



# Joint Task Force National Capital Region Medical **INSTRUCTION**

NUMBER 6000.02  
AUG 23 2011

J-7

SUBJECT: Funding and Administration of Clinical Investigation Programs (CIPs)

References: See Enclosure 1

1. **PURPOSE.** This Instruction, under the authority of JTF CapMed Directive 5707.05 (Reference (a)), establishes Joint Task Force National Capital Region Medical (JTF CapMed) policy and responsibilities for the administration and funding of CIPs in military Medical Treatment Facilities (MTFs) and Dental Treatment Facilities (DTFs) within the JTF CapMed in accordance with the guidance in DoD Instruction 6000.08 (Reference (b)).

2. **APPLICABILITY.** This Instruction:

a. Applies to JTF CapMed and all Joint MTFs and Centers in the National Capital Region (i.e., Fort Belvoir Community Hospital, Walter Reed National Military Medical Center, and the Joint Pathology Center).

b. Does NOT apply to the JTF CapMed units or organizations that do not conduct CIPs.

c. Does NOT apply to projects funded through the Defense Acquisition System or other projects under the provisions of DoD Directive (DoDD) 5000.1 (Reference (c)).

3. **DEFINITIONS.** See Glossary

4. **POLICY.** It is JTF CapMed policy that:

a. Clinical Investigation (CI) is an essential component of medical care and teaching intended to achieve the following objectives of JTF CapMed.

(1) Improve the quality of patient care.

(2) Support the graduate medical education (GME) programs of the JTF CapMed.

(3) Generate an atmosphere of inquiry in GME programs that is responsive to the dynamic nature of the health sciences.

(4) Promote high professional standing and accreditation of health education programs.

b. CIPs shall be funded with operating funds from Defense Health Program (DHP) appropriations provided by Congress through the annual DoD Authorization Act. CIPs may receive supplemental funding support from non-Federal sources through Cooperative Research and Development Agreements (CRADAs), agreements through the Uniformed Services University of the Health Services (USUHS), gifts, or reimbursements as set forth in this Instruction.

c. According to section 742 of Public Law 104-201 (Reference (d)), no JTF CapMed Joint MTF or Center official may obligate or expend DHP funds or other resources for any extramural (conducted outside the sponsoring JTF CapMed Joint MTF or Center) medical research project that involves human subjects and is conducted solely by a non-Federal entity unless the research protocol for the project has been approved by a formally designated peer review process as set forth in this Instruction.

d. Persons eligible for healthcare in MTFs and Centers according to Chapter 55 of title 10, United States Code (U.S.C.) (Reference (e)) may participate as CI study subjects as volunteers in accordance with DoDD 3216.02 (Reference (f)) and part 219 of title 32, Code of Federal Regulations (Reference (g)). Retired military personnel, dependents, and others not on active duty who voluntarily participate as CI subjects may be compensated subject to relevant DoD regulations, official JTF CapMed CI standard operating procedures, and when approved as appropriate by a JTF CapMed Institutional Review Board (IRB).

5. RESPONSIBILITIES. See Enclosure 2.

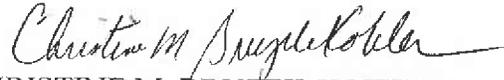
6. PROCEDURES. See Enclosure 3.

7. INFORMATION REQUIREMENTS. The reporting of the number, content, and funding of CIP grants to the ASD(HA) annually has been assigned Report Control Symbol (RCS) D-HA(A)2259 in accordance with DoD 8910.1-M (Reference (h)).

8. RELEASABILITY. UNLIMITED. This Instruction is approved for public release and is available on the Internet from the JTF CapMed Web Site at: [www.capmed.mil](http://www.capmed.mil).

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9. EFFECTIVE DATE. This Instruction is effective immediately.



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Executive Director for Healthcare Operations  
By direction of the Commander

