



# Department of Defense DIRECTIVE

NUMBER 6000.8

November 3, 1999

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ASD(HA)

SUBJECT: Funding and Administration of Clinical Investigation Programs

- References: (a) DoD Directive 6000.8, "Funding and Administration of Clinical Investigation Program," December 6, 1985 (hereby canceled)
- (b) [DoD Directive 5000.1](#), "Defense Acquisition," March 15, 1996
- (c) Section 3710a of title 15 United States Code
- (d) [DoD Directive 5535.3](#), "Department of Defense Technology Transfer (T2) Program," May 21, 1999
- (e) through (s), see enclosure 1

## 1. REISSUANCE AND PURPOSE

This Directive reissues reference (a) to update DoD policy and responsibilities regarding the administration and funding of Clinical Investigation Programs (CIPs) in Military Medical Treatment Facilities (MTFs), Dental Treatment Facilities (DTFs), and in the Uniformed Services University of the Health Sciences (USUHS).

## 2. APPLICABILITY AND SCOPE

2.1. This Directive applies to the Office of the Secretary of Defense (OSD), the Military Departments and the USUHS.

2.2. This Directive encompasses all elements of a CIP relating to the medical mission of the Military Departments and the basic biomedical science and clinical investigation projects at USUHS. This Directive does not apply to projects funded by Defense Acquisition or projects under the control of DoD Directive 5000.1 (reference (b)).

### 3. DEFINITIONS

The terms used in this Directive are defined in enclosure 2.

### 4. POLICY

It is DoD policy that:

4.1. Value of CIPs. Clinical investigation is an essential component of medical care and teaching that is intended to achieve the following objectives:

4.1.1. Improve the quality of patient care.

4.1.2. Support the Graduate Medical Education Program.

4.1.3. Generate an atmosphere of inquiry responsive to the dynamic nature of the health sciences.

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

4.2. CIP funding. CIPs shall be funded from operating funds from Defense Health Program appropriations. Supplementation of these funds through support from non-Federal sources is authorized only as provided in this Directive.

4.3. Support from Non-Federal Sources. CIPs may receive support from non-Federal sources through: Cooperative Research and Development Agreements (CRADAs), as provided in paragraph 4.4.; agreements through the Uniformed Services University of the Health Sciences (USUHS), as provided in paragraph 4.5.; gifts, as provided in paragraph 4.6; or reimbursements, as provided in paragraph 4.7.

4.3.1. Support from non-Federal sources is permitted only when it is consistent with and promotes the accomplishment of valid CIP objectives.

4.3.2. The receipt of support from non-Federal sources shall comply with applicable Military Department regulations.

4.4. Cooperative Research and Development Agreements (CRADAs). The Military Departments and USUHS may enter into CRADAs to conduct CI studies

under the authority of 15 U.S.C. 3710a (reference (c)) and DoD Directive 5535.3 (reference (d)) and consistent with the provisions of DoD Instruction 5535.8 (reference (e)). CRADAs provide the preferred mechanism to establish collaborative relationships with industry and academic institutions.

#### 4.5. Agreements through USUHS.

4.5.1. In accordance with 10 U.S.C. 2113(j) (reference (f)), DoD may, in connection with activities of USUHS, carry out cooperative enterprises in medical research, medical consultation, and medical education 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, and may accept gifts from those or other entities.

4.5.2. The USUHS President shall establish procedures for utilizing these authorities to support clinical investigations conducted by medical and dental treatment facilities affiliated with USUHS.

4.6. Gifts. Gifts of funds or personal property may be used to provide support for a clinical investigation study under procedures prescribed by 10 U.S.C. 2601 (reference (g)) or 10 U.S.C. 2113 (reference (f)), as applicable. A grant not covered by paragraph 4.5. may be accepted as a gift under this paragraph.

#### 4.7. Reimbursements.

4.7.1. Under 31 U.S.C. 9701 (reference (h)) and Chapter 4 of Volume 11A of the "DoD Financial Management Regulation" (reference (i)), whenever a CIP activity is carried out at the request of, or otherwise conveys a special benefit to, a non-Federal entity, it is generally DoD policy that such entity pay a reasonable charge for the CIP services provided. The reasonable charge shall be based on the full cost to DoD of providing the services or the fair market value of the services, whichever is higher. The determination of reasonable charges for a particular CIP activity should be established by agreement of the parties under paragraph 4.8.2.

