/cos/admin/pubs/SitePages/DHA%20Publication%20Systems%20Branch%20(PSB).aspx.

8. EFFECTIVE DATE. This DHA-AI:

a. Is effective upon signature.

b. Will expire 5 years from the date of signature if it has not been reissued or cancelled before this date in accordance with Reference (c) and (d).

9. FORMS.

a. The Standard Form 424, Application for Federal Assistance is available at: https://www.grants.gov/forms/forms-repository/sf-424-individual-family.

b. The Public Health Service (PHS) Form 398, Grant Application is available at: https://www.grants.gov/applicants.

10. SUMMARY OF CHANGES. The publication was updated for minor administrative changes including updates to references for webpage links, new mandatory sections from the publications template, and office contact information.

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REFERENCES

(a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, as amended
(b) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013, as amended
(c) DHA-Procedural Instruction 5025.01, "Publication System," August 24, 2018
(d) DHA-Administrative Instruction 5015.01, "Records Management Program," November 21, 2023
(e) DoD Manual 5400.07, "DoD Freedom of Information Act (FOIA) Program, January 25, 2017
(f) DoD Instruction 3210.07, "Research Integrity and Misconduct," May 14, 2004, as amended
(g) Code of Federal Regulations, Title 42, Parts 50 and 93
(h) U.S Department of Health and Human Services (HHS): Office of Research Integrity, "ORI Handbook for Institutional Research Integrity Officers", current edition
(i) U.S Department of Health and Human Services (HHS): Office of Research Integrity, "ORI checklist: Policies and Procedures for Handling Research Misconduct Allegations", current edition
(j) Federal Register, Volume 65, Page 76262, "Federal Policy on Research Misconduct," December 6, 2000
(k) DoD Instruction 1400.25-V2014, "DoD Civilian Personnel Management System: Defense Civilian Intelligence Personnel System (DCIPS) Employee Grievance Procedures," March 20, 2012
(l) United States Code, Title 10
(m) United States Code, Title 5
(n) DoD Directive 7050.06, "Military Whistleblower Protection," April 17, 2015, as amended
(o) Public Law 105-272, Section 701, "Intelligence Community Whistleblower Protection Act of 1998," October, 20, 1998

ENCLOSURE 2

RESPONSIBILITIES

1. DIRECTOR, DHA. The Director, DHA will:

a. Appoint a DHA Research Integrity Officer (RIO) who will represent DHA for the Office of the Under Secretary of Defense for Research and Engineering (OUSD(R&E)) RIM program on committees established by the OUSD(R&E)) in relation to RIM in accordance with References (f) and (g).

b. Report research misconduct to OUSD(R&E) and the Office of Research Integrity (ORI) in accordance with Enclosure 3 Section 1.11 of Reference (f) and Part 93 of Reference (g) respectively.

c. Establish, maintain, and properly resource the DHA RIM oversight program in a manner that facilitates efficient and effective operations.

d. Oversee the DHA RIO.

e. Promote and oversee procedures for the DHA RIM Program.

f. Ensure that DHA Activities comply with applicable RIM rules, regulations, and policies (References g through l).

g. Adjudicate allegations of research misconduct, when applicable, involving PHS research conducted or supported by DHA.

2. DHA RIO. The DHA RIO will:

a. Oversee the implementation of this DHA-AI.

b. Serve as the subject matter expert to the DHA regarding RIM for research conducted or supported by DHA Activities.

c. Manage the day-to-day implementation and operation of the DHA RIM Program.

(1) Recommend the appointment of members to DoD committees in accordance with Reference (f).

(2) Report research misconduct to OUSD(R&E), after approval from the DHA Director, in accordance with Enclosure 3 Section 1.11 of Reference (f), and Part 93 of Reference (g).

(3) Make recommendations to the DHA Director for the adjudication of research misconduct allegations.

(4) Provide reports about the overall DHA RIM Program, as requested, on behalf of the DHA Director, to OUSD(R&E) as outlined in the DHA RIM Program structure in Appendix 1.

d. Manage the day-to-day implementation and operation of the DHA RIM Program.

(1) Develop procedures to implement policies for the DHA RIM Program.

