



DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
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WASHINGTON DC 20372-5300

IN REPLY REFER TO:
BUMEDINST 6000.12B
BUMED-M00CR
25 Jun 2009

BUMED INSTRUCTION 6000.12B

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

Subj: CLINICAL INVESTIGATION PROGRAM AND OTHER RESEARCH ACTIVITIES
SUPPORTING GRADUATE MEDICAL EDUCATION, GRADUATE DENTAL
EDUCATION, AND GRADUATE HEALTH SCIENCE PROFESSIONAL
EDUCATION

Ref: (a) DoD Instruction 6000.08 of December 3, 2007
(b) DoD Directive 5000.01 of May 12, 2003
(c) DoD Directive 5535.3 of May 21, 1999
(d) DoD Directive 3216.02 of March 25, 2002
(e) 32 CFR, Part 219
(f) 10 U.S.C., Chapter 55
(g) 10 U.S.C., Chapter 2601
(h) BUMEDINST 4001.4A
(i) 15 U.S.C., Chapter 3710
(j) SECNAVINST 3900.39D
(k) SECNAVINST 3900.38C
(l) BUMEDINST 5721.3B
(m) BUMEDINST 6710.69
(n) BUMEDINST 6500.3
(o) DoD Instruction 5535.8 of May 14, 1999
(p) SECNAV M-5214.1 of December 2005

Encl: (1) Acronyms

1. Purpose. To reissue and establish policy, specify authority and to assign responsibility for implementing reference (a) for the administration and provision of resources for Clinical Investigation (CI) that support graduate education in medicine, dentistry, nursing, and other health sciences. This instruction is a complete re-write and should be read in its entirety.

2. Cancellation. BUMEDINST 6000.12A.

3. Applicability and Scope. This instruction applies to all Navy Medical Treatment Facilities (MTFs) where clinical research is conducted, and to the clinical research conducted therein or under their authority. It does not apply to other Navy research or development programs that support the operational mission of the Navy or Marine Corps using research, development, test, and evaluation funds (e.g., activities funded by Defense Acquisition or conducted under the provisions of references (b) and (c)), except when such research is carried out in an MTF, involves personnel engaged in Graduate Medical Education (GME), Graduate Dental Education

(GDE), or Graduate Health Science Professional Education (GHSPE); and/or is conducted by personnel who have an immediate and continuing primary clinical duty assignment with a Bureau of Medicine and Surgery (BUMED) component health care or maintenance organization providing GME, GDE, or GHSPE.

4. Definitions

a. Clinical Investigation (CI) is any research program, project, task, test, experiment, record review, evaluation, or similar undertaking that collects, organizes, evaluates, or interprets data collected from Department of Defense (DoD) health care beneficiaries, laboratory animals, or *in vitro* tests to study the maintenance of human health, or the prevention, alleviation, treatment, or cure of disease or injury, and whose primary purpose is designed with the intent to develop or contribute to generalized knowledge. This definition does not include: (a) the collection, or evaluation of data for purposes of internal/continuous quality assessment, maintenance or improvement; or (b) research and development programs conducted to support the operational mission of the Navy or Marine Corps.

b. The Clinical Investigation Program (CIP) is a component of BUMED, conducted under authority and direction of reference (a), with oversight directly responsible to the Chief, BUMED. This function supports basic biomedical science and CI projects that collect, organize, evaluate, or interpret data collected from DoD health care beneficiaries, laboratory animals, or *in vitro* tests to study the maintenance of human health or the prevention, alleviation, treatment, or cure of disease or injury, and whose primary purpose is designed with the intent to develop or contribute to the education of medical, dental, or other health care personnel, and in the process, to contribute to the support of the Navy medical mission and to generalized knowledge. CIP encompasses provision of strategic administration, the tactical support of research, and the provision and support of processes to fund clinical investigations supporting GME, GDE, and GHSPE at MTFs.

5. Background

a. GME, GDE, and GHSPE represent formalized education and training programs for individuals who have received their first professional degree in the practice of medicine, dentistry, nursing, or other health science disciplines, (e.g., Pharmacy, Psychology, Physical Therapy, Occupational Therapy, Speech Therapy, Social Work, Radiation Technology, etc.). To meet regulatory standards, these programs are required to provide specific minimum training requirements and are recognized in such achievement through accreditation by a regional or national professional standards and oversight body (e.g., the Accreditation Council for Graduate Medical Education (ACGME) - relative to GME).

b. Graduate education programs are utilized by Navy medical, dental, nursing, and other allied health care personnel to develop basic, expanded, and advanced skills, capabilities, and professional proficiencies. Maintenance of operational Force Health Protection and medical readiness is, in turn, dependent upon optimal provision of the highest standard of health care

delivery. The CIP supports research projects that provide appropriate education, training, and sustainment of skill development of personnel who are involved in health and medical care delivery in military settings. CIP research projects supplement, and may validate, teaching of applied skills and procedures beyond what is available through standard medical, dental, nursing, and allied health care training didactics. The graduate education experience provided by the Navy should include unique subject areas of investigation and be directed toward, not only providing an accredited educational experience, but one containing specific skills for provision of health care services to operational defense personnel.