4.7.2. Under 10 U.S.C. 1095(g) (reference (j)), amounts collected for healthcare services (including treatments and services provided as part of a clinical investigation protocol) provided under CIPs at or through an MTF or DTF shall be credited to the Defense Health Program account and made available to the MTF or DTF involved.

4.8. Program Integrity. The acceptance of non-Federal support for CIPs is subject to strict compliance with program integrity requirements as set forth in DoD Directive 5500.7 (reference (k)), the Joint Ethics Regulation (reference (l)), and this Directive.

4.8.1. 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.

4.8.2. In all cases involving non-Federal support for CIPs, there shall be an agreement or, in the case of a gift, a written acknowledgment, which shall describe:

4.8.2.1. The specific non-Federal support being provided and the clinical investigation activities to be carried out in connection with it.

4.8.2.2. For personal property or personal services (when authorized), a description of property or services, cost of the property or services, quantity provided, projected use, any expense anticipated in receiving or utilizing the property or services, and, in the case of personal property, its ultimate disposition (including disposition of any item(s) on loan).

4.8.2.3. Conditions accepted by the DoD CIP for provision of the non-Federal support.

4.8.2.4. Handling of the data or results of the CIP project, including any property rights.

4.8.2.5. That the support is to the DoD facility involved, that it is subject to applicable DoD regulations, and that it is not for the personal use of an individual.

4.8.3. Requests for gifts shall not be initiated by DoD personnel, except that completion of standard applications for, or responses to announcements of the availability of, non-Federal research grants is allowed.

4.8.4. The acceptance of non-Federal support shall be approved by the Commander of the MTF or DTF involved, or in the case of USUHS, by an official designated by the President of USUHS. (Additional approvals may also be required by Service regulation.)

4.8.4.1. The Commander or USUHS designee shall include in the CIP file a statement of any current or prospective business relationship with the Department of Defense of the non-Federal entity or entities involved.

4.8.4.2. The Commander or USUHS designee shall designate a management official of the MTF, DTF, or USUHS who is not directly involved in the clinical investigation receiving non-Federal support to administer the support provided in accordance with applicable regulations. DoD and Military Department regulations governing financial management, property management, travel, standards of conduct, and other management matters shall apply. The DoD Components shall refer to the "DoD Financial Management Regulation" (reference (i)) for all financial management policy and guidance.

4.8.4.3. The Commander or USUHS designee accepting non-Federal support for CIPs shall assure that it is received and administered so as to avoid giving special privileges to any entity, causing conflicts of interest, or creating the appearance of impropriety.

4.8.4.4. In any case in which more than one non-Federal entity exercises a degree of control over the support to be provided to the CIP, issues of acceptance and administration of the support shall be based on an assessment of all involved non-Federal entities.

4.8.5. All DoD CIP investigations involving human subjects shall comply with DoD Directive 3216.2 (reference (m)) and 32 CFR Part 219 (reference (n)).

4.8.6. All DoD CIP investigations involving animals as subjects shall comply with DoD Directive 3216.1 (reference (o)).

4.9. Participation of Volunteers as Subjects in CIPs. Persons eligible for healthcare in medical treatment facilities under 10 U.S.C. Chapter 55 (reference (p)) may participate as CI study subjects in accordance with DoD Directive 3216.2 (reference (m)) and 32 CFR Part 219 (reference (n)).

4.9.1. Retired military personnel, dependents, and others not on active duty who participate as CI subjects may be compensated when appropriate. Retired military personnel, dependents, and others not on active duty may participate as subjects without compensation, in which case records must be created documenting the subject's acknowledgment and agreement to participate without compensation for serving as subjects.

4.9.2. Due to the possibility of injuries arising from participation in CI research, for research involving more than minimal risk, every intramural CIP project shall include an arrangement for treatment of any research-related injuries. Such arrangement 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. In no case shall any such research 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.

