



# Defense Health Agency

## ADMINISTRATIVE INSTRUCTION

NUMBER 083

April 1, 2016

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A&MD/Privacy Office

SUBJECT: Regulatory Reviews of Research Studies

References: See Enclosure 1

1. **PURPOSE.** This Defense Health Agency-Administrative Instruction (DHA-AI), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (l), establishes the Defense Health Agency's (DHA) procedures by which the Privacy and Civil Liberties Office (DHA Privacy Office) will delegate regulatory compliance reviews of research studies seeking DHA data, as defined herein, to the DHA's National Capital Region Medical Directorate (NCR-MD) Military Treatment Facilities (MTFs), (hereinafter referred to as "NCR-MD MTFs"). This delegation streamlines separate and distinct reviews required by Reference (d) (also known as the "Common Rule" and implemented by Reference (f)), and Reference (g) (herein referred to as the Health Insurance Portability and Accountability Act "HIPAA Privacy Rule" and implemented by Reference (h)), so that a single board can simultaneously conduct both reviews. It further enables NCR-MD MTFs to conduct all necessary regulatory compliance reviews that would otherwise be conducted within the DHA Privacy Office, such that researchers can obtain all necessary compliance reviews at the NCR-MD-level without the need for second-tier reviews within the DHA Privacy Office.

2. **APPLICABILITY.** This DHA-AI:

a. Applies to all DHA personnel, to include: assigned or attached Service members, federal civilians, contractors (when required by the terms of the applicable contract), and other personnel assigned temporary or permanent duties at DHA to include regional and field activities (remote locations) and the NCR-MD activities (centers, clinics, and MTFs).

b. Does not address, or otherwise impact, the NCR-MD MTFs' required review of research studies for compliance with the Common Rule (Reference (d)) or U.S. Food and Drug Administration's human subject protection regulations as set forth in Reference (e).

3. POLICY IMPLEMENTATION. It is DHA policy, pursuant to References (d) through (l), that:

a. All non-exempt research studies involving human subjects and requesting DHA data must be reviewed by Institutional Review Boards (IRBs) for compliance with Reference (d).

b. All research studies requesting DHA data, including those that are exempt and not exempt from Reference (d), must be reviewed by IRBs, HIPAA Privacy Boards, and/or Department of Research Programs (DRPs) for compliance with Reference (f).

c. IRBs, HIPAA Privacy Boards, and/or DRPs within the NCR-MD MTFs will conduct appropriate HIPAA Privacy Rule reviews of research studies; the DHA Privacy Office will accept HIPAA-related determinations and findings made by the NCR-MD MTFs through the use of standardized HIPAA research templates and will not require secondary or administrative reviews.

d. All research studies requesting DHA data must be further reviewed for compliance with References (i) and (j), as well as other applicable DHA policies and procedures.

e. NCR-MD MTFs will further conduct compliance reviews of research studies in accordance with References (i) and (j) and other applicable DHA policies and procedures; the DHA Privacy Office will accept the NCR-MD MTFs' regulatory compliance determinations without requiring its own independent reviews.


4. RESPONSIBILITIES. See Enclosure 2

5. PROCEDURES. See Enclosure 3

6. RELEASABILITY. **Not cleared for public release.** This DHA-AI is available to DHA employees and contractor support personnel with Common Access Card authorization on the DHA Intranet.

