



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

IN REPLY REFER TO
BUMEDINST 6500.3A
BUMED-M2
17 Jun 2016

BUMED INSTRUCTION 6500.3A

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 3216.02 of 8 November 2011
(c) DoD Instruction 3210.7 of 14 May 2004
(d) SECNAVINST 3900.39D
(e) SECNAVINST 3900.38C
(f) BUMEDINST 6000.12B
(g) Institute of Medicine, Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct, National Academies Press, 2002
(h) NAVMED P-117, Manual of the Medical Department

Encl: (1) Definitions
(2) Principles of Research Ethics and Integrity
(3) Navy Medicine Research Integrity Programs
(4) Responsible Conduct of Research Education
(5) Research Misconduct
(6) Extramural Research
(7) Acronyms

1. Purpose

a. To update Navy Medicine policy per regulations found in references (a) through (f) for the promotion of research integrity, continuing education in responsible conduct of research (RCR), and the handling of allegations of research misconduct.

b. To establish Bureau of Medicine and Surgery (BUMED) subject matter expertise, support services, and resources to assist the Chief, BUMED, echelon 3 commanders, and commanding officers (CO) in meeting goals, objectives, and Department of Defense (DoD), and other applicable requirements.

2. Cancellation. BUMEDINST 6500.3

3. Background

a. 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.

b. Nationally recognized expertise, such as that found in reference (g), 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 Navy Medicine to meet its mission of readiness and patient-centered health care. Reference (g) is located at: <http://www.nap.edu/read/10430/chapter/1#vii>.

4. Applicability

a. All Navy Medicine medical treatment facilities (MTF), research laboratories, Ships, Stations, commands, and their subordinates per reference (h);

b. All Navy Medicine educational institutions, programs, and activities;

c. All Navy Medicine civilian employees, foreign national employees, and military members;

d. All Navy Medicine contractors and consultants, under the terms of their appointments;

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

f. Individuals other than DoD employees participating in research activities conducted by Navy Medicine, or under its auspices, including proposal reviewers not covered elsewhere in this section, individuals under special personnel appointments, and visiting scholars.

5. Scope. This instruction encompasses all Navy Medicine research efforts and programs, regardless of discipline or level, and provides guidance for research ethics, integrity, education, and management of misconduct. The requirements of this instruction supplement requirements for human research protections, use of animals in research, and clinical investigations program administration under references (d) through (f).

6. Definitions. See enclosure (1).

7. Policy. It is the policy of Navy Medicine that all personnel will uphold the highest principles of ethics, promoting research integrity, and the RCR as discussed in enclosure (2). This commitment includes active participation in continuing RCR education, and the effective and timely completion of requirements in the event of research misconduct.

8. Responsibilities

a. Chief, BUMED:

- (1) Is the Navy Medicine institutional official for the purposes of this instruction;
- (2) Directs echelon 3 commanders and COs with responsibility for the implementation of this instruction;
- (3) Reports serious research misconduct to higher authorities, as required;
- (4) Appoints the BUMED Research Integrity Leader.

b. BUMED Research Integrity Leader:

- (1) Assists Chief, BUMED with the implementation of this instruction, per enclosure (3);
- (2) Serves as the Navy Medicine subject matter expert (SME) relative to research ethics and research integrity, but not involving subject matter relative to human, or animal research regulations;
- (3) Represents Chief, BUMED to extramural agencies regarding research integrity, RCR education, and research misconduct prevention, correction, and amelioration;
- (4) Is the point of contact for reporting investigations and adjudication of research misconduct to Chief, BUMED;
- (5) Provides subject matter expertise to echelon 3 commanders and COs for the implementation of this instruction;
- (6) Provides on-site assistance as may be directed or requested;
- (7) Provides educational leadership and enrichment in specified research integrity and ethics content areas;
- (8) Coordinates BUMED-level processes for investigation of research misconduct or violation of research ethics, as applicable.

c. Navy Medicine Echelon 3 and Echelon 4 COs:

- (1) Ensure the implementation of this instruction within their commands, detachments and other subordinate organizations;

(2) Promote command authorized activities and services;

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

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

d. Navy Medicine COs and Officers in Charge:

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

(2) Establish processes to implement this instruction and appoint individuals to manage these processes, including appointment of a research integrity officer as a collateral duty position, per enclosure (3);

(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 the RCR educational goals, per enclosure (4);

(6) Complete requirements for the processing of research misconduct, as specified in enclosure (5);

(7) Make requests 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, as found in enclosure (6);

(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.

