



Department of Defense **INSTRUCTION**

NUMBER 6000.08
January 22, 2014

USD(P&R)

SUBJECT: Defense Health Program Research and Clinical Investigation Programs

References: See Enclosure 1

1. **PURPOSE.** This instruction:

a. Reissues DoD Instruction (DoDI) 6000.08 (Reference (a)) in accordance with the authority in DoD Directive (DoDD) 5124.02 (Reference (b)) and DoDD 5136.01 (Reference (c)).

b. Establishes DoD policy, assigns responsibilities, and provides procedures for funding and administration of Research and Clinical Investigation Programs (CIP) funded by the Defense Health Program (DHP) appropriation.

2. **APPLICABILITY.** This instruction:

a. Applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this instruction as the "DoD Components").

b. Encompasses all elements of research and CIP relating to the medical mission of the Military Health System (MHS) funded through DHP. CIP is funded by DHP operation and maintenance (O&M) funds and DHP research is comprised of research, development, test, and evaluation (RDT&E) funds.

3. **POLICY.** It is DoD policy that:

a. DHP-funded medical research and CIP are essential missions of the MHS, intended to achieve these objectives:

(1) Development and employment of health readiness solutions that protect, treat, and optimize the health and performance of the total force as envisioned in the Force Health

Protection Concept of Operations (Reference (d)) or other analyses or guidance the DoD's leadership may establish.

(2) Improve the quality of patient care in the MHS by improving medical knowledge, practices, materiel, devices, pharmaceuticals, and by providing the DoD beneficiary population with access to evidence-based diagnosis and treatment.

(3) Maintain a medical research portfolio that is responsive to the needs of the MHS and the dynamic nature of the health sciences.

b. CIP is an essential component of medical care and teaching. CIP will:

(1) Support Graduate Health Sciences Education (GHSE) and other allied health programs of the Military Services.

(2) Promote high professional standing and accreditation of health education and training programs within the MHS.

c. MHS facilities, military research laboratories, military treatment facilities, and dental treatment facilities, which collaborate with extramural researchers under DHP-funded grants, cooperative agreements, or procurement contracts, will be reimbursed for their direct and indirect costs in accordance with DoD 7000.14-R, Volume 11a, (Reference (e)). These facilities will be reimbursed either directly from the responsible or appropriate government resource management office, or from the extramural award recipients via cooperative research and development agreements (CRADAs), agreements carried out under the authority of DoDI 5535.11 (Reference (f)), intergovernmental agreements, or other such mechanisms as allowed by law or regulation.

4. RESPONSIBILITIES. Enclosure 2.

5. PROCEDURES. Enclosure 3.

6. INFORMATION COLLECTION REQUIREMENTS. The Clinical Investigation Program Annual Report, referred to in paragraph 2d of Enclosure 2 of this instruction, has been assigned report control symbol DD-HA(A)2259 in accordance with the procedures in Directive-type Memorandum 12-004 (Reference (g)) and DoD 8910.1-M (Reference (h)).

7. RELEASABILITY. **Unlimited**. This instruction is approved for public release and is available on the Internet from the DoD Issuances Website at <http://www.dtic.mil/whs/directives>.

8. EFFECTIVE DATE. This instruction:

a. Is effective January 22, 2014.

b. Must be reissued, cancelled, or certified current within 5 years of its publication to be considered current in accordance with DoDI 5025.01 (Reference (i)).

c. Will expire effective January 22, 2024 and be removed from the DoD Issuances Website if it hasn't been reissued or cancelled in accordance with Reference (i).


