



Defense Health Agency

PROCEDURAL INSTRUCTION

NUMBER 3200.01
August 9, 2019

DAD-R&D

SUBJECT: Research and Development (R&D) Enterprise Activity (EA)

References: See Enclosure 1.

1. PURPOSE. This Defense Health Agency-Procedural Instruction (DHA-PI), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (p):

a. Establishes the Defense Health Agency's (DHA) procedures for the Deputy Assistant Director (DAD), R&D to manage and execute, on behalf of the Assistant Secretary of Defense for Health Affairs (ASD(HA)), the portion of the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation assigned to it (referred to as the "DHP Science and Technology (S&T) Program)". The DHP S&T Program includes Budget Activities (BAs) 6.1-6.3 and 6.6. The ASD(HA) provides policy, direction, and guidance to inform planning, programming, budgeting, and execution of the DHP RDT&E appropriation in accordance with statute, regulation, and policy in Reference (a). The DAD-R&D, and Component Acquisition Executive (CAE) manage and execute DHP RDT&E Program funds aligned to them on behalf of the ASD(HA). The CAE is responsible for managing BAs 6.4, 6.5, and 6.7 funding, as well as Procurement and Operations and Maintenance funding required to support DHP-funded Acquisition Programs, regardless of acquisition activity.

b. Supports the Director, DHA, in developing appropriate DHA management models to maximize efficiencies in the management and execution of DHP RDT&E-funded activities carried out by the Combatant Commands (CCMDs), Services, Uniformed Services University of the Health Sciences (USU), Defense Agencies, and other DoD Components, as applicable.

c. Codifies processes to confirm DHP RDT&E funds are applied towards medical priorities and aligned to ASD(HA) policy, direction, and guidance to develop and deliver innovative medical products and solutions that increase the readiness of the DoD medical mission in accordance with Reference (a).

d. Supports the following objectives of the R&D EA:

(1) Increasing the quantity, quality, and pace of medical research through improved programmatic organization, processes, and oversight.

(2) Ensuring DHP RDT&E funded efforts align to ASD(HA) published program guidance that provides resourcing guidance and translates national, departmental, and Service priorities into specific program objectives.

(3) Verifying alignment of DHP RDT&E funds to medical priorities and to ASD(HA) policy, direction, and guidance to ensure the development and delivery of medical materiel and knowledge solutions.

(4) Facilitating coordination with the CCMDs, Services, USU, Defense Agencies, and other DoD Components, as applicable, to ensure DHP RDT&E funded activities address joint medical capability gaps, and avoid unnecessary duplication.

2. APPLICABILITY. This DHA-PI applies to the Defense Health Agency, DHA components, Combatant Commands, Office of the Chairman of the Joint Staff and the Joint Staff, the Military Departments, the Defense Agencies, the DoD Field Activities, USU, all other organization entities within the DoD, and all personnel to include assigned or attached active duty and reserved members, federal civilians, contractors (when required by the terms of the applicable contract), and other personnel assigned temporary or permanent duties within the Department of Defense.

3. POLICY IMPLEMENTATION. It is DHA's instruction, pursuant to References (b) through (p), that the Director, DHA will be responsible for managing and executing the DHP RDT&E funds aligned to medical priorities and to ASD(HA) policy, direction and guidance in order to deliver medical capabilities to the CCMDs, the Services, Defense Agencies, and other DoD Components, as applicable.

4. RESPONSIBILITIES. See Enclosure 2.


5. PROCEDURES. See Enclosure 3.

6. RELEASABILITY. **Cleared for public release**. This DHA-PI is available on the Internet from the Health.mil site at: www.health.mil/DHAPublications.

7. EFFECTIVE DATE. This DHA-PI:

a. Is effective upon signature.

b. Will expire 10 years from the date of signature if it has not been reissued or cancelled before this date in accordance with Reference (g).



