Defense Health Agency
PROCEDURAL INSTRUCTION

NUMBER 3201.05
June 20, 2019

Research and Development (R&D), J-9

SUBJECT: Technology Transfer (T2) Program

References: See Enclosure 1.

1. PURPOSE. This Defense Health Agency-Procedural Instruction (DHA-PI) based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (t), establishes responsibilities, procedures, and guidance for the Defense Health Agency's (DHA) T2 program.

2. APPLICABILITY. This DHA-PI applies to the DHA, laboratory directors or designees as defined in the Glossary, and all other organizational entities within the DHA (referred to collectively in this DHA-PI as the "DHA Components"). The DHA encourages all others to follow this DHA-PI to the maximum extent possible.

3. POLICY IMPLEMENTATION. It is DHA's instruction, pursuant to References (f), (g), and (i), that the DHA T2 program:

a. Shares, disseminates, and transfers knowledge, expertise, facilities, equipment, and other resources for application to military and non-military systems. T2 serves a key role for research in leveraging resources and transitioning technology to the warfighter or to other stakeholders for government and non-governmental applications. These activities often occur through collaborations and partnerships between industry/academia/other government agencies/non-profit organizations, and one or more DHA laboratories ("laboratory" or "laboratories").

b. Contributes to the DHA's mission by enabling technology to progress from bench to marketplace. The process is inclusive of identifying new technologies, protecting technologies through patents and copyrights, forming commercialization strategies, and advancing license agreements. The general criteria for a successful DHA T2 program are engaged researchers, well-managed intellectual property (IP), effective transfer mechanisms, and meaningful communication with industry in order to realize the fullest potential of the DHA's medical discoveries.

4. RESPONSIBILITIES. See Enclosure 2.

5. PROCEDURES. See Enclosure 3.

6. RELEASABILITY. **Cleared for public release**. This DHA-PI is available on the Internet from the Health.mil site at: www.health.mil/DHAPublications.

7. EFFECTIVE DATE. This DHA-PI:

a. Is effective upon signature.

b. Will expire 10 years from the date of signature if it has not been reissued or cancelled before this date in accordance with DHA-PI 5025.01 (Reference (c)).

R. C. BONO
VADM, MC, USN
Director

Enclosures
1. References
2. Responsibilities
3. Procedures

Glossary

ENCLOSURE 1

REFERENCES

(a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD (HA))," August 10, 2017, as amended
(b) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013
(c) DHA-Procedural Instruction 5025.01, "Publication System," August 24, 2018
(d) United States Code, Title 15, Sections 3701-3704, "Technology Innovation," October 20, 1986
(e) DoD Directive 5535.03, "DoD Domestic Technology Transfer (T2) Program," May 21, 1999, as amended
(f) DoD Instruction 5535.08, "DoD Technology Transfer (T2) Program," May 14, 1999, as amended
(g) Executive Order 12591, "Facilitating Access to Science and Technology," April 10, 1987
(h) National Defense Authorization Act for Fiscal Year 2017, Section 702
(i) DoD "Strategy & Action Plan for Accelerating Technology Transfer (T2) and Commercialization of Federal Research in Support of High Growth Businesses," October 4, 2012[1]
(j) United States Code, Title 10, Section 2371, "Research Projects: Transactions Other than Contracts and Grants," January 7, 2011
(k) United States Code, Title 10, Section 2194, "Education Partnerships," January 7, 2011
(l) United States Code, Title 15, Section 3710, "Utilization of Federal Technology," January 3, 2012
(m) Army Regulation 70-57, "Army Technology Transfer," June 12, 2018
(n) Navy "Department of the Navy Technology Transfer Handbook," September 2018
(o) Air Force Policy Directive 61-3, "Domestic Technology Transfer," May 20, 2013
(p) DoD 5500.7-R, "The Joint Ethics Regulation (JER), including Changes 1 – 7," November 17, 2011
(q) United States Code, Title 17, "Copyrights," October 19, 1976
(r) Code of Federal Regulations, Title 37, Section 404.7, "Exclusive, Co-Exclusive and Partially Exclusive Licenses," July 1, 2018
(s) United States Code, Title 35, Section 207, "Patent Rights in Inventions Made with Federal Assistance: Domestic and Foreign Protection of Federally Owned Invention," April 2019
(t) United States Code, Title 35, Section 209, "Patent Rights in Inventions Made with Federal Assistance: Licensing Federally Owned Inventions," January 3, 2012
(u) United States Code, Title 15, Section 3710a, "Cooperative Research and Development Agreements," January 3, 2012

[1] This reference can be found at: https://www.nist.gov/sites/default/files/documents/2017/05/09/DOD-Tech-Transfer-Plan.pdf

ENCLOSURE 2

RESPONSIBILITIES

1. DIRECTOR, DHA. The Director, DHA, or designee (herein after referred to as "Director, DHA"), will designate DHA laboratories.

2. DEPUTY ASSISTANT DIRECTOR, RESEARCH AND DEVELOPMENT (R&D), J-9. The Deputy Assistant Director, R&D, J-9, will designate a DHA T2 Program Manager (PM).

