



DEPARTMENT OF THE NAVY

NAVAL MEDICAL CENTER
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NAVMEDCENPTSVAINST 6500.10
14G300

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NAVMEDCENPTSVA INSTRUCTION 6500.10

From: Commander, Naval Medical Center, Portsmouth, Virginia

Subj: RESEARCH ETHICS VIOLATIONS

Ref: (a) JAGINST 5800.7E
(b) NAVMEDCENPTSVAINST 6500.2E
(c) NAVMEDCENPTSVAINST 6500.5C
(d) NAVMEDCENPTSVAINST 6710.10E
(e) DODD 5500.7-R
(f) 5 CFR 2635.201
(g) Office of Research Integrity Advisory Document of
April 1995
(h) 45 CFR 689

1. Purpose. To define the criteria and procedures for identifying, investigating, and taking action in cases of research ethics violations in medical research. While reference (a) provides clear guidelines for conducting most inquiries and investigations, it does not address issues specific to research ethics. References (b) through (d) establish policies and procedures for the submission, approval, and conduct of medical research at Naval Medical Center (NAVMEDCEN), Portsmouth. These explicit guidelines are based on federal laws and regulations. Deviations from these procedures may constitute violations of those laws and may expose the command to legal action. Accordingly, references (b) through (d) must be adhered to stringently.

2. Cancellation. NAVMEDCENPTSVAINST 6500.6B

3. Scope. This instruction applies to the core medical center and all outlying clinics which comprise the NAVMEDCEN command.

4. Background. Scientific investigation and clinical research are two important missions of NAVMEDCEN in support of its role as a teaching hospital. Meaningful research demands the highest levels of integrity and honesty, concepts which are clearly and thoroughly discussed in reference (e). This includes both the ethical treatment of human and animal experimental subjects and the acquisition, interpretation, and publication of the

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resulting information. Deviations from those procedures and policies outlined in references (b) through (f) will be promptly and fully investigated. This instruction details the responsibilities and procedures for reporting and investigating instances of ethics misconduct in scientific and clinical investigation at NAVMEDECEN. Of particular concern are areas addressed in reference (f). Other programs on the issue of scientific misconduct have been addressed in references (g) and (h) and provide non-military perspectives on the subject.

5. Definitions

a. Ethical Violations or Misconduct. Dishonest management of clinical investigation or research and ethical violations are laid out in the Declaration of Helsinki and the Belmont Report. Examples of violations include failure to properly obtain informed consent for human experimentation, failure to reduce the amount of risk the subject is exposed to, misleading subjects, not allowing the subject to withdraw at any time, the conduct of scientific research or clinical investigation without proper approval, and the receipt of gifts or grants not accepted by appropriate Naval authority.

b. Preliminary Inquiry. The directed, but informal, gathering of information conducted per section 0204 of reference (a) to determine whether reasonable suspicion of scientific fraud or misconduct exists. A preliminary inquiry may result in dismissal of the allegation as unfounded or the initiation of a full investigation.

c. Investigation. A formal inquiry into allegations of scientific fraud or misconduct conducted per section 0209 of reference (a).

d. Investigating Officer. An individual assigned to conduct an inquiry or investigation and collect information to determine whether reasonable suspicion of scientific fraud or misconduct exists.

6. Responsibilities

a. Principal and Associate Investigators. The Principal Investigator (PI) is primarily responsible for the ethical conduct of a research study and for the ethical behavior of all associate investigators (AI) regarding any work performed on the study. Additionally, all investigators are to perform all scientific and clinical investigations with proper regard to

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scientific validity, complete study documentation, protection for human and animal subjects, proper stewardship of gifts and services proffered to the U.S. Government as part of a monitored and properly documented research program, and interpretation and presentation of the resulting data in a manner that conforms to the highest standards of scientific integrity.

b. All NAVMEDCEN Personnel. Notify the Head, Clinical Investigation Department (CID) or the Staff Judge Advocate of any real or suspected fraud or scientific misconduct.

c. Head, CID. Ensure an appropriate inquiry is conducted for each instance of alleged ethical violation or misconduct, and that strict confidentiality of sources and investigators is maintained at all times.

d. Members of the Institutional Review Boards or Institutional Animal Care and Use Committee. Review the results of the inquiry and/or investigation process as requested by the Head, CID and maintain strict confidentiality when doing so.

e. Staff Judge Advocate. Assist the Investigating Officer in conducting inquiries or investigations per applicable regulations, and ensure full due process during the conduct of the same.

f. Investigating Officer. Conduct inquiries and/or investigations into allegations of ethical violations as directed by the Head, CID and per reference (a).

