Military Health System
DHA Privacy & Civil Liberties Office

DHA PRIVACY BOARD ANNUAL REPORT

FISCAL YEAR 2015

DECEMBER 2015

Defense Health Agency

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Message from the DHA Privacy Board Chair

On behalf of the Defense Health Agency (DHA) Privacy Board, I am pleased to present the Fiscal Year 2015 (FY15) DHA Privacy Board Annual Report. The Board continued to make tremendous achievements during FY15, serving as a valuable resource to the research community and the Military Health System (MHS) by providing clear guidance regarding the interpretation, application, and implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. In addition to its continually efficient and effective provision of HIPAA Privacy Rule reviews for research studies seeking DHA data, it advanced its work by staying abreast of current trends and topics in research and privacy, including the 21st Century Cures Act, the Health IT Policy Federal Advisory Committee's Big Data recommendations, and proposed changes to the current 42 CFR Part 2 regulations regarding the Confidentiality of Alcohol and Drug Abuse Patient Records.

The Board's FY15 accomplishments further extend to its strong outreach efforts. The Board continued to provide in-depth HIPAA Privacy subject matter expertise and guidance through requests for technical assistance, meetings, presentations, and online materials to a variety of stakeholders in the research community in order to protect the privacy of research subjects within the MHS and to enhance HIPAA compliance. FY15 saw significant progress in the Research Data Sharing Streamlining Initiative (Streamlining Initiative). This year focused on finalizing the Administrative Instruction (AI) and setting the groundwork for implementation of the Streamlining Initiative at DHA's National Capital Region-Medical Directorate (NCR-MD) Medical Treatment Facilities (MTFs), including providing trainings and socializing the AI's requirements to stakeholders outside of the NCR-MD Institutional Review Boards (IRB) and Department of Research Programs (DRP). The Board has worked, and will continue to work, closely with the research communities at Walter Reed National Military Medical Center (WRNMMC) and Fort Belvoir Community Hospital (FBCH) to ensure they are prepared to take on the responsibilities of the AI upon its approval.

As we begin FY16, we look forward to broadening the Streamlining Initiative and enhancing HIPAA compliance across the MHS by leveraging ongoing efforts to standardize Federal Policy for the Protection of Human Subjects (commonly referred to as the "Common Rule) and HIPAA Privacy Rule reviews throughout the MHS. Working closely with the DHA Human Research Protections Program (HRPP), the Board will seek opportunities to integrate HIPAA compliance into reviews conducted under the Common Rule, and the new electronic protocol management system. Implementing HIPAA into IRB review tools and processes even before a particular IRB

has joined the Streamlining Initiative will demonstrate the value of joining the Streamlining Initiative and, more importantly, will increase HIPAA compliance across the MHS.

Linda Thomas
Chief, DHA Privacy and Civil Liberties Office
Chair, DHA Privacy Board

Introduction

In the midst of the restructuring of the DHA Privacy Office's Data Sharing Program in the early part of 2009, the DHA Privacy Office identified that HIPAA reviews of research studies using DHA data were not taking place on a regular basis and required HIPAA documentation was not in place. After consultation with the DHA Office of General Counsel, the DHA Privacy Office (known as TRICARE Management Activity (TMA) Privacy Office at the time) was directed to cease approval of all research-related requests that did not provide appropriate HIPAA documentation when requesting TMA data for research studies. In addition, a conflict was identified in the Department of Defense (DoD) Health Information Privacy Regulation (DoD 6025.18-R), Section C7.9.1, which implements the HIPAA Privacy Rule's research provisions. It required DoD IRBs to conduct HIPAA Privacy Rule reviews; however, DoD IRBs were not trained to conduct HIPAA reviews and were not provided with information on how the HIPAA requirements differed in important ways from reviews required under the Common Rule. Furthermore, TMA did not have an IRB and was, therefore, not able to assist research studies in obtaining HIPAA Privacy Rule reviews and documentation. In order to quickly resolve the matter, the TMA Privacy Office advocated for the revision of DoD 6025.18-R to align its research provisions with the HIPAA Privacy Rule and to allow the TMA Privacy Office to establish the TMA Privacy Board. Approval was received on August 13, 2009 and the TMA Privacy Board was established, with the mission of conducting HIPAA Privacy Rule reviews of research studies seeking data owned or managed by TMA. The TMA Privacy Board became the DHA Privacy Board with the establishment of the DHA, and has continued to carry on its mission.

This report highlights the DHA Privacy Board's FY15 accomplishments in two areas: first, its operations and process improvements, and second, its research community outreach efforts. It also provides trend analysis, making comparisons with data collected in prior years and measuring the impact the Board. The report concludes with the Board's goals and vision for FY16, continuing its mission to increase the efficiency of research-related compliance reviews and to enhance HIPAA compliance across the MHS.