7. EFFECTIVE DATE. This DHA-AI:

- 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 Procedural Instruction 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)),” September 30, 2013
- (b) DoD Directive 5136.13, “Defense Health Agency (DHA),” September 30, 2013
- (c) DHA Procedural Instruction 5025.01, “Publication System,” August 21, 2015
- (d) Title 45, Code of Federal Regulations (CFR), Part 46, “Policy for Protection of Human Subjects” (also known as the “Common Rule”)
- (e) DoD Instruction 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research,” November 8, 2011
- (f) Title 32, CFR, Part 219, “Protection of Human Subjects”
- (g) Title 45, CFR, Parts 160 and 164, “HIPAA Administrative Simplification,” (also known as the “HIPAA Privacy Rule”)
- (h) DoD 6025.18-R, “DoD Health Information Privacy Regulation,” January 24, 2003
- (i) DoD Directive 5400.11, “DoD Privacy Program,” October 29, 2014
- (j) DoD Instruction 8580.02, “Security of Individually Identifiable Health Information in DoD Health Care Programs,” August 12, 2015
- (k) DoD Instruction 8910.01, “Information Collection and Reporting,” May 19, 2014
- (l) DoD Instruction 8582.01, “Security of Unclassified DoD Information on Non-DoD Information Systems,” June 6, 2012

ENCLOSURE 2

RESPONSIBILITIES

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

- a. Maintain oversight activities and management controls to ensure compliance with this DHA-AI.
- b. Oversee coordination of the implementation of this DHA-AI between DHA's Privacy Office and the NCR-MD MTFs.
- c. Delegate authority to the DHA Privacy Office to develop and update supporting templates, training, and guidance under this DHA-AI, as necessary.

2. CHIEF, DHA PRIVACY OFFICE. The Chief, DHA Privacy Office, will:

- a. Create and maintain standardized HIPAA research templates and guidance, and distribute templates and guidance to the NCR-MD MTFs through their Human Protection Administrator(s).
- b. Develop and maintain a System Security Verification (SSV) template and place the current version on the DHA Privacy Office website.
- c. Develop, maintain, and deliver "HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards" within NCR-MD MTFs, including providing certificates of completion.
- d. Address questions and requests for technical assistance submitted by NCR-MD MTFs in connection with their responsibilities for conducting regulatory reviews as required under this DHA-AI.
- e. Conduct periodic assessments of research activities within the NCR-MD MTFs to determine compliance with this DHA-AI.
- f. Review reports provided by the NCR-MD MTFs pertaining to data determinations, HIPAA reviews of research studies, and other regulatory compliance reviews on a quarterly basis, beginning 6 months after the signing of the AI and, after 1 year of quarterly reviews, semi-annually in order to review efficiency and compliance of the activities governed by this DHA-AI.

3. DIRECTOR, NCR-MD. The Director, NCR-MD, will:

a. Oversee compliance and delegate responsibilities set forth below, consistent with this DHA-AI, to the Deputy Institutional Officials (IOs) for NCR-MD MTFs, including the Deputy IOs for Walter Reed National Military Medical Center and Fort Belvoir Community Hospital, as appropriate.

b. Ensure contracts include provisions for compliance with this DHA-AI, when appropriate.

c. Require all IRB, HIPAA Privacy Board, and DRP staff (including contractors) involved in data determination or HIPAA Privacy Rule compliance reviews to complete “HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards” offered by the DHA Privacy Office *before* conducting any data determination or HIPAA Privacy Rule reviews, and maintain an up-to-date list of all trained board members and DRP staff.

d. Determine the type of data requested in a research study and, when applicable, conduct appropriate HIPAA Privacy Rule reviews of research studies requiring the need for protected health information (PHI), including those that may be exempt from IRB review under the Common Rule, through the use of standardized HIPAA research templates, training, and guidance provided by the DHA Privacy Office.

e. Request assistance, when necessary, from a Military Health System (MHS) data expert by email to [dha.ncr.pcl.mbx.privacyboard@mail.mil](mailto:dha.ncr.pcl.mbx.privacyboard@mail.mil) to ensure that NCR-MD MTFs make appropriate determinations as to the type of data sought for a research study and/or whether data sought by the researcher adheres to the HIPAA Privacy Rule’s minimally necessary standard.

f. Perform the following additional activities when researchers request DHA data:

(1) Conduct compliance reviews consistent with Reference (i).

(2) Conduct SSV reviews, using the most current SSV template from the DHA Privacy Office, when DHA data obtained for a research study will be stored, transmitted, processed, or otherwise maintained on an information system that has not been granted a DoD Authorization to Operate or Interim Authorization to Operate.

