DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
7700 ARLINGTON BOULEVARD
FALLS CHURCH VA 22042

BUMEDINST 6500.3B
BUMED-N2
12 Dec 2023

BUMED INSTRUCTION 6500.3B

From Chief, Bureau of Medicine and Surgery

Subj: RESEARCH INTEGRITY, RESPONSIBLE CONDUCT OF RESEARCH EDUCATION, AND RESEARCH MISCONDUCT

Ref: (a) 65 FR 76262
(b) DoD Instruction 3210.7 of 14 May 2004
(c) SECNAVINST 3900.39E
(d) Institute of Medicine, Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct, National Academies Press, 2002 (NOTAL)

Encl: (1) Definitions
(2) Allegations of Research Misconduct

1. Purpose

a. To update Navy Medicine's (NAVMED) policy on the promotion of research integrity, continuing education in responsible conduct of research (RCR), and the handling of allegations of research misconduct, per references (a) through (d). Enclosure (1) provides definitions.

b. This instruction encompasses all NAVMED research efforts and programs, regardless of discipline or level, and provides guidance for research integrity, education, and management of misconduct. This instruction is a complete revision and should be reviewed in its entirety.

2. Cancellation. BUMEDINST 6500.3A.

3. Scope and Applicability

a. This instruction applies to all budget submitting office 18 commands, units, personnel, and operational activities having medical personnel under the authority, direction, and control of Chief, Bureau of Medicine and Surgery (BUMED), including all NAVMED civilian employees, foreign national employees, military members, contractors and consultants, under the terms of their appointments.

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

c. Individuals other than Department of Defense (DoD) employees participating in research activities conducted by NAVMED, or under its auspices, including proposal reviewers not covered elsewhere in this section, individuals under special personnel appointments, and visiting scholars.

4. Background

a. Research misconduct violates the integrity of research, adversely affects research benefits, and erodes the public trust. NAVMED maintains a zero-tolerance policy regarding research misconduct. Personnel who commit research misconduct may be subject to disciplinary action.

b. Research ethics has evolved in response to historical events and continues to respond to the needs of society. Research ethics encompasses a broad body of knowledge that includes the promotion of research integrity, RCR education, and processes to address research misconduct. These areas have attained increasing governmental attention beginning in the 1980s. As a result, diverse federal requirements and recommendations have developed over time for federal agencies and federal awardees.

c. Nationally recognized expertise, such as that found in reference (d), has emerged promoting purposeful knowledge of, and professional competence in, relevant subject areas. Such expertise is critical for the ongoing development of a culture of integrity within research. This expertise and the promotion of a culture of integrity in research, assists to meet its mission of readiness and patient-centered health care.

5. Policy

a. It is the policy of NAVMED that all personnel will uphold the highest principles of ethics, promoting research integrity and the RCR. Consolidated summaries for principles of research ethics and integrity are accessible via the Director, Medical Information and Research and Development (BUMED-N2) Common Access Card-enabled SharePoint site at: https://esportal.med.navy.mil/bumed/rh/m2/Pages/Home.aspx. This commitment includes active participation in continuing RCR education, and the effective and timely completion of requirements in the event of research misconduct.

b. Research integrity officers must be appointed at each of the NAVMED research and development laboratories.

c. Commanders and commanding officers (CO) of commands outside of the NAVMED research and development laboratories that are conducting research, as defined in enclosure (2), appoint their own individual research integrity officers unless sufficient expertise and resources are not available locally.

d. Where local research integrity expertise and resources are limited or not available, commands may partner with each other or with NAVMED research and development laboratories to ensure that research integrity expertise, RCR, and research misconduct leadership and services are readily available, and to maximize the use of these potentially scarce resources.

e. Commands that do not conduct research, as defined in enclosure (2), are not obligated to meet the full requirements of this instruction. However, these commands must:

(1) Promote awareness of the requirements in this instruction, such as through the Plan of the Week announcements or other communication platforms.

