Defense Health Agency

PROCEDURAL INSTRUCTION

NUMBER 3200.02
September 24, 2019
Incorporating Change 1, August 5, 2022

DAD-R&E

SUBJECT: Clinical Investigations Program (CIP) in Military Medical Treatment Facilities (MTFs)

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 (z), establishes the Defense Health Agency's (DHA) procedures to:

a. Assign responsibilities and procedures for the funding and administration of the Clinical Investigations Program (CIP) within the DoD.

b. Serve as the DHA CIP Component Management Plan, referred to as the "Component Management Plan" in this DHA-PI.

2. APPLICABILITY. This DHA-PI applies to the DHA, DHA components (activities under the authority, direction, and control of the DHA), Military Departments, and all personnel to include: assigned or attached active duty and reserve members, federal civilians, contractors (when required by the terms of the applicable contract), and other personnel assigned temporary or permanent duties at DHA, to include DHA regional and field activities (remote locations), and subordinate organizations administered and managed by DHA.

3. POLICY IMPLEMENTATION. It is DHA's instruction, pursuant to Reference (e), that:

a. The CIP must support research and clinical investigations (CI) that meet at least one of the following criteria:

(1) Contribute to the high professional standing and accreditation of Graduate Medical Education (GME) programs by fostering the conduct of research by both trainees and faculty and by encouraging research on educational methods suitable to the healthcare professions.

(2) Improve the quality of patient care in the Military Health System (MHS) by improving medical knowledge, practices, materiel, devices, and pharmaceuticals and by obtaining access to investigational medical products and techniques through use of technology transfer mechanisms such as Cooperative Research and Development Agreements (CRADA) for the treatment and benefit of the military beneficiary population.

(3) Promote the development and employment of health readiness solutions that protect, treat, and optimize the health and performance of the total force by encouraging research conducted in accordance with DoD research priorities such as those efforts identified by the Joint Force Surgeons, Military Departments, and DHA.

(4) Respond to the needs of the MHS and the dynamic nature of the health sciences through a focus on emerging research and training priorities established by the DoD.

b. The CIP must support research and CIs that meet both of the following criteria, as applicable:

(1) Include reimbursement for Military Medical Treatment Facility (MTF) direct and indirect costs through use of CRADAs or other such mechanisms as allowed by law or regulation when collaborating with extramural researchers.

(2) Are feasible, scientifically sound, and reasonably expected to achieve their intended objectives when considering impacting factors such as the available patient population, competing or conflicting research priorities, and available resources such as laboratory facilities and personnel.

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: https://health.mil/Reference-Center/Policies and is also available to authorized users from the DHA SharePoint site at: https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx.

7. EFFECTIVE DATE. This DHA-PI:

a. Is effective upon signature.

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

8. SUMMARY OF CHANGES. The updated DHA-PI will serve as the Component Management Plan as required in Reference (e). Additionally, the publication was updated to be current with DHA reorganization changes.

/S/
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LTG, MC, USA
Director

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ENCLOSURE 1

REFERENCES

(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, as amended
(c) DHA-Procedural Instruction 5025.01, "Publication System," April 1, 2022
(d) United States Code, Title 10, Section 1073c
(e) DoD Instruction 6000.08, "Defense Health Program Research and Clinical Investigation Programs," January 22, 2014, as amended
(f) DoD Instruction 8510.01, "Risk Management Framework (RMF) for DoD Information Technology (IT)," March 12, 2014, as amended
(g) DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and-Supported Research," April 15, 2020
(h) DoD 7000.14-R, "Department of Defense Financial Management Regulation," date varies by volume
(i) United States Code, Title 10
(j) DoD Instruction 1015.15, "Establishment, Management, and Control of Nonappropriated Fund Instrumentalities and Financial Management of Supporting Resources," October 31, 2007, as amended
(k) DoD Instruction 5230.27, "Presentation of DoD-Related Scientific and Technical Papers at Meetings," November 18, 2016, as amended
(l) DoD Instruction 3200.12, "DoD Scientific and Technical Information Program (STIP)," August 22, 2013, as amended
(m) DoD Manual 3200.14, Volume 1, "Principles and Operational Parameters of the DoD Scientific and Technical Information Program (STIP): General Processes," March 14, 2014, as amended
(n) DoD Instruction 5000.02, "Operation of the Adaptive Acquisition Framework," January 23, 2020
(o) DoD Instruction 8910.01, "Information Collection and Reporting," May 19, 2014, as amended
(p) DoD Manual 8910.01, Volume 1, "DoD Information Collections Manual: Procedures for DoD Internal Information Collections," June 30, 2014, as amended
(q) DoD Instruction 3216.01, "Use of Animals in DoD Conducted and Supported Research and Training," March 20, 2019
(r) United States Code, Title 15
(s) DoD Directive 5535.03, "DoD Domestic Technology Transfer (T2) Program," May 21, 1999, as amended
(t) DoD Instruction 5535.08, "DoD Technology Transfer (T2) Program," May 14, 1999, as amended

