



DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
2300 E STREET NW
WASHINGTON DC 20372-5006

IN REPLY REFER TO
BUMEDINST 6500.3
BUMED-M00E
25 Jun 2009

BUMED INSTRUCTION 6500.3

From: Chief, Bureau of Medicine and Surgery
To: All Ships and Stations Having Medical Department Personnel

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

Ref: (a) Federal Register, Volume 65, page 76262, December 6, 2000, "Federal Policy on Research Misconduct," current edition
(b) DoD Directive 3216.02 of March 25, 2002
(c) DoD Instruction 3210.7 of May 14, 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
(i) SECNAV M-5214.1 of December 2005

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

1. Purpose

a. To establish Navy Medicine strategic policy per regulations found in references (a) through (f) for the promotion of research integrity, continuing education in the 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 assisting the Chief, BUMED, Echelon 3 commanders, and commanding officers to meet goals, objectives, and Department of Defense (DoD) and other applicable requirements.

2. 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 1980's. 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 patient-centered health care and Force Health Protection and Readiness.

3. Applicability

a. All Navy Medicine Medical Treatment Facilities, research laboratories, ships, stations, commands, and their subordinates;

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

c. All Navy Medicine civilian and military employees;

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.

4. Scope. This instruction encompasses all Navy Medicine research efforts and programs, regardless of discipline or level, and provides strategic guidance. The requirements of this instruction do not replace, but supplement requirements for human research protections, the use of animals in research and clinical investigations program administration, per references (d) through (f).

5. Definitions. See enclosure (1).

6. Policy

a. It is the policy of Navy Medicine that all personnel will uphold the highest principles of ethics promoting research integrity and the responsible conduct of research 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.

7. Responsibilities

a. Chief, BUMED:

(1) Is the Navy Medicine Institutional Official for the purposes of this instruction;

(2) Establishes the Navy Medicine Research Integrity Programs Network (RIPN) as detailed in enclosure (3);

(3) Directs Echelon 3 commanders and commanding officers with responsibility for the implementation of this instruction;

(4) Reports serious research misconduct to higher authorities, as required.

b. BUMED Special Assistant for Ethics and Professional Integrity (EPI):

(1) Is the Navy Medicine Executive Research Integrity Officer (ERIO) and Director, RIPN; assists the Chief, BUMED with the implementation of this instruction, per enclosure (3);

(2) Serves as the Navy Medicine subject matter expert relative to research ethics and research integrity, but not including subject matter relative to human or animal research. Represents the Chief, BUMED to extramural agencies regarding research integrity, RCR education, and research misconduct prevention, correction, and amelioration;

(3) Is the point of contact for reporting investigations and adjudication of research misconduct to the Chief, BUMED;

(4) Provides subject matter expertise to Echelon 3 commanders and commanding officers for the implementation of this instruction. Provides on-site assistance as may be directed or requested; provides educational leadership and enrichment in specified content areas;

(5) Coordinates BUMED-level processes for research misconduct, as applicable.

c. Navy Medicine Echelon 3 Commanders:

(1) Ensure the implementation of this instruction within their subordinate commands;

(2) Assist the ERIO with promoting RIPN activities and services;

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

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

d. Navy Medicine Commanders/Commanding Officers:

(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, per enclosure (3); assign resources to meet goals and responsibilities;

(3) Assist the ERIO and Echelon 3 commanders with promoting and implementing RIPN activities and services;

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

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

(6) Make requests to respective Echelon 3 commanders for research misconduct support, when requirements cannot be performed within the individual command;

(7) Ensure compliance with applicable extramural agency research integrity requirements, as found in enclosure (6);

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

8. Acronyms. See enclosure (7).

9. Authority. The authority for this instruction is derived from reference (h).

10. Point of Contact. My point of contact is the BUMED Special Assistant for Ethics and Professional Integrity (M00E) who can be reached via e-mail at:
Edward.Gabriele@med.navy.mil.

11. Report. The reporting requirements contained in this instruction are exempt from reports control per reference (i), paragraph 7n.