Enclosures

1. References
  2. Responsibilities
  3. Requirements and Procedures for CIP Activities
- Glossary

ENCLOSURE 1

REFERENCES

- (a) JTF CapMed-D 5107.01, "Education, Training, and Research Decision Making Committee Charter," March 24, 2010
- (b) DoD Instruction 6000.08, "Funding and Administration of Clinical Investigation Programs," December 3, 2007
- (c) DoD Directive 5000.1, "The Defense Acquisition System," May 12, 2003
- (d) Section 742 of Public Law 104-201, "The National Defense Authorization Act for Fiscal Year 1997," September 23, 1996
- (e) Sections 1095(g), 2113, 2601, 2361, and Chapter 55 of title 10, "Medical Dental Care," United States Code
- (f) DoD Directive 3216.02, "Protection of Human Subjects in DoD-Supported Research," March 25, 2002
- (g) Part 219 of title 32, Code of Federal Regulations, "Protection of Human Subjects"
- (h) DoD 8910.1-M, "Department of Defense Procedures for Management of Information Requirements," June 30, 1998
- (i) DoD 7000.14-R, "DoD Financial Management Regulation," March 1, 1997
- (j) Section 3710a of title 15, United States Code
- (k) DoD Directive 5535.3, "DoD Domestic Technology Transfer (T2) Program," May 21, 1999
- (l) DoD Instruction 5535.8, "DoD Technology Transfer (T2) Program," May 14, 1999
- (m) Section 9701 of title 31, United States Code
- (n) DoD Directive 5500.7, "Standards of Conduct," November 29, 2007
- (o) DoD 5500.7-R, "Joint Ethics Regulation," August 30, 1993
- (p) DoD Instruction 3216.01, "Use of Laboratory Animals in DoD Programs," September 13, 2010
- (q) Section 501(c)(3) of title 26, United States Code

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ENCLOSURE 2RESPONSIBILITIES

1. ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS) (ASD(HA)). The ASD(HA), under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, is responsible for monitoring implementation of this Instruction through annual briefings to ASD(HA) officials by the JTF CapMed activities, site visits, and review of IRB and annual reports.

2. COMMANDER, JTF CAPMED. The Commander, JTF CapMed shall:

a. Establish CIPs.

b. Ensure JTF CapMed compliance with this Instruction.

c. Establish policies and procedures to ensure compliance with this Instruction within the Joint MTFs, Centers, and DTFs of the JTF CapMed.

d. Report the number, content, and funding of CIP grants to the ASD(HA) annually.

e. In accordance with applicable regulations, designate a management official to administer the support provided to the CIP. This official associated with the Joint MTF or DTF must not be associated with the CI receiving non-Federal support. DoD regulations and JTF CapMed policy governing financial management, property management, travel, standards of conduct, and other management matters shall apply to the administration of such support. Refer to DoD 7000.14-R (Reference (i)) for governing financial management policy and guidance.

3. JOINT MTF COMMANDERS AND CENTER DIRECTORS. Joint MTF Commanders and Center Directors, under the authority, direction, and control of the Commander, Joint Task Force, shall approve the acceptance of non-Federal support for CIP activities and shall ensure that any additional approvals required by DoD issuances are secured.

a. In accepting non-Federal support for CIPs, ensure it is received and administered to avoid giving special privileges to any entity, causing conflicts of interest, or creating the appearance of impropriety or a conflict of interest.

b. When more than one non-Federal entity exercises control over the support to be provided to the CIP, make decisions regarding acceptance and administration of the support based on an assessment of all involved non-Federal entities.

ENCLOSURE 3

REQUIREMENTS AND PROCEDURES FOR CIP ACTIVITIES

1. CIP SUPPORT FROM NON-FEDERAL SOURCES. The JTF CapMed activities shall accept CIP support from non-Federal sources only when it is consistent with and promotes the accomplishment of valid CIP objectives. Support from non-Federal sources is authorized only as provided by law, applicable Military Department regulations, and this Instruction.

a. Authorized Support

(1) JTF CapMed activities may enter into CRADAs to conduct CI studies in accordance with section 3710a of title 15, U.S.C. (Reference (j)); DoDD 5535.3 (Reference (k)); and DoD Instruction 5535.8 (Reference (l)). CRADAs provide the preferred mechanism to establish collaborative relationships with industry and academic institutions.

(2) The JTF CapMed Joint MTF and Center activities may carry out cooperative enterprises in medical research, medical consultation, and medical education in accordance with section 2113 of Reference (e). These enterprises may be engaged through contracts with, grants to or from, and personal services from the Henry M. Jackson Foundation for the Advancement of Military Medicine, or any other nonprofit entity.

(3) JTF CapMed programs may use gifts of funds or personal property to support a CI study subject to compliance with sections 2113 and 2601 of Reference (e) and implementing DoD or applicable Military Department regulations.

b. Reimbursement for Support

(1) In accordance with section 1095(g) of Reference (e), amounts collected for healthcare services provided under CIPs at or through an MTF or Center shall be credited to the DHP account and made available to the Joint MTF or Joint Center involved. This includes amounts collected for treatments and services provided as part of a CI protocol.