(3) Require researchers to dispose of electronic and hard copy data containing personally identifiable information (PII) obtained or created in a research study, including derivative data and data in the possession of any business associate, agent, or subcontractor, at the point it is no longer needed for the research study, and in accordance with DoD privacy and security requirements.

(4) Review all organizations and individuals involved in the research study, including any subcontractors, and their role(s) in the study, and ensure that only those organizations and individuals with a need for DHA data for the study will be given access to it.

(5) Review the collection, flow, use, storage, and destruction of DHA data from the time of receipt through the research study's duration, and determine if the collection, flow, use, storage, and destruction is reasonable and appropriate for the particular study.

(6) If the research study involves a survey or information collection, verify that a survey license is in place (e.g., through Washington Headquarters Services or the Office of Management and Budget) if/when required in accordance with Reference (k).

(7) Determine whether information related to DHA data in the research study will be published, reported, or otherwise released. If so, review the method proposed by the research study to ensure that it is very low risk in terms of identifying/re-identifying individuals.

g. Place appropriate requirements on Principal Investigators (PIs) for regulatory compliance purposes, and monitor PIs for compliance on a regular ongoing basis.

h. Maintain, electronically or in hard copy, any and all completed HIPAA research templates relied upon to justify the use or disclosure of PHI for research purposes (as set forth in Enclosure 3, Section 1.a) for at least 6 years from the date they were last in effect or longer based on institutional requirements for records retention.

i. Provide documents pertaining to all regulatory compliance reviews of research studies to the DHA Privacy Office in connection with an assessment under this DHA-AI or a periodic audit by the Department of Health and Human Services' Office for Civil Rights.

j. Direct any requests to alter templates required for use under this DHA-AI by email to [dha.ncr.pcl.mbx.privacyboard@mail.mil](mailto:dha.ncr.pcl.mbx.privacyboard@mail.mil).

k. Submit questions or requests for technical assistance in connection with conducting regulatory reviews as required under this DHA-AI by email to [dha.ncr.pcl.mbx.privacyboard@mail.mil](mailto:dha.ncr.pcl.mbx.privacyboard@mail.mil).

l. Notify applicable MTFs engaged in the research study, as defined in Reference (k), if an IRB or HIPAA Privacy Board approves a research study in which patients will be contacted to participate and document the MTF's willingness to support the associated research study.

m. Coordinate with the DHA Privacy Office on HIPAA Privacy Rule assessments of research activities performed under this DHA-AI.

n. Review final reports regarding assessments of NCR-MD MTFs' activities performed under this DHA-AI, and take follow-up actions on all findings, as necessary, in collaboration with the DHA Privacy Office.

o. Develop reports on a quarterly basis beginning 6 months after the signing of the AI and, after 1 year of quarterly reviews, semi-annually pertaining to data determinations, HIPAA Privacy Rule reviews of research studies, and other regulatory compliance reviews.

ENCLOSURE 3

PROCEDURES

1. NCR-MD MTFs. The NCR-MD MTFs will:

a. Ensure its IRBs, HIPAA Privacy Boards, and DRPs utilize current versions of standardized HIPAA research templates provided by the DHA Privacy Office to the NCR-MD MTFs' Human Protection Administrator(s) as set forth in Enclosure 2, Section 2.a., including those listed in lines (1)–(9) below.