A. M. ROBINSON, JR.

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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. Fabrication. Making up data or results and recording or reporting them.
3. Falsification. Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
4. Finding of Research Misconduct. The conclusion proven by a preponderance of the evidence that there was research misconduct and that such misconduct represented a significant departure from accepted practices of the relevant research community and has been committed intentionally, knowingly, or recklessly.
5. Inquiry. The stage in the response to an allegation of research misconduct when an assessment is made to determine whether the allegation has substance and an investigation is warranted.
6. Investigation. The stage in the response to an allegation of research misconduct when the factual record is formally developed and examined to determine whether to dismiss the case, recommend for a finding of research misconduct, and/or take other appropriate remedies.
7. Plagiarism. The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
8. 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, some demonstration and service 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.
9. 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 Medical Treatment Facilities, intramural research laboratories, federally funded research and development centers

affiliated with the Department of Defense, colleges and universities, national user facilities, industrial laboratories, and other research institutes, centers, or organizations.

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

11. 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.

GENERAL PRINCIPLES OF RESEARCH ETHICS AND INTEGRITY

- Ref:
- (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) Federal Register, Volume 65, page 76262, December 6, 2000, "Federal Policy on Research Misconduct," current edition
 - (e) Public Health Service (PHS) Instruction in the Responsible Conduct of Research, December 1, 2000
 - (f) 42 CFR 50 and 93, Public Health Service Policies on Research Misconduct; Final Rule, May 17, 2005
 - (g) DoD Directive 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, March 25, 2002
 - (h) DoD Instruction 3210.7, Research Integrity and Research Misconduct, May 14, 2004
 - (i) SECNAVINST 3900.39D, Human Research Protection Program
 - (j) SECNAVINST 3900.38C, The Care and Use of Laboratory Animals in DoD Programs
 - (k) Public Law 110-69, America COMPETES Act of 2007
 - (l) Institute of Medicine. Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct. National Academies Press, 2002

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. Responsibility for preserving the 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 principles found in reference (l) of this enclosure.

THE NAVY MEDICINE RESEARCH INTEGRITY PROGRAMS NETWORK

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

1. The Navy Medicine Research Integrity Programs Network (RIPN)

a. The 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. To assist with these responsibilities, the Chief, BUMED has established the RIPN. The RIPN assists the Chief, BUMED in research ethics areas, but not including areas specific to human and animal research.

b. The Chief, BUMED has established the RIPN to promote mutual support, share subject matter expertise, develop and share best practices, promote educational enrichment, and foster continuous quality improvement and communication. The RIPN services are based upon principles developed by the Institute of Medicine, as found in reference (a) of this enclosure.

c. The BUMED Special Assistant for Ethics and Professional Integrity (EPI) is the Navy Medicine Executive Research Integrity Officer (ERIO). The ERIO is the Director, RIPN. As such, the ERIO develops, coordinates, and promotes all RIPN services. The ERIO:

(1) Coordinates/promotes communication; shares subject matter expertise and best practices among commands and within BUMED;

(2) Provides subject matter expertise and strategic assistance to commanding officers for the development and quality improvement of local procedures in implementing this instruction;

(3) Assists with the development of local RCR educational initiatives, per enclosure (4) of this instruction; and 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 human and animal research;

(4) Coordinates communications to the Chief, BUMED, and among relevant BUMED Special Assistants, BUMED offices, and subordinate commands for all matters relative to instances of research misconduct;

(5) Serves as the BUMED action officer for all research misconduct investigation and adjudication reports being forwarded to the Chief, BUMED and/or higher authority.

d. The ERIO coordinates processes and procedures in the event of research misconduct relative to BUMED assigned personnel.

e. The ERIO coordinates processes within BUMED for research misconduct that must be forwarded to the BUMED level, per paragraph 1j of enclosure (5) of this instruction.

f. The ERIO is the Chief, BUMED's liaison officer with extramural agencies regarding research integrity, RCR education, and matters relative to research misconduct.

2. Local Research Integrity Services

a. Within each command, the commanding officer is responsible for implementing this instruction, actively promoting RIPN participation, and establishing various services to meet the guidance contained in this enclosure.

b. To implement this instruction, it is recommended each commanding officer establish, in some manner, a local research integrity subject matter program or other suitably named entity. Such a resource does not need to be a separate or new entity. A commanding officer can utilize current subject matter experts, and integrate research integrity services within relevant, already existing programs or departments. As in other areas, Echelon 3 commanders must ensure commands are provided with sufficient resources. Every attempt should be made to avoid additional costs and any duplication of effort. Any command that anticipates significant, unexpected costs may consult the ERIO to explore cost avoidance strategies.

