



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

IN REPLY REFER TO
BUMEDINST 3910.2
BUMED-M2
30 Jul 2013

BUMED INSTRUCTION 3910.2

From: Chief, Bureau of Medicine and Surgery

To: Ships and Stations Having Medical Department Personnel or Conducting Medical Research Activities

Subj: FINANCIAL MANAGEMENT, INTERNAL CONTROL, AND ACCOUNTABILITY OF MEDICAL RESEARCH ACTIVITIES

Ref: (a) BUMEDINST 6000.12B
(b) BUMEDINST 7050.1B
(c) DoD 7000.14-R (DoD Financial Management Regulations)
(d) GAO/AIMD-00-21.3.1 (Standards for Internal Control in the Federal Government)
(e) DoDD 5000.01 of May 12, 2003
(f) DoDINST 5000.02 of December 8, 2008
(g) Navy Standard Cooperative Research and Development Agreement (CRADA) Handbook, 2nd Edition, February 2009
(h) BUMED Financial Policy Directive 09-03
(i) 31 USC 1517
(j) SECNAVINST 4001.2J

Encl: (1) Definitions/Acronyms

1. Purpose. To establish authority, policy, regulations, and assignment of responsibility for the oversight, administration, and use of funding for medical research (MR) that supports Force Health Protection and beneficiary medical care within Navy Medicine. This document will provide guidance for the administration and management of monies/resources received and expended for conduct of medical research by personnel attached to, working within, or receiving resources from/through the Bureau of Medicine and Surgery (BUMED) and its subordinate commands and directorates.

2. Applicability and Scope. This instruction pertains to all funding provided from BUMED to conduct MR, as well as to funding from external sources for reimbursable MR and investigation activities. These research and investigation activities are referred to hereafter as MR. This instruction applies to all Navy Medicine research facilities (MRFs), medical treatment facilities (MTFs), or field sites (FS) where MR is conducted, from the level of basic science and discovery to translational and clinical investigation; and to clinical research conducted therein or under their authority; and to scientists, medical researchers, and managers involved in design, conduct,

and oversight of such research, and to acquisitions, procurement, and budget personnel engaged in support of MR activities. This instruction also applies to research conducted by entities external to Navy Medicine, but conducted in Navy Medicine facilities or using personnel managed or credentialed by Navy Medicine.

a. All researchers that receive funding or support for projects definable as: MR, Research and Development (R&D), Clinical Investigation Program (CIP); must comply with this instruction. 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. See enclosure (1) for definitions and acronyms.

b. The requirements of this instruction are intended to be consistent with and in support of the references, as well as other existing applicable laws, regulations, and instructions, and should not be interpreted to circumvent or deviate from those existing authorities.

3. Background. Execution of MR requires monies appropriated to fund the specific area and level of effort. These funds are usually appropriated (or designated by the customer, in the case of reimbursable R&D work) for specific MR activities, including infrastructure support for those MR activities. Within the Department of Defense (DoD) such medical efforts are generally funded out of Program 6 or Program 8 funds:

a. Program 6 (P6): R&D. Used to discover and develop medical products such as technology based devices, biochemistry based drugs and biologicals, and intelligence based knowledge and processes. These programs and activities have not yet been approved for operational use. DoD generally funds P6 efforts using Research, Development, Test, and Evaluation (RDT&E) appropriations.

b. Program 8 (P8): Training, Medical, and Other General Personnel Activities. Used for training and education as well as health care of personnel. P8 MR activities include health care maintenance and delivery based medical improvements as well as the CIP. Navy Medicine generally funds CIP efforts using Defense Health Program Operation and Maintenance (O&M) dollars. Although Navy Medicine receives some direct funding to conduct R&D, most of Navy Medicine's R&D work is competitively awarded. Competitively awarded funding is received either via funding authorization document from BUMED, or through reimbursable orders that are placed by DoD or non-DoD customers. Within DoD, individual R&D projects are funded by Congress as specific line items in the DoD and Service budgets. It is a violation of Congressional intent to use R&D project funds for anything other than the specific purpose and category of support for which they were appropriated. Proper execution of R&D projects for non-DoD sponsors at Navy MRFs, MTFs, and FSs requires documentation in a support agreement that must be approved per reference (b). Reference (b) provides detailed guidance on preparing and submitting support agreements for approval. These projects must meet all financial requirements per reference (c), which is available at: <http://comptroller.defense.gov/fmr/>. Approved R&D projects must be properly accounted for in

the Standardized Accounting and Reporting System – Field Level, utilizing project-specific lines of accounting and the standard job order structure as determined by BUMED Accounting (BUMED-M84).

