Defense Health Agency

TECHNICAL MANUAL

NUMBER 3200.01
October 5, 2021

DAD-R&D

SUBJECT: Reimbursement of Research-Related Expenses for Clinical Investigations in Military Medical Treatment Facilities

References: See Enclosure 1.

1. PURPOSE. This Defense Health Agency-Technical Manual (DHA-TM), based on the authority of References (a) through (c) and section 1073c of Reference (d); and in accordance with the guidance of section 1073d of Reference (d) and References (e) through (m), establishes the DHA's procedures for reimbursement of research-related expenses for clinical investigations (CIs) in military medical treatment facilities (MTFs) in order to implement DHA's instruction in Reference (e).

2. APPLICABILITY. This DHA-TM applies to the DHA, DHA components (activities under the authority, direction, and control of DHA), and all personnel to include: assigned or attached active duty or reserve members, members of the commissioned corps of the Public Health Service, federal civilians, contractors (when required by the terms of the applicable contract), and other personnel assigned temporary or permanent duties at DHA and DHA Components.

3. POLICY IMPLEMENTATION. It is DHA's instruction, pursuant to Reference (f) that:

a. MTFs that collaborate with extramural researchers under Defense Health Program-funded grants, cooperative agreements, Other Transaction Agreements or procurement contracts must be reimbursed for both direct costs and overhead including indirect costs.

b. MTFs that collaborate with extramural researchers under funding vehicles that are not described in section 3a, such as Cooperative Research and Development Agreements (CRADAs):

(1) Must be reimbursed for direct costs.

(2) May be reimbursed for overhead including indirect costs, as long as such costs are included in the budgets submitted for sponsored funding, and as long as such costs are not directly charged to the Uniformed Services University of the Health Sciences (USUHS), to DHA (including, but not limited to, other MTFs), or to other DoD Components.

c. MTFs which collaborate with intramural researchers:

(1) May be reimbursed for direct costs.

(2) Must not charge overhead including indirect costs directly to USUHS, to DHA (including, but not limited to, other MTFs), or to other DoD Components.

4. RESPONSIBILITIES. See Enclosure 2.

5. PROCEDURES. See Enclosure 3. The procedures in this DHA-TM address the requirements of References (e) through (f).

6. PROPONENT AND WAIVERS. The proponent of this publication is the Deputy Assistant Director (DAD), Research and Development (R&D). When activities are unable to comply with this publication, the activity may request a waiver that must include a justification, to include an analysis of the risk associated with not granting the waiver. The activity director or senior leader will submit the waiver request through their supervisory chain to the DAD-R&D to determine if the waiver may be granted by the Director, DHA or a designee.

7. RELEASABILITY. **Cleared for public release**. This DHA-TM is available on the Internet from the Health.mil site at: https://health.mil/Reference-Center/Policies and is also available to authorized users from the DHA SharePoint site at: https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx.

8. EFFECTIVE DATE. This DHA-TM:

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 Reference (c).

/S/
RONALD J. PLACE
LTG, MC, USA
Director

Enclosures
1. References
2. Responsibilities
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Glossary

ENCLOSURE 1

REFERENCES

(a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, 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 10
(e) DHA-Procedural Instruction 3200.02, "Clinical Investigation Program (CIP) in Military Medical Treatment Facilities (MTFs)," September 24, 2019
(f) DoD Instruction 6000.08, "Defense Health Program Research and Clinical Investigation Programs," January 22, 2014, as amended
(g) DHA-Procedural Instruction 3201.05, "Technology Transfer (T2) Program," June 20, 2019
(h) DoD 7000.14-R, "Department of Defense Financial Management Regulation," dates vary by volume
(i) DoD Instruction 5535.08, "DoD Technology Transfer (T2) Program," May 14, 1999, as amended
(j) DoD Instruction 4000.19, "Support Agreements," December 16, 2020
(k) DoD Instruction 5535.11, Availability of Samples, Drawings, Information, Equipment, Materials, and Certain Services to Non-DoD Persons and Entities," March 19, 2012, as amended
(l) United States Code, Title 31
(m) United States Code, Title 15

ENCLOSURE 2

RESPONSIBILITIES

1. DIRECTOR, DHA. Under the authority, direction, and control of the Assistant Secretary of Defense for Health Affairs, the Director, DHA will:

a. Develop, issue, and monitor the DHA's Component Management Plan for the Clinical Investigations Program (CIP) as it applies to oversight of reimbursement of research-related expenses for CIs in MTFs in accordance with References (e) and (f).

b. Oversee the implementation of this DHA-TM to ensure consistent application across the Military Health System in accordance with Reference (e).

c. Serve as the approval authority for waivers from this DHA-TM, as allowed by law or regulation, in accordance with Reference (e).

