



DEPARTMENT OF THE NAVY
NAVAL MEDICAL CENTER
34800 BOB WILSON DR.
SAN DIEGO, CALIFORNIA 92134-5000

IN REPLY REFER TO:

NAVMEDCEN SDIEGOINST 1600.2
AVA

01 APR 2006

NAVMEDCEN SDIEGO INSTRUCTION 1600.2

From: Commander

Subj: SCIENTIFIC MISCONDUCT

Ref: (a) JAGINST 5800.7C
(b) NAVMEDCEN SDIEGOINST 6500.4D
(c) NAVMEDCEN SDIEGOINST 6500.5B
(d) NAVMEDCEN SDIEGOINST 6500.2A
(e) NAVMEDCEN SDIEGOINST 6500.7A
(f) NAVMEDCEN SDIEGOINST 6710.16D
(g) DOD Directive 5500.7R
(h) 5 CFR Section 2635.201
(i) Office of Research Integrity Advisory Document of
April 1995
(j) 45 CFR Part 689

1. Purpose. To define the criteria and procedures for identifying, investigating, and taking action in cases of scientific misconduct in medical research. While reference (a) provides clear guidelines for conducting most inquiries and investigations, it does not address issues specific to scientific research. References (b) through (f) establish policy and procedure for the submission, approval, and conduct of medical research at Naval Medical Center, San Diego (NMCS D). 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 (f) must be stringently adhered to.

2. Background. Scientific investigation and clinical research are two important missions of NMCS D in support of its role as a teaching medical center. Meaningful research demands the highest levels of integrity and honesty, concepts which are clearly and thoroughly discussed in reference (g). This includes both the ethical treatment of experimental subjects and the acquisition, interpretation, and publication of the resulting information. Deviations from those procedures and policies outlined in

references (b) through (h) will be promptly and fully investigated. This instruction details the responsibilities and procedures for reporting and investigating instances of misconduct in scientific and clinical investigation at NMCSO. Of particular concern are areas addressed in reference (h). Other programs on the issue of scientific misconduct have been addressed in references (i) and (j) and provide non-military perspectives on the subject.

3. Definitions

a. Fraud. The willful and deliberate fabrication, falsification, or misrepresentation of research data. This includes the deliberate misuse of property or services tendered to the U.S. Navy under the aegis of a clinical investigation protocol for personal gain.

b. Misconduct. Dishonest management of the clinical investigation. Examples include plagiarism, failure to properly obtain informed consent for human experimentation, the conduct of scientific research or clinical investigation without proper approval, and the receipt of gifts or grants not accepted by appropriate naval authority.

c. Preliminary Inquiry. The directed but informal gathering of information conducted per reference (a), paragraph 0204 to determine whether reasonable suspicion of scientific fraud or misconduct exists. The results of a preliminary inquiry can be either to dismiss the allegation as unfounded or to proceed to a full investigation.

d. Investigation. A formal inquiry into allegations of scientific fraud or misconduct conducted per reference (a), paragraph 0209.

e. 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.

4. 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, they are to perform all scientific and clinical investigations with proper regard to scientific validity, complete study documentation, protection for human 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 NMCS D personnel. To notify the Head, Clinical Investigation Department (CID) or the Command Judge Advocate of any real or suspected fraud or scientific misconduct.

c. Head, CID. To ensure that an appropriate inquiry is conducted for each instance of alleged scientific fraud or misconduct and that strict confidentiality of sources and investigators is maintained at all times.

d. Members of the Institutional Review Board. To review the results of the inquiry and/or investigation process as requested by the Head, CID and to maintain strict confidentiality when doing so.

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

f. Investigating Officer. To conduct inquiries and/or investigations into allegations of scientific misconduct as directed by the Head, CID and per reference (a).

5. Procedure

a. Review by Head, Clinical Investigations Department

(1) When notified of an alleged instance of scientific fraud 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 person(s) making the allegation and the investigator will be exercised. However, the specific mechanism for looking into these allegations will be at the 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.

b. Preliminary Inquiry

(1) If warranted, the Head CID may, at his discretion, appoint an officer to conduct a preliminary inquiry. Upon the appointment of said officer the PI and the Commander, NMCS D will be immediately notified in writing. The investigating officer will treat all material collected as confidential. Reference (a), paragraph 0204 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 NMCS D and the PI will be notified in writing of that fact and the investigating officer's records will be preserved and secured. Reference (a), paragraph 0209 provides guidance on the conduct of the investigation.

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

(3) Should the determination be made that misconduct 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 three years.

(4) Should a finding of scientific misconduct be made, a report will be prepared which will then be reviewed and signed by the Head, CID and Commander, NMCS D and will then be forwarded to the Bureau of Medicine and Surgery. The officer accused of misconduct 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.

e. Possible Disposition

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

(a) How serious the misconduct was.

(b) Whether it was deliberate or merely careless.

(c) Whether it was an isolated event or part of a pattern.

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

(a) Send a letter of reprimand to the individual or department.

NAVMEDCEN SDIEGOINST 1600.2

(b) Require as a condition of an award that for a specified period an individual or department obtain special prior approval of particular research efforts.

(c) Require for a specified period that an official other than those guilty of misconduct certify the accuracy of pertinent reports or provide assurance of compliance with particular policies, regulations, guidelines, or special terms and conditions.

(d) Restrict for a specified period designated activities or expenditures under an active award.

(e) Require for a specified period special reviews of all requests for funding from an affected individual or department to ensure that steps have been taken to prevent repetition of the misconduct.

(f) Immediately suspend or terminate an active award.

(g) Suspend an individual or department from participation in CID programs for a specified period after further proceedings under applicable regulations.

(h) Prohibit participation of an individual as a reviewer, advisor, or consultant for a specified period.

(i) Prosecution for violations of reference (g).

(j) No action required.

(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 CID protocol approval/funding.

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

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

6. Policy

a. Only after careful inquiry will a finding of misconduct be made.

b. A final report will normally be due 30 days from the convening date. Extensions may be granted as necessary. Requests and authorizations for extensions need not be in writing but must be memorialized in the preliminary statement of the Investigating Officer.

c. The Commander may impose administrative sanctions or recommend criminal prosecution based on the findings of the formal investigation.

d. The utmost confidence must be maintained when conducting these investigations to ensure that the reputations of those involved is protected to the maximum extent possible. This is especially critical for those cases where the allegations are found to be unsubstantiated.

7. Action. All NMCS D personnel will ensure that any research efforts maintain the highest standards of scientific integrity and will report occurrences of and concerns about scientific misconduct per this instruction.


R. A. NELSON

Distribution:
Lists 1 and 3