1. Completed reviews of 43 submissions requesting DHA data and protected the privacy of approximately 9.5 million beneficiaries in adherence to the HIPAA Privacy Rule standards (See page 7)
2. Implemented revised DHA Privacy Board templates and new, more detailed Standard Operating Procedures (See page 9)
3. Served 16 healthcare and research-related Centers and Institutions with HIPAA compliance reviews for the Army, Navy, Air Force, enhanced Multi-Service Markets (eMSMs), Civilian sites, and Uniformed Services University of Health Sciences (USUHS) (See page 10)
4. Achieved an average completion of reviews within fewer than two days from the date of perfection[1] (See page 11)
5. Successfully continued to advance the work of the Board through quarterly meetings and provided a platform for discussion and expertise from Board members to guide and enhance the mission of the DHA Privacy Board (See page 12)

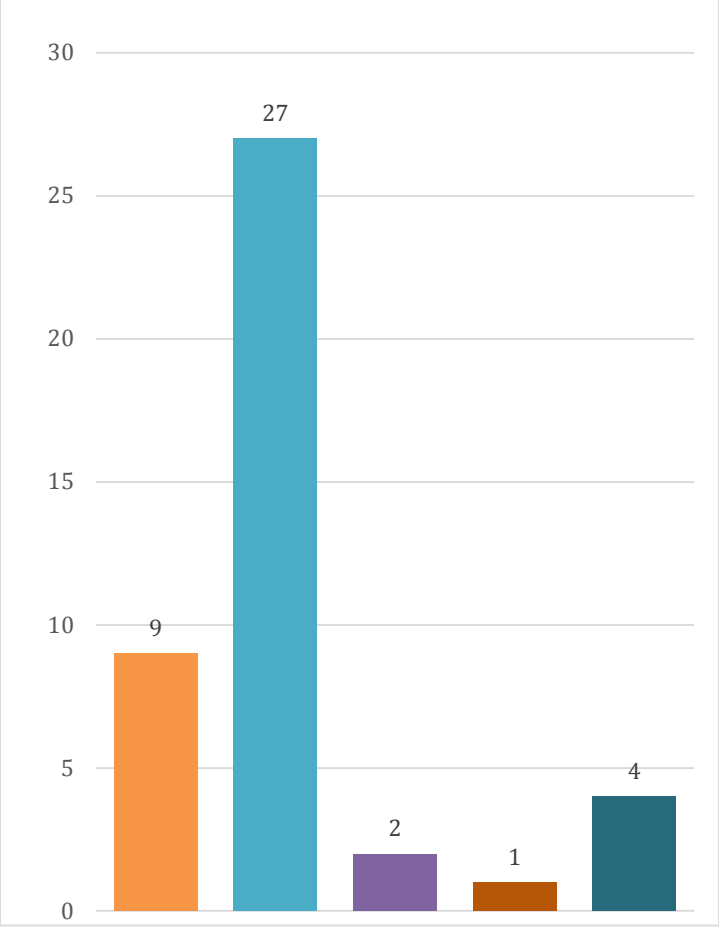
[1]Date of perfection is the date on which compliant information necessary to review the application has been submitted

Board Operations and Process Improvements Accomplishments

Completed reviews of 43 submissions requesting DHA data and protected the privacy of approximately 9.5 million beneficiaries data in strict adherence to the HIPAA Privacy Rule standards

The DHA Privacy Board conducts reviews of research studies requesting the protected health information (PHI) of MHS beneficiaries from systems managed by the DHA[2] in order to ensure compliance with the HIPAA Privacy Rule and the DoD Health Information Privacy Regulation (DoD 6025.18-R). The DHA Privacy Board maintains templates that request the information necessary to conduct HIPAA compliance reviews, and

Figure 1: Frequency of Types of Submissions



DHA FULL WAIVER: Based on review of an application and specific circumstances, the need for individual Authorizations was waived for the entire research study.

IRB FULL WAIVER: Based on an administrative review, the Board support staff confirmed that all required regulatory criteria for a full waiver were documented by the IRB.

IRB PARTIAL WAIVER: Based on an administrative review, the Board support staff confirmed that all required regulatory criteria for a partial waiver were documented by the IRB.

IRB ALTERED AUTHORIZATION: Based on an administrative review, the Board support staff confirmed that all required criteria for an altered authorization were documented by the IRB.