c. Each commanding officer must appoint a local research integrity leader. This appointment need not involve additional hiring. The commanding officer can assign research integrity leader responsibilities to a suitably qualified individual's regular or collateral duties following personnel requirements. The individual, however, must be a member of the military, a Federal employee, or a Federal employee equivalent with the capability to direct inherently governmental functions. This individual can be appointed under various titles. Depending upon need, the appointment need not involve full time involvement. The individual should have direct or related subject matter experience, not be at risk of conflict of interest, and not be compromised by undue influence.

d. The command research integrity leader must coordinate local research integrity services per paragraph 2b above, and assist the commanding officer with meeting the goals and requirements of this instruction.

e. The command research integrity leader must assist the commanding officer with the processes to meet research misconduct incidents detailed in enclosure (5) of this instruction.

f. The command research integrity leader can serve as the local point of contact with the ERIO.

RECOMMENDATIONS FOR RESPONSIBLE CONDUCT OF RESEARCH EDUCATION

- Ref: (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 Directive 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, March 25, 2002
- (d) DoD Instruction 3210.7, Research Integrity and Research Misconduct, May 14, 2004
- (e) SECNAVINST 3900.39D, Human Research Protection Program
- (f) SECNAVINST 3900.38C, The Care and Use of Laboratory Animals in DoD Programs
- (g) Public Law 110-69, America COMPETES Act of 2007
- (h) Institute of Medicine. Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct. National Academies Press, 2002

1. Effective responsible conduct of research (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, that was suspended in 2001.

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. Commanders/commanding officers must ensure compliance with the requirements arising from references (e) and (f) of this enclosure; and as directed by the Department of the Navy (DON), Human Research Protections Program (HRPP), the BUMED Special Assistant for Research Protections, and the BUMED Director of Veterinary Affairs. All personnel are to note with due diligence that 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/commanding officers 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. The ERIO will assist commanding officers and supply information about content and appropriate educational resources that will sufficiently meet professional personnel needs.
5. In consultation with in-house research leaders, commanding officers 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 of this enclosure 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. Commanding officers may find it useful for RCR educational offerings to be applicable for graduate professional education hours. The ERIO will assist in all areas, and will provide commanding officers with pertinent information about beneficial and appropriate no-cost, on-line resources.
7. It is recommended that RCR programs include initial and continuing education. To ensure common awareness of standards and responsibilities, it is recommended that new personnel complete the initial education within the first quarter of service. Education from previous duty stations should be credited. Time between continuing education experiences should be reasonable. To reduce time and effort burdens yet assist personnel to remain current, it is recommended that continuing RCR education be expected no more than once a year and no less than once every three years. Implementation of all of these measures is at the discretion of the commanding officer.
8. To assist individuals and their professional development, completion of educational offerings should be credited in appropriate records.
9. The ERIO will serve as the BUMED RCR education leader and subject matter expert, except for any content and requirements regarding human and animal research. For RCR subject areas outside of human and animal research, the ERIO may sponsor, provide, or promote relevant educational events; or develop and distribute applicable educational tools as may be beneficial or requested. The ERIO will be available to provide strategic guidance to commanding officers for RCR content and learning standards, except those regarding human and animal research education and training.

REQUIREMENTS FOR RESEARCH MISCONDUCT

- Ref: (a) DoD Instruction 3210.7, Research Integrity and Research Misconduct, May 14, 2004
(b) SECNAVINST 3900.39D, Human Research Protection Program
(c) SECNAVINST 3900.38C, The Care and Use of Laboratory Animals in DoD Programs
(d) SECNAVINST 5370.7C, Military Whistleblower Reprisal Protection
(e) SECNAV M-5210.1, DON Records Management Manual, November 2007

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 shall comply with reference (a) of this enclosure, and this instruction. 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 Executive Research Integrity Officer (ERIO) will consult with the BUMED Special Assistant for Research Integration and Mission Development, the BUMED Special Assistant for Clinical Research, the BUMED Special Assistant for Research Protections, and the BUMED Director of Veterinary Affairs, upon receipt of any investigation or adjudication notices or reports.

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

(3) The ERIO will ensure the BUMED Office of Medical-Legal Affairs is informed in all instances and will comply with directives as given. The ERIO will work with the BUMED Public Affairs Office, as needed.

d. To counter research misconduct, two areas are required and a third is strongly recommended for 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 shall be carried out following reference (a) and paragraphs 2 and 3 of this enclosure.