c. Research is therefore an integral component supporting provision of premier “state-of-the-art” health care in the Navy. Research conducted at MTFs:

(1) Is required for accreditation of GME, GDE, and GHSPE programs;

(2) Provides an organized scientific structure for knowledge acquisition, as well as medical skill development, and should support an academic environment enhancing medical professionalism and credentials on parity with leading civilian institutions;

(3) Generates an atmosphere of scientific inquiry essential to accommodate the development, testing, and evaluation of new insights and technology that benefit the care of active duty personnel, as well as dependent and retired beneficiaries, supports health science education, and provides general contribution to knowledge; and

(4) Improves quality of care for all health care beneficiaries.

6. Policy

a. The Special Assistant for Clinical Research and Director, CIP for the Chief, BUMED is the program manager for Navy CIP; and maintains review authority relative to feasibility, significance, military relevance, and war fighter/beneficiary support, as well as suspension authority over all CI conducted within the CIP, on behalf of the Chief, BUMED.

b. All researchers that receive CIP funding or support, or who meet definitions in paragraph 4a, must comply with this instruction and the requirements of references (a), and (d) through (n). This includes research that is conducted at MTFs or that involves personnel engaged in graduate medical or health science education, or is conducted by personnel whose primary clinical duty assignment is with a BUMED component organization.

c. Per reference (k), all animal protocols involving non-human primates, dogs, cats, and marine mammals must be reviewed and approved by the BUMED Director for Veterinary Affairs, prior to initiation.

d. DoD personnel are prohibited from accepting compensation, in addition to their regular salaries, for conducting research.

e. Only persons entitled to receive care in DoD MTFs, according to reference (f), are eligible to participate as human research subject volunteers, per references (d) and (e), unless other persons are approved under appropriate policies and procedures (e.g., certified Secretary of Defense or Secretary of the Navy Designees). Retired military personnel and dependents may be compensated, when Navy officials determine it appropriate, and when approved by an Institutional Review Board.

f. Data collected, as a result of approved research activity that is subject to this instruction, is the property of the Department of the Navy (DON), and any other use, transfer, retention, or disposal must be cleared, following reference (l). If released, the data must be for the benefit of medical science. When released for publication, 'interpretative findings and opinions must be identified as those of the author(s) and not necessarily those of the United States Navy, the Department of Defense, or the Government of the United States of America.'

g. Clinical research, conducted under the Navy CIP, shall be funded from operating funds from Defense Health Program appropriations provided by Congress. Supplementation of these funds, through support from other Federal and non-Federal sources, is authorized only as provided in this instruction.

h. Support for conduct of joint projects funded from Federal sources external to direct Navy CIP appropriations, shall be regulated by applicable Federal Code and DoD/DON regulations, and structured by a Memorandum of Agreement (MOA) appropriate to the project and the joint interests of the Federal components involved.

i. Support from Non-Federal sources may be received through Cooperative Research and Development Agreements (CRADAs), as provided below; agreements through the Uniformed Services University of the Health Sciences (UHS), as provided below; gifts, as provided below; or reimbursements, as provided below:

(1) Support from non-Federal sources is permitted only when it is consistent with, and promotes the accomplishment of valid CIP objectives.

(2) The recipient of support from non-Federal sources shall comply with applicable Navy regulations and statutes.

j. Navy MTFs may enter into CRADAs, granted and administered through an authorized Navy organization, to conduct clinical investigation studies under the authority of references (c) and (i), and consistent with the provisions of reference (o). CRADAs provide the preferred mechanism to establish collaborative relationships with industry and academic institutions.

k. Navy MTFs may utilize gifts of funds or personal property to provide support for a clinical investigation study under procedures prescribed by references (g) or (h), as applicable.

l. Investigators may not maintain custody of funds or other resources obtained for support of research protocols or activities. Such resources must remain under the control of the comptroller, at the medical or research activity facilitating the research, or in the custody of a third party, specified under an approved Memorandum of Understanding (MOU), or other authorized support agreement.

m. Research protocols are subject to military contingency requirements, and may not compete with available commercial facilities in providing special services to agencies outside the Federal Government.