2. DAD-R&D. The DAD-R&D must:

a. Implement procedures, guidance, and instructions consistent with this DHA-TM.

b. Support the responsibilities and functions of the Director, DHA listed in this DHA-TM in accordance with Reference (e).

3. DAD, FINANCIAL OPERATIONS. The DAD-Financial Operations (DAD-FO) must advise and assist the DAD-R&D in the review and approval of MTF policies and procedures for reimbursement of research-related expenses for CIs.

4. CHIEF, CLINICAL INVESTIGATIONS PROGRAM OFFICE (CIPO). The Chief, CIPO must:

a. Support the DAD-R&D in developing, issuing, and monitoring the Component Management Plan for the CIP as it applies to oversight of reimbursement of research-related expenses for CIs in MTFs in accordance with Reference (e).

b. Support the DAD-R&D in establishing and overseeing Component implementing policies and procedures for the CIP with respect to oversight of reimbursement of research-related expenses for CIs at MTFs in accordance with Reference (e).

c. In coordination with DAD-FO, review and approve MTF policies and procedures with respect to reimbursement of research-related expenses for CIs in accordance with Reference (e).

d. As described in Enclosure 3 of this DHA-TM, consider granting exceptions to specific procedures, as allowed by law or regulation, based upon an appropriate justification.

5. DIRECTORS OF MEDICAL CENTERS. The Directors of Medical Centers must ensure, for CIs conducted within their MTF, reimbursement of research-related expenses in accordance with Reference (e) and in accordance with this DHA-TM.

6. DIRECTORS, MTF, FOR EDUCATION, TRAINING, AND RESEARCH. The Directors, MTF, for Education, Training, and Research must:

a. Oversee the establishment and implementation of MTF policies and procedures that integrate appropriate policy and guidance with respect to reimbursement of research-related expenses for CIs in accordance with Reference (e).

b. Ensure MTF reimbursement of research-related expenses for CIs in accordance with Reference (e).

7. DIRECTORS, MTF, FOR RESOURCE MANAGEMENT. The Directors, MTF, for Resource Management must:

a. Advise and assist Directors, MTF, for Education, Training, and Research in developing and implementing MTF policies and procedures for reimbursement of research-related expenses for CI.

b. Advise and assist Directors, MTF, for Education, Training, and Research in determining reasonable charges, including the establishment of overhead rates in accordance with this DHA-TM.

8. CHIEFS, MTF, DEPARTMENT OF CLINICAL INVESTIGATION (DCI). The Chiefs, MTF, DCI must:

a. Coordinate with Directors, MTF, for Education, Training, and Research to develop and implement MTF policies and procedures for reimbursement of research-related expenses for CIs that support the requirements of this DHA-TM and guidance from CIPO.

b. Submit MTF policies and procedures for reimbursement of research-related expenses for CIs to the Chief, CIPO, in accordance with Reference (e).

9. DHA LABORATORY DIRECTORS. The DHA Laboratory Directors must ensure that the requirements of this DHA-TM are met before executing CRADAs that involve CIs in accordance with Reference (g).

10. TECHNOLOGY TRANSFER SPECIALISTS. For CRADAs involving MTFs that are laboratories, the Technology Transfer Specialists must prepare CRADAs that include provisions for MTF reimbursement for all direct costs, and, at the discretion of the DHA Laboratory Director, overhead including indirect costs when applicable, in accordance with Reference (g).

11. INTRAMURAL RESEARCHERS. The intramural researchers will advise and assist Technology Transfer Specialists in the identification and quantification of potential direct costs and overhead including indirect costs for their respective research projects when a CRADA is utilized.

