Defense Health Agency
Privacy and Civil Liberties Office

HIPAA Privacy Board Overview

April 30, 2015

DHA Privacy Board Overview

Objectives

The purpose of this presentation is to:

- Provide an overview of the DHA Privacy and Civil Liberties Office (Privacy Office) Privacy Board's function and operations, including:
  - Establishment of the DHA Privacy Board and Regulatory Requirements
  - Difference between Common Rule and the HIPAA Privacy Rule
  - Types of Privacy Rule Reviews

DHA Privacy Board Overview

The DHA Privacy Board

- HIPAA compliance reviews and documentation are required by an IRB or Privacy Board, set up in accordance with the HIPAA regulations, when PHI is used and/or disclosed for research purposes
- DHA does not have an IRB; therefore, the DHA Privacy Office established a HIPAA Privacy Board, known as the DHA Privacy Board
- The DHA Privacy Board is critical for DHA's compliance with the HIPAA Privacy Rule and DoD 6025.18-R
- The DHA Privacy Board accepts and relies on HIPAA reviews conducted by DoD or outside IRBs – provided that the IRB's HIPAA-required documentation meets regulatory requirements

DHA Privacy Board Overview

The Difference Between the Common Rule and the HIPAA Privacy Rule

	The Common Rule	The HIPAA Privacy Rule
Federal Regulation	Protection for Human Subjects (45 CFR 46)	HIPAA Privacy Rule (45 CFR 160 and 164)
DoD Implementing Regulation	Protection of Human Subjects (32 CFR 219); Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research (DoDI 3216.02)	DoD Health Information Privacy Regulation (DoD 6025.18-R)
Primary Purpose	Protect individuals who are the subject of research projects. Consideration is given to how various aspects of the research project, including privacy, confidentiality, data collection, data maintenance and data retention, impact physical, emotional, financial, and informational harms.	Protect individuals against information harm while allowing the necessary flow of health information with specific rules pertaining to the privacy and security of PHI.
Threshold Requirement	Informed consent from each research participant (oral and/or written)	HIPAA Authorization from each research participant *(must be written and signed)*
Enforcement	Office for Human Research Protections, HHS, and DoD Assistant Secretary of Defense for Research and Engineering	Office for Civil Rights, HHS
Administration	IRBs	IRBs or HIPAA Privacy Boards
Exemptions	IRBs can exempt certain research projects from review in accordance with 32 CFR 219.101(b)	None. All research projects seeking PHI from a HIPAA covered entity, including DHA, must comply with the HIPAA Privacy Rule

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Four Types of DHA Privacy Board Reviews

- Required Representations for Research on Decedent's Information
  - Use or disclosure of PHI *solely for research on decedents*
- Required Representations for Review Preparatory to Research
  - Use or disclosure of PHI *solely* for preparing a research protocol or for similar purposes
  - *Researchers agree not to remove the PHI from MHS in the course of the review*
- Studies that must obtain HIPAA Authorizations
- Studies that Require a Waiver of Authorization or an Altered Authorization

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HIPAA Authorizations – Presumed to be Required

- Researchers are required to obtain a written and signed HIPAA Authorization from every participant in the research study
- Authorizations must contain all core elements and required statements set forth in the HIPAA Privacy Rule and DoD 6025.18-R
- PIs are required to initial and sign a certification assuring
  - That the signed authorization of each research participant whose PHI is used or disclosed will be maintained electronically and/or in hard copy for a period of six years from the date the Authorization expires; *and,*
  - That any and all of the signed Authorizations will be provided to DHA immediately upon request

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Waiver of HIPAA Authorization

- Where it is impossible or impracticable to obtain a written Authorization from each and every research participant
- Two types of waivers
  - **Full**: waiving authorizations for the entire study
  - **Partial**: waiving authorizations for part of the project (*e.g.,* for recruiting or screening potential research participants), thereafter PHI is no longer needed or Authorizations can be obtained at that point from each research participant
- Documentation by an IRB or Privacy Board of approval of a waiver must contain all required criteria set forth in the HIPAA Privacy Rule, 45 CFR 164.512(i)(2) and DoD 6035.18-R, C.7.9.2

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Altered Authorization

- Appropriate when a research study requires a modification or removal of some, but not all, required elements from an Authorization (*e.g.,* to remove the core element that describes each purpose of the requested use or disclosure where the identification of the specific study would affect the results of the project)
- Documentation by an IRB or Privacy Board of approval of an alteration to the Authorization must contain all required criteria set forth in the HIPAA Privacy Rule, 45 CFR 164.512(i)(2) and DoD 6035.18-R, C.7.9.2
- An approved alteration only applies to the study for which it is requested and cannot be used for any subsequent use or disclosure of PHI in a different project

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Modifications, Extensions and Renewals

- DHA Privacy Board approvals document HIPAA compliance in support of a *specific* research-related DSA
- When a DSA is modified, the DHA Privacy Board is contacted and will email the PI to determine if the study has changed and if the responses or representations in any documents/templates approved or accepted by the DHA Privacy Board remain the same.
  - Any substantial changes in the previous information reviewed and relied upon by the DHA Privacy Board will require further review in support of a modification
- When a DSA is extended or renewed, the applicant certifies that there have been no changes to the study, and thus it does not need DHA Privacy Board review again

DHA Privacy Board Overview

Impact of Termination or Expiration of a DSA

- When a research-related DSA expires or is otherwise terminated, any related Privacy Board approvals will also expire or be terminated
- When a research-related DSA expires or is otherwise terminated and a new DSAA is submitted, the PI is required to complete a new submission to the Board

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QUESTIONS

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Additional Resources

- Privacy Office Web site:

http://www.health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/Privacy-Board

- Email DHAPrivacyBoard@mail.mil for HIPAA research related questions