7. Responsibilities

a. The Chief, BUMED shall:

(1) Establish policy and maintain total program oversight;

(2) Assure the periodic inspection of facilities, identification of areas of non-compliance; recommend appropriate corrective action, and recommend policy changes, as required;

(3) Provide financial allocation through the annual budget process, as available, for research activities at MTFs supporting GME, GDE, and GHSPE program requirements; and

(4) Report the number, content, and funding of CIP grants to the Assistant Secretary of Defense (Health Affairs) annually.

b. The Special Assistant for Clinical Research and Director, CIP for the Chief, BUMED shall:

(1) Advise Chief, BUMED on all budget and implementation issues pertaining to CIP and to BUMED oversight of Clinical Investigation within the Navy. Administer centrally funded aspects of the CIP, including Investigator travel and bulk grants for CIP research funding to MTFs;

(2) Advise and maintain ongoing communication with Commanders/Commanding Officers of Medical and Dental facilities with Clinical Investigation Department (CID) activities regarding local CID productivity, level of customer support/satisfaction, and adherence to established research administration standards;

(3) Prepare annual summary reports for the Chief, BUMED and the Deputy Chief, Office of the Assistant Secretary of Defense (Health Affairs); and

(4) Serve as the liaison and point of contact for official communications with outside funding sources, including other Federal agencies.

c. The Commanders of Navy Medical Regions shall:

(1) Ensure the preparation and submission of annual budget requests to BUMED, through the appropriate Navy Medical Region Command channels, for CIP support of GME/GDE/GHSPE activities within institutions and facilities within their Region, as developed and approved from requests originating from collaboration between the CID and GME/GDE/GHSPE Directors at or supportive of institutions and facilities within the Medical Region they Command;

(2) Oversee the activity, productivity, and adherence to standards of research supported by CID activities within their Region, with input provided by the BUMED CIP Director;

(3) Establish and maintain an Institutional Animal Care and Use Committee(s) (IACUC), if animals are used or intended to be used for research within their Region, per reference (k); and

(4) Establish and maintain a Human Research Protection Program(s) (HRPP) to support CI in their Region that complies with the requirements of references (e), (j), (k), (m), and (n).

d. The Commanders/Commanding Officers of Navy MTFs shall:

(1) Ensure the preparation and submission of annual budget requests, through the Commander of the Medical Region within which their facility is located, for submission to BUMED for CIP support of GME/GDE/GHSPE activities within institutions and facilities within their Command, approved from requests originating from collaboration between the CID and GME/GDE/GHSPE Directors responsible for research support of training within their Command;

(2) Oversee the activity, productivity, and adherence to standards of research supported by CID activities within their Command;

e. The Director, CID at Navy MTFs shall:

(1) Act as the local program manager and central point of contact for individual investigators at the MTF(s) for which they have support responsibility, to include management resources and support responsibility for all Navy institutions and facilities within the Navy Medicine Region to which they are attached;

(2) Support, promote, and manage research through the provision of administrative services, active procurement of resources, and provision of research training and guidance for support of investigators and research projects assigned to the MTF(s) for which they have support responsibility, to include management resources, and support responsibility for all Navy institutions and facilities within the Navy Medical Region to which they are attached;

(3) Collaborate with the MTF leaders of GME/GDE/GHSPE to develop strategy, procedures, and budgets to adequately and effectively support the requirements for maintenance of sufficient research activity for each GME/GDE/GHSPE program located at the MTF(s) within the Navy Medical Region to which they are attached;

(4) Provide one (1) copy of each approved research protocol to the Special Assistant to the Chief, BUMED & Director, CIP within 15 days of each approval;

(5) Prepare an annual report for the Chief, BUMED containing essential information on performance within their area of program oversight (reporting schedule, report content, and format to be provided by the Special Assistant to the Chief BUMED and Director, CIP). The following are areas of content which may be included in the annual report:

(a) Budgeted and unbudgeted income and expenditures for the support of research at the MTF(s) from Program 6 funds, Program 8 funds, Congressionally directed funds, and other extramurally sourced funds (with separation of those that are of Federal Government origin vs. non-Federal origin);

(b) Total number of active human use and animal protocols administered during the fiscal year (FY);

(c) Total number of new and total number of closed protocols administered during the FY;

(d) Total number and category of assignment (staff, GME, GDE, or GHSPE trainee) of all investigators conducting research at the MTF(s);

(e) Total number of peer reviewed publications, and other publications or book chapters authored by personnel attached to their institution; and

(f) Titles of all new and all ongoing active research protocols.

(6) Enforce and comply with higher authority policies.

8. Reports

a. The reporting requirements outlined in paragraph 7a(4) are covered under Report Control Symbol (RCS) D-HA(A)2259, established by reference (a).

b. Report Control Symbol NAVMED 6000-11 is assigned to the reporting requirements contained in paragraph 7e(5), per reference (p), and is valid for three years from the date of this instruction.


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ACRONYMS

ACGME	Accreditation Council for Graduate Medical Education
BUMED	Bureau of Medicine and Surgery
CI	Clinical Investigation
CID	Clinical Investigation Department
CIP	Clinical Investigation Program
CRADAs	Cooperative Research and Development Agreements
DoD	Department of Defense
DON	Department of the Navy
FY	Fiscal Year
GDE	Graduate Dental Education
GHSPE	Graduate Health Science Professional Education
GME	Graduate Medical Education
HRPP	Human Research Protection Program
IACUC	Institutional Animal Care and Use Committee
MOA	Memorandum of Agreement
MOU	Memorandum of Understanding
MTFs	Medical Treatment Facilities
NAVMED	Navy Medicine
RCS	Report Control Symbol
USU	Uniformed Services University of the Health Sciences