



# Department of Defense **INSTRUCTION**

**NUMBER** 6000.08

December 3, 2007

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USD(P&R)

**SUBJECT:** Funding and Administration of Clinical Investigation Programs

- References:**
- (a) DoD Directive 6000.8, "Funding and Administration of Clinical Investigation Programs," November 3, 1999 (hereby canceled)
  - (b) Acting Deputy Secretary of Defense Memorandum, "DoD Directives Review – Phase II," July 13, 2005
  - (c) DoD Directive 5124.02, "Under Secretary of Defense for Personnel and Readiness (USD(P&R))," October 17, 2006
  - (d) DoD Directive 5136.1, "Assistant Secretary of Defense for Health Affairs ASD(HA)," May 27, 1994
  - (e) through (s), see Enclosure 1

## 1. REISSUANCE AND PURPOSE

This Instruction:

1.1. Reissues Reference (a) as a DoD Instruction in accordance with the guidance in Reference (b) and the authority in References (c) and (d).

1.2. Establishes DoD policy and responsibilities for the administration and funding of Clinical Investigation (CI) Programs (CIPs) in Military Medical Treatment Facilities (MTFs), Dental Treatment Facilities (DTFs), and the Uniformed Services University of the Health Sciences (USUHS).

## 2. APPLICABILITY AND SCOPE

This Instruction:

2.1. Applies to the Office of the Secretary of Defense, the Military Departments, the Office of the Chairman of the Joint Chiefs of 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 Department of Defense (hereafter referred to collectively as the "DoD Components").

2.2. Encompasses all elements of a CIP relating to the medical mission of the Military Departments and the basic biomedical science and CI projects at USUHS.

2.3. Does not apply to the DoD Components that do not conduct CIPs.

2.4. Does not apply to projects funded through the Defense Acquisition System or other projects under the control of DoD Directive (DoDD) 5000.1 (Reference (e)).

### 3. DEFINITIONS

3.1. 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.

3.2. 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).

3.3. 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.

3.4. Nonprofit Entity. A corporation, fund, or foundation exempt from Federal income taxation under section 501(c)(3) of title 26, United States Code (U.S.C.) (Reference (f)).

3.5. 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.

### 4. POLICY

It is DoD policy that:

4.1. CI is an essential component of medical care and teaching intended to achieve the following objectives of the Department of Defense.

4.1.1. Improve the quality of patient care.

4.1.2. Support the graduate medical education (GME) programs of the Services and USUHS.

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

4.1.4. Promote high professional standing and accreditation of health education programs.

4.2. CIPs shall be funded from 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 USUHS, gifts, or reimbursements as set forth in paragraph 6.1.

4.3. According to section 742 of Public Law 104-201 (Reference (g)), no DoD official may obligate or expend DHP funds for any extramural (conducted outside the sponsoring organization) 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 the external peer review process set forth in paragraphs 6.1.4.1 and 6.1.4.2.

4.4. Persons eligible for healthcare in medical treatment facilities according to Chapter 55 of title 10, U.S.C. (Reference (h)) may participate as CI study subjects as volunteers in accordance with DoDD 3216.2 (Reference (i)) and part 219 of title 32, Code of Federal Regulations (Reference (j)). Retired military personnel, dependents, and others not on active duty who voluntarily participate as CI subjects may be compensated when Military Department or USUHS officials believe it appropriate and when approved by an Institutional Review Board (IRB).

## 5. RESPONSIBILITIES

5.1. The Assistant Secretary of Defense (Health Affairs) (ASD(HA)), under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, shall monitor implementation of this Instruction through annual briefings to ASD(HA) officials by the DoD Components, site visits, and review of IRB and annual reports.

5.2. The Secretaries of the Military Departments shall:

5.2.1. Establish CIPs.

5.2.2. Ensure their Component's compliance with this Instruction.

5.3. The Surgeons General of the Military Departments, under the authority, direction, and control of the Secretaries of the Military Departments, shall:

5.3.1. Establish policies and procedures to ensure compliance with this Instruction within the MTFs and DTFs of their respective Military Departments.

