



Defense Health Agency

TECHNICAL MANUAL

NUMBER 3200.02

June 7, 2021

DAD-R&D

SUBJECT: Scientific Review of 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 in accordance with the guidance of Sections 1073c and 1073d of References (d), and References (e) through (i), establishes the Defense Health Agency's (DHA's) procedures for scientific review of clinical investigations (CIs) and research within DoD Military Medical Treatment Facilities (MTFs) in order to implement DHA's instruction in Reference (e).

2. APPLICABILITY. This DHA-TM applies to the DHA, MTFs (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 MTFs under the authority, direction, and control of the DHA.

3. POLICY IMPLEMENTATION. It is DHA's instruction, pursuant to References (e) through (g), that DoD MTFs conducting CIs and research will develop and implement local scientific review policies and procedures with appropriate headquarters review and oversight.

4. RESPONSIBILITIES. See Enclosure 2.

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

June 7, 2021

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 their 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).

9. FORMS. DHA Form 201, Scientific Review is available on the internet at: https://info.health.mil/cos/admin/DHA_Forms_Management/Lists/DHA%20Forms%20Management/AllItems.aspx

/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 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) DoD Instruction 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research,” April 15, 2020
- (h) Force Health Protection Concept of Operations (CONOPS), November 17, 2011¹
- (i) DHA-Administrative Instruction 5015.01, “Records Management Program,” February 6, 2020

¹ This reference can be obtained by e-mailing DHA at: dha.ncr.comm.mbx.health-affairs@mail.mil

ENCLOSURE 2

RESPONSIBILITIES

1. DIRECTOR, DHA. The Director, DHA will:

a. Develop, issue, and monitor policies and procedures for the DHA's Component responsibilities for the Clinical Investigation Program (CIP) with respect to oversight of scientific review at MTFs in accordance with Reference (f).

b. Oversee the implementation and administration of this DHA-TM to ensure consistent application across the Military Health System (MHS).

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 under this DHA-TM.

3. CHIEF, CLINICAL INVESTIGATION PROGRAM OFFICE (CIPO). The Chief, CIPO must:

a. Support the DAD-R&D in establishing and overseeing Component implementing policies and procedures for the CIP with respect to oversight of scientific review at MTFs in accordance with Reference (e)

b. Review and approve MTF implementing policies and procedures for the CIP with respect to scientific review in accordance with Reference (e).

c. As described in Enclosure 3, grant exceptions to specific procedures based upon an appropriate justification.

4. DIRECTORS OF MEDICAL CENTERS. The Directors of Medical Centers must resource the MTF scientific review process appropriately to support the requirements of this DHA-TM in accordance with Reference (e).

5. MTF DIRECTORS FOR EDUCATION, TRAINING, AND RESEARCH. The MTF Directors for Education, Training, and Research must coordinate scientific review to support the requirements of this DHA-TM in accordance with Reference (e) and guidance from CIPO.

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

a. Develop and implement scientific review policies and procedures that support the requirements of this DHA-TM and guidance from CIPO.

b. Submit scientific review policies and procedures to Chief, CIPO for review and approval in accordance with Reference (e).

7. SCIENTIFIC REVIEWERS. The scientific reviewers, absent of a waiver, must conduct their review in accordance with this DHA-TM and local MTF implementing policies and procedures.

ENCLOSURE 3

PROCEDURES

1. MTF SCIENTIFIC REVIEW POLICIES AND PROCEDURES. In order to accomplish the responsibilities described in Enclosure 2, paragraphs 4 through 7, MTF scientific review policies and procedures must:

a. Incorporate the minimum requirements in this enclosure.

b. Include the following elements:

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

(2) Evaluation of scientific reviewer qualifications, in accordance with paragraph 3 of this enclosure.

(3) Scientific review process, including:

(a) Materials, in accordance with paragraph 4 of this enclosure.

(b) Procedures, in accordance with paragraph 5 of this enclosure, addressing:

1. Identification, management, and assignment of scientific reviewers.

2. Conduct of the review.

3. Use of abbreviated review procedures, if any.

4. Disposition of protocols determined to have inadequate scientific merit or feasibility and procedures and timelines for investigator appeals.

(4) Documentation of the review, in accordance with paragraph 6 of this enclosure.

(5) Maintenance of records, in accordance with paragraph 7 of this enclosure.

c. For each activity identified in paragraph 1b in this enclosure, identify the responsible personnel by position, in accordance with paragraph 8 of this enclosure.

2. APPLICABILITY

a. Required Category. Scientific review is required for non-exempt human subjects research, as defined in Reference (g).

b. Excepted Categories.

(1) Scientific review is not required for the following categories of research previously determined to have scientific merit:

(a) Research funded by a federal source external to the MTF (e.g., a grant from the DoD, from the National Institutes of Health, from the U.S. Centers for Disease Control and Prevention).

(b) Research developed and sponsored by industry (e.g., a clinical trial sponsored by a pharmaceutical company).

(c) Amendments or modifications to research that previously underwent scientific review at an MTF, when such modifications do not substantially impact the items listed in DHA Form 201, Scientific Review (e.g., personnel changes).

(2) Excepted research in accordance with paragraph 2b(1) of this enclosure still requires local MTF review to ensure the following:

(a) Local investigator qualifications.

