

Change 125
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To: Holders of the Manual of the Medical Department

1. **This Change** Completely revises Chapter 20, Research and Development.
2. **Action**
 - a. Remove Chapter 20 and replace with the new Chapter.
 - b. Record this Change 125 in the Record of Page Changes.



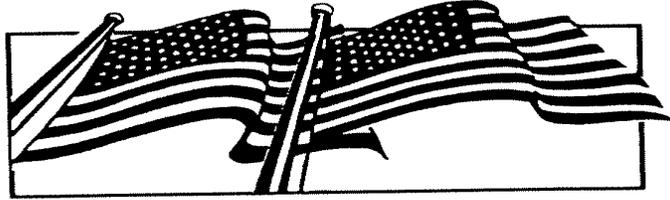
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Chapter 20

Research and Development

Chapter 20

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Section I

GENERAL

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20-1 Policy

(1) The fundamental policy of the Navy Medical Department encourages and supports research and development (R&D) in medical, dental, nursing, and allied sciences. This R&D is directed at the solution of problems affecting the health, safety, selection, and efficiency of Navy and Marine Corps personnel.

20-2 Departmental Responsibilities

(1) **General.** The Assistant Secretary of the Navy for Research, Development and Acquisition (ASN (RD&A)), under the direction of the Secretary of the Navy (SECNAV), exercises responsibility for Department-wide supervision of all research, development, testing, and evaluation (RDT&E) efforts, and appropriations management. The principal advisors for support and assistance are: The Chief of Naval Research, the Chief, Bureau of Medicine and Surgery (BUMED); and SECNAV-designated project managers. The interpretation and promulgation of Department of Defense (DOD) policies and procedures by either SECNAV or ASN(RD&A) provide the framework for planning and implementing the RDT&E Program.

(2) **Medical Department.** Under policy guidance of Chief, BUMED, the management and coordination of the RDT&E programs of the Medical Department of the Navy (DON) are the responsibility of the Director, Navy Medicine Research and Development.

(3) **Chief, BUMED.** The Director, Navy Medicine Research and Development is responsible for the overall management of R&D matters, and:

(a) Serves as senior medical R&D advisor to the Chief, BUMED.

(b) Identifies, defines, and communicates requirements for medical RDT&E consistent with higher authority.

(c) Assesses and oversees RDT&E programs to ensure responsiveness to defined requirements.

(d) Monitors and coordinates Medical Department responsibilities concerning the use and protection of human subjects utilized in studies conducted under the auspices of the DON.

(e) Monitors and coordinates Medical Department responsibilities concerning the use and protection of animals utilized in studies conducted under the auspices of the DON.

(f) Monitors and coordinates Medical Department responsibilities concerning the Clinical Investigation Programs (CIP) at military treatment facilities under the auspices of the DON.

(g) Directs, plans, programs, budgets, and documents Navy Medical Department RDT&E efforts in response to Navy and Marine Corps RDT&E requirements.

(h) Recommends the qualifications, procurement, training, assignment, and distribution of R&D personnel.

(i) Provides professional medical and dental technical guidance in the planning of Navy and Marine Corps RDT&E on weapons systems, life-support systems, and personnel protection.

(j) Coordinates research efforts with other Navy commands and offices, other Government agencies, civilian organizations, and foreign governments.

(k) Provides headquarters oversight for the Naval Medical Research Center (NAVMEDRSCHCEN) and the Naval Health Research Center (NAVHLTHRSCHCEN).

20-3**Scope**

(1) Medical Department R&D programs shall be organized to support Navy, Marine Corps, and Medical Department missions, and shall be directed toward improving and protecting the health, safety, and performance effectiveness of Navy and Marine Corps personnel in operational environments.

(2) Medical Department RDT&E programs shall address medical requirements promulgated by the Chief of Naval Operations (CNO), the Commandant of the Marine Corps (CMC), and the Chief of Naval Research (CNR), following validation by the Chief, BUMED. To meet these requirements and objectives, a broad program of RDT&E shall be maintained in the basic and applied sciences, with major emphasis placed on combat casualty care, casualty prevention, and maintenance of a healthy and fit force.