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ENCLOSURE 1

REFERENCES

- (a) DoD Instruction 6000.08, "Funding and Administration of Clinical Investigation Programs," December 3, 2007 (hereby cancelled)
- (b) DoD Directive 5124.02, "Under Secretary of Defense for Personnel and Readiness (USD(P&R))," June 23, 2008
- (c) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013
- (d) Force Health Protection Concept of Operations (CONOPS), November 17, 2011
- (e) DoD 7000.14-R, "Department of Defense Financial Management Regulation," dates vary by volume
- (f) DoD Instruction 5535.11, "Availability of Samples, Drawings, Information, Equipment, Materials, and Certain Services to Non-DoD Persons and Entities," March 19, 2012
- (g) Directive-type Memorandum 12-004, "DoD Internal Information Collections," April 24, 2012, as amended
- (h) DoD 8910.1-M, "DoD Procedures for Management of Information Requirements," June 30, 1998
- (i) DoD Instruction 5025.01, "DoD Directives Program," September 26, 2012, as amended
- (j) DoD Directive 5134.3, "Director of Defense Research and Engineering (DDR&E)," November 3, 2003
- (k) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013
- (l) DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," November 8, 2011
- (m) Title 32, Code of Federal Regulations
- (n) DoD Instruction 3216.01, "Use of Animals in DoD Programs," September 13, 2010
- (o) Section 742 of Public Law 104-201, "National Defense Authorization Act for Fiscal Year 1997," September 23, 1996
- (p) Title 10, United States Code
- (q) Title 15, United States Code
- (r) DoD Instruction 4000.19, "Support Agreements," April 25, 2013
- (s) DoD Directive 5500.07, "Standards of Conduct," November 29, 2007
- (t) DoD 5500.07-R, "Joint Ethics Regulation (JER)," August 30, 1993, as amended
- (u) DoD Instruction 6000.16, "Military Health Support for Stability Operations," May 17, 2010
- (v) Title 31, United States Code
- (w) DoD Directive 5535.3, "DoD Domestic Technology Transfer (T2) Program," May 21, 1999
- (x) DoD Instruction 5535.8, "DoD Technology Transfer (T2) Program," May 14, 1999
- (y) Section 501(c)(3) of Title 26, United States Code

ENCLOSURE 2

RESPONSIBILITIES

1. ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS (ASD(HA)). Under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, the ASD(HA):

a. Exercises authority, direction, and control over DHP research and CIP as they relate to this instruction.

b. Monitors implementation of this instruction through the process of review and approval of DoD Component plans for executing CIP funds and DHP research funds, reports, and briefings in accordance with section 3 above the signature line.

c. Conducts site visits and program reviews as appropriate.

d. Oversees the execution of both technical and financial matters for CIP and DHP funded research to ensure programs are meeting the objectives stated in accordance with the policy in this instruction.

e. Develops and issues strategic guidance in coordination with the Assistant Secretary of Defense for Research and Engineering in accordance with section 4 of DoDD 5134.3 (Reference (j)).

2. OSD AND DOD COMPONENT HEADS THAT CONDUCT OR SUPPORT RESEARCH AND CIP. The OSD and DoD Component heads that conduct or support research and CIP covered by this instruction:

a. Develop, issue, and monitor their Component's management plan. The Component's implementing policies and procedures for the administration of DHP research and CIP funding will be contained in the management plan.

(1) The authority and responsibility for implementing and overseeing the Component management plan will only be delegated to a single, senior official at the general or flag officer, Senior Executive Service, or equivalent level, or higher.

(2) For RDT&E, Component management plans will be integrated by and across components and evaluated and approved by the ASD(HA) or a designee on the basis of interoperability, effectiveness, and elimination of unwarranted duplication.

b. Establish and oversee Component implementing policies and procedures in support of this instruction. Component policies may be more restrictive than the requirements in this instruction, but they may not be less restrictive.

c. In coordination with the Office of Assistant Secretary of Defense for Health Affairs (OASD(HA)), 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 ASD(HA), or a designee, as requested on CIP and DHP funded research activities conducted in accordance with this instruction. Separately, for CIP, at the beginning of the fiscal year, OASD(HA) will provide the list of data elements to be included in the annual report for that year.

3. DIRECTOR, DEFENSE HEALTH AGENCY (DHA). Under the authority, direction, and control of the ASD(HA) and DoDD 5136.13 (Reference (k)), the Director, DHA, will, in addition to responsibilities under section 2 of this enclosure, with respect to other responsibilities and functions of the DHA:

- a. Implement this instruction.
- b. Support the responsibilities and functions of the ASD(HA) under this instruction.