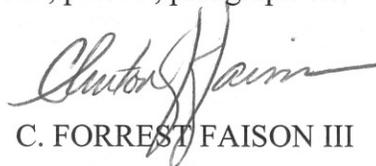
9. Acronyms. See enclosure (7).

10. Records. Records created as a result of this instruction, regardless of media and format, must be managed per SECNAV M-5210.1 of January 2012.

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11. Reports. The reporting requirements contained in this instruction are exempt from reports control per SECNAV M-5214.1 of December 2005, part IV, paragraph 7n.



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<http://www.med.navy.mil/directives/Pages/BUMEDInstructions.aspx>

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), special approvals, correction of the research record, or other similar actions); however, if there is an indication of violation of civil or criminal statutes, civil or criminal sanctions may be pursued.
2. Extramural. Refers to research-related activities not conducted within naval installations, or managed internally by naval personnel (a naval manager can, potentially, manage a project being executed outside of a naval installation as an extramural project).
3. Fabrication. Making up data or results without scientific or historical basis 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 an investigation is warranted.
7. Intramural. Refers to research-related activities performed within naval installations by naval personnel. In similar manner, there may be a modifier following use of the noun, "intramural," to define the following situations: intramural DoD research refers to research related activities performed within DoD installations by DoD personnel; intramural component research refers to research related activities performed within either naval, Air Force, or Army installations.
8. 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.
9. Plagiarism. The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

10. Research. A systematic investigation, including research development, testing and evaluation, designed to develop, or contribute to generalizable knowledge. Activities that meet this definition constitute research, whether or not they are conducted, or supported under a program that is considered research for other purposes. For example, demonstration, service, and quality control/quality assurance programs may include research activities. This includes all fields of academic and professional research, such as, but not limited to, economics, education, history, languages, linguistics, medicine, psychology, physical sciences, social sciences, statistics, and research involving human subjects, or animals regardless of the funding appropriation used to support it.

11. Research Institution. All organizations using Navy Medicine resources (including funds, personnel, equipment, facilities, and other resources) for research or research-related activities. Research institutions include, but are not limited to, Navy Medicine MTFs, intramural research laboratories, federally funded research and development centers affiliated with the DoD, colleges and universities, national user facilities, industrial laboratories, and other research institutes, centers, or organizations.

12. 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.

13. Research Record. The record of data or results that embodies the facts resulting from academic, professional, or scientific inquiry of any discipline. 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.

14. RCR. 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.

PRINCIPLES OF RESEARCH ETHICS AND INTEGRITY

References:

- (a) Institute of Medicine, The Responsible Conduct of Research in Health Sciences, 1989
- (b) National Academy of Sciences. Responsible Science: Ensuring the Integrity of the Research Process 1992
- (c) 1990 National Institutes of Health (NIH) Requirement for Instruction in the Responsible Conduct of Research in National Research Service Award Institutional Training Grants. As found in the NIH Guide for Grants and Contracts. Updated June 17, 1994 (Volume 23, Number 23)
- (d) 65 FR 76262
- (e) Public Health Service (PHS) Instruction in the Responsible Conduct of Research, December 1, 2000
- (f) 42 CFR §50 and §93
- (g) DoD Instruction 3216.02 of 8 November 2011
- (h) DoD Instruction 3210.7 of 14 May 2004
- (i) SECNAVINST 3900.39D
- (j) SECNAVINST 3900.38C
- (k) Public Law 110-69
- (l) Institute of Medicine, Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct. National Academies Press, 2002
- (m) BUMEDINST 3910.2