(2) Meet all requirements of this instruction prior to initiation of research if an intent to conduct research as defined by enclosure (2) should arise.

f. Some of the research covered by this instruction may also 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.

6. Roles and Responsibilities

a. BUMED-N2 will:

(1) Serve as the institutional official with final authority and responsibility for all matters relative to research integrity, RCR education, and research misconduct in NAVMED.

(2) Ensure echelon 3 commands adhere with the responsibilities and implementation of this instruction.

(3) Report serious research misconduct to higher authorities, as required.

(4) Ensure appointment of the BUMED Research Integrity Leader by Chief, BUMED.

(5) Ensure subordinate commands are supported and sufficiently resourced to meet the goals and responsibilities of the instruction.

b. BUMED Research Integrity Leader will:

(1) Be appointed by Chief, BUMED.

(2) Serve as the NAVMED subject matter expert (SME) relative to research integrity, but not involving subject matter relative to human or animal research regulations.

(3) Represent BUMED-N2 to extramural agencies regarding research integrity, RCR education, and research misconduct prevention, correction, and amelioration.

(4) Serve as the BUMED action officer for all research misconduct investigation and adjudication reports being forwarded to BUMED-N2 or higher authority, or both.

(5) Coordinate processes and procedures in the event of research misconduct involving BUMED assigned personnel.

(6) Coordinate processes within BUMED for research misconduct that must be forwarded to the BUMED level as referenced in enclosure (2) subparagraph 1f.

(7) Consult and mutually collaborate with the BUMED Director of Research Protections, and the BUMED Director of Veterinary Affairs (as pertinent), or both, upon receipt of any investigation or adjudication notices or reports, which bear upon human or animal research activities.

(8) Coordinate with and ensure that the Office of General Counsel (BUMED N01L) and the Public Affairs Office (BUMED-N01P) are informed in all instances and will comply with directives as given.

(9) Be available for consultation during all stages of investigation, adjudication, and appeal in the case of an allegation of research misconduct at echelon 3 or below commands.

c. Echelon 3 Commanders will:

(1) Implement this instruction within their commands, detachments, and other subordinate organizations.

(2) Ensure subordinate commands are supported and sufficiently resourced to meet the goals and responsibilities of this instruction.

(3) Provide subordinate COs with competent alternatives for meeting research misconduct processes when not available in the local command.

(4) Promote research integrity and ethics education participation, and establish as well as maintain processes to meet the guidance contained in this instruction.

(5) Appoint a research integrity officer who is a current SME, or has direct or related subject matter experience, ethical conduct, and integrity; does not have conflicts of interest; and who would not be compromised by undue influence.

d. COs and Officers in Charge (OIC) of Budget Submitting Office 18 Activities:

(1) Implement this instruction, ensuring all personnel meet its goals and comply with its requirements.

(2) Appoint a research integrity officer who is a current SME or has direct or related subject matter experience, ethical conduct, and integrity; does not have conflicts of interest; and who would not be compromised by undue influence.

(3) Assign resources to meet goals and responsibilities.

(4) Assist the BUMED Research Integrity Leader and echelon 3 commanders with promoting and implementing research integrity and ethics educational activities and services.

(5) Promote RCR education by utilizing consolidated resources via the BUMED-N2 Common Access Card-enabled SharePoint site at: https://esportal.med.navy.mil/bumed/rh/m2/Pages/Home.aspx.

(6) Complete requirements for the processing of research misconduct, as specified in enclosure (2).

(7) Request to respective echelon 3 commanders for research misconduct support when requirements cannot be performed within the individual command.

(8) Ensure compliance with applicable extramural agency research integrity requirements per subparagraph 5f of this instruction.

(9) Ensure research misconduct procedures are carried out with due regard for the rights of individuals and the integrity and ethical conduct of research itself.

e. Research Integrity Officers, Echelons 3 and 4 will:

(1) Assist the commander, CO, or OIC with meeting the goals and requirements of this instruction, including the processes to address incidents of research misconduct.

(2) Serve as the local point of contact for matters related to research integrity and RCR.