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

5.3.3. In accordance with applicable regulations, designate a management official to administer the support provided to the CIP. This official associated with the MTF or DTF must not be associated with the CI receiving non-Federal support. DoD and Service regulations governing financial management, property management, travel, standards of conduct, and other management matters shall apply to the administration of such support.

5.3.4. Refer to DoD 7000.14-R (Reference (k)) for all financial management policy and guidance.

5.4. The President, USUHS, or his or her designee, under the authority, direction, and control of the Director, TRICARE Management Activity, shall:

5.4.1. Approve the acceptance of non-Federal support for CIP activities and shall ensure that any additional approvals required are secured.

5.4.2. Establish procedures for utilizing the authorities cited in paragraph 6.1.1.2. to support CIs conducted by MTFs and DTFs or affiliated with USUHS.

5.4.3. Ensure USUHS compliance with applicable portions of this Instruction.

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

5.4.5. Include in the CIP file a statement of any current or prospective business relationship that the Department of Defense may have with any non-Federal entity involved in USUHS CI activities.

5.4.6. Designate a management official to administer the support provided in accordance with applicable regulations. This official associated with USUHS must not be associated with the CI receiving non-Federal support. DoD and USUHS regulations governing financial management, property management, travel, standards of conduct, and other management matters shall apply to the administration of such support.

5.4.7. Refer to Reference (k) for all financial management policy and guidance.

5.4.8. 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.

5.4.9. 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.

5.5. MTF and DTF commanders, under the authority, direction, and control of the Surgeons General of the Military Departments, shall approve the acceptance of non-Federal support for CIP activities and shall ensure that any additional approvals required by Service regulations are secured.

5.5.1. 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.

5.5.2. 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.

## 6. REQUIREMENTS AND PROCEDURES

The DoD Components shall adhere to the following requirements and procedures in conducting CIP activities.

6.1. CIP Support from Non-Federal Sources. The DoD Components 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, Military Department regulations, and this Instruction.

### 6.1.1. Authorized Support

6.1.1.1. CRADAs. The Military Departments and USUHS may enter into CRADAs to conduct CI studies in accordance with section 3710a of title 15, U.S.C. (Reference (l)); DoDD 5535.3 (Reference (m)); and DoD Instruction 5535.8 (Reference (n)). CRADAs provide the preferred mechanism to establish collaborative relationships with industry and academic institutions.

6.1.1.2. Agreements through USUHS. The Department of Defense may, in connection with USUHS activities, carry out cooperative enterprises in medical research, medical consultation, and medical education in accordance with section 2113(j) of Reference (h). These enterprises may be engaged in 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; they may accept gifts from these or other entities.

6.1.1.3. Gifts. Service and USUHS GME programs may use gifts of funds or personal property to support a CI study under procedures prescribed by sections 2601 and 2113 of Reference (h). Service and GME programs may accept under this paragraph a grant not covered by paragraph 6.1.1.2.

### 6.1.2. Reimbursement for Support

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

6.1.2.2. In accordance with section 9701 of title 31, U.S.C. (Reference (o)) 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.

6.1.2.3. 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 Department of Defense 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 6.1.3.

6.1.3. Determination of Reasonable Charges. In all cases involving non-Federal support for CIPs, the parties shall execute a written agreement, or, in the case of a gift, a written acknowledgment, which shall describe:

6.1.3.1. 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 senior CIP official, the parties to the agreement shall specify for personal property or personal services:

6.1.3.1.1. A description of the property or services.

6.1.3.1.2. The cost of the property or services.

6.1.3.1.3. The quantity provided.

6.1.3.1.4. The projected use.

6.1.3.1.5. Any expense anticipated in receiving or utilizing the property or services.

6.1.3.1.6. For personal property, its ultimate disposition, including the disposition of any item(s) on loan.

6.1.3.2. The conditions accepted by the DoD CIP senior official for provision of the non-Federal support.

6.1.3.3. The manner in which designated CIP personnel will handle data, including any property rights.

6.1.3.4. The stipulation that the support is for the DoD facility involved, is subject to applicable DoD regulations, and is not for the personal use of an individual.

