



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

NUMBER 5535.01

MAR 27 2012

J-7

SUBJECT: Domestic Technology Transfer (T2)

References: See Enclosure 1

1. PURPOSE. This Instruction, in accordance with (IAW) the authority in References (a) through (d), establishes Joint Task Force National Capital Region Medical (JTF CapMed) policy and responsibilities for implementation of domestic T2 within the JTF CapMed IAW Title 15 USC, Chapter 63, sections 3701-3718 (Reference (e)), DoD Directive (DoDD) 5535.3 (Reference (f)), and DoD Instruction 5535.8 (Reference (g)).

2. APPLICABILITY. This Instruction applies to:

a. The JTF CapMed Headquarters, Walter Reed National Military Medical Center (WRNMMC), Fort Belvoir Community Hospital (FBCH) [hereafter, WRNMMC and FBCH are referred to as Medical Treatment Facilities (MTFs)], and the Joint Pathology Center (JPC).

b. Does not apply to projects funded through the Defense Acquisition System or other projects under the control of DoDD 5000.1 (Reference (h)).

3. DEFINITIONS. See Glossary

4. POLICY. It is JTF CapMed policy to:

a. Promote domestic T2 as an integral part of a clinical investigation and other research programs and concurrently improve the economic, environmental, and social well-being of U.S. citizens.

b. Allow MTF Commanders or the JPC Director designated by memorandum, to have the responsibility and the authority to enter into cooperative research and development agreements (CRADAs) IAW Reference (e); to license, assign, or waive rights to intellectual property developed by their activity; and to support active marketing and assistance by their laboratories

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or centers, including participation in economic development organizations, contracting with partnership intermediaries, and providing technical assistance to State and local governments and local educational systems further delineated in the responsibilities in Enclosure 2.

c. Encourage T2, which will occur through a variety of T2 legal instruments (see Glossary for a partial list of transfer instruments).

d. Specify efforts under CRADAs to be for specified research projects consistent with the missions of the MTF or Center laboratory and to be for a specified duration. Special consideration will be given to entering into CRADAs with small-business firms and consortia involving small-business firms as well as to businesses located in the U.S. or those that agree that products embodying inventions made under the CRADA or produced through the use of such inventions will be manufactured substantially in the U.S. MTF Commanders or the JPC Director will apply principles of fairness and sound judgment in the selection of parties with whom to enter into CRADAs. Competitive procedures normally associated with awards of procurement contracts need not be applied to CRADAs. A CRADA will not be used when a government procurement contract is the appropriate instrument for accomplishing the research effort.

5. RESPONSIBILITIES. See Enclosure 2

6. PROCEDURES. See Enclosure 3

7. INFORMATION REQUIREMENTS. Reports from the JTF CapMed federal laboratories will be submitted to the JTF CapMed Domestic T2 Program Manager on a quarterly basis. Input for special reports will be as required.

8. RELEASABILITY. UNLIMITED. This Instruction is approved for public release and is available on the Internet from the JTF CapMed Issuances Web Site at: www.capmed.mil.

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9. EFFECTIVE DATE. This Instruction is effective upon its publication to the JTF CapMed Issuances Website.



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By direction of the Commander

Enclosures

1. References
 2. Responsibilities
 3. Procedures for T2 Activities
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ENCLOSURE 1

REFERENCES

- (a) Deputy Secretary of Defense Memorandum, "Establishing Authority for Joint Task Force National Capital Region Medical (JTF CapMed) and JTF CapMed Transition Team (Unclassified)," September 12, 2007
- (b) Deputy Secretary of Defense Action Memorandum, "Civilian and Military Personnel Management Structures for the Joint Task Force National Capital Region Medical," January 15, 2009
- (c) Comprehensive Master Plan for the National Capital Region Medical, April 23, 2010
- (d) Supplement to the Comprehensive Master Plan for the National Capital Region Medical, August 31, 2010
- (e) Title 15 USC, chapter 63, sections 3701-3718, "Technology Innovation"
- (f) DoD Directive 5535.3, "DoD Domestic Technology Transfer (T2) Program," May 14, 1999
- (g) DoD Instruction 5535.8, "DoD Domestic Technology Transfer (T2) Program," May 21, 1999
- (h) DoD Directive 5000.1, "The Defense Acquisition System," May 12, 2003
- (i) Executive Order 12591, "Facilitating Access to Science and Technology"
- (j) Title 15 USC, chapter 14A, section 632, "Small Business Concerns"

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ENCLOSURE 2

RESPONSIBILITIES

1. COMMANDER, JOINT TASK FORCE NATIONAL CAPITAL REGION MEDICAL (CJTF). The CJTF is vested with all the authorities provided to the head of an agency (Reference (e)) and is responsible for all domestic T2 within WRNMMC, FBCH, and the JPC. The CJTF will:

a. Institute policies and procedures under which JTF CapMed MTFs and the JPC may be authorized to license, assign, or waive rights to intellectual property and distribute royalties and other payments in accordance with Reference (g).

b. Designate MTF and the JPC laboratories authorized to participate in the JTF CapMed Domestic T2 Program and those that must establish an Office of Research and Technology Applications (ORTA) or equivalent organizational element.

c. Designate a Domestic T2 Program Manager for JTF CapMed.

d. Designate an intellectual property counsel office or attorney to provide appropriate legal service support to the JTF CapMed Domestic T2 Program Manager.