1. The principles of research ethics have developed from diverse historical sources, as found in references (a) through (l) of this enclosure, but coalesce around four general areas of academic and professional commitment:

a. Academic and professional excellence including, but not limited to: personal integrity and honesty, maintaining academic/discipline-specific standards and methodologies, continuous scholarly and professional formation, peer review, and openness to scholarly critique/quality improvement, substantive and effective mentoring, and sound publication practices and responsible authorship.

b. Ethical obligations and compliance responsibilities for research protections including areas such as, but not limited to: human subject protections, animal welfare, environmental protections and safety, sound personnel practices, protections against undue influence, and data integrity.

c. The ongoing development of the institution and its services including areas such as, but not limited to: mission relevance and adaptation/expansion, discovery and invention in intellectual property and technology transfer, support for the translation of research efforts for public benefit, effective research collaborations and academic interdisciplinary, and international and cross-cultural enrichment.

d. Preservation of public trust including areas such as, but not limited to: compliance with sponsor and socio-cultural requirements, financial stewardship, appropriate and transparent management of conflicts of interest and commitment, refusal to engage in research misconduct and a commitment to report all such matters to legitimate authority.

2. Under the broad discipline of research ethics and the representative areas cited above, specific content and requirements regarding research integrity and the responsible conduct of research are in continual development. Research integrity content is distinct from, but supplemental to, regulations regarding human research protections and animal welfare, per references (i) and (j) of this enclosure. Within the broad discipline of research ethics, all of these areas complement each other. However, it is important that personnel maintain clarity about the distinct nature of each and comply with their unique regulatory requirements.

3. In addition to fulfilling basic regulatory compliance requirements in research integrity and the responsible conduct of research, all personnel will foster and promote a culture of integrity for the conduct of research within their institutions, in following the Institute of Medicine (IOM) principles found in reference (l) of this enclosure and in complying with the requirements found in reference (m) of this enclosure.

NAVY MEDICINE RESEARCH INTEGRITY PROGRAMS

Reference:

- (a) Institute of Medicine, Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct, National Academies Press, 2002

1. Chief, BUMED is the institutional official with final authority and responsibility for all matters relative to research integrity, RCR education, and research misconduct in Navy Medicine.
2. Research integrity leader is established to assist Chief, BUMED with implementation and oversight of Navy Medicine responsibilities enterprise-wide. Responsibilities are based upon principles developed by the IOM, per reference (a) of this enclosure. The research integrity leader:
 - a. Assists the Chief, BUMED in areas of research ethics, but not including areas specific to regulations pertaining to human and animal research.
 - b. Promotes mutual support, shares subject matter expertise, develops and shares best practices, promotes educational enrichment, and fosters continuous quality improvement and communication.
 - c. Coordinates/promotes communication; shares subject matter expertise and best practices among commands and within BUMED.
 - d. Provides subject matter expertise and strategic assistance to COs for the development and quality improvement of local procedures in implementing this instruction.
 - e. Assists with the development of local RCR educational initiatives, per enclosure (4).
 - f. Promotes, designs, develops, and/or provides relevant lectures, seminars, workshops, courses, conferences, and diverse educational resources as may be useful or requested in relevant research ethics areas outside of specific regulations pertaining to human and animal research.
 - g. Coordinates communications to the Chief, BUMED, and among relevant BUMED offices, and subordinate commands for all matters relative to instances of research misconduct.
 - h. Serves as the BUMED action officer for all research misconduct investigation and adjudication reports being forwarded to the Chief, BUMED and/or higher authority.
 - i. Coordinates processes and procedures in the event of research misconduct relative to BUMED assigned personnel.

j. Coordinates processes within BUMED for research misconduct that must be forwarded to the BUMED-level, per enclosure (5), paragraph 1k.

k. Is the Chief, BUMED's liaison officer with extramural agencies regarding research integrity, RCR education, and matters relative to research misconduct.