R. C. BONO
VADM, MC, USN
Director

Enclosures

1. References
2. Responsibilities
3. Procedures

Glossary

ENCLOSURE 1

REFERENCES¹

- (a) DoD Directive 5136.01, “Assistant Secretary of Defense for Health Affairs (ASD(HA)),” September 30, 2013, as amended
- (b) DoD Directive 5136.13, “Defense Health Agency (DHA),” September 30, 2013
- (c) DoD 7000.14-R, “Department of Defense Financial Management Regulation (DoD FMR),” June 2017
- (d) Chairman of the Joint Chiefs of Staff Instruction 5123.01H, “Charter of The Joint Requirements Oversight Council (JROC) and Implementation of The Joint Capabilities Integration and Development System (JCIDS),” August 31, 2018
- (e) DoD Directive 5000.01, “The Defense Acquisition System,” May 12, 2003, as amended
- (f) DoD Instruction 5000.02, “Operation of the Defense Acquisition System,” January 7, 2015, as amended
- (g) DHA-Procedural Instruction 5025.01, “Publication System,” August 24, 2018
- (h) Coordinated Concept of Operations, “Defense Health Agency (DHA) Research, Development and Acquisition (RDA),” June 4, 2014
- (i) Chairman of the Joint Chiefs of Staff, “Combat Support Agency Report Team (CSART) FY 2016 Preliminary Report,” August 2017
- (j) Research and Development Enterprise Support Activity Working Group Charter, September 14, 2017
- (k) Coordinated Concept of Operations, Medical Research and Development, June 2014
- (l) DoD Instruction 6000.08, “Defense Health Program Research and Clinical Investigation Programs,” January 22, 2014, as amended
- (m) Delegation of Authority for Joint Capabilities Integration and Development System Requirements Management to Assistant Director, Combat Support Agency, June 7, 2018
- (n) DoD Directive 3000.06, “Combat Support Agencies (CSAs),” June 27, 2013, as amended
- (o) DHA Interim Procedure Memo 18-006, Deputy Assistant Director Information Operations J-6 Enterprise Activity
- (p) MHS Governance Business Rules, October 1, 2018

¹ This reference can be found at: <https://info.health.mil/rd/Documents/Forms/AllItems.aspx>, or by e-mailing DHA Research Program Administration Division at: dha.ncr.j-9.mbx.rpa@mail.mil

ENCLOSURE 2
RESPONSIBILITIES

1. DIRECTOR, DHA. Under the authority, direction, and control of the ASD(HA), the Director, DHA will:
 - a. Exercise management responsibility for Enterprise Activities (EAs) in the Military Health System (MHS), including the R&D EA, and develop appropriate management models and organizational structures for particular functions and processes.
 - b. Identify key DHA and DoD Component representatives to carry out the procedures in this DHA-PI.
 - c. Recommend medical R&D initiatives in response to CCMDs' military operations and developmental requirements to address capability gaps.
 - d. Receive Service-specific requirements and requests relating to the R&D EA from the Secretaries of the MILDEPs in accordance with Reference (b).

2. CAE. The CAE or delegated Milestone Decision Authority is responsible for DHP RDT&E-funded activities brought into the DoD Acquisition process. The CAE must:
 - a. Initiate acquisition programs, and approve tailored joint acquisition strategies in response to validated requirements to accelerate the development and fielding of medical operational capabilities.
 - b. Confirm acquisition programs support policy and guidance issued by the ASD(HA), and Director, DHA, and the objectives set forth in the DHP Program Objective Memorandum (POM).
 - c. Approve the annual spend plan recommendations for current acquisition programs, and recommend POM input for current and future acquisition programs to DAD, Financial Operations (FO), consistent with References (e) and (f) to fully fund programs.
 - d. Coordinate with DAD-R&D to ensure alignment and transition of S&T Program investments to future acquisition programs, as appropriate.

3. DAD-R&D. Under the authority, direction, and control of the Director, DHA; the DAD-R&D; or a delegate will:

a. Exercise management and execution responsibilities for the implementation of the DHP S&T Program in accordance with this DHA-PI, including:

(1) Integration of DoD Component management plans for ASD(HA) evaluation and approval on the basis of interoperability, effectiveness and elimination of unwarranted duplication, in accordance with Reference (a).

(2) Approve annual spend plan recommendations for the DHP S&T Program.

(3) Recommend POM submission input for the DHP S&T Program to the DAD-FO.

(4) Coordinate with CAE to align S&T Program investments to future acquisition programs, as appropriate.

(5) Participate in the review of Acquisition programs, which are approved by the CAE, or assigned Milestone Decision Authority, in accordance with References (e) through (f).

b. Develop and implement processes to manage and execute the DHP S&T Program.

c. Serve as the Chair, Medical R&D Flag Officer Group (FOG).

d. Consider input from the FOG in determining the composition of the DHP S&T Program.

e. Confirm the DHP S&T Program supports policy, direction, and guidance issued by the ASD(HA), Director, DHA, and the objectives set forth in the DHP POM in accordance with Reference (a).