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Section II

RESEARCH PROGRAM RESPONSIBILITIES

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20-4

Professional Personnel Assignments

(1) The Navy Medical Department sponsors research programs in aviation medicine, diving medicine, submarine medicine, fleet health care, fleet occupational health, infectious diseases, oral and dental health, human performance, and electromagnetic radiation. Research efforts under these programs are conducted at U.S. Navy medical research laboratories located within the contiguous United States, as well as at selected overseas locations. The Director, Navy Medicine Research and Development, will serve as the R&D point of contact for assignments to R&D billets. Personnel of the Medical Corps, Dental Corps, Medical Service Corps, and Nurse Corps are encouraged to contact their appropriate detailers regarding assignment possibilities within the Navy biomedical R&D community. Qualified personnel will be given guidance and aid in securing assignments contingent upon availability of billets and requirements in given programs.

20-5

Program Management

(1) **Structure.** The technical and administrative management of medical RDT&E is accomplished within the planning, programming, and budgeting system. Under this system, RDT&E is categorized under the DOD Program RDT&E Budget Activities and is divided into seven broad categories:

- 1 - Basic Research
- 2 - Applied Research
- 3 - Advanced Technology Development
- 4 - Advanced Component Development and Prototypes
- 5 - System Development and Demonstration
- 6 - RDT&E Management Support
- 7 - Operational System Development

(2) **Budget Activity.** Programs are conducted under the following categories:

(a) **Budget Activity 1, Basic Research.** A systematic study directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind. It includes all scientific study and experimentation directed toward increasing fundamental knowledge and understanding in those fields of the physical, engineering, environmental, and life sciences related to long-term national security needs. It is far-sighted, high-payoff research that provides the basis for technological progress. Basic research may lead to:

(1) Subsequent applied research and advanced technology developments in defense-related technologies.

(2) New and improved military functional capabilities in areas such as communications, detection, tracking, surveillance, propulsion, mobility, guidance and control, navigation, energy conversion, materials and structures, and personnel support.

Note: The program elements in this category involve pre-Milestone A efforts.

(b) **Budget Activity 2, Applied Research.** A systematic study to understand the means to meet a recognized and specific national security requirement. It is a systematic application of knowledge to develop useful materials, devices, and systems or methods. It may include design, development, and improvements of prototypes and new processes to meet general mission area requirements. Applied research translates promising basic research into solutions for broadly defined military needs, short of system development. This type of effort may vary from systematic mission-directed research beyond that in Budget Activity 1, Basic Research, to sophisticated hardware, study programming, and planning efforts that establish the initial feasibility and practicality of proposed solutions to technological challenges. It includes studies, investigations, and non-system specific technology efforts. The dominant characteristic is that applied research is directed toward general military needs with a view toward developing and evaluating the feasibility and practicality of proposed solutions and determining their parameters. Applied Research precedes system specific research.

Program control of the Applied Research program element is normally exercised by general level of effort.

Note: The program elements in this category involve pre-Milestone B efforts, also known as concept and technology development phase tasks, such as concept exploration efforts and paper studies of alternative concepts for meeting a mission need.

(c) **Budget Activity 3, Advanced Technology Development (ATD).** Includes development of subsystems and components and efforts to integrate subsystems and components into system prototypes for field experiments and/or tests in a simulated environment. ATD includes concept and technology demonstrations of components and subsystems or system models. The models may be form, fit, and function prototypes, or scaled models that serve the same demonstration purpose. The results of this type of effort are proof of technological feasibility and assessment of subsystem and component operability and producibility rather than the development of hardware for service use. Projects in this category have a direct relevance to identified military needs. ATD demonstrates the general military utility or cost reduction potential of technology when applied to different types of military equipment or techniques.

Note: The program elements in this category involve pre-Milestone B efforts, such as system concept demonstration, joint and Service-specific experiments, or technology demonstration. Projects in this category do not necessarily lead to subsequent development or procurement phases.

(d) **Budget Activity 4, Advanced Component Development and Prototypes (ACD&P).** Efforts necessary to evaluate integrated technologies, representative modes or prototypes systems in a high fidelity and realistic operating environment are funded in this budget activity. The ACD&P phase includes system-specific efforts that help expedite technology transition from the laboratory to operational use. Emphasis is on proving component and subsystem maturity prior to integration in major and complex systems and may involve risk reduction initiatives.