(u) Force Health Protection Concept of Operations (CONOPS), November 17, 2011[1]
(v) DHA-Procedural Instruction 3201.05, "Technology Transfer (T2) Program," June 20, 2019
(w) DoD Instruction 1100.13, "DoD Surveys," January 15, 2015, as amended
(x) DoD Instruction 6015.24, "DoD Graduate Medical Education Program," April 9, 2021
(y) DHA-Technical Manual 3200.02, "Scientific Review of Clinical Investigations in Military Medical Treatment Facilities," June 7, 2021
(z) DHA-Technical Manual 3200.01, "Reimbursement of Research-Related Expenses for Clinical Investigations in Military Medical Treatment Facilities," October 5, 2021

[1] This reference can be found by emailing DHA personnel at: dha.ncr.comm.mbx.health-affairs@mail.mil

ENCLOSURE 2

RESPONSIBILITIES

1. DIRECTOR, DHA. Under the authority, direction, and control of the Assistant Secretary of Defense for Health Affairs, the Director, DHA, will:

a. Develop, issue, and monitor a Component Management Plan for CIP.

b. Establish and implement policies and procedures to support this DHA-PI.

c. In coordination with the Office of the Assistant Secretary of Defense for Health Affairs, strengthen ties to other federal and non-federal medical research programs to facilitate the transition of MHS-related candidate medical products to advanced development or clinical practice guidelines.

d. Report to the Assistant Secretary of Defense for Health Affairs, or a designee, as requested on CIP funded research activities in accordance with Enclosure 2, section 1d of Reference (e).

e. Serve as the approval authority for waiver requests to this DHA-PI.

2. DIRECTOR, ADMINISTRATION AND MANAGEMENT (J-1). The Director, J-1, will:

a. Advise and assist the Deputy Assistant Director (DAD)-Research and ~~Development~~ Engineering (R&E) in developing and making available standardized position descriptions for CIP personnel in Departments of Clinical Investigation (DCI) at MTFs.

b. Advise and assist the DAD-R&E in determining requirements for the manning and resourcing of CIP services at each MTF in accordance with Enclosure 3, section 1b(6) of Reference (e).

3. DAD, MEDICAL AFFAIRS. The DAD, Medical Affairs, will:

a. Advise and assist the DAD-R&E regarding the role of CIs in support of GME programs.

b. By November 1st of every year, provide to the DAD-R&E a list of:

(1) Accredited GME programs

(2) Current scholarly activity requirements for maintenance of accreditation for each program

(3) Publications and abstracts that support those requirements in accordance with section 3b(2) (policy section) of Reference (e) and in accordance with Enclosure 3, sections 1b(2) and 1b(5) of Reference (e).

4. DIRECTOR, DHA CONTRACTING ACTIVITY. The Director, DHA Contracting Activity, will:

a. Award and administer contracts for personnel, supplies, or equipment in support of CIs at MTFs.

b. Support the DAD-R&E in establishing and maintaining grants programs for MTF-based investigators in accordance with Enclosure 3, section 1b(4) of Reference (e).

5. DIRECTOR, INFORMATION OPERATIONS (J-6). The Director, J-6, will:

a. Advise and assist the DAD-R&E in developing DHA Component implementing policies and procedures regarding the use of MHS-wide electronic research management tools in accordance with Enclosure 3, section 1b(8) of Reference (e).

b. Assist the DAD-R&E with their collection of data elements and CIP performance metrics through MHS-wide electronic research management tools, as referenced in Enclosure 2, section 2d and Enclosure 3, sections 1b(2) and 1b(5) of Reference (e).

c. Facilitate the assessment and authorization of information technologies in support of CIs in accordance with Reference (f).