2. JTF CAPMED DOMESTIC TECHNOLOGY TRANSFER PROGRAM (DTTP) MANAGER. The JTF CAPMED DTTP Manager will:

a. Monitor the T2 Program and the levels of effort of all JTF CapMed specified laboratories.

b. Provide policy guidance on domestic T2 to designated JTF CapMed federal laboratories.

c. Coordinate and support the activities of JTF CapMed ORTAs.

d. Serve as the JTF CapMed Agency Representative in matters concerning domestic T2.

e. Review, or have reviewed on behalf of CJTF, all agreements with foreign entities that license DoD-owned intellectual property (including patent license agreements (PLAs)) and other invention licenses, but excluding trademark license) and all signed CRADAs that are with a foreign entity as defined in Executive Order 12591 (Reference (i)) or involve the receipt of more than \$1 million in funds in any one fiscal year from a non-Federal partner. This review for conformance with applicable law, regulation, and policy will be completed within 30 days of receipt of the proposed agreement by the DTTP Manager.

f. Maintain an archival file of all JTF CapMed CRADAs and PLAs.

g. Establish and maintain a database for the collection of program data for the evaluation of program activity and effectiveness.

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- h. Provide input for periodic and special reports, as required.

3. JTF CAPMED INTELLECTUAL PROPERTY COUNSEL (IPC). The IPC is responsible for reviewing the legal sufficiency of all CRADAs and PLAs requiring review as set forth in paragraphs below. Until such time as the JTF CapMed quantifies its legal services support requirements for IPC services, this legal support service requirement will be met through a memorandum of agreement with the U.S. Army Medical Research and Materiel Command and on an ad hoc basis in consultation with the DoD Office of T2.

4. MTF COMMANDERS AND CENTER DIRECTORS OF DESIGNATED FEDERAL LABORATORIES. Commanders and Directors of all CJTF designated federal laboratories may enter into CRADAs and license, assign, or waive rights to intellectual property created in their organizations. They are responsible for ensuring compliance with applicable policies, law (References (f) and (g)), and this Instruction. Specifically, the Commander or Director of each designated laboratory:

- a. May enter into CRADAs and Partnership Intermediary Agreements (PIA) and license, assign, or waive rights to intellectual property created in their organization as appropriate.

- b. Will ensure that CRADAs and other T2 mechanisms comply with appropriate conflict of interest and ethics rules, security regulations, and other policies governing militarily critical technologies, and export control laws and regulations.

- c. Will establish and resource a staff-level ORTA to execute the policies and perform the functions required by law or specified in this Instruction. Staffing must be adequate to accomplish the T2 mission of the laboratory.

- d. Will ensure that domestic T2 is a priority in their research program planning.

- e. Will include goals for, and objectives of, domestic T2 in the performance standards of appropriate technical managers and scientists and engineers of the activity and assure that domestic T2 efforts are considered positively in job descriptions, promotion policies, and evaluations of job performance.

- f. Will execute an awards program, including cash awards, to recognize domestic T2 accomplishments IAW (Reference (e)).

- g. May provide technical assistance to State and local governments and local educational organizations.

- h. Consistent with applicable export control laws and regulations, may loan or give research equipment or educationally useful federal equipment that is excess to the needs of the designated federal laboratory to educational institutions or nonprofit institutions for the conduct of technical and scientific education and research activities (Reference (e)).

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- i. Will establish administrative procedures and support staff training on compliance with export control laws and regulations and foreign disclosure regulations to ensure that the appropriate international T2 is used and that no restricted or controlled technologies are inadvertently transferred to foreign entities.
- j. Will provide appropriate and adequate training to ORTA personnel involved in T2 activities and ensure that they are included in the activity's management development program.
- k. Will support participation of ORTA and legal staff in T2 activities and networking opportunities including, but not limited to: Federal Laboratory Consortium for T2 (FLC), the DoD T2 Integrated Planning Team, and State and local economic development, and educational organizations.