(2) Issue routine guidance and procedures to DHA Activities on research integrity programs.

(3) Ensure adherence to required RIM education and training.

(4) Head a RIO Network comprised of all Human Protection Administrators (HPA)/Human Protection Directors (HPD) (supported by DHA RIM Program staff) providing a platform for:

(a) HPA/HPDs to share best practices and new concepts in promoting research integrity.

(b) The DHA RIM Program to communicate strategic initiatives related to RIM.

e. Coordinate processes and procedures related to research misconduct.

(1) Serve as the Appeals Official for a research misconduct investigation.

(2) Monitor and adjudicate, if required, allegations of research misconduct and assure resolution at the appropriate level.

(3) Maintain records of actions and activities as required by law and regulation.

(4) Maintain records, files, and correspondence related to research misconduct in accordance with this DHA-AI.

3. LOCAL MILITARY MEDICAL TREATMENT FACILITY (MTF) AND DENTAL TREATMENT FACILITY (DTF) IO. The local MTF/DTF IO for the Human Research Protection Program (HRPP) is the senior person with the authority to commit the institution to comply with Federal, DoD, and DHA RIM Program requirements. The IO will:

a. Maintain a RIM program in compliance with this DHA-AI within their institution.

b. Maintain compliance with the DHA RIM Program in accordance with References (f) and (g), and this DHA-AI.

c. Ensure adequate resources are available to comply with Reference (f) and this DHA-AI.

d. Evaluate and act on allegations of research misconduct in accordance with References (f) and (g), and this DHA-AI in support of the investigations.

e. Oversee investigations of misconduct in accordance with Reference (f) and this DHA-AI.

f. Designate an individual at the institution to assist the DHA RIO with investigations in accordance with References (f) and (g), and this DHA-AI.

g. Oversee the adjudication state of a research misconduct investigation.

4. HPA/HPD. The HPA/HPD will:

a. Oversee the implementation of this DHA-AI at their institution.

b. Serve as the MTFs/DTFs local point of contact to the DHA regarding RIM for research conducted or supported at their institutions.

c. Receive and manage all allegations of research misconduct that may arise out of their institution.

d. Inform the IO and the DHA RIO of any allegations and subsequent investigations.

e. Document RIM allegations, consult with the DHA RIO, and the DHA General Counsel, collect evidence related to RIM allegations, conduct inquiries, and participate in investigations of research misconduct allegations.

f. Assist the DHA RIO on investigations at other DHA MTFs/DTFs and institutions as requested.

g. Be sufficiently removed from research to avoid the appearance of a conflict of interest and undue influence.

5. PRINCIPAL INVESTIGATOR (PI) AND STUDY STAFF. PIs and study staff will:

a. Be responsible and accountable to the institution and sponsor for the proper conduct of the research activities.

b. Cooperate with any allegations of research misconduct and subsequent inquiries and investigations.

ENCLOSURE 3

PROCEDURES

1. RESEARCH MISCONDUCT AND THE PROCEDURES FOR REPORTING.

a. Definition of Research Misconduct

(1) According to Part 93.103 of Reference (g), research misconduct is the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(2) Research misconduct does not include honest error or differences of opinion.

b. Reporting Research Misconduct

(1) All instances of research misconduct occurring at an MTF/DTF with a HRPP program for PHS supported research must be reported to the HPA/HPD. The Institutional Review Board of Record must be informed if the alleged misconduct occurs in non-exempt research where an action to the research needs to be implemented.

(2) Allegations of research misconduct involving the HPA/HPD or IO can be reported directly to the DHA RIM Program at dha.hrpp@health.mil.

(3) Similarly, allegations of research misconduct involving PHS supported research only sites without a local HRPP or RIM Program will be reported directly to the DHA RIM Program at the above-named email address.

2. CONFIDENTIALITY.

a. To the extent allowed by law and DoD regulations, the DHA RIM Program and DHA Activities will maintain securely and confidentially the identity of respondents and complainants and will not disclose any identifying information, except to the following parties:

(1) Those who need to know in order to carry out a thorough, competent, objective, and fair research misconduct proceeding.