7. Records Management

a. Records created as a result of this instruction, regardless of format or media, must be maintained and dispositioned per the records disposition schedules located on the Department of the Navy Directorate for Administration, Logistics, and Operations, Directives and Records Management Division portal page at https://portal.secnav.navy.mil/orgs/DUSNM/DONAA/DRM/Records-and-Information-Management/Approved%20Record%20Schedules/Forms/AllItems.aspx

b. For questions concerning the management of records related to this instruction and the records disposition schedules, please contact the local records manager or the Department of the Navy Directorate for Administration, Logistics, and Operations, Directives and Records Management Division program office.

8. Review and Effective Date. Per OPNAVINST 5215.17A, BUMED-N2 will review this instruction annually around the anniversary of the issuance date to ensure applicability, currency, and consistency with Federal, DoD, Secretary of the Navy, and Navy policy and statutory authority using OPNAV 5215/40 Review of Instruction. This instruction will be in effect for 10 years, unless revised or cancelled in the interim, and will be reissued by the 10-year anniversary date if it is still required, unless it meets one of the exceptions in OPNAVINST 5215.17A, paragraph 9. Otherwise, if the instruction is no longer required, it will be processed for cancellation as soon as the need for cancellation is known following the guidance in OPNAV Manual 5215.1 of May 2016.

D. K. VIA

Releasability and distribution:
This instruction is cleared for public release and is available electronically only via the Navy Medicine Web site, https://www.med.navy.mil/Directives/

DEFINITIONS

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.

3. Fabrication. Making up data or results and recording or reporting them.

4. 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.

5. 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.

6. 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 whether an investigation is warranted.

7. 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, or take other appropriate remedies.

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

9. 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.

10. 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 DoD, colleges and universities, national user facilities, industrial laboratories, and other research institutes, centers, or organizations.

11. 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.

12. 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.

13. Responsible Conduct of Research. The utilization of knowledge gained through study of standards of propriety, ethics, honesty, and protection as found in educational and training materials developed as guidance for those engaged in all forms of research and data analysis. The application of such knowledge to all endeavors relating to design and execution of research activities. The avoidance of fabrication, falsification, or plagiarism in proclamation, production, or publication of research and data reports. In executing the preceding, promotes a culture of integrity and quest for the highest level of validity and veracity in description findings and outcomes from technical endeavors.

ALLEGATIONS OF RESEARCH MISCONDUCT

1. Allegations of Research Misconduct

a. Commanders and COs are responsible for the inquiry, investigation, and adjudication of research misconduct for any instance reported to them. Older instances may need to be pursued if ongoing recurrence, public safety, or other grave concerns are at risk.

b. Per SECNAVINST 5370.7E, the rights, privacy, and protection against retribution of those who make allegations must be secured. The rights and privacy of those against whom allegations have been made must be equally protected.

c. Research misconduct processes will be initiated by the command in which the individual who is alleged to have committed research misconduct is currently assigned or employed. Should this command not be the command where the alleged incident of research misconduct occurred, the current command may delegate, in writing, execution of the misconduct investigation to the command where the incident allegedly took place. If the individual transfers or leaves during these processes, the initial command will inform the receiving command or entity of the matter. Both will agree upon a proper course for the continuation and final disposition of the matter.

d. Commanders and COs are encouraged to seek counsel and advice from the BUMED-N01L, as needed.

e. Inquiries, investigations, or adjudication of research misconduct will be conducted at the command where the question of research misconduct originated.

f. In cases where a command is unable to process an allegation (e.g., unavailability of competent experts, potential conflicts of interest, or allegations against a CO), the inquiry, investigation, or adjudication will be elevated to the next higher echelon command. Should questions elevate to the level of BUMED, BUMED-N2 will determine how the allegations will be resolved, with advice from the BUMED Research Integrity Leader and BUMED-N01L, as needed.

g. Initial Reporting. Personnel who become aware of potential research misconduct must report such concerns to the command's research integrity officer.