ENCLOSURE 3

PROCEDURES

1. DOD COMPONENT MANAGEMENT PLAN. In order to accomplish the responsibilities described in section 2 of Enclosure 2, DoD Component management plans must:

a. Incorporate the minimum requirements in this enclosure.

b. Include policies and procedures that:

(1) Comply with this instruction.

(2) Collect the data required for reports to the ASD(HA).

(3) Establish Component headquarters review and oversight of activities conducted in accordance with this instruction.

(4) Delineate the management and administration of funds for research and CIP conducted in accordance with this instruction.

(5) Collect CIP performance metrics per the data call for this instruction.

(6) Ensure research involving human and animal subjects is appropriately resourced to support the requirements of DoD policy and federal law as contained in DoDI 3216.02 (Reference (l)), part 219 of Title 32, Code of Federal Regulations (Reference (m)), and DoDI 3216.01 (Reference (n)). This will include the eligibility of human subject volunteers to participate and will address research related injuries.

(7) Reimburse MHS facilities for research-related expenses in accordance with federal law, DoD issuances, including Reference (e), and Military Department regulations.

(8) Manage records for research and CIP conducted in accordance with this instruction (e.g., for CIP use of the MHS-wide web based electronic research management tool for workflow processing).

(9) Provide education and training for implementation, management, and oversight in accordance with the policy in this instruction.

(10) Integrate applicable policy and guidance.

c. For each activity identified in paragraph 1b in this enclosure, identify the responsible Component office.

2. DHP EXTRAMURAL FUNDING AND ADMINISTRATION ACTIVITIES

a. Before committing or spending DHP funds on an extramural medical research project that involves human subjects and is conducted solely by a non-federal entity, the research project protocol must be reviewed through an external peer review process in accordance with section 742 of the National Defense Authorization Act for Fiscal Year 1997 (Reference (o)).

b. DHP funds must not be used to support an extramural medical research activity in a college or university if such support violates section 2361 of Title 10, United States Code (U.S.C.) (Reference (p)).

3. OVERALL FUNDING AND ADMINISTRATION ACTIVITIES

a. All research activities and clinical investigations (CIs) using DHP funds must refer to Reference (e) for all financial management policy and guidance.

b. CIP infrastructure support is funded with DHP O&M approved by Congress in the annual DoD Appropriation Act. CIP may receive funding support from DHP RDT&E funds or other federal and non-federal sources to the extent permissible by law and federal regulations.

c. OSD and DoD Components will give priority to authorizing CIP and DHP funded research projects that are aligned with the strategic guidance from the ASD(HA).

d. DoD Components will accept support from other federal sources in accordance with section 2358 of Reference (p) (e.g., National Institutes of Health and U.S. Centers for Disease Control and Prevention), only when it is consistent with and promotes the accomplishment of valid mission objectives.

e. DoD Components will accept support from non-federal sources only when it is consistent with and promotes the accomplishment of valid mission objectives. Support from non-federal sources is authorized as provided by law, DoD issuances, Military Department regulations, and this instruction. DoD Components will establish management controls to ensure legal review of the acceptance and use of such funds and to comply with any other procedures established by the ASD(HA).

f. In addition to core funding, DHP-funded medical research, including CIs, may, if consistent with the management controls referred to in paragraph 3e of this enclosure, be funded and administered through any mechanism authorized by law, DoD issuances, and Military Department regulations, including, but not limited to:

- (1) Contracts.
- (2) Grants.
- (3) Cooperative agreements.

(4) CRADA pursuant to section 3710a of Title 15, U.S.C. (Reference (q)).

(5) Agreements pursuant to section 2539b of Reference (p).

(6) Agreements through the Uniformed Services University of the Health Sciences (USUHS).

(7) Gifts in accordance with section 2601 of Reference (p) and volume 12, chapter 30 of Reference (e).

(8) Interagency and interservice agreements, including support agreements in accordance with DoDI 4000.19 (Reference (r)).