(2) The ORI as it conducts its review of the research misconduct proceeding and any subsequent proceedings as further detailed in References (h) and (i).

b. To the extent allowed by law and DoD regulations, the DHA RIM Program and DHA Activities will maintain securely and confidentially any information obtained during the research misconduct proceeding that might identify the subjects of research and will not disclose this information, except to those who need to know in order to carry out the research misconduct proceeding.

3. ENSURING A FAIR RESEARCH MISCONDUCT PROCEEDING.

a. The DHA RIM Program will take all reasonable steps to ensure an impartial and unbiased research misconduct proceeding to the maximum extent practicable.

b. Individuals selected to conduct the inquiry or investigation will be selected based on their scientific expertise that is pertinent to the matter.

c. Prior to selection, all individuals selected to conduct the inquiry or investigation will be screened for any unresolved personal, professional, or financial conflicts of interest with the respondent(s), complainant(s), potential witness(es), or others involved in the matter.

d. Any such conflict, which a reasonable person would consider to demonstrate potential bias, will disqualify an individual from selection.

4. RESEARCH MISCONDUCT PROCEEDINGS.

a. Pre-Investigation Steps.

(1) Assessment of the Criteria. Promptly after receiving an allegation of research misconduct, the allegation will be assessed by either the institutional HPA/HPD or the DHA RIO to determine if either of the following are true:

(a) It meets the definition of research misconduct in Part 93.103 of Reference (g).

(b) It involves either PHS supported research, applications for PHS research support, or research records as specified in Part 93.102 of Reference (g).

(c) The allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

(2) Initiation of Inquiry.

(a) Per Part 50, Paragraphs 103-105 of Reference (g), if it is determined that an inquiry (i.e., an initial review of the evidence to determine if the criteria for conducting an investigation has been met) is warranted, the HPA/HPD will complete the inquiry, including preparation of the inquiry report and give the respondent(s) a reasonable opportunity to comment on it, within 60 calendar days of its initiation, unless the circumstances warrant a longer period.

(b) Prior to or at the beginning of the inquiry, the DHA RIO, or the DHA Activities' HPA/HPD conducting the inquiry, will provide the respondent(s) written notification of the research misconduct proceeding.

(c) If the initial assessment determines that an inquiry is warranted, the entity receiving the allegation (i.e., the HPA/HPD or DHA RIO) will complete the inquiry report, containing the following information:

1. The name and position of the respondent(s).

2. A description of the allegations of research misconduct.

3. The PHS support involved, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support.

4. The basis for recommending that the alleged actions warrant an investigation.

5. Any comments on the report by the respondent(s) or the complainant(s).

(d) If the inquiry subsequently identifies additional respondents, they will be promptly notified in writing.

(e) If the inquiry takes longer than 60 days to complete, the HPA/HPD will include documentation of the reasons for the delay in the inquiry record.

(3) Comment on the Inquiry Report.

(a) The respondent(s) will be given 60 calendar days from the initiation of the inquiry report to provide comments that can be attached to the report, unless the circumstances warrant a longer period.

(b) If the inquiry takes longer than 60 days to complete, the DHA Activities' HPA/HPD or the DHA RIO will include documentation of the reasons for the delay in the inquiry record.

(4) Results of the Inquiry.

(a) The IO and DHA RIO will review the inquiry report and any associated respondent(s)'s comments and make a written determination of whether an investigation is warranted.

(b) The respondent(s) will be notified of the results of the inquiry and will be provided with a copy of the inquiry report, institutional policies, and procedures for the handling of research misconduct allegations.

(c) If the inquiry determines that an investigation is warranted, the investigation will begin promptly but no later than 30 calendar days after that determination, and the IO or DHA RIO will notify the respondent(s) in writing of the allegations to be investigated.

(d) The IO or DHA RIO will give the respondent(s) written notice of any new allegations within a reasonable time frame after determining to pursue allegations not addressed in the inquiry or in the initial notice of the investigation.

(e) Allegations that are determined to have not been reported by the complainant(s) in good faith or are determined to be without merit will be closed.

1. Records will be retained in accordance with the approved National Archives and Records Administration (NARA) records disposition schedule and Part 93.317 of Reference (g).