6. DIRECTOR, FINANCIAL OPERATIONS (J-8). The Director, (J-8) will include CIP infrastructure support in the planning, programming, budgeting, and execution process in accordance with Enclosure 3, section 1b(6) of Reference (e).

7. DAD-R&E. The DAD-R&E, will:

a. Establish and maintain the Clinical Investigation Program Office (CIPO) to oversee CIP policies and procedures in accordance with Enclosure 3, sections 1a, 1b(1), and 1b(3) of Reference (e).

b. Support the responsibilities of the Director, DHA, listed in this DHA-PI.

8. SECRETARIES OF THE MILITARY DEPARTMENTS. The Secretaries of the Military Departments will communicate the applicable graduate health sciences education (GHSE) portions of Reference (e) and this DHA-PI when a CI is proposed at a non-MTF (e.g., U.S. Air Force School of Aerospace Medicine).

9. DIRECTORS, MARKETS, SMALL MARKET AND STAND-ALONE MILITARY MEDICAL TREATMENT FACILITY ORGANIZATION, AND DEFENSE HEALTH AGENCY REGIONS. The Directors, Markets, Small Market and Stand-Alone Military Medical Treatment Facility Organization, and Defense Health Agency Regions will coordinate with the Chief, CIPO to ensure the information disseminated by the Chief, CIPO is comprehensively communicated to the MTF leadership.

10. CHIEF, CIPO. The Chief, CIPO, will:

a. Support the DAD-R&E in developing, issuing, and monitoring the Component Management Plan for the CIP in accordance with Enclosure 2, section 2a and Enclosure 3, section 1 of Reference (e).

b. Support the DAD-R&E in establishing and overseeing Component implementing policies and procedures for the CIP in accordance with Enclosure 2, section 2b and Enclosure 3, sections 1a, 1b(1), and 1b(3) of Reference (e).

c. Support the DAD-R&E in strengthening ties to other medical research programs in accordance with Enclosure 2, section 2c of Reference (e).

d. Report to the DAD-R&E on CIP-funded scholarly activities, studies, and other supported research in accordance with Enclosure 2, section 2d of Reference (e).

e. Review and approve MTF implementing policies and procedures for the CIP in accordance with Enclosure 3, sections 1a, 1b(1), and 1b(3) of Reference (e).

f. Collect data elements and CIP performance metrics referenced in Enclosure 2, section 2d, and Enclosure 3, sections 1b(2) and 1b(5) of Reference (e) and establish benchmarks for CIP performance.

g. Provide oversight of CIs, research, and CI support services at MTFs in accordance with Enclosure 3, section 1b(3) of Reference (e).

h. Determine the scope of CIP services and coordinate with Director, J-1 and Director, (J-8) regarding the manning and resources required to support those services at each MTF in accordance with Enclosure 3, section 1b(6) of Reference (e).

i. Establish programs that provide funding, recognition, and training to facilitate CIs at MTFs in accordance with section 3b (policy section) of Reference (e) and in accordance with Enclosure 3, section 1b(9) of Reference (e).

j. Receive and disseminate research and training priorities to Chiefs, MTF, DCI in accordance with Enclosure 3, section 1b(10) of Reference (e).

k. Coordinate with other DHA activities in support of the CIP.

11. DIRECTORS OF MEDICAL CENTERS. The Directors of Medical Centers will:

a. Ensure for CIs conducted within their MTF:

(1) The adherence of the CIP portfolio with the requirements of paragraphs 3a and 3b (policy implementation section) of this DHA-PI.

(2) The provision of scientific, technical, and administrative support services by DCIs in accordance with documented utilization of those services and guidance from CIPO.

(3) Prioritization of CIP- and Defense Health Program (DHP)-funded research projects that are conducted in accordance with strategic guidance in accordance with Enclosure 3, section 3c of Reference (e).