(9) Royalties, in accordance with section 3710c of Reference (q).

g. All research activities and CIs using DHP funds must ensure procurement contracts, grants, and cooperative agreements for DHP-funded awards that provide for the use of MHS facilities, include in their award budgets appropriate reimbursement for direct and indirect costs to such facilities, in accordance with Reference (e), and other relevant DoD issuances and guidance.

h. In all cases involving determination of reasonable charges for collaborations or cooperation with non-federal entities, the parties involved in the collaboration or cooperation will execute a written agreement or, in the case of a gift, a written acknowledgment that will describe:

(1) What the non-federal entity will provide in terms of specific support and the activities it will carry out in connection with that support. Before approval by the designated DoD senior official, the parties involved in the agreement will specify for personal property a description of property, quantity provided, projected use and its ultimate disposition (including disposition of any item(s) on loan).

(2) The conditions accepted by the designated DoD senior official for provision of the non-federal support.

(3) The manner in which designated personnel (e.g., research or CIP personnel) will handle data, intellectual property, and any other property rights.

i. All research activities and CIs using DHP funds must ensure DoD senior officials accept non-federal support for medical research and CIP only in strict compliance with the program integrity requirements in DoDD 5500.07 (Reference (s)), DoD 5500.07-R (Reference (t)), and in accordance with the policy in this instruction:

(1) Acceptance of non-federal support will be well documented and transparent and avoid the appearance of preferential treatment of any entity or other impropriety. Where non-

competitive selection is permitted under law (e.g., under CRADAs or simplified acquisition procedures), local procedures will ensure appropriate safeguards and justification.

(2) Except as specifically authorized by law, DoD healthcare personnel are prohibited from accepting any compensation from any non-federal source for performing duties within the scope of the CIP. This includes any off-duty employment in connection with a CI activity.

(3) DoD personnel will not accept payment in connection with a CI activity or direct payment to third parties, including to non-federal entities that support DoD CI activities.

(4) DoD personnel will not direct the use of funds of a non-federal entity in connection with a CI activity except as specifically provided by an applicable approved agreement.

(5) DoD personnel will not initiate requests for gifts. They may:

(a) Complete standard applications for, and respond to announcements of, non-federal research grants.

(b) Initiate non-binding discussions with non-federal parties regarding potential collaborations that would be carried out under CRADAs, material transfer agreements, and non-disclosure agreements.

j. DoD Components will 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 such cases:

(1) The extramural investigator must include, with the proposal, a letter from the intramural collaborator's commanding officer or facility director that authorizes the involvement of the intramural collaborator.

(2) The intramural collaborator will ensure applicable and reasonable reimbursements for MHS facility support are included in the submitted extramural proposal, e.g., through coordination of estimated applicable costs with the local resource management office or relevant technology transfer office.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

ASD(HA)	Assistant Secretary of Defense for Health Affairs
CI	clinical investigation
CIP	clinical investigation program
CRADA	cooperative research and development agreement
DHA	Defense Health Agency
DHP	Defense Health Program
DoDD	DoD directive
DoDI	DoD instruction
GHSE	graduate health sciences education
MHS	Military Health System
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
O&M	operation and maintenance
RDT&E	research, development, test, and evaluation
U.S.C.	United States Code
USUHS	Uniformed Services University of the Health Sciences

PART II. DEFINITIONS

These terms and their definitions are for the purpose of this instruction.

agreements through the USUHS. The DoD may, in connection with USUHS activities, carry out cooperative enterprises in medical research, medical consultation, and medical education in accordance with section 2113(g) of Reference (p). These enterprises may be engaged through contracts with, grants to or from, and personal services from nonprofit entities; they may accept gifts from these or other entities.

CI. An organized inquiry into and possible development of knowledge or products related to clinical health problems for any conditions of concern in providing healthcare to the 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 quality of medical, dental, nursing and allied health science care provided to beneficiaries of DoD health services or support the GHSE programs, other allied health programs of the Military Services, and USUHS.