3. Echelon 3 Commanders and Echelon 4 COs will:

a. Implement this instruction, actively promoting research integrity and ethics education participation, and establish/maintain processes to meet the guidance contained in this enclosure.

b. 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. A suitably qualified individual may be a military member or Federal employee, with the capability to direct inherently governmental functions and to integrate research integrity services as a part-time collateral duty within relevant, already existing, or newly created programs, or departments. Hiring of new personnel is not intended. Echelon 3 commanders are to ensure that subordinate commands are provided with sufficient resources to meet the requirements of this instruction within their areas of responsibility. Every attempt should be made to avoid additional costs and duplication of effort. Any command that anticipates significant, unexpected costs may consult the BUMED Research Integrity Leader to explore strategies.

4. Echelon 3 and Echelon 4 Research Integrity Officers will:

a. Coordinate local research integrity services per enclosure (3), paragraph 2b, and assist the CO with meeting the goals and requirements of this instruction.

b. Assist the commander or CO with the processes to meet research misconduct incidents detailed in enclosure (5).

c. Serve as the local point of contact with the BUMED-M2.

RESPONSIBLE CONDUCT OF RESEARCH EDUCATION

References:

- (a) 1990 National Institutes of Health (NIH) Requirement for Instruction in the Responsible Conduct of Research in National Research Service Award Institutional Training Grants. As found in the NIH Guide for Grants and Contracts. Updated June 17, 1994 (Volume 23, Number 23)
- (b) Public Health Service (PHS) Instruction in the Responsible Conduct of Research, December 1, 2000 (suspended)
- (c) DoD Instruction 3216.02 of 8 November 2011
- (d) DoD Instruction 3210.7 of 14 May 2004
- (e) SECNAVINST 3900.39D
- (f) SECNAVINST 3900.38C
- (g) Public Law 110-69
- (h) Institute of Medicine, Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct, National Academies Press, 2002

1. Effective RCR education is an important goal and is addressed in diverse regulations and recommendations, per references (a) through (h) of this enclosure. The National Institutes of Health (NIH), Department of Health and Human Services (DHHS) initiated such requirements, per reference (a) of this enclosure. In 2000, the DHHS Office of Research Integrity (ORI) specified requirements further and issued reference (b) of this enclosure.

2. Although suspended as a regulatory requirement, reference (b) has become a substantive guidance for Federal agencies and non-DHHS awardees to address nine core RCR areas. These areas include: (1) acquisition, management, sharing, and ownership of data; (2) conflict of interest and commitment; (3) human subjects; (4) animal welfare; (5) research misconduct; (6) publication practices and responsible authorship; (7) mentor/mentee responsibilities; (8) peer review; and (9) collaborative science. In addition, other critical areas that affect research integrity have emerged over time, e.g., financial stewardship, undue influence, interdisciplinary cooperation, globalization and multiculturalism, sponsored research regulatory requirements, institutional mission development/relevance, and sound strategic planning.

3. In two of these areas, human research protections and animal welfare, education and training requirements exist under the authority of references (e) and (f) of this enclosure. While commanders and COs must, otherwise, ensure compliance with the requirements arising from references (e) and (f) of this enclosure; and as required by the Department of the Navy Human Research Protections Program, guided by the BUMED Director of Human Research Protections and guided by the Navy Director of Veterinary Affairs, human research and animal research subject matter and training requirements are outside the scope of this instruction.

4. RCR education, in areas outside of human and animal research, benefits institutional compliance and can enrich professional development significantly. One important RCR area is research misconduct. Due to its particularly critical importance, commanders and COs must require the completion of some form of educational awareness activity regarding research misconduct by anyone who potentially could be an author, or contributor on a research publication or data report on areas critical to command knowledge and processes. Such education or training can be either in-person, Web-based, or completed as part of an audio, or printed source review with subsequent registry of such review with title and date. A recommended initial or basic educational source is reference (h) as listed at the beginning of this enclosure. The BUMED Research Integrity Leader will assist COs, and supply information about content and appropriate educational and training resources that will sufficiently meet professional personnel needs.

5. In consultation with in-house research integrity officers, COs should determine, at their discretion, other individual RCR subject areas that may be beneficial in their context and for the research disciplines conducted in their programs. RCR education should be flexible enough to meet diverse needs and roles. Creative integration into existing educational programs is strongly encouraged.