ENCLOSURE 3

PROCEDURES

1. MTF REIMBURSEMENT POLICIES AND PROCEDURES. In order to accomplish the responsibilities described in paragraphs 5 through 11 of Enclosure 2, MTF reimbursement policies and procedures must:

a. Incorporate the minimum requirements in this enclosure.

b. Include the following:

(1) Applicability, in accordance with paragraph 2 of this enclosure.

(2) Procedures for identifying and verifying research-related expenses, to include MTF review and approval of research budget estimates associated with grant proposals prior to submission.

(3) Methods for determining reasonable charges for research-related expenses, including methods for calculating both direct costs and overhead rates in accordance with paragraph 3 of this enclosure.

(4) Procedures for collecting, managing, and using funds received, in accordance with paragraph 4 of this enclosure.

(5) Maintenance of records, in accordance with paragraph 5 of this enclosure.

c. For each activity identified in section 1b of this enclosure, identify the responsible office or personnel by position.

2. APPLICABILITY

a. Required reimbursements. MTFs that collaborate with extramural researchers:

(1) Under Defense Health Program-funded grants, cooperative agreements, Other Transaction Agreements or procurement contracts must be reimbursed for both direct costs and overhead including indirect costs, pursuant to Reference (f); such costs must be included in the budgets submitted for sponsored funding and are subject to the approval of the sponsor.

(2) Under funding vehicles other than those listed in paragraph 2a(1) of this enclosure must be reimbursed for direct costs.

b. Permissible reimbursements. MTFs that collaborate with:

(1) Extramural researchers under funding vehicles other than those listed in paragraph 2a(1) of this enclosure may be reimbursed for overhead including indirect costs as long as such costs are included in the budgets submitted for sponsored funding, and as long as such costs are not directly charged to USUHS, to DHA (including, but not limited to, other MTFs), or to other DoD Components.

(2) Intramural researchers may be reimbursed for direct costs.

c. Prohibited reimbursements. MTFs that collaborate with:

(1) Extramural researchers under funding vehicles other than those listed in paragraph 2a(1) of this enclosure must not charge overhead including indirect costs directly to USUHS, to DHA (including, but not limited to, other MTFs), or to other DoD Components.

(2) Intramural researchers must not charge overhead including indirect costs directly to USUHS, to DHA (including, but not limited to, other MTFs), or to other DoD Components.

3. DETERMINING REASONABLE CHARGES

a. When reimbursement is required in accordance with paragraph 2a(1) of this enclosure, MTFs must determine reasonable charges in accordance with Volume 11A, Chapter 1, Paragraph 010203 of Reference (h) and charge the full amount of all direct and overhead costs.

b. When reimbursement is either required in accordance with paragraph 2a(2) of this enclosure or permissible in accordance with paragraph 2b of this enclosure, MTFs must follow the guidance on determination of reasonable charges applicable to the specific funding vehicle used, most commonly:

(1) If a CRADA is utilized in accordance with Reference (g), MTFs may set reasonable charges at any amount up to the fair market value of the services or goods provided, except that labor costs for government intramural researchers must not be charged, and in accordance with Reference (i), the cost and expense of development, negotiation, and implementation of CRADAs should be funded from laboratory resources.

(2) If a support agreement (e.g., a memorandum of understanding or memorandum of agreement between two commands within a DoD Component, between two DoD Components, or between a DoD Component and a federal agency) is utilized in accordance with Reference (j), MTFs must follow the guidance of Reference (j).

(3) If an agreement for the provision of samples, drawings, information, equipment, materials, or certain services to non-DoD persons and entities is utilized in accordance with Reference (k), MTFs must follow the guidance of Reference (k).

c. MTF must re-evaluate methods to determine overhead rates including indirect costs at least biennially.

4. COLLECTING, MANAGING, AND USING FUNDS

a. General considerations.

(1) Collection. MTFs must direct collaborators to send funds to the MTF's resource management office.

(2) Management. Funds must be credited to the appropriation initially charged with the related expenditure. If the appropriation is closed, reimbursements must be credited to the General Fund of the U.S. Treasury.