2. The HPA/HPD will notify the DHA RIO in advance if the institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent(s) has/have admitted guilt, a settlement with the respondent(s) has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage, that must be reported to ORI under Part 93.316 of Reference (g).

b. Investigations, Investigating Reports, and Appeals.

(1) Investigations. If, during the inquiry stage, an allegation of research misconduct is found to have merit, a DHA RIM Program investigation committee should be formed within 14 calendar days after the HPA/HPD submits the inquiry report to the DHA RIO.

(a) The HPA/HPD should work together with the DHA RIO and the IO to appoint 3-5 individuals to sit on this committee.

1. Members of the investigation committee must not have any conflict of interest with the investigation or the alleged research misconduct case.

2. Investigation committee members must have sufficient expertise and training to comprehend the circumstances of the alleged research misconduct and to make an independent determination regarding any wrongdoing.

3. The HPA/HPD can act as a non-voting, ex-officio member of the investigation committee.

(b) The complainant(s) and respondent(s) must be notified in writing of the composition of the investigative committee including the names of the members appointed.

1. The complainant(s) and respondent(s) will have 7 calendar days from the time they receive notice of the investigation committee to refute membership of the investigative committee by providing justification for the removal of investigation committee members in writing.

2. The IO has 7 calendar days to replace the refuted committee members or provide justification to the complainant(s) and the respondent(s) as to why the request to replace an investigation committee member was denied.

3. The DHA RIM Program must be notified of any changes made to the investigation committee.

(c) Once the investigative committee is finalized, interviews will be scheduled, and the respondent(s) will be notified at least 5 calendar days in advance of the scheduling of their

interview in the investigation so that the respondent(s) may prepare for the interview and arrange for the attendance of legal counsel, if the respondent(s) wish(es).

(d) The investigation report must be completed and forwarded to the IO and the DHA RIO, within 120 calendar days of the initiation of an investigation, per Part 50 Paragraphs 103-105 of Reference (g).

(e) If an extension is required, the investigative committee must submit a request outlining the reason for the extension to the IO for approval. This correspondence must be forwarded to the DHA RIM Program.

(2) The Investigation Report.

(a) The investigation report should include the following:

1. Description of the allegation(s) (fabrication, falsification, or plagiarism).

2. Methods and procedures used to gather the information and evaluate the allegation.

3. Outcome of the investigation.

4. Findings and supportive evidence, if any.

5. Degree of seriousness of the allegation.

6. Determinations of research misconduct and recommendations for personnel actions under applicable law and regulations, including Reference (k) for civilian personnel and Chapter 47 of Reference (l) for military personnel.

(b) The HPA/HPD must forward the investigation report to the DHA RIM Program within 7 business days of receipt.

(c) The HPA/HPD will give the respondent(s) a copy of the draft investigation report, and concurrently, a copy of, or supervised access to, the evidence on which the report is based and notify the respondent(s) that any comments must be submitted within 30 calendar days of the date on which he/she received the draft report.

1. If comments are received, the HPA/HPD, DHA RIO and Investigation Committee will consider those comments and incorporate the appropriate changes into the final report.

2. Generally, the complainant(s)'s comments are also sought and considered when they have cooperated with the institution in providing evidence relevant to the investigation and has/have complied with all procedures regarding confidentiality.

(d) The HPA/HPD must forward a copy of the final investigation report to the complainant(s) and the respondent(s) in writing within 14 calendar days of finalizing the investigation report by DHA RIO.

1. This correspondence will outline appeal options and include a redacted copy of the committee's report, with all names, contact information, and other potentially identifying information removed.

2. A copy of this correspondence must be sent to the DHA RIO and the IO.

(e) When the HPA/HPD issues a final report on an inquiry or investigation, they will notify the institution, the complainant(s), and the respondent(s).

(f) If the HPA/HPD does not find misconduct, they will close the file on the matter.

(3) Appeals.

(a) Any appeal process must be completed within 120 days unless the institution has requested and received an extension from ORI (this 120-day deadline does not apply to institutional termination hearings that are conducted separately from the appeal process).

(b) When the institution (i.e., HPA/HPD) conducts the initial investigation, the DHA RIO will be the Appeals Official.