5. HEAD OF ORTA. The Head of each ORTA is responsible for managing the domestic T2 activities of the MTF or the JPC designated federal laboratory. The ORTA will:

- a. Assess, or refer for assessment, selected research projects for potential commercial application.
- b. Provide and disseminate information on federally owned or federally originated products, processes, and services.
- c. Cooperate with and assist the FLC and other organizations that link the research resources of that activity, and the Federal Government as a whole, to potential users in State and local government, academia, and U.S. private industry.
- d. Provide technical assistance, as appropriate, to State and local governments, school systems, and nonprofit organizations.
- e. Participate, where feasible, in regional, State, and local public and private programs designed to facilitate or stimulate the transfer of technology for the benefit of the region, State, or local jurisdiction in which the MTF or the JPC is located.
- f. Perform marketing and outreach activities in accordance with Reference (g).
- g. Provide laboratory representation and support to the FLC.
- h. Assist in identifying technologies suitable for transfer and for which application assessments need to be developed.
- i. Identify patents and patent applications for which notification of availability for exclusive licensing is required by law and publicize such availability.

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j. Coordinate domestic T2 activities with the designated intellectual property counsel to determine rights to technical data, patent, and licensing implications, as well as the commercial potential of patentable technology.

k. Negotiate or assist in negotiating CRADAs, PIAs, and PLAs and provide appropriate staff coordination.

l. Ensure all CRADAs, PIAs, and PLAs receive legal review prior to entering into an agreement to ensure that the agreement conforms to all applicable statutes, regulations, Executive Orders, Directives, and Instructions issued within DoD.

m. Ensure that no domestic T2 activities substantially compete with services available in the private sector.

n. Document determinations made by laboratory officials when entering into agreements with foreign entities that ensure no domestic T2 activities violate or conflict with export control regulations, policies governing militarily critical technology, or any of the additional requirements, responsibilities, and procedures for T2 control within the DoD.

o. Prepare an annual T2 business plan in accordance with Reference (g), describing how T2 requirements and responsibilities were addressed in the current year and identifying planned activities for the year ahead for submission to the JTF CapMed DTTP manager.

p. Forward a signed copy of the final negotiated version of all CRADAs and license agreements to the JTF CapMed DTTP Manager and intellectual property counsel for entry into the official JTF CapMed database.

q. Maintain data and program records in accordance with JTF CapMed policy which are subject to submission or review by the JTF CapMed DDTP Manager at any time.

r. Provide T2 advice and expertise to scientific, engineering, and technical personnel within the designated federal laboratory and ensure the staff receives T2 education and training.

ENCLOSURE 3

PROCEDURES

1. DESIGNATION AS A FEDERAL LABORATORY. In accordance with this Instruction, and prior to entering into a CRADA, PIA, or a PLA (or Invention License Agreement), the following procedure is required for a covered MTF or the JPC laboratory to be designated as a JTF CapMed federal laboratory:

a. The MTF Commander or JPC Director shall sign and submit a memorandum, on official letterhead, requesting designation as a federal laboratory to the JTF CapMed DTTP Manager. This request for designation memorandum must contain information that responds to the following questions:

(1) Do personnel at the MTF or Center laboratory have a working knowledge of References (e), (f), and (g) and this Instruction (or, when appropriate, any superseding statute, order, Directive or Instruction)?

(2) Does the laboratory meet the definition of a laboratory (Reference (g))?

(3) What is the mission of the laboratory?

(4) Does the laboratory have sufficient T2, security, and access to legal counsel to advise the MTF Commander or Center Director regarding the laboratory's T2 mission?

(a) Who will be responsible for providing legal reviews and recommendations relating to CRADAs, PIAs, PLAs, and other legal advice and counsel to the laboratory regarding T2? Provide a copy of any agreement related to the provision of T2 legal services, and identify the intellectual property (IP) attorney(s) that will support such services.

(b) Are security personnel assigned to your activity? If not, who will be responsible for providing security reviews relating to CRADAs, PIAs, or PLAs?

b. The request for designation memorandum will be reviewed by the JTF CapMed DTTP Manager and forwarded to the JTF CapMed Legal Advisor for legal review. Upon completion of JTF CapMed's Legal Advisor's review, a determination whether the activity meets the criteria for designation as a laboratory will be made by CJTF. If approved, a federal laboratory designation memorandum will be issued by CJTF to the requesting MTF or Center. If the designation request is disapproved, a memorandum explaining the reasons for the disapproval will be provided to the MTF or Center by the CJTF or designee.

c. If the MTF or Center receives a federal laboratory or technical activity designation memorandum approving its request, and the MTF or Center's current ORTA has not been designated and approved by CJTF; the MTF Commander or Center Director shall submit a memorandum to JTF CapMed requesting approval of the proposed ORTA representative.

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d. The request for federal laboratory or technical activity designation memorandum should be on official letterhead, signed by the MTF Commander or JPC Director and forwarded to the JTF CapMed DTTP Manager.