(4) Reimbursement for research-related expenses when collaborating with extramural researchers in accordance with section 3c (policy section) of Reference (e) and in accordance with Enclosure 3, section 1b(7) of Reference (e).

(5) Achievement of benchmarks for CIP performance metrics established by CIPO in accordance with Enclosure 3, section 1b(5) of Reference (e).

b. Establish and maintain DCIs for CI support.

c. Support the Human Research Protection Program, Institutional Review Board, and Institutional Animal Care and Use Committee as applicable, ensuring research involving human subjects and animals is appropriately resourced to support regulatory requirements in accordance with Enclosure 3, section 1b(6) of Reference (e).

12. CHIEFS, MTF, DCI. The Chiefs, MTF, DCI must:

a. Provide scientific, technical, and administrative CI support services to investigators that are conducted in accordance with investigator needs, documented utilization of those services, and guidance from CIPO.

b. Establish and implement MTF policies and procedures for the CIP that integrate appropriate policy and guidance in accordance with Enclosure 3, section 1b(10) of Reference (e), subject to approval by CIPO.

c. Coordinate scientific review in accordance with Reference (y) and guidance from CIPO.

d. Perform other assigned activities under the Component Management Plan in accordance with Enclosure 3, section 1b of Reference (e) and guidance from CIPO, including:

(1) Managing and administering funds for research in accordance with Enclosure 3, section 1b(4) of Reference (e) and guidance from CIPO.

(2) Ensuring reimbursement for facility expenses in accordance with Reference (z) and guidance from CIPO.

(3) Collecting and reporting CIP data and CIP performance metrics in accordance with Enclosure 3, sections 1b(2) and 1b(5) of Reference (e) and guidance from CIPO.

(4) Utilizing MHS-wide electronic research management tools in accordance with Enclosure 3, section 1b(8) of Reference (e) and guidance from CIPO.

(5) Providing education and training for the implementation, management, and oversight of CIP policies and procedures in accordance with Enclosure 3, section 1b(9) of Reference (e) and guidance from CIPO.

(6) Receive and disseminate research and training priorities provided through the Chief, CIPO to GME programs in accordance with Enclosure 3, section 1b(10) of Reference (e) and guidance from CIPO.

ENCLOSURE 3

PROCEDURES

1. GENERAL FUNDING CONSIDERATIONS

a. CIs, regardless of funding source, must be conducted in accordance with the requirements of paragraphs 3a and 3b (policy implementation section) of this DHA-PI.

b. CIs using DHP funds must refer to Reference (h) for all financial management policy and guidance in accordance with the requirements of Enclosure 3, section 3a of Reference (e).

c. CIP infrastructure support for MTFs (i.e., DCIs), is funded through DHP Operations and Maintenance (O&M) funds from Major Force Program 8. In addition, MTFs may receive funding support from DHP Research, Development, Test, and Evaluation (RDT&E) funds from Major Force Program 6 or from other federal and non-federal sources to the extent permissible by law and federal regulations in accordance with Enclosure 3, section 3b of Reference (e).

d. MTF Directors may accept support from other federal sources in accordance with Section 2358 of Reference (i), (e.g., National Institutes of Health and U.S. Centers for Disease Control and Prevention) in accordance with Enclosure 3, section 3d of Reference (e).

e. MTF Directors may accept CI support from non-federal sources only when it is consistent with paragraphs 3a and 3b (policy implementation section) of this DHA-PI. Support from nonfederal sources is authorized as provided by law, DoD issuances, and this DHA-PI. MTF Directors must establish management controls to ensure legal review of the acceptance and use of such funds and to comply with any other procedures in accordance with Enclosure 3, section 3e of Reference (e).

f. In addition to core funding, CIs may, if consistent with the management controls referred to in paragraph 1e of this enclosure, be funded and administered through any mechanism authorized by law or DoD issuances, including, but not limited to, those listed in Enclosure 3, section 3f, of Reference (e).

2. ACCEPTANCE OF NON-FEDERAL SUPPORT FOR CIs

a. CIs, regardless of funding source, must be conducted in accordance with paragraphs 3a and 3b (policy implementation section) of this DHA-PI.

b. MTF Directors must establish procedures to require that all CIs using DHP funds accept non-federal support for the CIP only in strict compliance with the program integrity requirements in accordance with Enclosure 3, section 3i of Reference (e).

c. MTF personnel must adhere to additional requirements for collaborations with extramural researchers when an intramural investigator is named as a collaborator in a proposal submitted by an extramural investigator, in accordance with Enclosure 3, section 3j of Reference (e).