CIP. Programs in which CIs are conducted for health sciences education to develop the MHS Force, or CIs are conducted for the advancement of medical science and its military and nonmilitary application to patient care. CIP is funded with DHP O&M funds and may have procurement funds for purchase of equipment as applicable. The CIP may receive DHP RDT&E funding for CIs on health problems encountered by DoD eligible beneficiaries if such investigations are in support of human clinical trials in the DHP RDT&E research areas. The CIP may receive funding on a case by case basis from non-DHP research funds in accordance with applicable federal laws and written agreements with the non-DHP sponsor. Investigations that address medical stability operations must follow DoDI 6000.16 (Reference (u)). CIs may be conducted with funds obtained by grants from another federal agency or other non-federal sources as permissible by law and federal regulations. Military contingency requirements take precedence over the requirements of the CIP.

contract. A mutually binding legal relationship obligating the seller to furnish the supplies or services (including construction) and the buyer to pay for them. It includes all types of commitments that obligate the U.S. Government to an expenditure of appropriated funds and that, except as otherwise authorized, are in writing. In addition to bilateral instruments, contracts include (but are not limited to) awards and notices of awards; job orders or task letters issued under basic ordering agreements; letter contracts; orders, such as purchase orders, under which the contract becomes effective by written acceptance or performance; and bilateral contract modifications. Contracts do not include grants and cooperative agreements covered by sections 6304 and 6305 of Title 31, U.S.C. (Reference (v)).

cooperative agreement. A legal instrument which, consistent with section 6305 of Reference (u), is used to enter into the same kind of relationships as a federal grant, except that substantial involvement is expected between the DoD and the recipient when carrying out the activity contemplated by the cooperative agreement. The term does not include “cooperative research and development agreements” as defined in section 3710a of Reference (q).

CRADA. An agreement that DoD Components, the Military Departments and USUHS may enter into to conduct research including CI studies in accordance with section 3710a of Reference (q), DoDD 5535.3 (Reference (w)), and DoDI 5535.8 (Reference (x)). A CRADA provides the preferred mechanism to establish collaborative relationships with industry and academic institutions.

data call. The document OASD(HA) provides at the beginning of the fiscal year to the CIP representatives of the Military Services, Defense Health Agency, and USUHS with the list of data elements to be included in the annual report for that year.

DHP appropriation. A single appropriation consisting of operation and maintenance; research, development, test, and evaluation; and procurement funds designed to finance the non-military personnel requirements of the MHS.

DoD MHS. The DoD medical and dental programs, personnel, facilities, and other assets of the Military Services operating pursuant to Chapter 55 of Reference (p) 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.

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

gift. Any donation of funds, or 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 (p). Service and GHSE programs may accept a grant not covered by agreements through the USUHS in accordance with sections 2601 and 2113 of Reference (p).

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.

infrastructure support. Support for Institutional Review Board and Institutional Animal Care and Use Committee functions, research support, statistical support, grant writing assistance, funds for research related to maintaining accredited, training programs, and other funds associated with maintaining research in the CIP.

Multi-Service Markets. The DoD's approach to coordinating care in military markets served by more than one Military Department. Enhanced Multi-Service Markets are Multi-Service

Markets identified by Reference (k). These markets are provided with “enhanced” authorities that include the authority to manage the allocation of the budget for the market, direct the adoption of common clinical and business functions for the market, optimize readiness to deploy medically ready forces and ready medical forces, and direct the movement of workload and workforce between or among the medical treatment facilities. These authorities are effective October 1, 2013.

nonprofit entity. A corporation, fund, or foundation exempt from federal income taxation under section 501(c)(3) of Title 26, U.S.C. (Reference (y)).

O&M funds. DHP funding that supports the delivery of health care in the military treatment facilities 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 one fiscal year.

research. Any systematic study directed toward fuller scientific knowledge or understanding of military healthcare and in support of health readiness solutions that protect, treat, and optimize the health and performance of the total force as envisioned Reference (d) or in other analysis or guidance that may be established by the DoD’s leadership in these fields of study.

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.