[NOTE: A designated DoD IP legal office or attorney must be available to provide T2 legal support prior to obtaining federal laboratory designation.]

2. DESIGNATION OF ORTA REPRESENTATIVE

a. IAW this Instruction, and prior to entering into a CRADA, PIA, or a PLA (or Invention License Agreement), an ORTA representative for the MTF or JPC must be identified and approved by CJTF.

b. The MTF Commander or JPC Director of a laboratory designated as a federal laboratory shall sign and submit a memorandum on official letterhead identifying an ORTA representative for the MTF or the JPC to the JTF CapMed DTTP Manager. The ORTA representative approval memorandum must answer the following questions:

(1) What is the name of the person being designated as the ORTA representative?

(2) Are procedures in place (if not, when will procedures be established) for entering into CRADAs, PIAs, and PLAs?

(3) Does the ORTA representative, who will be responsible for implementing the procedures, have training or experience in DoD T2?

[NOTE: Each ORTA representative must have completed initial T2 training commensurate with needs of the MTF or the JPC to be approved by CJTF. Thereafter, each ORTA representative is required to complete and document annual T2 training. The annual training may include, but is not limited to; the annual T2 Integrated Planning Team Workshop, the annual FLC National Conference, or any other T2 related training.]

3. CJTF (or designee) will notify the federal laboratory by memorandum approving or rejecting the proposed ORTA representative.

4. The MTF Commander or JPC Director of a laboratory designated as a JTF CapMed federal laboratory or technical activity must notify the JTF CapMed DTTP Manager within 60 days of a change of the activity's approved ORTA representative and should propose a new ORTA representative for CJTF's designation in accordance with Enclosure 3, paragraphs 2 and 3 above in this Instruction.

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GLOSSARYPART I. ABBREVIATIONS

CJTF	Commander, Joint Task Force National Capital Region Medical
CRADAs	Cooperative research and development agreement(s)
DoDD	Department of Defense Directive
DTTP	Domestic Technology Transfer Program
FBCH	Fort Belvoir Community Hospital
FLC	Federal Laboratory Consortium for Technology Transfer
IAW	in accordance with
IPC	Intellectual Property Counsel
IP	intellectual property
JPC	Joint Pathology Center
JTF CapMed	Joint Task Force National Capital Region Medical
MTF	Medical Treatment Facility
ORTA	Office of Research and Technology Applications
PIA	Partnership Intermediary Agreement
PLA	Patent License Agreement
T2	Technology Transfer
WRNMMC	Walter Reed National Military Medical Center

PART II. TERMS

Cooperative research and development agreement (CRADA). A legal agreement that implements the authority specified in Reference (e), as amended. CRADAs include agreements between one or more Federal laboratories and one or more non-Federal parties under which the laboratory provides personnel, services, facilities, equipment, or other resources (but not funds), with or without reimbursement, and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts that are consistent with the missions of JTF CapMed. The term may include material transfer agreements and non-disclosure (or confidentiality) agreements which otherwise qualify

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with the above definition. Non-disclosure agreements should be negotiated by the ORTA only if a disclosure is pursuant to future potential research. The term does not include procurements, grants, or other types of cooperative agreements made under the authority of any other legislation.

Invention. A discovery that is or may be patentable or otherwise protected (Reference (e)).

Partnership intermediary. An agency of a State or local government or a nonprofit entity owned in whole or in part by, chartered by, funded in whole or in part by, or operated in whole or in part by or on behalf of a State or local government, that assists, counsels, advises, evaluates, or otherwise cooperates with small business firms that need or can make demonstrably productive use of technology-related assistance from a Federal laboratory.

Patent License Agreement (PLA). A legal agreement that grants a license to use or practice an invention.

Practical application. To manufacture, in the case of a composition or product; to practice, in the case of a process or method; or to operate, in the case of a machine or system-in each case, under such conditions as to establish that the invention is being used and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.

Small-business firm. This term is precisely defined by 15 USC, Chapter 14A, section 632 (Reference (j)), the implementing regulations of the Administrator of the Small Business Administration.

Designated laboratories and centers. JTF CapMed organizations and centers that conform to the definition of a laboratory in Reference (e) and have been designated by the CJTF as organizations authorized to participate in the JTF CapMed DTTP.

Technical assistance. Problem analysis; assistance in the development and interpretation of technical information; hands-on technical help from laboratory volunteers, or limited projects in the laboratory where they do not compete with available services in the private sector (Reference (g)).

Technology transfer (T2). The intentional communication or sharing of knowledge, expertise, facilities, equipment, and other resources for application to military and non-military systems. T2 includes spin-off, spin-on, and dual-use activities (Reference (g)).