3. DHA T2 PM. The DHA T2 PM will:

a. Formulate, direct, and execute the overall DHA T2 strategy to align with DHA objectives and priorities.

b. Establish and lead the DHA T2 office to:

(1) Develop DHA T2 policies, standard operating procedures, and templates to achieve efficient, effective and standardized/streamlined T2 practices.

(2) Develop a DHA T2 system to, among other things, report new inventions, track T2 activities, generate T2 reports, and serve as a T2 database for the best T2 practices.

(3) Develop and oversee a DHA T2 site for posting the latest versions of T2 templates.

(4) Foster communication and harmonization among DHA and non-DHA laboratories.

(5) Coordinate between DHA and industry/academia/other government entities/non-profit organizations in alignment with strategic partnerships.

c. Establish inter-agency and intra-agency working group(s), drawing from subject matter experts (SMEs) (e.g., scientists, medical doctors, researchers, policy experts, regulatory affairs experts, research and technology application managers, lawyers, business managers, information technology experts), to advise the DHA T2 PM.

d. Prepare the annual T2 report.

e. Serve as the DHA's primary point of contact, represent DHA at T2-related activities, and advise DHA senior leadership.

f. Commend superior performance within laboratories, either the laboratory as a whole, individuals therein, or both.

g. Ensure all DHA laboratories make T2 a high priority in accomplishing their programs in accordance with Reference (f).

h. Oversee use of foundation support in accordance with Reference (j).

i. Assist the laboratory directors or designees in coordinating with resources as needed.

4. LABORATORY DIRECTORS OR DESIGNEES. Laboratory directors or designees (hereto after referred to as "laboratory directors"), will:

a. Oversee their laboratory's T2 office.

b. Execute T2 agreements, including but not limited to:

(1) Cooperative Research and Development Agreements (CRADAs)

(a) For general research

(b) For clinical trials or research

(c) Material Transfer Agreements

(d) Non-Disclosure Agreements

(2) Partnership Intermediary Agreements

(3) Educational Partnership Agreements

(4) Patent License Agreements

(5) Commercial Test Agreements

(6) Data Use Agreements

(7) Knowledge Translation Agreements

(8) Collaborative Research Agreements (e.g., other T2-related transactions)

(9) Animal Research Agreements

(10) Pre-clinical Agreements

c. License, assign, or waive rights to IP in accordance with Reference (l).

d. Perform T2 functions, consult with, and obtain guidance from the DHA's T2 Office when lacking resources (manpower, expertise, and experience).

5. T2 SPECIALIST. The T2 Specialist may have various titles, to include T2 Manager, Senior T2 Manager, Director or Chief of the Business Office, or Director or Chief of the Office of Research and Technology Application. Herein, the term T2 Specialist shall encompass all the various titles. The T2 Specialist will:

a. Report to the laboratory directors.

b. Apply business, marketing, and technical acumen to T2 activities (see References (e), (f), and (m) through (o)).

c. Promote utilization of laboratory facilities and expertise through marketing and outreach to potential collaborators.

d. Participate in inter-agency and intra-agency working group(s) upon request.

e. Identify and facilitate technologies suitable for T2.

f. Identify technologies or R&D projects for potential commercial partnerships.

g. Solicit, draft, review, have executed, and monitor T2 agreements.

h. Consult with counsel from the subject laboratory, or DHA as needed, before entering T2 agreements.

i. Work with laboratory counsel; coordinate T2 activities to determine rights to technical data as well as copyright, patent, and licensing implications; and secure appropriate rights.

j. Evaluate the commercial potential of patentable technology.

k Receive, review, and assist in processing invention disclosures, consulting with counsel as needed.

l. Continuously engage with inventors throughout the invention lifecycle.

m. Participate in foreign patent application filing and maintenance.

n. Identify patents and patent applications available for exclusive licensing and publish such availability (e.g., Federal Register, U.S. Patent and Trademark Office publications).

o. Organize and provide T2 training.

p. Represent laboratory to support the Federal Laboratory Consortium, as needed.

q. Nominate inventors and T2 staff for awards.

r. Attend and present at T2 conferences, tradeshows, and training events.

s. Participate in regional, state, and local public and private programs designed to facilitate or stimulate T2.

t. Ensure domestic T2 activities do not materially compete with the private sector.

u. Identify process improvements to enhance T2 success.

v. Assist laboratory directors in creating a culture of invention and innovation.

w. Assist non-DHA laboratories as needed.

x. Assist the laboratory in expediting T2, in general, and the award of T2 agreements in particular.

ENCLOSURE 3

PROCEDURES

The following procedures pertain to T2-related agreements. Examples include, but are not limited to, those listed in Enclosure 2, Section 4.b.

1. IDENTIFYING AGREEMENT REQUIREMENTS

a. DHA laboratories will identify the appropriate type of DHA agreement templates based on DHA and laboratory needs and consult with the DHA T2 PM as needed.

b. Non-DHA laboratories are encouraged to contact the DHA T2 PM regarding best practices.