4. Internal Controls

a. The Government Accountability Office, through reference (d), prescribes standards for internal control in the Federal Government as required by the Federal Managers' Financial Integrity Act of 1982. Reference (d) is available at: <http://www.gao.gov/special.pubs/ai00021p.pdf>. These standards provide the overall framework for establishing and maintaining internal control and for identifying and addressing major performance and management challenges and areas at greatest risk of fraud, waste, abuse, and mismanagement. Well designed and effective internal controls provide reasonable assurance that the following objectives are being achieved. Meeting such objectives is to be the standard for each person involved in receiving, managing, and expending financial assets for Navy MR. The objectives are:

- (1) Effectiveness and efficiency of operations,
- (2) Reliability of financial reporting, and
- (3) Compliance with applicable laws and regulations.

b. Reference (d) defines five standards for internal control that represent the minimum level of quality acceptable for internal control in government and provides a basis against which internal controls are to be evaluated:

- (1) Control environment,
- (2) Risk assessment,
- (3) Control activities,
- (4) Information and communications, and
- (5) Monitoring.

c. In addition to these responsibilities, Navy Medicine MR must be in compliance with the further provisions of references (e) and (f), which respectively provide authority and policy for the Defense Acquisition System and operation guidelines for the same. Finally, all financial activity executed within or for BUMED MR and development activities is to comply with the controls set forth in any BUMED financial policy directives as necessary.

5. Policy

a. Compliance. Naval Medical Research and Development Command (NAVMEDRSCHDEVCOM) shall oversee and support the responsibilities of the commander, commanding officers (COs) of the echelon 4 Naval MR activities. Processes and procedures contained in or referenced by this document are mandatory at all BUMED MTFs and R&D activities. Activities will not deviate from them without prior BUMED approval. Guidance provided by other agencies and activities external to BUMED does not constitute authority for deviation from processes outlined in this document unless authority is forwarded under official BUMED cover letter. Conflicting guidance received from external agencies should be forwarded to BUMED through NAVMEDRSCHDEVCOM for review and action. Reviews to ensure compliance will be incorporated into the Managers' Internal Control Program and compliance review criteria.

b. Programming and Budgeting. The DoD uses Planning, Programming, Budgeting, and Execution as the primary tool for determining long and short range budget requirements. While DoD budget formulation is a biennial process, in practice, Congress continues to require an annual budget submission with appropriations being approved just prior to fiscal year (FY) commencement. Activities may have costs properly chargeable to RDT&E and O&M appropriations; accordingly comptrollers at BUMED activities using both appropriations are required to have a firm understanding of both RDT&E and O&M budget processes and timelines. These processes and timelines are to be adhered to by all comptrollers.

c. Accountability and Responsibility

(1) The commander, CO, and OIC of the activity to which the Principal Investigator (PI) is attached, or which is sponsoring the effort through which the funding resource is passing is responsible for execution management of all direct and reimbursable funding for programs at that activity. The subject activity will coordinate uses, distributions, and/or changes in planned investments in intramural and extramural research programs via Program Managers (PM)/ Program Officers at the NAVMEDRSCHDEVCOM or, if so assigned/directed, through PMs at that local activity. Commanders, COs, or OICs of MTFs will additionally comply with the requirements contained in reference (h). The PMs will use integrated process teams (IPTs) composed of requirement developers, resource sponsors, and end-users to ensure that MR programs are effective, requirements-driven, and transitionable to Navy and Marine Corps operational forces.

(2) Deputy Chief, Medical Research and Development (BUMED-M2) will also ensure that Naval MR programs are directed toward meeting Navy and Marine Corps medical requirements, focused on explicit MR and product strategies needed for Fleet/Force readiness and mission effectiveness; and generally invested in requirements-driven programs having little or no significant funding elsewhere in the military, government, and industry for development and/or enhancement of Fleet/Force system capabilities and configurations. BUMED is not

responsible for setting medical requirements, but will facilitate identification and establishment of medical requirements by medical representatives authorized to do so, including the Office of the Chief of Naval Operations staff of the Surgeon General, the Medical Combat Developer, Surgeons of the Fleet Commanders, Marine Corps Combat Development Command, and the Medical Officer of the Marine Corps.

(3) The responsible use of federally procured or managed MR funds requires PIs and PMs to craft technically excellent project proposals that address real Navy/Marine Corps needs or deficiencies; to document plans, modifications, and progress on a routine basis; to continually assess productivity; to implement means for improvement; and to report their work to others through technical and government channels.