(c) The Appeals Official will review all documents and evidence related to the case.

(d) If newly provided evidence indicates that the appeal has merit, the DHA RIO as the Appeals Official will appoint members to an appeals investigation committee within 14 calendar days.

1. Individuals from the previous investigation committee cannot serve on the appeals committee.

2. The complainant(s) and respondent(s) will have 7 calendar days from the time they receive notice that members have been appointed to the appeals investigation committee to refute members of the committee in writing.

(e) A final decision regarding the appeal should be completed by the appeals investigation committee and forwarded to the Appeals Official within 120 calendar days of receipt of the appeals request.

(f) If the DHA RIO is not the Appeals Official, it would be upon the Director, DHA to appoint an Appeals Official, the final decision regarding the appeal must be forwarded to DHA ORP in writing within 7 business days.

(g) The final decision regarding the appeal must be sent to the complainant(s), respondent(s), IO, and HPA/HPD within 14 calendar days of completion.

1. 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)'s reputation. (See Enclosure 3, Paragraph 7 on Restoring Reputations).

2. If the decision is to maintain the findings of the original committee's research misconduct investigation, the IO will continue with the adjudication as outlined below.

(h) 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 and Part 93.317(a) of Reference (g).

(4) Adjudication.

(a) Per Reference (f), adjudication will be handled at the IO level, when possible, with the assistance of the DHA RIO, if necessary, and the institution's General Counsel.

1. The IO, in consultation with General Counsel, and any other applicable civilian processes and consultants (per Reference (k)) or military consultants must approve action plans and remedies resulting from an investigation.

2. The IO will inform the DHA RIO and assist them in reporting the outcome to OUSD(R&E) and ORI.

(b) Adjudication must be finalized 14 calendar days after the complainant(s) and respondent(s) have been given the opportunity to appeal the investigation outcome.

(c) The adjudication report will be completed by the IO.

1. If the IO is not the adjudication authority, the IO must receive a copy of the adjudication report.

2. The adjudication report must be sent to the DHA RIO, the respondent(s), and any other authorities or offices involved with the adjudication phase within 7 calendar days of finalizing the adjudication.

3. The complainant(s) may receive a copy of the report, but Freedom of Information Act (Part 552 of Reference (m)) standards must be applied to the information contained in the report. General Counsel or the MTF Privacy Officer must be consulted.

4. The adjudication report should include:

a. A summary of findings to include whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard.

b. Actions or remedies taken and/or pending.

c. Impact on the institution, if feasible.

d. Impact on future research, if feasible.

c. Institutional Actions in Response to final findings.

(1) Personnel Actions. When misconduct is found, corrective and/or punitive actions may follow as discussed below.

(a) Military Personnel. Any Service member found responsible of research misconduct is also subject to the Uniform Code of Military Justice proceedings, actions and penalties.

(b) DHA RIM Program Responsibility. The DHA RIM Program will cooperate with and assist ORI and HHS, as needed, to carry out any administrative actions HHS may impose as a result of a final finding of research misconduct by HHS. The administrative actions that HHS may take against the respondent(s) include, but are not limited to:

1. Debarment from eligibility to receive Federal funds for grants and contracts.

2. Prohibition from service on PHS advisory committees, peer review committees, or as a consultant.

3. Implementation of special procedures for supervising the respondent(s) and certifying data and sources.

4. Correction or retraction of published scientific articles.

(c) Institutional Responsibility. ORI generally relies on the cooperation of the institution where the respondent(s) is/are currently employed to assist in implementing these administrative actions.

(d) Findings Report. If the respondent(s) does not request a hearing or the findings of scientific misconduct and proposed administrative actions are affirmed by the HHS Departmental Appeals Board (DAB) (and Deputy Assistant Secretary for Grants and Acquisition Management (DASGAM) in cases of debarment), these findings and administrative actions will be published in the Federal Register, the National Institutes of Health Guide for Grants and Contracts, the ORI Newsletter, and the ORI Annual Report.

1. A copy of the final notification letter containing the findings and administrative actions is sent to the institution where the investigation was conducted and to the current employing institution if the respondent(s) has/have relocated.