3. REIMBURSEMENT FOR RESEARCH-RELATED EXPENSES

a. Following the execution of an appropriate agreement, MTFs that collaborate with extramural researchers under DHP-funded grants, cooperative agreements, or procurement contracts must be reimbursed for their direct and indirect costs in accordance with Enclosure 3, section 1b(7) of Reference (e) and guidance from CIPO. Specifically, for all research and CIs using DHP funds, procurement contracts, grants, and cooperative agreements for DHP-funded awards that provide for the use of DHA facilities must include in their award budgets appropriate reimbursement for direct and indirect costs to such facilities in accordance with Enclosure 3, section 3g of Reference (e), and guidance from CIPO.

b. In all cases involving determination of reasonable charges for collaborations or cooperation with non-federal entities, the parties involved in the collaboration or cooperation must execute a written agreement or, in the case of a gift, a written acknowledgment, in accordance with the requirements of Enclosure 3, section 3h of Reference (e).

c. Utilize the procedures for the reimbursement of research-related expenses for CIs in MTFs identified in Reference (z).

4. ADMINISTRATION

a. Funding for CIs. CIs, regardless of funding source, must be conducted in accordance with the requirements of paragraphs 3a and 3b (policy implementation section) of this DHA-PI and must adhere to the requirements of Reference (h).

b. Gifts for CIs. CIs, involving gifts, must be conducted in accordance with the requirements of paragraphs 3a and 3b (policy implementation section) of this DHA-PI and must adhere to the requirements of Reference (j).

c. Management of records. CIP personnel (e.g., investigators and DCIs) must utilize MHS wide, web-based electronic management tools for workflow processing whenever possible as referenced in Enclosure 3, section 1b(8) of Reference (e) in accordance with guidance from CIPO.

5. PUBLICATIONS, PRESENTATIONS, AND TECHNICAL REPORTS

a. CI-related information or materials proposed for release to the public (e.g., publications and presentations reporting the results of CIs) must be reviewed and cleared in accordance with Reference (k).

b. RDT&E studies funded by Major Force Program 6 must comply with References (k) through (m), including submission of reports to the Defense Technical Information Center in the required format.

6. ADDITIONAL CONSIDERATIONS FOR CIs

a. CIs involving human subjects:

(1) Must be conducted in accordance with Reference (g).

(2) Medical care for research-related injury must be provided in accordance with Reference (g).

(3) That constitute non-exempt research require scientific review in accordance with Reference (g) and in accordance with the procedures in Reference (y).

(4) Identification and assessment of health hazards associated with military materiel (e.g., weapons platforms, munitions, equipment, clothing, training devices, and other materiel systems) must be conducted in accordance with Reference (n).

(5) Involving collection of information via a survey as defined in Reference (o) or survey instrument as defined in Reference (w) must be reviewed in accordance with the policies and procedures contained in Reference (w).

b. CIs involving laboratory animals must be conducted in accordance with Reference (q).

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

CI	clinical investigation
CIP	Clinical Investigations Program
CIPO	Clinical Investigation Program Office
CRADA	Cooperative Research and Development Agreement
DAD	Deputy Assistant Director
DCI	Department of Clinical Investigation
DHA	Defense Health Agency
DHA-PI	Defense Health Agency-Procedural Instruction
DHP	Defense Health Program
GHSE	graduate health sciences education
GME	Graduate Medical Education
J-1	Administration and Management
J-6	Information Operations
J-8	Financial Operations
MHS	Military Health System
MTF	Military Medical Treatment Facility
O&M	Operations and Maintenance
R&E	Research and Engineering
RDT&E	Research, Development, Test, and Evaluation
USUHS	Uniformed Services University of the Health Sciences

PART II. DEFINITIONS

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

CI. An organized inquiry into and possible development of knowledge or products related to clinical health problems for any conditions of concern in providing health care to beneficiaries of the MHS, including active duty personnel, dependents, and retired personnel. CIs represent a special category of healthcare research. CIs are intended to improve the quality of medical, dental, nursing, and allied health science care provided to beneficiaries of DoD health services or

to support GHSE programs, other allied health programs of the Military Services, and the Uniformed Services University of the Health Sciences (USUHS).