(4) PIs and PMs are the key individuals responsible for constructing and maintaining high quality in-house projects. PIs and PMs must concur on project baseline plans and subsequent modifications, and to critically assess progress and keep each other informed of any issues that might impact the MR effort. MR documents (pre-proposals, proposals, documentation, incremental reports, and summary reports) are necessary and effective vehicles for ensuring this communication and for allowing meaningful review by other managers, external scientific peers, sponsors, and government auditors.

(5) All work performed at or through the oversight of Navy Medicine activities must be conducted under an approved project registration, regardless of funding source (i.e., Navy, Marine Corps, Army, Air Force, other Federal agencies, or external partners through appropriate agreements and other legally compliant instruments, etc.). Resources (i.e., funding, personnel, equipment, drugs, material, and devices) intended for one project cannot be diverted to another research project.

(6) Each project proposal must include an obligation phasing plan indicating, by FY quarter, how funding is expected to be obligated in relation to research milestones and deliverables. The proposal must also identify the source of all funds and other resources (including personnel, equipment, travel reimbursement, and work space) used in planning and conducting the project.

(7) By 30 June of each FY, each PM will provide to the Comptroller of the command where research is being conducted, a report for each project managed, detailing:

- (a) The obligation phasing plan for that FY from the initial project proposal.
- (b) An explanation for any variance of more than 2 percent of actual execution versus the obligation phasing plan.

(c) A determination on whether the project remains viable from a research and financial perspective.

(d) Whether additional funds are needed from the research sponsor, or the amount of excess funds that can be returned.

(8) As a general principle, resources (e.g., money, equipment, consumables, manpower, contract services) for one project cannot be used to conduct research on other projects. There may be instances, however, when an exception is warranted (e.g., a piece of unique equipment is purchased for one project and funded out of that project's funds but later, a new project subsequently requires use of that same equipment). In such instances, resources can be used across multiple projects, provided that all of the following occur:

(a) The funding sponsor of each project agrees, in writing, and with concurrence of the research activity Comptroller and/or, in the case of reimbursement for direct costs of research which transits to the activity directly from external sponsors under appropriate agreements (i.e., non-Federal sponsors as further discussed below), the responsible Comptroller of the involved Navy Medicine region, MRF, or MTF to share use of the resource;

(b) A practical and auditable methodology is developed to track use of the resource by each benefiting project (e.g., man hours, equipment usage hours, pro rata allocations);

(c) Each benefiting project pays for the resource according to the above methodology; and,

(d) The written agreement addresses the disposition of the shared resources, assuming any residual value (i.e., who assumes ownership of a piece of equipment at the end of both projects).

(e) Noncompliance with any of these provisions may constitute a violation of Federal statute or DoD, Department of the Navy (DON), or BUMED policy.

d. Comptroller Approval. The Comptroller of the command where the research is being conducted will approve all reimbursable research proposals before work begins.

e. Budgeting Process

(1) The PMs will coordinate with activity Comptrollers, commanders, COs, OICs, and Resource Sponsors to ensure participation in the Program Objective Memorandum (POM) process within which medical science and technology requirements are identified and prioritized as part of the Force Health Protection Future Capabilities document, setting the basis for approving, funding, and executing research projects.

(2) The program guidance which will be developed and applied to the activity portfolio will:

(a) Provide general and specific information regarding DON direction, priority, and funding of research projects by work unit; and

(b) Serve as the basis for the budget submission, review, updating, and approval.

f. Approvals. Budgets will be submitted to the command Comptroller or command designated financial officer for review, finalization, primary approval, and subsequent submission to the next higher financial authority for secondary approval and positioning for audit, as appropriate. Standard audit practices, as disseminated by the Office of the Deputy Chief, Resource Management/Comptroller (BUMED-M8) will be applied to review and oversight of compliance with reference to applicable DoD, DON, BUMED, and standard financial principles.

g. Budget Review and Compliance. It is the responsibility of the PI, PM, and the executing activity Comptroller, to ensure that expenditure of assets falls within the parameters set by the approved budget. Observation and tracking will be conducted both by the PI and the PM on a continuous basis and any anticipated shortfalls or situations of resource inadequacy will be reported immediately to the activity Comptroller and to the NAVMEDRSCHDEVCOM Comptroller.

h. Executive Oversight Officer. Deputy Chief, BUMED-M2 is the executive oversight officer for Navy MR and maintains review authority relative to feasibility, compliance, significance, military relevance, and war fighter/beneficiary support, as well as suspension authority over all projects conducted within MRFs, MTFs, or FSs on behalf of Chief, BUMED.