4. DAD-FO. On behalf of the ASD(HA), in accordance with Reference (b), the DAD-FO must:

a. Coordinate, formulate, and submit the DHP POM, which includes the RDT&E subsection of the appropriation, and President's Budget submissions to the Under Secretary of Defense (Comptroller).

b. Coordinate the submission of DHP RDT&E year of execution plans.

c. Monitor DHP RDT&E funds execution to verify compliance with all applicable statutes, regulations, directives, instructions, and guidance.

d. Provide financial guidance on the planning, programing, budgeting, and execution of DHP RDT&E funding.

e. Provide financial management support services to DAD-R&D, including allocating DHP S&T Program funding as communicated by the DAD-R&D.

f. Provide updates to DAD-R&D on financial actions and performance related to the execution of DHP S&T Program funding as requested. Provide updates to the CAE on financial actions and performance related to the execution of DHP 6.4, 6.5, and 6.7 funding as requested.

g. Include DHA R&D representation in all financial discussions, reviews, and decisions concerning DHP S&T Program funds. Include CAE representation in all financial discussions, reviews, and decisions concerning DHP RDT&E 6.4, 6.5, and 6.7 funds.

5. MEDICAL R&D FOG. The Medical R&D FOG will:

a. Serve as the primary forum for the DAD-R&D to receive input from CCMDs, the Services, USU, Defense Agencies, and other DoD Components regarding activities and issues related to the prioritization, dispensation, and use of DHP S&T Program funding.

b. Support execution of strategy, policy, and directives by identifying and recommending solutions to issues related to DHP S&T Program funding investments.

c. Recommend medical priorities requiring DHP S&T Program funding.

d. Communicate member organizations' medical S&T Program investments to the DAD-R&D to coordinate and leverage DHP S&T Program funding across the military medical S&T enterprise.

6. DIVISION CHIEF, OPERATIONS, PLANS, AND REQUIREMENTS DIVISION. The Division Chief, Operations, Plans and Requirements Division must:

a. Serve as the central office responsible for defining, documenting, coordinating, and managing DHA operational capabilities through the Joint Capabilities Integration and Development System (JCIDS), consistent with Reference (m).

b. Manage DHA participation in JCIDS activities, workshops, and related actions to ensure compliance with responsibilities outlined in Reference (n).

c. Serve as official responsible for staffing, coordination, and preparation of DHA position on all JCIDS requirements with DHA equity; advocates DHA approved position at relevant JCIDS boards and working groups.

d. Ensure Agency compliance with processes, procedures, and timelines documented in Reference (d).

e. Be Responsible for the management and execution of approved Joint doctrine, organization, training, materiel, leadership and education, personnel, facilities, and policy change recommendations where DHA is designated as Sponsor, Office of Primary Responsibility, or Office of Collateral Responsibility.

7. DIVISION CHIEF, RESEARCH PROGRAM ADMINISTRATION DIVISION (RPAD), R&D. Under the authority, direction, and control of the DAD-R&D, the Chief, RPAD, R&D must:

- a. Coordinate with the Director, Medical R&D on all aspects of policy, direction, and guidance related to the management and execution of the DHP S&T Program.
- b. Serve as the principal RDT&E advisor to the DAD-R&D for the DHP S&T Program.
- c. Supervise RPAD staff, synchronize efforts with other Directorates and Divisions, and manage the DHP S&T Program in accordance with direction and guidance received from the DAD-R&D.
- d. Represent the DHP S&T Program to MHS Governance.
- e. Conduct strategic planning for DHP S&T Program investments with appropriate stakeholders.
- f. Coordinate with appropriate stakeholders on all phases of planning, programming, budgeting, and execution of DHP S&T Program funds.
- g. Establish and maintain collaborative medical S&T partnerships across the Federal Government as directed by ASD(HA); Director, DHA; and DAD-R&D to enhance DHA's ability to develop and deliver medical operational capabilities.
- h. Develop and maintain an integrated, harmonized management plan and master schedule for the DHP S&T Program, including implementation guidance based on ASD(HA) policy direction to DAD-R&D for managing and executing the DHP S&T Program.
- i. Create and implement standardized metrics and business processes to guide the management and execution of the DHP S&T Program.
- j. Coordinate responses to DHP S&T Program reporting requirements.
- k. Include appropriate S&T representation in the development and prioritization of medical research requirements through Capability Based Assessments, as well as requirements and capabilities documents.
- l. Develop and maintain standardized business processes for the transition of knowledge products.
- m. Chair the R&D Enterprise Activity Working Group (EAWG).
- n. Adhere to DHA R&D policy, procedures and reporting requirements.