2. DRAFTING T2 AGREEMENTS

. The T2 Specialist will be responsible for compiling initial drafts of T2 agreements with input from SMEs (e.g., scientists, physicians, and counsels), collaborators, and partner organizations.

3. REVIEWING/NEGOTIATING AGREEMENTS

a. The T2 Specialist, with support from SMEs, will review and negotiate draft agreements to ensure requirements, terms, and conditions are appropriate.

b. Technical personnel (e.g., scientists, physicians, researchers), will assist with reviewing draft agreements and modifications as needed (see Enclosure 3, Section 5, "Administering Agreements, Including Modification And Termination").

c. The laboratory director or designee will obtain legal review before signing any T2 agreement. Legal non-concurrence will be accompanied by rationale along with detailed guidance as to how to address the deficiencies.

d. Standards of conduct and conflicts of interest issues will be immediately directed to the laboratory's ethics counsel, copying the DHA T2 PM for situational awareness.

e. Laboratories will consult with the U.S. Trade Representative before entering into CRADAs and licensing arrangements with foreign persons or entities. A memorandum documenting such discussion shall be included in T2 agreement and/or licensing files (in accordance with Reference (p)).

f. The DHA Component Acquisition Executive should be consulted on material products to determine their applicability to existing and future acquisition programs before the laboratory director or designee signs any relevant T2 agreement.

4. EXECUTING/APPROVING AGREEMENTS

a. The T2 Specialist shall prepare the T2 agreement package that, at minimum, contains the following:

(1) T2 agreement;

(2) Summary sheet (value statement, legal opinion if applicable, technical documents such as the statement of work);

(3) Coordination sheet; and

(4) Cost breakdown/description, if applicable.

b. Formal coordination and approval will be done expeditiously. Signatures from laboratory director and collaborator(s)/licensee(s) will be obtained.

c. The T2 Specialist shall transmit relevant T2 agreement to the collaborator(s) within 10 days of execution as appropriate.

5. ADMINISTERING AGREEMENTS, INCLUDING MODIFICATION AND TERMINATION

a. The T2 Specialist will manage executed T2 agreements such as modification and termination.

b. The T2 Specialist will draft and negotiate the modifications/amendments and/or extensions with SME support (i.e., technical, counsel).

c. Modifications/amendments will be signed by the laboratory director or designee and collaborator(s)/licensee(s).

d. For inventions resulting from T2 agreements, DHA inventors will promptly provide to T2 Specialists their formal invention disclosure as well as assist with analysis of commercial application and patentability.

6. PROTECTION OF IP. The T2 Specialist and other T2 professionals shall be versed in IP practices and ensure that inventions are properly reported and processed. This includes inventions made by laboratory personnel; by CRADA collaborators; and by contractors performing R&D work for the laboratory (in accordance with Reference (m) through (o)).

7. LICENSING

a. Laboratories may license their technologies to industry, non-profit organizations, foundations, universities, and other non-Federal Organizations in accordance with Reference (m) through (o).

b. Licensable technologies encompass inventions/patentable subject matter, utility, design and plant patents; provisional applications; pending utility patent applications; pending design patent applications; pending plant patent applications; their continuation, continuation-in-part, divisional, reissue applications; trademarks; service marks; copyrights; proprietary interests, including but not limited to, prototypes, research materials, biological and tangible materials; preclinical, clinical and technical data; know-how; industrial designs; data and databases; computer software, including source code, object code, firmware; and internet domain names.

c. Patent License Agreements may be exclusive, or nonexclusive in accordance with Reference (r).

d. Laboratories may grant an exclusive license to a government-owned invention only if the exclusive license is in the best interest of the U.S. government and the public in accordance with References (r) through (t).

e. Laboratories are responsible for marketing technologies available for license through such means as publications, the Federal Register, websites, trade shows, and other efforts.

f. Laboratories will provide a "Notice of Intent to Grant an Exclusive License" in the Federal Register prior to execution of the license in accordance with Reference (r).

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

CRADA	Cooperative Research and Development Agreement
DHA	Defense Health Agency
DHA-PI	Defense Health Agency-Procedural Instruction
IP	intellectual property
PM	Program Manager
R&D	Research and Development
SME	subject matter expert
T2	Technology Transfer

PART II. DEFINITIONS

DHA Laboratories. As broadly defined in 15 U.S.C. 3710a(d)(2)(A), a Federal Laboratory is a facility or group of facilities owned, leased, or otherwise used by a Federal Agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government; for applicability within the DHA, the definition is inclusive of all laboratories/technical activities/organizations which are capable of supporting or making use of technology transfer mechanisms/programs. More specifically, a DHA laboratory encompasses a wide range of DHA components, including but not limited to Military Treatment Facilities, Clinical Centers, or Headquarters Directorates with sponsoring and/or managing activities. All DHA laboratories should receive formal laboratory designation from the DHA Director or delegee.

DHA Laboratory Director. The official leads a DHA-designated laboratory as described above, and thus is authorized to enter into cooperative research and development agreements and licensing agreements per 15 USC 3710a, as well as enter into educational partnership agreements per 10 USC 2194.