7. Procedures

a. Initial Response to Allegations of Misconduct

(1) When notified of an alleged instance of ethical violation or misconduct, the Head, CID will determine whether the information in the allegation justifies further investigation. In making this determination, personal judgment and proper concern for the confidentiality and protection of both the persons making the allegation and the investigator will be exercised. However, the specific mechanism for looking into these allegations will be at the sole discretion of the Head, CID.

(2) If the Head, CID determines that no further investigation is warranted, the matter may be terminated. In this case, no permanent record will be kept.

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b. Preliminary Inquiry

(1) If warranted, the Head, CID may, at his/her discretion, appoint an officer to conduct a preliminary inquiry. Upon the appointment of said officer, the PI and the Commander will be immediately notified in writing. The investigating officer will treat all material collected as confidential. Paragraph 0204 of reference (a) provides guidance regarding the conduct of the preliminary inquiry.

(2) If the investigating officer finds that there is insufficient justification for a formal inquiry, and if the Head, CID concurs, the matter may be terminated and any relevant records will be destroyed.

c. Formal Investigation/Inquiry

(1) If the investigating officer concludes that a formal inquiry is warranted, and the Head, CID concurs, the Commander and PI will be notified, in writing, of that fact and the investigating officer's records will be preserved and secured. Paragraph 0209 of reference (a) provides guidance on the conduct of the investigation.

(2) The investigating officer will be appointed by the Commander, based upon recommendations provided by the Head, CID. This person may be the person who conducted the preliminary inquiry.

(3) If the determination is made that ethical violations did not occur, any minutes will be secured in confidentiality, along with copies of supporting data and testimony (where appropriate) and maintained in the CID for a period of 3 years.

(4) If a finding of ethics violation is made, a report will be prepared which will then be reviewed and signed by the Head, CID and the Commander, and will then be forwarded to Department of the Navy (DON) Human Research Protection Program (HRPP) at the Bureau of Medicine and Surgery (BUMED). The subject-named member accused of ethical violation will be given the opportunity to comment upon the completed formal investigation before it is forwarded to the Commander. At a minimum, further research under the project in question will be temporarily suspended. The suspension will be communicated in writing (observing confidentiality at all times) to appropriate agencies and sponsors.

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d. Possible Disposition

(1) In deciding what additional actions are appropriate when misconduct is found, the investigating officer will consider factors as:

- (a) The seriousness of the violation.
- (b) Whether it was deliberate or careless.
- (c) Whether it was an isolated event or part of a pattern.

(2) The investigating officer may recommend any corrective or administrative actions considered appropriate. Options include, but are not limited to:

- (a) A letter of reprimand to the individual.
- (b) Requiring, as a condition of an award, that an individual or work area obtain special prior approval of particular research efforts for a specified period.
- (c) Requiring, for a specified period, that an official other than those who have committed the violation certify the accuracy of pertinent reports or provide assurance of compliance with particular policies, regulations, guidelines, or special terms and conditions.
- (d) Restricting, for a specified period, designated activities or expenditures under an active award.
- (e) Requiring, for a specified period, special reviews of all requests or funding from an affected individual or work area to ensure steps have been taken to prevent repetition of the misconduct.
- (f) Immediate suspension or termination of an active award.
- (g) Suspension of an individual or work area from participation in Clinical Investigation and Research programs for a specified period after further proceedings under applicable regulations.
- (h) Prohibition of participation of an individual as a reviewer, advisor, or consultant for a specified period.

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(i) Prosecution for violations of the Uniform Code of Military Justice.

(j) No action.

(k) Adverse personnel action.

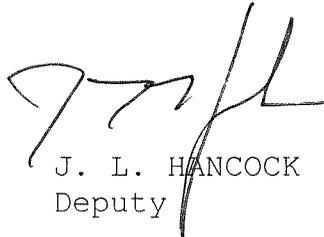
(3) The Head, CID may choose to take interim actions which may include, but are not limited to:

(a) Totally or partially suspending an existing protocol approval/funding.

(b) Totally or partially suspending eligibility for Clinical Investigation protocol approval/funding.

(c) Restricting particular research activities, for example, to protect human or animal subjects.

(d) Requiring special certifications, assurances, or other administrative arrangements to ensure compliance with applicable regulations.



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Distribution:

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