6. RCR content can be chosen from topics found in paragraph 2, enclosure (4), or from other sources. In addition to traditional content, topic areas should meet local and emerging needs. Commands may utilize existing programs of instruction, both traditional and on-line. Programs should meet the general principles of adult learning, contain substantive information, and promote ethics and critical thinking above and beyond minimal behavioral compliance. RCR educational offerings may be applicable for graduate professional education hours. BUMED-M2 officer will assist in all areas and provide COs with pertinent information about beneficial and appropriate no-cost, online resources.

7. RCR programs will include initial and recurrent education on research ethics and integrity. To ensure common awareness of standards and responsibilities, new personnel should complete the initial education within the first quarter of service. Initial education minimum experience should include completion of the Collaborative Institutional Training Initiative module on RCR. Subsequent training can include updates of this module, or documented review of published guidance on research ethics, and research integrity from independent academic, and professional institutions such as the Institute of Medicine, U.S. Department of Health and Human Services, U.S. Public Health Service, NIH, or peer reviewed major publications on the subject area from major academic institutions. Education received at previous duty stations should be credited. Time between recurrent education experiences should be reasonable. To reduce time and effort burdens, yet assist personnel in remaining current, it is recommended that recurrent RCR education be expected no more than once a year and no less than once every 3 years. Implementation of all of these measures is at the discretion of the CO. Recommended sources to meet minimum standards of such periodic education updates are publications from the

National Academy of Medicine and/or the NIH, including any updates of previously reviewed publications from these bodies. All references provided in enclosure (4) should be readily available within the compendium of materials maintained by the RCR program at the command-level.

8. To assist individuals and their professional development, completion of educational offerings should be credited in appropriate records.

9. BUMED Research Integrity Leader will serve as the BUMED RCR subject matter expert, except for any content and requirements regarding human and animal research protection compliance. For RCR subject areas outside of human and animal research protection compliance, the BUMED Research Integrity Leader may sponsor, provide, or promote relevant educational events, or develop, and distribute applicable educational tools as may be beneficial, or requested. The BUMED Research Integrity Leader will be available to provide strategy and guidance to COs for RCR content and learning standards.

RESEARCH MISCONDUCT

References:

- (a) DoD Instruction 3210.7 of 14 May 2004
- (b) SECNAVINST 3900.39D
- (c) SECNAVINST 3900.38C
- (d) SECNAVINST 5370.7D
- (e) SECNAV M-5210.1 of 20 Jan 2012

1. General Principles

a. Research misconduct violates the integrity of research, adversely affects research benefits, and erodes the public trust. Navy Medicine maintains a zero-tolerance policy regarding research misconduct. All personnel must comply with this instruction and reference (a) of this enclosure. Personnel who commit research misconduct may be subject to disciplinary action.

b. Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or differences of opinion. It must represent a significant departure from accepted practices of the relevant research community. It must have been committed intentionally, knowingly, or recklessly.

c. The reporting requirements detailed in this enclosure do not relieve other obligations for the reporting of research misconduct. This includes the reporting of research misconduct involving human research, or animal research protocols under the authority of references (b) and (c) of this enclosure. The following pertain:

(1) To ensure diverse research oversight requirements are met without conflict or confusion, the BUMED Research Integrity Leader will consult with the BUMED Director of Research Protections, and/or the BUMED Director of Veterinary Affairs (as pertinent), upon receipt of any investigation or adjudication notices or reports which bear upon human or animal research activities.

(2) If research misconduct occurs on a human or animal research protocol, the BUMED Research Integrity Leader, the BUMED Director of Research Protections, and/or the BUMED Director of Veterinary Affairs will mutually collaborate to ensure all requirements are successfully met.

(3) The BUMED Research Integrity Leader will work with and ensure that Medical-Legal Affairs (BUMED-M00J) and Public Affairs Office (BUMED-M00P) are informed in all instances and will comply with directives as given.

d. To counter the emergence of research misconduct, two areas are required and a third is strongly recommended to provide professional growth and development. In that order, these are:

(1) Prevention: Prevention strategies and tactics must include educational and other awareness activities, systems of academic and/or professional mentoring and consistent zero tolerance regarding research misconduct.