#### 4.10. Peer Review of Extramural CIP Projects.

4.10.1. In accordance with sec. 742 of Pub. L. 104-201 (reference (q)), Defense Health Program (DHP) funds may not be obligated or expended for any extramural 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 an external peer review process consisting of a person or persons who are not officers or employees of the Federal Government. The external peer review process must evaluate the scientific merit of the research protocol and assure the project has been approved by an institutional review board under 32 CFR Part 219 (reference (n)).

4.10.2. The external peer review requirements are established as of October 1, 1996, and 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 pursuant to any provision of law enacted after October 1, 1996, that exempts the project from section 742 of Pub. L. 104-201 (reference (q)).

4.11. Competition in Grants and Contracts to Colleges and Universities. Defense Health Program funds may not be used to support an extramural CIP activity in a college or university in violation of 10 U.S.C. 2361 (reference (r)).

## 5. RESPONSIBILITIES

5.1. The Assistant Secretary of Defense (Health Affairs)(ASD(HA)), under the Under Secretary of Defense for Personnel and Readiness, shall monitor the implementation of this Directive.

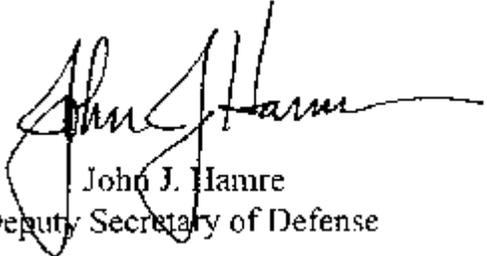
5.2. The Secretaries of the Military Departments, or their designees, shall establish programs for clinical investigation, and ensure compliance with this Directive.

5.3. The Surgeon General of each Military Department shall establish policy to ensure compliance with this Directive within the MTFs and DTFs of his or her respective Military Department and report the number, content and funding of CIP grants to ASD(HA) annually.

5.4. The President of the Uniformed Service University of Health Sciences (USUHS) shall ensure compliance with applicable portions of this Directive for USUHS and report the number, content and funding of CIP grants to ASD(HA) annually.

## 6. EFFECTIVE DATE

This Directive is effective immediately.



John J. Hamre  
Deputy Secretary of Defense

Enclosures - 2

E1. References, continued

E2. Definitions

E1. ENCLOSURE 1

REFERENCES, continued

- (e) [DoD Instruction 5535.8](#), "DoD Technology Transfer (T2) Program Procedures," May 14, 1999
- (f) Section 2113 of title 10, United States Code
- (g) Section 2601 of title 10, United States Code
- (h) Section 9701 of title 31, United States Code
- (i) DoD 7000.14-R, "DoD Financial Management Regulation," March 1, 1997
- (j) Section 1095(g) of title 10, United States Code
- (k) [DoD Directive 5500.7](#), "Standards of Conduct," August 30, 1993
- (l) DoD 5500.7-R, "Joint Ethics Regulation," August 30, 1993
- (m) [DoD Directive 3216.2](#), "Protection of Human Subjects in DoD Supported Research," January 7, 1983
- (n) Title 32, Code of Federal Regulations, Part 219, "Protection of Human Subjects"
- (o) [DoD Directive 3216.1](#), "Use of Laboratory Animals in DoD Programs," April 17, 1995
- (p) Chapter 55 of title 10, United States Code
- (q) Section 742 of the National Defense Authorization Act for Fiscal Year 1997, Pub. L. 104-201
- (r) Section 2361 of title 10, United States Code
- (s) Section 501(c)(3) of title 26, United States Code

## E2. ENCLOSURE 2

### DEFINITIONS

E2.1.1. Clinical Investigation. An organized inquiry into clinical health problems for any conditions that are of concern in providing healthcare to the beneficiaries of the military healthcare system including active duty personnel, dependents, and retired personnel.

E2.1.2. 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 gift or unconditional gift).

E2.1.3. Grant. An award of funds, services, or real or personal property from a corporation, foundation, trust, institution, or other entity not organized for profit, and that does not provide any net earnings to shareholders or individuals, for the purpose of stimulating higher learning or research.

E2.1.4. Nonprofit Entity. A corporation, fund, or foundation exempt from Federal income taxation under the authority of 26 U.S.C. 501(c)(3) (reference (s)).