CIP. A program in which CIs are conducted for health sciences education to develop the MHS Force or for the advancement of medical science and its military and nonmilitary application to patient care.

CRADA. An agreement the DoD Components, Military Departments, and USUHS may enter into to conduct research, including CI studies, in accordance with Section 3710a of Reference (r), References (s), (t), and (v). A CRADA provides the preferred mechanism to establish collaborative relationships with industry and academic institutions.

direct costs. Research costs which are readily and directly identifiable to the particular project or activity and, as applicable, allowable under the sponsoring organization's guidelines. Examples of direct costs include, but are not limited to, compensation of non-DoD employees such as research assistants and consultants; project-related equipment, materials, and supplies (including animals and cell lines); travel; publication costs; Institutional Review Board services; computer services; sub-award, consortium, or contractual costs; equipment or facility rental/user fees; communication costs; and, only when essential and unique to the proposed project, computers and software.

GHSE. Programs of the uniformed services and USUHS, such as GME, Graduate Dental Education, Graduate Nursing Education, and Graduate Allied Health Science Education that promote the high professional standing and accreditation of health education programs.

gift. Any donation of funds, real or personal property from a non-federal source for which there is no compensation or promise of compensation on behalf of the donor. A gift may be offered and accepted with or without specified limitations on ownership or use (i.e., may be a conditional or unconditional gift). Service and USUHS GHSE programs may use gifts of funds or personal property to support a CI study under procedures prescribed by Sections 2601 and 2113 of Reference (i). Service and GHSE programs may accept a grant not covered by agreements through the USUHS in accordance with Sections 2601 and 2113 of Reference (i).

grant. When provided from a federal agency, a grant is a legal instrument used to enter into a relationship, the principal purpose of which is to transfer a thing of value (e.g., money) to the recipient to carry out a public purpose of support or stimulation authorized by law. Substantial involvement between the DoD and the recipient is not expected when carrying out the activity contemplated by the grant. When provided by a non-federal entity, a grant is an award of funds, services, or real or personal property, for the purpose of stimulating higher learning or research, from a corporation, foundation, trust, institution, or other entity that is not organized for profit and does not provide any net earnings to shareholders or individuals.

Major Force Program 6. DoD funds appropriated for R&E.

Major Force Program 8. DoD funds appropriated for training, medical, and other general purpose activities, including the provision of health care.

MHS. The DoD medical and dental programs, personnel, facilities, and other assets of the Military Services operating pursuant to Chapter 55 of Reference (i) by which the DoD provides health care services to the Military Services during military operations and supports the military mission by fostering, protecting, sustaining, and restoring health. It also provides the direction, resources, healthcare providers, and other means necessary for promoting the health of the beneficiary population (e.g., members of the Military Services, their family members, and others entitled to DoD medical care). These include developing and promoting health awareness issues to educate customers, discovering and mitigating environmentally based health threats, providing health services, including preventive care and problem intervention, Multi-Service Markets with enhanced authorities, and improving the means and methods for maintaining the health of the beneficiary population by constantly evaluating the performance of the healthcare services system.

O&M funds. DHP funding that supports the delivery of health care in the MTFs and private sector and associated operating activities, education, base operating support, and management oversight, including infrastructure management of CIs. O&M funds are available for obligation for the period of 1 fiscal year.

research. In accordance with Reference (e), any systematic study directed toward fuller scientific knowledge or understanding of military health care and in support of health readiness solutions that protect, treat, and optimize the health and performance of the total force as envisioned in Reference (u) or in analysis or guidance that may be established by the DoD's leadership in these fields of study.

RDT&E funds (research funds). Funding that supports the DHP RDT&E portfolio at both intramural and extramural medical research activities. The DHP RDT&E appropriation also funds research programs for medical information management/information technology, medical research to reduce capability gaps, support to medical laboratory facilities inside and outside the continental United States, and the Armed Forces Radiological Research Institute. Funds are available for obligation for the period of 2 fiscal years.