2. In addition, PHS findings and administrative actions are posted on the PHS Administrative Action Bulletin Board.

3. Debarments are also published in the General Services Administration's List of Parties Excluded from Federal Procurement and Non-procurement Programs.

(2) Institutional actions as determined by the IO and the respondent(s)'s chain of command and/or supervision.

e. Allegations without Merit.

(1) If the DAB rules in favor of the respondent(s), the finding of misconduct will be overturned, and the proposed administrative actions will not take effect.

(2) DAB rulings on proposed debarments are subject to final approval by the DASGAM, HHS' debarring official.

f. Institutional Implications (Non-Compliance). Per paragraph E.3.1.11 of Reference (f).:

(1) Instances of any PHS supported research conducted at an institution failing to comply with the requirements of this DHA-AI will be referred for resolution to a management level that is at least one level above where the non-compliance is alleged to have occurred.

(2) The DHA RIO will provide the OUSD(R&E) reports of all actions taken under this paragraph.

5. NOTIFYING THE ORI OF THE DECISION TO OPEN AN INVESTIGATION AND OF INSTITUTIONAL FINDINGS AND ACTIONS FOLLOWING THE INVESTIGATION.

a. Per Part 50 Paragraphs 103-105 of Reference (g), on or before the date on which the investigation begins (the investigation must begin within 30 calendar days of the finding that an investigation is warranted), the DHA RIO will provide ORI with the written findings and a copy of the inquiry report containing the information required by Part 93.309(a) Reference (g).

b. Per Part 50 Paragraphs 103-105 of Reference (g), the DHA RIO will report to ORI any proposed settlements, admissions of research misconduct, or institutional findings of misconduct that arise at any stage of a misconduct proceeding, including the allegation and inquiry stages.

c. As necessary, the DHA RIO will ensure that a complete record of relevant evidence, all witnesses, research records, and other evidence under its control or custody, or in the possession of, or accessible to, all persons subject to DHA RIM Program's authority is developed to submit to ORI.

d. The DHA RIM Program will cooperate fully on a continuing basis with ORI during its oversight reviews of DHA Activities and its research misconduct proceedings and during the process under which the respondent(s) may contest ORI findings of research misconduct and proposed HHS administrative actions.

(1) Upon a request from ORI, the DHA RIO will promptly send them:

(a) A copy of the DHA RIM Program's institutional policies and procedures under which the inquiry was conducted.

(b) The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents.

(c) The charges for the investigation to consider.

(2) The DHA RIO will promptly provide to ORI after the investigation:

(a) A copy of the investigation report, all attachments, and any appeals.

(b) A statement of whether the institution found research misconduct and, if so, who committed it.

(c) A statement of whether the institution accepts the findings in the investigation report.

(d) A description of any pending or completed administrative actions against the respondent(s).

6. INTERIM PROTECTIVE ACTIONS.

a. Per Part 50 Paragraphs 103-105 of Reference (g), at any time during a research misconduct proceeding, DHA Activities and the DHA RIM Program will take appropriate interim actions to protect public health, Federal funds and equipment, and the integrity of the PHS supported research process.

b. The necessary actions will vary according to the circumstances of each case, but examples of actions that may be necessary include one or more of the following:

(1) Delaying the publication of research results.

(2) Providing for closer supervision of one or more researchers.

(3) Requiring approvals for actions relating to the research that did not previously require approval.

(4) Auditing pertinent records.

(5) Taking steps to contact other institutions that may be affected by an allegation of research misconduct.

7. RESTORING REPUTATIONS.

a. Respondents. The DHA RIM Program will undertake all reasonable, practical, and appropriate efforts to protect and restore the reputation of any person alleged to have engaged in research misconduct, but against whom no finding of research misconduct was made.

b. Complainants, Witnesses, and Committee Members. Per Chapters 53.1034 and 141.4701 of Reference (l) and References (m) through (o), the DHA RIM Program will undertake all reasonable and practical efforts to protect and restore the position and reputation of any complainants, witnesses, or committee members and to counter potential or actual retaliation against those complainants, witnesses and committee members.