Note: The program elements in this category involve efforts prior to Milestone B and are referred to as advanced component development activities and include technology demonstration. Completion of Technology Readiness Levels 6 and 7 should be achieved for major programs. Program control is exercised at the program and project level. A logical progression of program phases and development and/or production funding must be evident in the Five-Year Defense Plan (FYDP).

(e) **Budget Activity 5, System Development and Demonstration (SDD).** SDD programs have passed Milestone B approval and are conducting engineering and manufacturing development tasks aimed at meeting validated requirements prior to full-rate production. This budget activity is characterized by major line item projects and planned operational system levels. Characteristics of this budget activity involve mature system development, integration, and demonstration to support Milestone C decisions, and conducting live fire test and evaluation (LFT&E) and initial operational test and evaluation (IOT&E) of production representative articles. A logical progression of program phases and development and production funding must be evident in the FYDP consistent with the Department's full funding policy.

(f) **Budget Activity 6, RDT&E Management Support.** This budget activity includes RDT&E efforts and funds to sustain and/or modernize the installations or operations required for general RDT&E. Test ranges, military construction, and maintenance support of laboratories are funded in this budget activity or as line items in the Basic Research, Applied Research, or ATD Budget Activities, as appropriate. Military construction costs directly related to major development programs are included.

(g) **Budget Activity 7, Operational System Development.** This budget activity includes development efforts to upgrade systems that have been fielded or have received approval for full rate production and anticipate production of weapon system elements in other programs. Program control is exercised by review of individual projects. Programs in this category involve systems that have received Milestone C approval. A logical progression of program phases and development and production funding must be evident in the FYDP, consistent with the Department's full funding policy.

(3) **Projects and Task Areas.** Projects, task areas, and tasks for medical RDT&E will be established in a manner consistent with the requirements specified in article 20-3(2).

(4) **Work Units.** Work units under the above projects, task areas, and tasks will be assigned either to activities directly by NAVMEDRSCHCEN or NAVHLTHRSCHCEN or as approved R&D proposals submitted by the activities.

(a) Proposals for Navy medical RDT&E support shall be submitted to any DOD activities by the performing activities.

(b) The selection and approval of medical RDT&E proposals will be based on program objectives and operational requirements, immediacy of need, operational impact, experience and competence of the investigators, scientific merit, availability of facilities and funds, and probability of success, level of effort outside the Navy, and the special opportunities that may be offered by the location and environment of particular facilities. Programs are reviewed systematically by in-house scientific advisory committees and program managers. A variety of ad hoc mechanisms are also employed, including but not limited to external peer review groups, technical workshops and program or resources sponsor reviews.

(5) **Reporting Requirements.** Program managers will require regular progress reports on work units under their management responsibility. Interim progress reports are required annually on all active work units. Final reports are required at the earliest practicable time on completion or termination of work units.

20-6

Independent Research Program

(1) **Objective.** The principal objective of this Office of Naval Research (ONR) funded and executed program is to enable laboratories to expand basic research capabilities. Through this program, highly competent investigators are encouraged to initiate new and challenging work that may ultimately enhance regular laboratory programs or lead to innovative long-term efforts.

(2) **Funds.** Subject to the current availability of funds, ONR will invite Navy medical R&D laboratories to submit proposals to conduct independent research. These funds, being allocated in addition to those used to support other approved or assigned work units, will provide flexibility for the investigation of new ideas generated during the year. Primarily, independent research funds are to augment technical competence and to be used for work that has clear Navy relevance.

(3) **Controls.** Projects are proposed to ONR by investigators through their laboratory chain of command and should address innovative new work that has Navy relevance. ONR sets project execution and reporting requirements and has sole oversight authority for the program.

(4) **Management Reports.** Annual progress reports for projects funded under ONR's Independent Research Program shall be submitted to ONR in accordance with policy and directives.

officers in charge, heads of activities, scientific and technical program managers, project directors, Institutional Review Board (IRB) members, IRB support staff, and investigators shall maintain concern for the safety and welfare of volunteer subjects. No human subject research shall be initiated until the institution holds a valid assurance, and the research protocol has been reviewed by an IRB and approved by an appropriate research approval authority. Approval of research is required prior to recruiting subjects, enrolling subjects, collecting data or specimens, analyzing data, conducting research interventions, or preparing publications or presentations.