(2) In accordance with section 9701 of title 31, U.S.C. (Reference (m)) and Chapter 4 of Volume 11A of Reference (k), whenever a CIP activity is carried out at the request of, or otherwise conveys a special benefit to, a non-Federal entity, such entity shall pay a reasonable charge for the CIP services provided.

(3) In establishing a reasonable charge for a non-Federal entity where the entity requests or receives special benefit from the CIP activity, the reasonable charge shall be based on the full cost to the Joint MTF or Center of providing the services, or on the fair market value of the services, whichever is higher. The determination of reasonable charges for a particular CIP activity shall be established by agreement of the parties in accordance with the procedures in paragraph 1.c.

c. Determination of Reasonable Charges. In all cases involving non-Federal support for

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CIPs, the parties shall execute a written agreement, or, in the case of a gift, a written acknowledgment, which shall describe:

(1) What the non-Federal entity will provide in terms of specific support and the CI activities it will carry out in connection with that support. Before approval by a designated JTF CapMed Joint MTF or Center senior official, the parties to the agreement shall specify for personal property or personal services:

- (a) A description of the property or services.
- (b) The cost of the property or services.
- (c) The quantity provided.
- (d) The projected use.
- (e) Any expense anticipated in receiving or utilizing the property or services.
- (f) For personal property, its ultimate disposition, including the disposition of any item(s) on loan.

(2) The conditions accepted by the JTF CapMed Joint MTF or Center senior official for provision of the non-Federal support.

(3) The manner in which designated CI personnel will handle data, including any property rights.

(4) DoD regulations and stipulation that the support is for the JTF CapMed Joint MTF or Center involved, is subject to applicable DoD regulations and JTF CapMed policy, and is not for the personal use of an individual.

(5) Additional requirements for extramural projects:

(a) Prior to obligating or expending DHP funds or other resources on an extramural medical research project that involves human subjects and is conducted solely by a non-Federal entity, a formally designated peer review process shall approve the project. It shall evaluate the scientific merit of the research protocol and ensure the project has been approved by an IRB in accordance with Reference (f).

(b) Regarding fairness of competition in grants and contracts to colleges and universities, DHP funds shall not be used to support an extramural CIP activity in a college or university if such support violates section 2361 of Reference (e).

(6) The acceptance of non-Federal support for CIPs is subject to strict compliance with the program integrity requirements set forth in DoDD 5500.7 (Reference (n)), DoD 5500.7-R (Reference (o)), and this Instruction.

(a) Except as specifically authorized by law, JTF CapMed Joint MTF and Center healthcare personnel are prohibited from accepting any compensation from any non-Federal source for performing duties within the scope of a CIP. This includes any off-duty employment in connection with a CIP activity.

(b) JTF CapMed personnel shall not initiate requests for gifts. They may complete standard applications for, and respond to announcements of, non-Federal research grants.

2. CONDUCT OF CIP INVESTIGATIONS. All CIP investigators shall:

- a. Ensure all investigations involving human subjects comply with References (f) and (g).
- b. Ensure all investigations involving animals as subjects comply with DoD Instruction 3216.01 (Reference (p)).
- c. Ensure, for CI subjects participating without compensation, that case records document these individuals' acknowledgement and agreement to participate without compensation. Such subjects may include retired military personnel, dependents, and others not on active duty.
- d. Ensure for research involving more than minimal risk (as determined by the IRB having jurisdiction over the study) that an arrangement is in place for treatment of any research-related injury and is described in the protocol. Such an arrangement may be that all subjects are eligible healthcare beneficiaries or that they are granted Secretarial designation as healthcare beneficiaries under applicable DoD or Service regulations, or that specific obligations for such treatment have otherwise been undertaken.
- e. Ensure that no volunteer signs, or is requested to sign a statement that purports to limit any right of a subject to compensation for possible injuries arising from participation in the research.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

CI	clinical investigation
CIP	Clinical Investigation Program
CRADA	Cooperative Research and Development Agreement
DHP	Defense Health Program
DTF	Dental Treatment Facility
GME	Graduate Medical Education
IRB	Institutional Review Board
JTF CapMed	Joint Task Force, National Capital Region Medical
MTF	Military Treatment Facility
U.S.C.	United States Code
USUHS	Uniformed Services University of the Health Services

PART II. DEFINITIONS

Unless otherwise noted, the following definitions apply to the JTF CapMed funding and administration of CIPs.

CI. An organized inquiry into clinical health problems for any conditions of concern in providing healthcare to the beneficiaries of the military healthcare system including active duty personnel, dependents, and retired personnel.

gift. Any donation of funds, services, 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).

grant. 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.

minimal risk. Term applies to medical research where the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of itself than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

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