8. RECORD MANAGEMENT.

a. The PI will maintain on file at all times copies of current and active Assurances of Compliance issued to PHS supported research granted once the PHS Form 398, Grant Application or Standard Form 424, Application for Federal Assistance is signed pursuant to Part 93.301 of Reference (g).

b. Either before or when the HPA/HPD or the DHA RIO notifies the respondent(s) of the allegation, the institution or DHA RIM Program will promptly take all reasonable and practical steps to obtain custody of and secure and maintain all research records and evidence needed to conduct the research misconduct proceeding.

c. The research records will be inventoried and sequestered in a secure manner.

d. Custody may be limited to copies of the data or evidence on such instruments in those cases where the research records or evidence encompass scientific instruments shared by a number of users, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

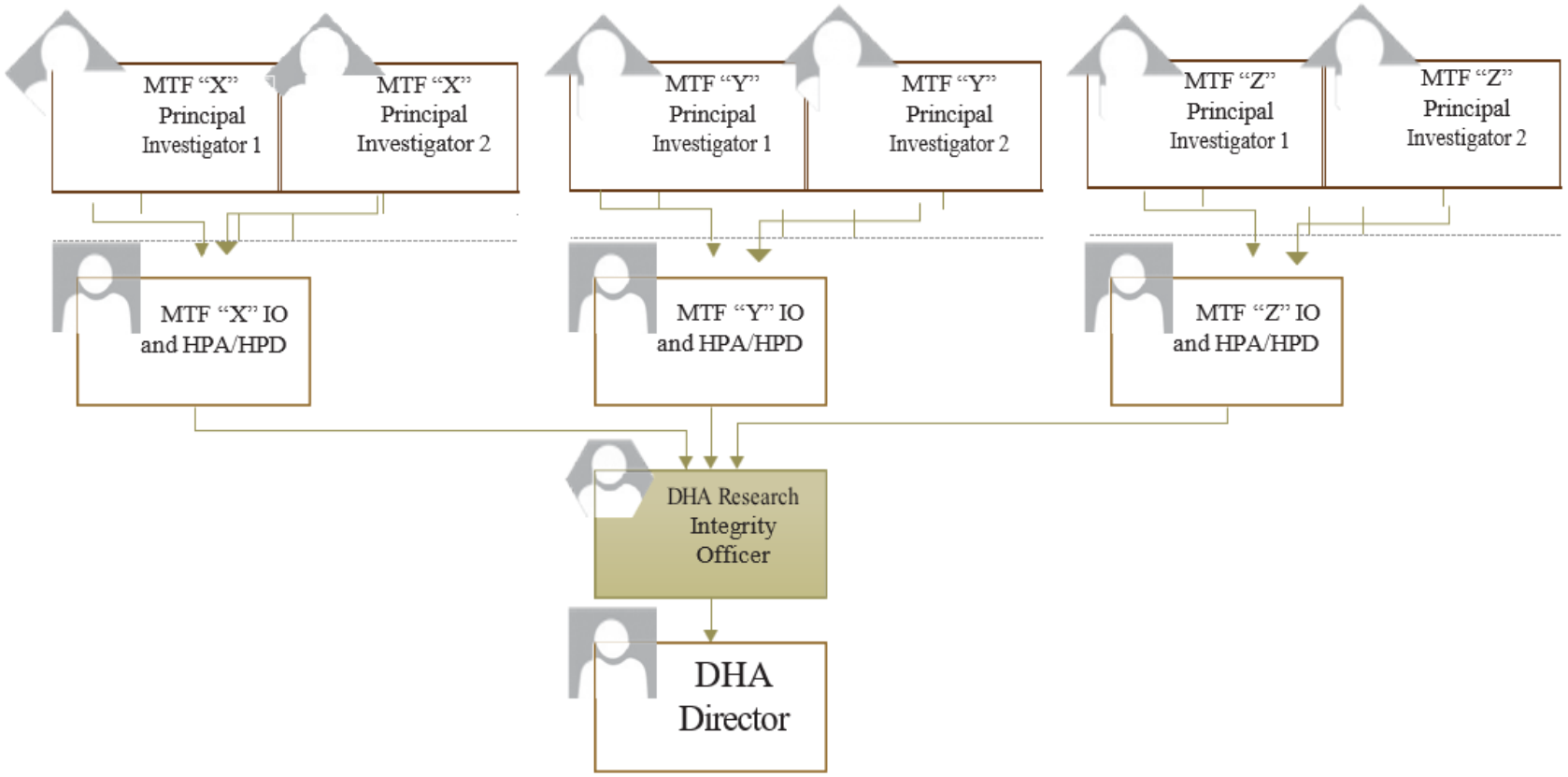
e. As appropriate, the respondent will be given copies of, or reasonable, supervised access to the research records.