(2) Correction: Allegations of research misconduct require inquiry. If substantiated, a formal investigation follows. If proven, adjudication is required. All such processes must be carried out following reference (a) and enclosure (5), paragraphs 2 and 3.

(3) Amelioration: When research misconduct has been found, COs will encourage prudent and appropriate initiatives which can restore professional trust.

e. 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.

f. To implement, oversee, and ensure the processes detailed in this enclosure for the prevention, correction, and amelioration of research misconduct, each CO will appoint an appropriately qualified research integrity officer within the command. The research integrity officer's role is detailed further in enclosure (3).

g. Per reference (d) of this enclosure, 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.

h. 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.

i. Commanders and COs are encouraged to seek counsel and advice from a Navy Medicine attorney as needed.

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

k. In cases where a command is unable to process an allegation, such as due to unavailability of competent experts, or due to potential conflicts of interest, such as 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, Chief, BUMED, with advice from the BUMED Research Integrity Leader and BUMED-M00J as needed, will determine how the allegations will be resolved.

2. Research Misconduct in Intramural Efforts

a. Initial Reporting. Personnel who become aware of potential research misconduct must report such concerns to the command's research integrity officer, whose role is defined in enclosure (3), paragraphs 3 and 4 and in paragraph 1f above.

b. 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 nor 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.

c. 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 SMEs, 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.

d. 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 echelon 3 Judge Advocate General and/or General Counsel 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.

e. 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-M00J, Medical-Legal Affairs to review and advise Chief, BUMED. Chief BUMED will be the final authority in such matters.

f. Consultation. The BUMED Research Integrity Leader will be available for consultation at all stages of due process.

g. Retention. Per reference (e) of this enclosure, all hard copy and/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.

3. Research Misconduct in Navy Medicine 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 Navy Medicine research misconduct per paragraph 1 above. All award instruments must reference this instruction 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 reference (a) of this enclosure, 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).

EXTRAMURAL RESEARCH

References:

- (a) 65 FR. 76262
- (b) DoD Instruction 3210.7 of 14 May 2004
- (c) 1990 National Institutes of Health (NIH) Requirement for Instruction in the Responsible Conduct of Research in National Research Service Award Institutional Training Grants. As found in the NIH Guide for Grants and Contracts. Updated June 17, 1994 (Volume 23, No.23)
- (d) 42 CFR §50 and §93
- (e) Public Law 110-69

1. Per reference (a) of this enclosure, each Federal agency has responsibility for implementing policy and establishing norms regarding research integrity and countermeasures, in the event of research misconduct.
2. Per reference (b) of this enclosure, Navy Medicine activities that receive research funds from extramural agencies, must comply with the requirements of the awarding agency, in addition to this instruction.
3. Navy Medicine activities that are recipients of DHHS funding must comply with all relevant requirements arising from references (c) and (d) of this enclosure. Depending upon the direction of relevant DHHS program officers, such requirements may include receiving "Assurances" from the DHHS ORI, per paragraph 301 of reference (e) of this enclosure. In those instances where ORI Assurances are required, COs will note with due diligence that ORI assurances are distinct/separate from and unrelated to the Federal wide assurance given by the DHHS Office of Human Research Protections.
4. For efforts funded by the National Science Foundation, the provisions of reference (e) of this enclosure, for RCR education must be met, as determined by relevant program officers of that agency.
5. If an extramural agency requires copies of local policy for review or approval, the submission of this instruction suffices. Extramural agency questions regarding the same are to be directed to the BUMED Research Integrity Leader.
6. Commands should contact the BUMED Research Integrity Leader for any questions and concerns regarding compliance with extramural requirements, especially if such requirements appear to be in conflict.

ACRONYMS

BUMED	Bureau of Medicine and Surgery
CO	Commanding Officer
DHHS	Department of Health and Human Services
DoD	Department of Defense
IOM	Institute of Medicine
MTF	Medical Treatment Facility
NIH	National Institutes of Health
ORI	Office of Research Integrity
RCR	Responsible Conduct of Research
SME	Subject Matter Expert