8. R&D EAWG. The R&D EAWG will:

a. Serve as the primary forum for the CCMDs, the Services, USU, and other DoD Components, as applicable, to advise the Chief, RPAD, on managing and executing the DHP S&T Program funds that support medical priorities.

b. Support the Chair, R&D EAWG, in:

(1) Coordinating reports, analyses, or related information requests with the CCMDs, the Services, USU, Defense Agencies, and other DoD Components, as applicable.

(2) Reviewing and analyzing, at least annually, the CCMDs', Services', USUHS', Defense Agencies', and other DoD Components', as applicable, current and planned DHP S&T Program investments and activities to recommend to the Chair, R&D EAWG adjustments to the DHP S&T Program to improve alignment with ASD(HA) policy, direction, and guidance and synchronization with Component requirements.

(3) Developing, validating, and tracking metrics for DHP S&T Program performance.

(4) Communicating with the CCMDs, the Services, USU, Defense Agencies, and other DoD Components, as applicable, to report on relevant DHA and R&D EAWG activities, and provide actionable information, including discussion and resolution of DHP S&T Program issues.

c. Advise the ASD(HA); Director, DHA; DAD-R&D; and MHS Governance on:

(1) Issues related to enterprise capabilities regarding the disposition of DHP S&T Program funds.

(2) Recommendations to revise or modify governance rules to streamline processes and procedures.

9. DHP S&T MANAGERS. DHP S&T Managers are responsible for coordinating with the Chief, RPAD, to:

a. Support policy and guidance issued by the ASD(HA); Director, DHA; and DAD-R&D regarding BA 6.1–6.3 (basic research, applied research, and advanced technology development) of DHP S&T Program investments.

b. Align DHP S&T Program funds to medical priorities to support the development and delivery of medical materiel and knowledge solutions.

c. Coordinate with the CCMDs, the Services, USU, Defense Agencies, and other DoD Components, regarding DHP S&T Program activities to reduce duplicative efforts.

d. Provide information on the progress of DHP RDT&E funded efforts to DAD-R&D when requested.

e. Align DHP S&T efforts associated with the translation of research into evidence-based practice with appropriate MHS enterprise knowledge translation business processes.

f. Coordinate transition of medical materiel solutions with the appropriate CAE-chartered Program Managers or other designated Component Product Managers, and follow appropriate acquisition guidance and business processes.

10. ACQUISITION PROJECT/PRODUCT MANAGERS. The Acquisition Project/Product Managers are responsible for executing joint acquisition programs using DHP Acquisition Program funds (BAs 6.4, 6.5, and 6.7) on behalf of the CAE.

ENCLOSURE 3

PROCEDURES

1. BACKGROUND. The DHA R&D manages and executes the DHP S&T Program with a focus on addressing medical priorities to deliver medical capabilities. It reports program performance to the MHS leadership through appropriate MHS Governance councils. The Office of the Joint Staff Surgeon, the Services, and other DoD Components, as applicable, support DHP S&T Program management and execution by providing appropriate subject matter experts to DHA R&D led working groups and through active staff coordination. These DoD organizations may participate in DHP S&T Program funds execution in accordance with relevant guidance.

2. GENERAL PROCESS. This DHA-PI supports a total lifecycle approach to DHP investments as articulated in References (d) through (f), to align DHP S&T Program funds to medical priorities to deliver medical capabilities. The maturity of a capability and that capability's alignment to priorities will inform where it enters the S&T or acquisition processes. As appropriate new requirements should be submitted through the MHS Request Submission portal in accordance with all applicable DHA guidance. Items entered through the portal will be tracked and forwarded to the DAD-R&D for consolidation and prioritization while providing the Agency transparency of requests for DHP S&T Program funding. The effective use of DHP S&T Program funds requires:

- a. The development and coordination of medical priorities.
- b. The allocation of S&T funds to further explore and refine approaches to delivering medical operational capabilities that address medical priorities.
- c. The development of transition agreements to confirm that S&T efforts are integrated with acquisition program activities to deliver materiel solutions.
- d. The development of knowledge transition agreements so that knowledge products have a well-defined development path that concludes with their dissemination and implementation.