6.1.4. Additional Requirements for Extramural Projects

6.1.4.1. Prior to obligating or expending DHP funds on an extramural medical research project that involves human subjects and is conducted solely by a non-Federal entity, an external peer review process shall approve the project. Such process shall involve a person or persons who are not officers or employees of the Federal Government. It shall evaluate the scientific merit of the research protocol and ensure the project has been approved by an IRB in accordance with Reference (i).

6.1.4.2. The external peer review requirements were established as of October 1, 1996. They apply to all external medical research projects funded after that date, except a medical research project that has been substantially completed by October 1, 1996, or a medical research project funded under any provision of law enacted after October 1, 1996, that exempts the project from Reference (g).

6.1.4.3. 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 (h).

6.1.5. Program Integrity. 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 (p)), DoD 5500.7-R (Reference (q)), and this Instruction.

6.1.5.1. 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 a CIP. This includes any off-duty employment in connection with a CIP activity.

6.1.5.2. DoD personnel shall not initiate requests for gifts. They may complete standard applications for, and respond to announcements of, non-Federal research grants.

6.2. Conduct of CIP Investigations. All CIP investigators shall:

6.2.1. Ensure all investigations involving human subjects comply with References (i) and (j).

6.2.2. Ensure all DoD CIP investigations involving animals as subjects comply with DoDD 3216.1 (Reference (r)).

6.2.3. For retired military personnel, dependents, and others not on active duty participating as CI subjects without compensation, create case records documenting these individuals' acknowledgment and agreement to participate as subjects without compensation.

6.2.4. Because subjects may be injured while participating in CI research, for research involving more than minimal risk as determined by the IRB having jurisdiction over the study, include in every intramural (in-house) CIP protocol an arrangement for treatment of any research-related injuries. Such arrangement in the protocol may be that all subjects are eligible DoD healthcare beneficiaries, that they are granted Secretarial designation as DoD healthcare

beneficiaries under applicable Service regulations, or that specific obligations for such treatment have otherwise been undertaken.

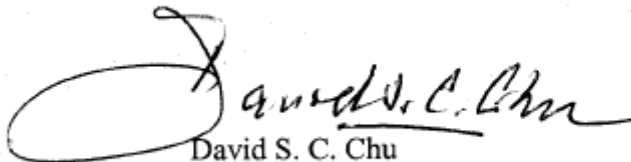
6.2.5. Under no circumstances, request or permit volunteers to sign a statement that purports to limit any right of a subject to compensation for possible injuries arising from participation in the research.

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 (s)).

8. EFFECTIVE DATE

This Instruction is effective immediately.



David S. C. Chu  
Under Secretary of Defense for  
Personnel and Readiness

Enclosure

References, continued



E1. ENCLOSURE 1

REFERENCES, continued

- (e) DoD Directive 5000.1, "The Defense Acquisition System," May 12, 2003
- (f) Section 501(c)(3) of title 26, United States Code
- (g) Section 742 of Public Law 104-201, "The National Defense Authorization Act for Fiscal Year 1997," September 23, 1996
- (h) Sections 1095(g), 2113, 2601, 2361, and Chapter 55 of title 10, United States Code
- (i) DoD Directive 3216.02, "Protection of Human Subjects in DoD Supported Research," March 25, 2002
- (j) Part 219 of title 32, Code of Federal Regulations, "Protection of Human Subjects"
- (k) DoD 7000.14-R, "DoD Financial Management Regulation," March 1, 1997
- (l) Section 3710a of title 15, United States Code
- (m) DoD Directive 5535.3, "Department of Defense Technology Transfer (T2) Program," May 21, 1999
- (n) DoD Instruction 5535.8, "DoD Technology Transfer (T2) Program Procedures," May 14, 1999
- (o) Section 9701 of title 31, United States Code
- (p) DoD Directive 5500.7, "Standards of Conduct," August 30, 1993
- (q) DoD 5500.7-R, "Joint Ethics Regulation," August 30, 1993
- (r) DoD Directive 3216.1, "Use of Laboratory Animals in DoD Programs," April 17, 1995
- (s) DoD 8910.1-M, "DoD Procedures for Management of Information Requirements," June 30, 1998