(3) **Records.** Medical research documentation and records must be completed and retained following the provisions of SECNAVINST 3900.39 series.

20-7

Human Subject Protections in Biomedical and Social-Behavioral Research

(1) **Authority.** Research with human subjects, regardless of the source of funding, funding appropriation, nature of support, or site of performance, must comply with 32 CFR 219 and the instructions and directives in the DOD Directive 3216.2 series, SECNAVINST 3900.39 series, BUMEDINST 3900.6 series, BUMEDINST 6000.12 series, NSHS-BETHINST 6000.41 series. The Chief, Bureau of Medicine and Surgery/Surgeon General of the Navy is the single authority for policy development, oversight, compliance, and ongoing monitoring concerning human research protections in the Department of the Navy (DON).

(2) **Command Responsibility.** All Navy and Marine Corps personnel conducting, supporting, reviewing, approving or managing human research shall view the protection of human subjects as an important command issue at all echelons, both ashore and afloat. Commanders, commanding officers,

20-8

Use of Animals in Medical Research

(1) **Authority.** DOD Directive 3216.1 series and implementing SECNAVINST 3900.38 series establish policies and procedures governing the responsible use, humane care, and review of the use of animals in RDT&E programs. These instructions shall be followed for any biomedical R&D efforts involving the use of animals.

(2) **Personnel and Technical Assistance.** The BUMEDINST 6401.1 series delineates the policies governing military veterinary medical support for Naval activities. SECNAVINST 3900.38 series assigns BUMED the responsibilities of coordinating and overseeing the use of animals by the Naval Establishment, the BUMED Director, Veterinary Affairs will provide specialized assistance as needed.

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20-9

**Use of Investigational
Items Under Federal
Food and Drug
Administration Control**

(1) The use of investigational drugs, biologics and devices in Navy-sponsored research, in studies involving Navy and Marine Corps personnel as volunteers, or by Navy Medicine activities or contractors supported by the Navy Medicine, must comply with 21 CFR 50, 56, 312, 600, and 812, and the instructions and directives in the DOD Directive 3216.2 series, DOD Directive 6200.2 series, SECNAVINST 3900.39 series and BUMEDINST 6710.69 series.

20-10

**Resident Research
Associateships**

(1) ONR, in cooperation with the National Research Council (NRC), National Academy of Sciences, and the National Academy of Engineering offers numerous postdoctoral research opportunities for qualified civilian biomedical scientists and bio-engineers in areas of major concern to the scientific and technological community.

(2) Resident Research Associateship awardees may be offered appointments by NRC. Award applications will be received by the NRC Associateship Office and evaluated on a competitive basis by special NRC panels of scientists and engineers. Each applicant is responsible for formulating a specific research plan on a problem related to the Navy or Marine Corps. Individuals having research interests relating to one or more of the opportunities described in this chapter are advised to communicate directly with ONR (Code 34) for further information.

20-11

**Force Health
Protection Future
Capabilities and
Core Medical R&D
Capabilities Programs**

(1) ONR's Science and Technology (S&T) program supports the DON's Force Health Protection Future Capabilities Program, which provides the naval warfighter with casualty care and management, casualty prevention, and healthy and fit force capabilities. Program management is provided by ONR with coordination provided by the Chief, Bureau of Medicine and Surgery in articulating Navy medical needs and requirements, and by the Commanding General, Marine Corps Combat Development Command (MCCDC), in articulating United States Marine Corps needs and requirements. An Executive Integrated Product Team (EIPT) composed of ONR, BUMED, and MCCDC members prioritizes the capabilities to be pursued and supports transitioning medical capabilities to the Fleet and Force.

(2) ONR provides annual funding (6.1 and 6.2) to support identified BUMED core medical R&D capabilities. BUMED distributes the funds to maintain a sound Navy S&T base at its R&D laboratories through management and oversight of operationally-relevant, basic and applied research. The funds serve to provide a stable cadre of scientific talent that can address core biomedical S&T in time of conflict and peace; provide surge capacity in a crisis; preclude technical surprise by adversaries; provide research continuity; and allow flexibility in the development of new areas of science research that address warfighters' needs.

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