(3) Use. Funds should be used for MTF reimbursement for costs associated with conducting the studies and/or funded research and are subject to fiscal guidance and constraints within Reference (l).

b. Special considerations.

(1) Pursuant to Reference (f), when reimbursement is required in accordance with paragraph 2a(1) of this enclosure, the reimbursement must be either directly from the responsible or appropriate government resource management office, or the reimbursement must be from the extramural award or sub-award recipient via a CRADA, an agreement carried out under the authority of Reference (k), intergovernmental agreements (Reference (j)), or other such mechanisms allowed by law or regulation.

(2) Funds received under CRADA authority.

(a) In accordance with section 3710a(b)(3)(A) of Reference (m), MTFs with laboratory designation may directly accept, retain, and use funds from a non-federal extramural collaborating party. This authority provides a statutory exemption to the general prohibition of augmenting an appropriation.

(b) Such funds are not considered User Charges or User Fees in accordance with Reference (h), and their retention and use by an MTF-laboratory is not in violation of the Miscellaneous Receipts statute (Section 3302(b) of Reference (l)).

5. MAINTENANCE OF RECORDS. The MTF must maintain records of the following:

a. Calculations and supporting documentation used in all determinations of reasonable charges in accordance with paragraph 3 of this enclosure.

b. Detailed accounting of required reimbursements in accordance with paragraph 2a of this enclosure, including whether such funds were received and used.

c. Copies of grants, agreements, contracts, or other funding vehicles related to the extramural collaboration under which funds were received.

6. REQUESTS FOR SPECIFIC EXEMPTIONS. Chiefs, MTF, DCI may submit requests for specific exemptions to procedures in this enclosure with appropriate justification through Directors, MTF, Education, Training, and Research to Chief, CIPO, but are not required if a waiver for compliance with this DHA-TM has already been granted by the Director, DHA in accordance with paragraph 6 of the policy section in this DHA-TM.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

CI	clinical investigation
CIP	Clinical Investigations Program
CIPO	Clinical Investigations Program Office
CRADA	Cooperative Research and Development Agreement
DAD	Deputy Assistant Director
DCI	Department of Clinical Investigation
DHA-TM	Defense Health Agency-Technical Manual
G&A	General and administrative
MTF	Military Medical Treatment Facility
R&D	Research and Development
USUHS	Uniformed Services University of the Health Sciences

PART II. DEFINITIONS

These terms and their definitions are for the purposes of this DHA-PI.

CI. See References (e) and (f).

CIP. See References (e) and (f).

CRADA. See References (g) and (i). See also Reference (m) and Reference (f) for the distinction between CRADA and cooperative agreement.

DHA Laboratory Director. See Reference (g).

direct costs. Research costs which are readily and directly identifiable to the particular project or activity and, as applicable, allowable under the sponsoring organization's guidelines. Examples of direct costs include, but are not limited to, compensation of non-DoD employees such as research assistants and consultants; project-related equipment, materials, and supplies (including animals and cell lines); travel; publication costs; Institutional Review Board services; computer services; sub-award, consortium, or contractual costs; equipment or facility rental/user fees;

communication costs; and, only when essential and unique to the proposed project, computers and software.

extramural researcher. Researchers who are not included in the definition of an intramural researcher. Examples of extramural researchers include, but are not limited to, individuals who are employed by or affiliated with non-DoD organizations such as academia, biotechnology companies, foundations, government, and research institutes.

intramural researcher. A DoD military or civilian employee working within a DoD facility or a DoD activity embedded within a non-DoD facility.

Medical Centers. A MTF operating pursuant to section 1073d of Reference (d).

Military Health System. See References (e) and (f).

overhead. General and administrative (G&A) costs, or some combination of G&A and indirect costs, which cannot readily or directly be identified. Examples of such costs include supervision, office supplies, and utility costs. See Reference (h).

overhead rate. The rate determined by performing organizations to allocate operating costs not directly identifiable to the work order. The rate may include supervisory and G&A expenses as well as miscellaneous material and supplies. See Reference (h).

research. See References (e) and (f).

Technology Transfer Specialist. See Reference (g).