(1) Section 5.5.5 of the Protocol Application: Data Collection

(2) Data Determination Guide

(3) HIPAA Authorization Language Checklist

(4) HIPAA Authorization

(5) Application for a Waiver of Authorization or an Altered Authorization

(6) Internal Checklist: Review of the Application for a Waiver of Authorization or an Altered Authorization

(7) Required Representations for Review Preparatory to Research

(8) Required Representations for Research on Decedent's Information

(9) Data Use Agreement (DUA) for a Limited Data Set (LDS)

b. Ensure that its Chief Information Management Officer and/or Information Assurance Manager conducts SSV reviews as required under this DHA-AI and utilizes the current version of the SSV template developed by the DHA Privacy Office and available on the DHA Privacy Office's website at <http://health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties>.

c. When approving research studies that will obtain appropriate HIPAA Authorizations or an approved Altered Authorization, require the PI to do the following:

(1) Maintain (electronically or in hard copy) the signed authorization of each research participant whose PHI is used and/or disclosed for a period of 6 years from the date the authorization was last in effect (which may mean indefinitely for an authorization with no expiration that is not otherwise revoked) or longer based on institutional requirements for records retention.



(2) Provide any and all of the signed authorizations immediately upon request to the NCR-MD MTFs' IRB or HIPAA Privacy Board and the DHA Privacy Office.

d. When a Waiver of Authorization is approved, require the PI to notify the NCR-MD MTFs' IRB or HIPAA Privacy Board promptly if there is any change in the research study, and review the change to determine whether another HIPAA Privacy Rule review is required in light of the change that was made.

e. When approving a research study that will use an LDS:

(1) Ensure that the LDS will be created by an MHS employee or business associate, as permitted by the health care operations provision of the HIPAA Privacy Rule, or by a researcher that has otherwise been approved by the NCR-MD MTFs' IRB or HIPAA Privacy Board to obtain PHI for research purposes through approved HIPAA Authorizations from all research subjects whose data will be contained in the LDS, or through an approved Waiver of Authorization or an Altered Authorization.

(2) Require the PI of the research study to review and sign a DUA *before* the LDS is used or disclosed within the study.

f. Document how all DHA data, including derivative data and data in the possession of any business associate, agent, or subcontractor, is disposed of at the end of a research study in accordance with DoD privacy and security requirements using one or more of the following methods:

(1) Data Destruction. Ensure the researcher shreds or burns hard copy files or data and overwrites/degausses (e.g., demagnetizes) and/or physically destroys electronically stored media. Clearing data (e.g., deleting files) is not an approved method of sanitizing electronic storage media.

(2) Data Return. Ensure all data utilized for research purposes consistent with this DHA-AI are returned to the DHA.

(3) Data Transfer. Only permit a researcher to transfer data to another research study if the new study to which data is transferred has undergone its own, independent regulatory compliance reviews consistent with the requirements of this DHA-AI.

g. Develop reports, to include, at a minimum, the following data elements, for a given reporting period in a format agreed upon with the DHA Privacy Office.

(1) Total number of studies reviewed by the NCR-MD MTFs' IRB, HIPAA Privacy Board, and DRP, including a breakdown of exempt and non-exempt research studies.

(2) Number of studies determined to be requesting or using deidentified data, PII not including PHI, PHI, and LDS.

(3) Total number of HIPAA reviews performed of exempt research studies, including a breakdown of the number of approved Authorizations, Altered Authorizations, Full Waivers of Authorization, Partial Waivers of Authorization, Required Representations for Review Preparatory to Research, and Required Representations for Research on Decedent's Information.

(4) Total number of HIPAA reviews performed of non-exempt research studies, including a breakdown of the number of approved Authorizations, Altered Authorizations, Full Waivers of Authorization, Partial Waivers of Authorization, Required Representations for Review Preparatory to Research, and Required Representations for Research on Decedent's Information.

(5) Total number of SSV reviews performed for research studies.

(6) Names of IRB and HIPAA Privacy Board members and DRP staff who have performed data determinations and HIPAA Privacy Rule reviews.

(7) Number and a brief description of any and all HIPAA complaints and violations.