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

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

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

(3) Navy MRFs and MTFs may enter into CRADAs, granted and administered through an authorized Navy organization to conduct studies under the authority of references as specified. CRADAs provide the preferred mechanism to establish collaborative relationships

with industry and academic institutions. All CRADAs must be developed per reference (g) and reviewed by NAVMEDRSCHDEVCOM prior to final approval. Reference (g) is available at: http://www.onr.navy.mil/en/ScienceTechnology/Directorates/Transition/Technology-Transfer-T2/Partnership-Options/~//media/Files/Transition-Docs/orta/CRADA-HANDBOOK_2009-FEB.ashx.

(4) Navy MTFs may use gifts of funds or personal property to provide support for a study per applicable DoD and DON gift authority. All gifts must be accepted per reference (j) and no Federal employee may solicit a gift.

j. Custody and Control of Funds. Investigators may not maintain custody of funds obtained for support of research protocols or activities. Such funds must remain under control of the Comptroller at the medical or research activity facilitating the research, or in the custody of a third party specified under a support agreement approved by BUMED-M8.

k. Military Contingency. 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.

l. Requests for Waiver from Requirements in this Instruction

(1) A waiver for performing specific processes using a non-standard methodology may be obtained by submission of a waiver request. Waiver requests of a generalized nature will not be approved. Waiver requests must identify:

- (a) Specific procedure requested to be waived,
- (b) Sufficient detail and explanation to provide a clear understanding of the issue and benefits associated with the request,
- (c) Point of contact information for discussing the issue by telephone and/or electronic mail.

(2) Requests for waiver must be submitted by the commander, CO, or OIC under formal command letterhead via the Navy Medicine region and NAVMEDRSCHDEVCOM to BUMED-M8. Requests submitted by other means will be returned without action. Requests received by BUMED-M8 will be confirmed by electronic mail within 3 working days. Confirmation of receipt does not imply approval or authority for deviation from standard procedures. The request will be reviewed and an answer provided by electronic mail within 10 working days. In the event the review process takes longer, an interim response will be provided electronically. A waiver is not considered officially granted until BUMED-M8 has provided formal approval in either written or electronic mail format. A copy of any approved waivers must be maintained at the activity and is subject to review during compliance reviews.

6. Responsibilities

a. Chief, BUMED shall:

- (1) Establish policy and maintain total program oversight; and
- (2) Report the number, content, and funding of MR grants to the Assistant Secretary of Defense for Health Affairs (ASD(HA)) annually.

b. Deputy Chief, BUMED-M8 will:

(1) Develop and oversee implementation of financial policy and internal controls over MR funding, to include ensuring proper custody and stewardship of all funding Navy Medicine receives, issues, or otherwise executes for MR.

(2) Advise Chief, BUMED on all budget and implementation issues and oversight pertaining to MR within the Navy.

(3) Distribute direct funding for R&D and support of CIP executed within Navy Medicine.

c. Director, Headquarters Resource Management (BUMED-M85) will:

(1) Hold responsibility and accountability per reference (i) for administrative control of direct and reimbursable funding, which Navy MR, has allocated to, or through NAVMEDRSCHDEVCOM for further distribution.

(2) Establish, maintain, and monitor internal controls over all direct and reimbursable funding which Navy MR, under NAVMEDRSCHDEVCOM, receives and distributes, to include ensuring compliance with all appropriate laws, regulations, policies, and procedures governing those funds.

d. Deputy Chief, BUMED-M2 will:

(1) Develop guidance and tools for Navy Medicine regions to support development and sustainment of their respective CIP;

(2) Provide executive oversight for Navy MR and maintain review authority relative to feasibility, significance, military relevance, and war fighter/beneficiary support; and

(3) Execute suspension authority, when appropriate, over any projects conducted within MRFs, MTFs, or FSs found to be non-compliant or illegal on behalf of the Chief, BUMED.

e. CO, NAVMEDRSCHDEVCOM will:

(1) Oversee and support the responsibilities of the commanders, COs, and OICs of the echelon 4 Naval MR activities.

(2) With the support of the Comptroller, NAVMEDRSCHDEVCOM, develop an annual submission of required POM requests to the Deputy Chief, BUMED-M8.

(3) Advise and maintain ongoing communication with commanders, COs, and OICs of MRFs and MTFs, OICs of FSs and of dental treatment facilities (DTFs) supporting or conducting MR activities regarding productivity, level of customer support/satisfaction, and adherence to established research administration and financial standards.