3. IMPLEMENTATION. Pursuant to Reference (b), DAD R&D will develop procedures and processes, in accordance with Reference (g), to:

- a. Manage and execute DHP S&T Program funds.
- b. Reduce duplication of efforts within the DHP S&T Program.
- c. Implement business processes to ensure the DHP S&T Program addresses medical priorities supporting the development and delivery of medical materiel and knowledge solutions.

- d. Improve transparency in the management and execution of DHP S&T Program funds.
 - e. Document effectiveness of these procedures and processes, by developing and applying EA-wide metrics.
4. GOVERNANCE. The R&D EA is subject to the governance processes established by MHS Governance bodies as outlined in Reference (p).
5. REPORTING. The Chief, DHA RPAD, will provide reports regarding current initiatives to the ASD(HA); Director, DHA; DAD-R&D, and other entities, as needed, or when updates are requested.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

ASD(HA)	Assistant Secretary of Defense for Health Affairs
BA	Budget Activity
CAE	Component Acquisition Executive
CCMD	Combatant Command
DAD	Deputy Assistant Director
DHA	Defense Health Agency
DHA-PI	Defense Health Agency-Procedural Instruction
DHP	Defense Health Program
EA	Enterprise Activity
EAWG	Enterprise Activity Working Group
FOG	Flag Officer Group
JCIDS	Joint Capabilities Integration and Development System
MHS	Military Health System
MILDEP	Military Department
POM	Program Objective Memorandum
R&D	Research and Development
RDT&E	Research, Development, Test, and Evaluation
RPAD	Research Program Administration Division
S&T	Science and Technology
USU	Uniformed Services University of the Health Sciences

PART II. DEFINITIONS

These terms and their definitions are for the purpose of this DHA-PI.

Acquisition Program. A directed, funded effort that provides a new, improved, or continuing materiel, weapon, information system, or service capability in response to a validated requirement. Acquisition programs are divided into categories that are established to facilitate

decentralized decision making, execution, and compliance with statutory requirements described in Reference (e). These are typically funded by the RDT&E BA of advanced component development and prototypes (BA 6.4), system development and demonstration (BA 6.5), and operational system development (BA 6.7).

BA. Categories within each appropriation and fund account that identify the purposes, projects, or types of activities financed by the appropriation or fund.

Component. MILDEP or agency of the DoD.

DHP RDT&E Funds. A subsection of the DHP appropriation consisting of all RDT&E funded activities that support the health and medical mission of the MHS.

EA. A DHA directorate or division that provides shared services for MHS entities. In this case, a shared service includes a provision of a service by one part of an organization or group, where that service had previously been found in more than one part of the organization or group. Thus, the funding and resourcing of the service is shared, and the providing department effectively becomes an internal service provider.

Knowledge Solution. A non-materiel capability that translates research into practice; including, but not limited to: clinical support tools, recommendations, and practice guidelines, policy, journal articles, treatment protocols, and training products. Knowledge Solutions are non-materiel but may accompany a materiel solution as part of a strategy to bring about practice change. Knowledge Solutions are often also referred to as Knowledge Products.

Knowledge Translation. A systematic and iterative process intended to identify and close the gap between scientific developments and current practice across the organization by putting into action state-of-the-art practices as rapidly as possible to confidently accelerate the adoption of the targeted knowledge product(s) to enhance health care delivery and improve health outcomes.

Materiel Solution. A new item (including ships, tanks, self-propelled weapons, aircraft, etc., and related spares, repair parts, and support equipment, but excluding real property, installations, and utilities), developed or purchased to satisfy one or more capability requirements (or needs) and reduce or eliminate one or more capability gaps. Medical Materiel Solutions may include, but are not limited to, Pharmaceuticals, Biologicals, Devices, Diagnostics, and Medical Support Systems.

S&T Program. Consists of projects funded by the RDT&E BAs of basic research (BA 6.1), applied research (BA 6.2), and advanced technology development (BA 6.3).