(8) Number and a brief description of any and all substantiated HIPAA complaints and violations.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHA-AI	Defense Health Agency-Administrative Instruction
DRP	Department of Research Program
DUA	Data Use Agreement
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
LDS	Limited Data Set
MHS	Military Health System
MTF	Military Treatment Facility
NCR-MD	National Capital Region Medical Directorate
PHI	protected health information
PI	Principal Investigator
PII	personally identifiable information
SSV	System Security Verification

PART II. DEFINITIONS

business associate. Except as provided below, business associate, with respect to a DoD-covered entity, is a person who:

On behalf of such DoD-covered entity or of an organized health care arrangement in which the DoD-covered entity participates, but other than in the capacity of a member of the workforce of such DoD-covered entity or arrangement, creates, receives, maintains, or transmits PHI for a function or activity regulated by this instruction, or performs, or assists in the performance of a function or activity involving the use or disclosure of PHI or other function or activity regulated by this instruction; or

Provides, other than in the capacity of a member of the workforce of such DoD-covered entity, legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services to or for such DoD-covered entity, or to or for an

organized health care arrangement in which the DoD-covered entity participates, where the provision of the service involves the disclosure of PHI from such DoD-covered entity or arrangement, or from another business associate of such DoD-covered entity or arrangement, to the person.

A DoD or other covered entity performing HIPAA-covered functions on behalf of another covered entity may be a business associate. This circumstance occurs only when the first covered entity is not acting as either a health plan or a provider covered entity in its dealings with the other covered entity. For example, some of the managed care support contractors act as health plan covered entities (insurers) in their commercial business but act as administrative service providers (and thus as business associates) with respect to the TRICARE health plan.

Business associate includes:

A Health Information Organization, E-prescribing Gateway, or other person who provides data transmission services with respect to PHI to a DoD-covered entity and who requires access on a routine basis to such PHI.

A person who offers a personal health record to one or more individuals on behalf of a DoD-covered entity.

A subcontractor who creates, receives, maintains, or transmits PHI on behalf of the business associate.

Business associate does not include:

A health care provider, with respect to disclosures by a DoD-covered entity to the health care provider concerning the treatment of the individual.

A government agency, with respect to determining eligibility for, or enrollment in, a government health plan that provides public benefits and is administered by another government agency, or collecting PHI for such purposes, to the extent such activities are authorized by law.

A DoD-covered entity participating in an organized health care arrangement that performs a function or activity as described by the second paragraph of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in the third paragraph of this definition to or for such organized health care arrangement by virtue of such activities or services.

data determination. For purposes of this instruction, the process of reviewing the type of DHA data requested for a research study and determining whether the data requested is deidentified data, PII (not including PHI), LDS, or PHI.

DHA data. For purposes of this instruction, DHA data is defined as PII, including PHI, maintained on a DHA-managed system, as documented in the Defense Health Program System Inventory Reporting Tool. For example, DHA-managed systems include, but are not limited to: Armed Forces Health Longitudinal Technology Application (AHLTA), Management Analysis and Reporting Tool (M2), MHS Data Repository (MDR), Theater Medical Data Store (TMDS), Composite Health Care System (CHCS), Essentris, Patient Encounter Processing and Reporting (PEPR), Defense Medical Human Resource System-Internet (DMHRSi), and Pharmacy Data Transaction Service (PDTS).

LDS. PHI that meets the regulatory parameters for an LDS established in Reference (h).

MTF. A military treatment facility established for the purpose of furnishing medical and/or dental care to eligible individuals.

PHI. Individually identifiable health information created, received, or maintained by a covered entity, including DHA, that is transmitted or maintained by electronic or any other form or medium, except as otherwise contained in employment records held by DHA in its role as an employer.

PII. Information which can be used to distinguish or trace an individual's identity, such as name, social security number, date and place of birth, mother's maiden name, biometric records, home phone numbers, and any other demographic, personnel, medical, and financial information. PII includes any information that is linked to a specified individual, alone, or when combined with other personal or identifying information.

SSV. The SSV is a tool used to document compliance with the requirements of References (j) and (l) for information systems that will be used to store, transmit, process, or otherwise maintain DHA data but have not been granted a DoD Authorization to Operate or an Interim Authorization to Operate.