h. Inquiry. The command research integrity officer makes a preliminary, informal determination to determine if the reported instance falls under research misconduct definitions or has any substance. If the command research integrity officer determines the matter does not fall under research misconduct definitions or has no substance, the matter is closed. If the command Research Integrity Leader determines the incident has substance; the command research integrity officer will notify the CO. The CO notifies the respective individual about whom the allegation

has been made. The CO, in consultation with the command research integrity officer, appoints an ad hoc committee to conduct a preliminary inquiry. The committee will be chaired by the command research integrity officer and consist of three to five local experts. Members must not have conflicts of interest with the instance. The inquiry will be completed within 60 days. If the inquiry results in a determination that no misconduct was performed, the CO will notify the individual and the matter is closed, with all records secured.

i. Investigation. If initial inquiry determines that there had been evidence of research misconduct, the CO notifies the individual and the matter proceeds to formal research misconduct investigation. For research misconduct matters requiring investigation, the BUMED Research Integrity Leader must be notified immediately.

(1) For formal investigations, the CO, in consultation with the command research integrity officer, appoints a committee of three to five intramural subject matter experts, chaired by the command research integrity officer as a non-voting, ex officio member. The investigating committee members must not be the same as those from the inquiry phase.

(2) The CO notifies the individual against whom the allegation has been made regarding the committee membership and the proceedings to be followed. The individual has 30 days to indicate to the CO issues with the proceedings, committee members that may have conflicts of interest, or other matters that may affect objectivity and fairness. The CO resolves such issues accordingly. After the 30-day period has ended, the investigation will begin immediately.

(3) Once an investigation has begun, the committee will complete its work with the command research integrity officer, sending a complete report to the CO, all within 120 days. If the investigation determines research misconduct has not been committed, the matter is closed, and the individual is notified. Regardless of the findings, a complete report must be sent immediately to the BUMED Research Integrity Leader. All relevant records will be secured.

j. Adjudication. If an investigation determines research misconduct has occurred, the CO will notify the individual and implement adjudication processes. If circumstances such as conflict of interest warrant, the CO can request the echelon 3 commander be the adjudicating official. In either case, the adjudicating official should consult with the BUMED-N01L and Staff Judge Advocate (BUMED-N01J) for direction on adjudication measures and remedies. In some cases, disciplinary action may be required. Adjudication will be finalized within 30 days after the investigation has been completed. Immediately upon completion of adjudication, a full report is sent to the BUMED Research Integrity Leader.

k. Appeal. Individuals determined to have committed research misconduct can appeal in writing, the results of the investigation, or adjudication, within 30 days of each action. This appeal can be directed to the CO who accepted the adjudication that research misconduct had taken place, or to higher command, via the chain of command. Should the concern and appeal of

the individual so accused elevate to the BUMED Research Integrity Leader, the records to the investigation will be forwarded to BUMED N01L, to review and advise BUMED-N2. The final authority in such matters will be BUMED-N2.

l. Retention. Per Secretary of the Navy Manual 5210.1, all hard copy or electronic reports related to research misconduct allegations or incidents will be maintained for a period compliant with the requirement for retention of other official command administrative records. Upon the expiration of the retention period, all records will be destroyed.

2. Research Misconduct in NAVMED Sponsored Extramural Efforts

a. Commands that sponsor extramural research through grants, contracts, cooperative agreements, or other equivalent instruments are responsible for ensuring awardees are aware of what constitutes NAVMED research misconduct per paragraph 1 of this enclosure. All award instruments must reference this instruction or DoD equivalent and its content.

b. Awardees are responsible for compliance with this instruction.

c. Grants officers, contracting officers, contracting officer's representatives, or other award officers will work with awardees to ensure compliance with this instruction.

d. As applicable, commands must implement the provisions directed in enclosure (4) of DoD Instruction 3210.7, regarding research misconduct that may occur in extramural awards.

e. Within 5 business days after having learned of such an incident, COs are required to inform the BUMED Research Integrity Leader through the echelon 3 chain of commands of allegations of research misconduct occurring in extramural awards sponsored or contracted by the command (see paragraph 2 of this enclosure).