f. All reasonable and practical efforts to take custody of additional research records and evidence discovered during the course of the research misconduct proceeding will be undertaken, including at the inquiry and investigation stages, or if new allegations arise, subject to the exception for scientific instruments detailed above.

g. The institution, in accordance with NARA policies, will maintain all records of the research misconduct proceeding, as defined in Part 93.317(a) of Reference (g), for 7 years after completion of the proceeding, or any ORI or HHS proceeding under Subparts D and E of Part 93 of Reference (g), whichever is later, unless it has transferred custody of the records and evidence to HHS, or ORI has advised that is no longer necessary to retain the records.

APPENDIX 1

DHA RIM PROGRAM STUCTURE



GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

DAB	Departmental Appeals Board
DASGAM	Deputy Assistant Secretary for Grants and Acquisition Management
DHA	Defense Health Agency
DHA-AI	Defense Health Agency-Administrative Instruction
DTF	Dental Treatment Facility
HHS	United States Department of Health and Human Services
HPA	Human Protection Administrator
HPD	Human Protection Director
HRPP	Human Research Protection Program
IO	Institutional Official
MTF	Military Medical Treatment Facility
NARA	National Archives and Records Administration
ORI	Office of Research Integrity
OUSD(R&E)	Office of the Under Secretary of Defense for Research and Engineering
PHS	Public Health Service
PI	Principal Investigator
RIM	research integrity and misconduct
RIO	Research Integrity Officer

PART II. DEFINITIONS

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.

allegation. Disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institution, DHA or HHS official.

appeal. Response stage of an allegation of research misconduct when the respondent has an opportunity to refute/challenge the decision of the investigation.

Appeals Official. The DHA RIO is the Appeals Official.

complainant. An individual who reports a research misconduct allegation. DHA requires that any person filing a research misconduct allegation does so in good faith, maintains confidentiality, and cooperates with all stages of the misconduct.

good faith. An allegation made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if it is made with knowing or reckless disregard for information that would negate the allegation or testimony.

DAB. HHS DAB.

DASGAM. The HHS' debarring official.

degree of seriousness of allegation. The recurrence or continuation of conduct, which has previously been found to be research misconduct; a failure to follow research protocols approved by research ethics committees or statutory license conditions, where that failure has resulted in an unreasonable risk or actual harm to participants or the environment; deliberately publishing false research results that become part of the public record; conduct that is alleged to be research misconduct but where the consequences of the alleged breach result in serious harm to the participants, or other staff, students or visitors, and the conduct is characterized by a reckless and willful disregard for the consequences of the alleged conduct.

fabrication. Making up data or results and recording or reporting them.

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.

finding of research. The conclusion proven by a preponderance of the evidence that their misconduct 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.

IO. A senior person with the authority to commit the institution to comply with Federal, DoD, and DHA RIM Program requirements.

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.

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.

PHS. PHS of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

PHS supported research. PHS support means PHS funding, or applications or proposals therefore, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: Funding for PHS intramural research; PHS grants, cooperative agreements, or contracts or sub-grants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.

PI. The individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project.

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

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.

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. 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.

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.

respondent. A person against whom a research misconduct allegation has been made. The Respondent is responsible for maintaining confidentiality and cooperating with the research misconduct investigation.

RIO. The subject matter expert directly responsible for matters associated with RIM.

RIO Network. A formal network comprised of the DHA RIO, IOs, and HPA/HPDs from the respective DHA MTFs/DTFs and HRPPs that are under the DHA RIM Program's purview. This network performs RIM oversight and activities at their respective institutions and an

environment of support and education, best practices, new concepts in promoting research integrity, and will communicate strategic initiatives related to the DHA RIM program.