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

e. Commanders/commanding officers are responsible for the inquiry, investigation, and adjudication of research misconduct for any instance reported within 5 years of the alleged incident. Commanders/commanding officers may need to pursue older instances 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 commanding officer will appoint an appropriately qualified research integrity leader within the command. The research integrity leader'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, shall be secured. The rights and privacy of those against whom allegations have been made, shall be equally protected.

h. Research misconduct processes will be performed by the command in which the individual who is alleged to have committed research misconduct is currently assigned or employed. 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/commanding officers may use Echelon 3 Judge Advocates General and/or General Counsel as expert resources or oversight officers.

j. Except for urgent public need or the unavailability of all other competent subordinate experts, BUMED will not perform inquiries, investigations, or adjudication of research misconduct for cases at the command level. The Chief, BUMED will determine how the two exceptions noted above will be processed at the BUMED level.

2. Required Procedures for 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 leader, whose role is defined in paragraph 1f of this enclosure.

b. Inquiry. The command research integrity leader 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 leader 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 leader will notify the commanding officer. The commanding officer notifies the respective individual about whom the allegation has been made. The commanding officer, in consultation with the command research integrity leader, appoints an ad hoc committee to conduct a preliminary inquiry. The committee will be chaired by the command research integrity leader 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 commanding officer 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 commanding officer notifies the individual and the matter proceeds to formal research misconduct investigation. For research misconduct matters requiring investigation, the ERIO shall be notified immediately.

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

(2) The commanding officer 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 commanding officer issues with the proceedings, committee members that may have conflicts of interest, or other matters that may affect objectivity and fairness. The commanding officer 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 leader, sending a complete report to the commanding officer, all within 120 days. If the investigation determines that research misconduct has not been committed, the matter is closed and the individual is notified. Regardless of the findings, a complete report shall be sent immediately to the ERIO. All relevant records will be secured.

d. Adjudication. If an investigation determines that research misconduct has occurred, the commanding officer will notify the individual and implement adjudication processes. If circumstances such as conflict of interest warrant, the commanding officer 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 ERIO.

e. Appeal. Individuals determined to have committed research misconduct can appeal the results of the investigation or adjudication, within 30 days of each action.

f. At all stages, the ERIO will be available for consultation.

g. 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 of 2 years. Upon the expiration of the retention period, all records will be destroyed.

3. Required Procedures for 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 Navy Medicine research misconduct requirements. All award instruments shall reference this instruction within standard terms and conditions.

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 shall 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, commanding officers are required to inform the ERIO, through the Echelon 3 chain of command, of allegations of research misconduct occurring in extramural awards sponsored or contracted by the command.

REQUIREMENTS FOR EXTRAMURAL RESEARCH

- Ref: (a) Federal Register, Volume 65, page 76262, December 6, 2000, "Federal Policy on Research Misconduct," current edition
- (b) DoD Instruction 3210.7, Research Integrity and Research Misconduct, May 14, 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, Number 23)
- (d) 42 CFR 50 and 93, Public Health Service Policies on Research Misconduct; Final Rule, May 17, 2005
- (e) Public Law 110-69, America COMPETES Act of 2007

1. Per reference (a) of this enclosure, each Federal agency has responsibility for implementing policy and norms regarding research integrity and countermeasures, in the event of research misconduct. 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.

2. Navy Medicine activities that are recipients of Department of Health and Human Services (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 Office of Research Integrity (ORI), per paragraph 301 of reference (e) of this enclosure. In those instances where ORI Assurances are required, commanding officers 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.

3. For efforts funded by the National Science Foundation, the provisions of reference (e) of this enclosure, for Responsible Conduct of Research (RCR) education must be met, as determined by relevant Program Officers of that Agency.

4. 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 Executive Research Integrity Officer (ERIO).

5. Commands should contact the ERIO 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
DHHS	Department of Health and Human Services
DoD	Department of Defense
DON	Department of the Navy
EPI	Ethics and Professional Integrity
ERIO	Executive Research Integrity Officer
HRPP	Human Research Protections Program
NIH	National Institutes of Health
ORI	Office of Research Integrity
PHS	Public Health Service
RCR	Responsible Conduct of Research
RIPN	Research Integrity Programs Network