(b) Feasibility, including confirmation the research is reasonably expected to achieve its intended objectives when considering impacting factors such as the available patient population, competing or conflicting research priorities, and available resources, in accordance with Reference (e).

c. Discretionary Categories. MTF scientific review policies and procedures may require scientific review or abbreviated scientific review for categories of research or activities other than that listed in paragraph 2a of this enclosure (e.g., exempt human subjects research, research involving cadavers, laboratory research, animal research).

3. SCIENTIFIC REVIEWER QUALIFICATIONS. Personnel conducting scientific reviews will:

a. As determined by local policy, be appropriately trained and experienced working within their scope of subject matter expertise or in consultation with a subject matter expert to review research protocols for the items listed in DHA Form 201.

b. Adhere to all policy and institutional requirements for managing conflicts of interest or perceptions of possible conflicts related to the research or to the personnel conducting research.

4. MATERIALS. At a minimum, the following materials will be assessed during scientific review:

- a. Protocol, including local application and sponsor protocol, if applicable.
- b. All questionnaires, surveys, and data collection forms.
- c. Local investigator curriculum vitae.
- d. Impact statements or letters of support from all MTF departments involved, listing the resources necessary to support the research. The details of implementing this standard of all MTF departments involved are left to the MTF.

5. REVIEW PROCEDURES

- a. Procedures for identifying, managing, and assigning scientific reviewers will be at the discretion of the MTF and will be described in local MTF policies and procedures.
- b. Procedures for conducting the review will be at the discretion of the MTF and will be described in local MTF policies and procedures.
- c. Abbreviated scientific review procedures may be designated for use with some or all discretionary categories of research in accordance with paragraph 2c of this enclosure.
- d. Protocols determined to have inadequate scientific merit or feasibility will not proceed to an institutional review board (IRB) for further consideration. Investigators will have the opportunity to appeal such determinations.

6. DOCUMENTATION

- a. Scientific review will be documented using DHA Form 201.
- b. A completed and signed DHA Form 201 will serve as documentation of scientific merit in subsequent submission packages to an IRB.

7. MAINTENANCE OF RECORDS. The MTF DCI will maintain records of the following in accordance with Reference (i):

- a. Scientific reviewer qualifications, in accordance with paragraph 3 of this enclosure.

- b. Materials reviewed in accordance with paragraph 4 of this enclosure.
- c. Resolution of investigator appeals, in accordance with paragraph 5d of this enclosure.
- d. The completed and signed DHA Form 201, in accordance with paragraph 6 of this enclosure.

8. ASSIGNMENT OF RESPONSIBLE PERSONNEL

- a. Assignment of personnel will be at the discretion of the MTF and will be described in local MTF policies and procedures.
- b. Personnel whose primary responsibilities concern the administration and management of the IRB will not be assigned any of the activities in paragraph 1b of this enclosure.

9. REQUESTS FOR SPECIFIC EXCEPTION

- a. Specific exceptions to procedures in this enclosure may be granted by the Chief, CIPO, based upon appropriate justification, 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.
- b. MTF requests for specific exception will be made by the MTF Chiefs, DCI and routed through MTF Directors, Education, Training, and Research to the Chief, CIPO.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

CI	clinical investigation
CIP	Clinical Investigation Program
CIPO	Clinical Investigation Program Office
DAD	Deputy Assistant Director
DCI	Department of Clinical Investigation
DHA	Defense Health Agency
DHA-TM	Defense Health Agency-Technical Manual
IRB	institutional review board
MHS	Military Health System
MTF	Military Medical Treatment Facility
R&D	Research and Development

PART II. DEFINITIONS

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

abbreviated scientific review. A modified review procedure, such as use of a single reviewer rather than committee review for certain types of research or situations, as defined by local policy.

CI. An organized inquiry into and possible development of knowledge or products related to clinical health problems for any conditions of concern in providing health care to beneficiaries of the MHS, including active duty personnel, dependents, and retired personnel. CIs represent a special category of healthcare research. CIs are intended to improve the quality of medical, dental, nursing, and allied health science care provided to beneficiaries of DoD health services or to support graduate health sciences education programs, other allied health programs of the Military Services, and Uniformed Services University of the Health Sciences.

CIP. A program in which CIs are conducted for health sciences education to develop the MHS Force or for the advancement of medical science and its military and nonmilitary application to patient care. CIPs are under the funding and administration as directed by Reference (f).

graduate health sciences education. Programs of the uniformed services and Uniformed Services University of the Health Sciences, such as Graduate Medical Education, Graduate Dental Education, Graduate Nursing Education, and Graduate Allied Health Science Education that promote high professional standing and accreditation of health education programs.

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

MHS. The DoD medical and dental programs, personnel, facilities, and other assets of the Military Services operating pursuant to Chapter 55 of Reference (d), by which the DoD provides health care services to the Military Services during military operations and supports the military mission by fostering, protecting, sustaining, and restoring health. It also provides the direction, resources, healthcare providers, and other means necessary for promoting the health of the beneficiary population (e.g., members of the Military Services, their family members, and others entitled to DoD medical care). These include developing and promoting health awareness issues to educate customers, discovering and mitigating environmentally based health threats, providing health services, including preventive care and problem intervention, Multi-Service Markets with enhanced authorities, and improving the means and methods for maintaining the health of the beneficiary population by constantly evaluating the performance of the healthcare services system.

research. In accordance with Reference (f), any systematic study directed toward fuller scientific knowledge or understanding of military health care and in support of health readiness solutions that protect, treat, and optimize the health and performance of the total force as envisioned in Reference (h), or in analysis or guidance that may be established by the DoD's leadership in these fields of study.