(4) Prepare annual summary reports for the Deputy Chief, BUMED-M2; Chief, BUMED; Office of the ASD(HA); and Office of the Assistant Secretary of Defense (Research, Testing and Evaluation) annually, or more often - as requested, on resource utilization including metrics of efficacy, productivity, and adherence to budget.

(5) Act as a liaison and point of contact for official communications with outside funding sources, including other Federal agencies.

f. The Comptroller, NAVMEDRSCHDEVCOM will:

(1) Develop information for annual submission of required POM requests for support of MR projects executed within the NAVMEDRSCHDEVCOM area of responsibility (AOR) to Deputy Chief, BUMED-M8;

(2) Receive direct allotments of funds for medical R&D to be conducted within the NAVMEDRSCHDEVCOM AOR and distribute such funds for execution; and

(3) Provide necessary policy and oversight over all financial resources executed at and distributed by NAVMEDRSCHDEVCOM.

g. Commander, CO, or OIC of each MTF and DTF shall:

(1) Ensure the preparation and submission of annual budget requests through the Commander of the appropriate Navy Medicine region; and

(2) Oversee the activity, productivity, and adherence to standards of research supported by activities within their command.

h. Comptrollers at the Navy Medicine region, MRF, or MTF will:

(1) Oversee and administer the requirements of fund handling and control consistent with DON, DoD, and BUMED policy; including those responsibilities contained in reference (h) and legal requirements, as well as this instruction;

(2) Provide necessary policy and oversight for all financial resources executed within their respective AORs; and

(3) Assure prompt return of unobligated funds to the customer (for reimbursement funds) when the funds expire.

i. The PI, Co-Investigator, and PM at the MRF, MTF, or FS will comply with all requirements of this instruction and of the grant/award regarding use of funds and custody of the assets procured through the use of the funds.

j. The Navy Medicine Inspector General will:

(1) Conduct periodic inspection of facilities,

(2) Identify and investigate areas of non-compliance and recommend appropriate corrective action, and

(3) Recommend policy changes, as required.

7. Records. Records created as a result of this instruction, regardless of media and format, shall be managed per SECNAV Manual 5120.1 of January 2012.



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DEFINITIONS/ACRONYMS

1. Area of Responsibility (AOR)
2. Assistant Secretary of Defense for Health Affairs ASD(HA)
3. Bureau of Medicine and Surgery (BUMED)
4. Clinical Investigation Program (CIP). A specific DoD program, conducted under authority and direction of reference (a), under the oversight of the Commanding Officer, Naval Medical Research & Development Command (NAVMEDRSCHDEVCOM) – Frederick. This function supports basic biomedical science and CIP projects that collect, organize, evaluate or interpret data collected from DoD health care beneficiaries, laboratory animals, or *in vitro* tests to study maintenance of human health or 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 support of the Navy medical mission and to generalized knowledge. CIP encompasses provision of strategic administration, the tactical support of research, and provision and support of processes to fund clinical investigations supporting Graduate Medical Education (GME), Graduate Dental Education (GDE), and Graduate Professional Education (GPE) at medical treatment facilities (MTFs).
5. Commanding Officer (CO)
6. Cooperative Research and Development Agreement (CRADA)
7. Dental Treatment Facility (DTF)
8. Department of Defense (DoD)
9. Department of the Navy (DON)
10. Field Site (FS)
11. Fiscal Year (FY)
12. Medical Research (MR). 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. MR includes Research and Development (R&D) as well as investigations performed under the CIP. MR encompasses provision of strategic administration,

the tactical support of research, and provision and support of processes to fund MR. MR does not include collection or evaluation of data for purposes of internal/continuous quality assessment, maintenance, or improvement.

13. Medical Research Facility (MRF)
14. Medical Treatment Facility (MTF)
15. Naval Medical Research and Development Command (NAVMEDRSCHDEVCOM)
16. Officer in Charge (OIC)
17. Operation and Maintenance (O&M)
18. Principal Investigator (PI)
19. Program 6 (P6)
20. Program 8 (P8)
21. Program Manager (PM)
22. Program Objective Memorandum (POM)
23. Research and Development (R&D). Within DoD, R&D pertains to MR conducted from the level of basic science through multiple transition levels all the way to product release for approved use, implementation or medical intervention for Force Health Protection (FHP), Human Performance Optimization (HPO), disease and injury treatment, tissue reconstruction, or tissue regeneration.
24. Research, Development, Test, and Evaluation (RDT&E)