IRB AUTHORIZATION REVIEW: Based on an administrative review, the Board support staff confirmed that the HIPAA Authorizations to be used in a research study contained all core elements and

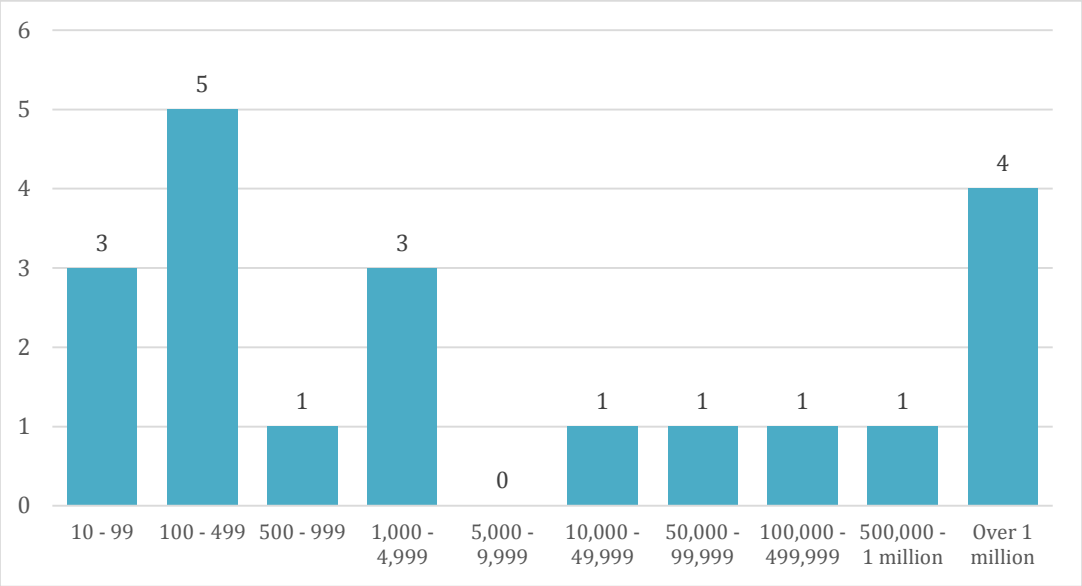
[2]DHA-managed system is defined as a system documented in the Defense Health Program System Inventory Reporting Tool (DHP SIRT)

which guide the reviewers through making and documenting their findings. Details on the Board's review process can be found in Appendix C.

In FY15, the DHA Privacy Board received and completed the review of 43 submissions, including nine DHA full waivers of HIPAA authorization, 27 IRB full waivers of HIPAA authorization, two IRB partial waivers of HIPAA authorization, one IRB altered authorization, and four IRB Authorizations. In these submissions, researchers requested access to or data extracts from MHS systems containing information on approximately 9.5 million beneficiaries.

The exact number of participants in a research study is not always known when the study comes to the DHA Privacy Board for HIPAA Privacy Rule review. Researchers seeking data about a particular ailment or type of individual may not have a clear sense of how many individuals' records fit their study's needs. In addition, when the Board performs an administrative review of IRB HIPAA review documentation, that documentation rarely includes information about the number of research subjects. During FY15, the actual or approximate number of research participants was specified for 20 of the 43 submissions. Of those 20 studies, the number of research participants ranged from 20 to approximately nine million individuals. As illustrated in the graph below, only three of those 20 studies had fewer than 100 participants and eight studies had fewer than 500 participants. A majority of the 20 studies (12) involved fewer than 5,000, however, four studies had more than one million participants.

Figure 2: Number of Research Subjects Affected as Specified in 20 Studies



Implemented revised DHA Privacy Board templates and new, more detailed Standard Operating Procedures

In FY15, the Board, leveraging the work performed to develop the standard HIPAA research templates, developed and implemented seven templates. These templates are designed to make the DHA Privacy Board process easier for both researchers and Board reviewers. The new waiver application template allows researchers to reference the pages in their research protocol where relevant information can be found rather than requiring them to re-write information into the application. This reduces the burden on the researcher and expedites their completion of the application. This also allows the Board to ensure that the description of the research activities and data elements described in the waiver application are consistent with the IRB-approved protocol.

DHA Privacy Board Templates

- Waiver/Altered Authorization Application
- Internal Review Checklist for the Review of Waiver/Altered Authorization Application
- Required Representations for Review Preparatory to Research
- Required Representations for Research on Decedents
- HIPAA Authorization Template
- HIPAA Authorization Language Checklist
- PI Certification

The Board also introduced a model HIPAA authorization template. The template provides standard language and explanations to help researchers develop a HIPAA-compliant authorization. If the researcher uses this template to develop their authorization, the Board's review can be more efficient with limited, if any, back and forth with the researcher prior to approval. Except for the authorization template, all of the review templates expand as text is entered, making it so researchers no longer have to append additional pages to their application. This also makes it easier on reviewers, who no longer have to flip between pages to complete their review of a particular response.

The Board recognized that the implementation of the new templates offered the perfect opportunity to develop a more detailed set of Standard Operating Procedures (SOP) and a collection of standardized email templates. The more detailed, step-by-step SOP will ensure that the review process is consistent over time and from reviewer to reviewer. In particular, it will help with more uncommon types of reviews. Rather than trying to remember how something was handled in the past, the Board reviewer can simply refer to the SOP. Having consistent processes will not only help reviewers, but will also help researchers understand what to expect. Researchers have provided feedback that they often discuss the process with fellow researchers at their institution to help them prepare for their own submissions, therefore, consistency will help the broader research community understand the role of the DHA Privacy Board and HIPAA requirements.

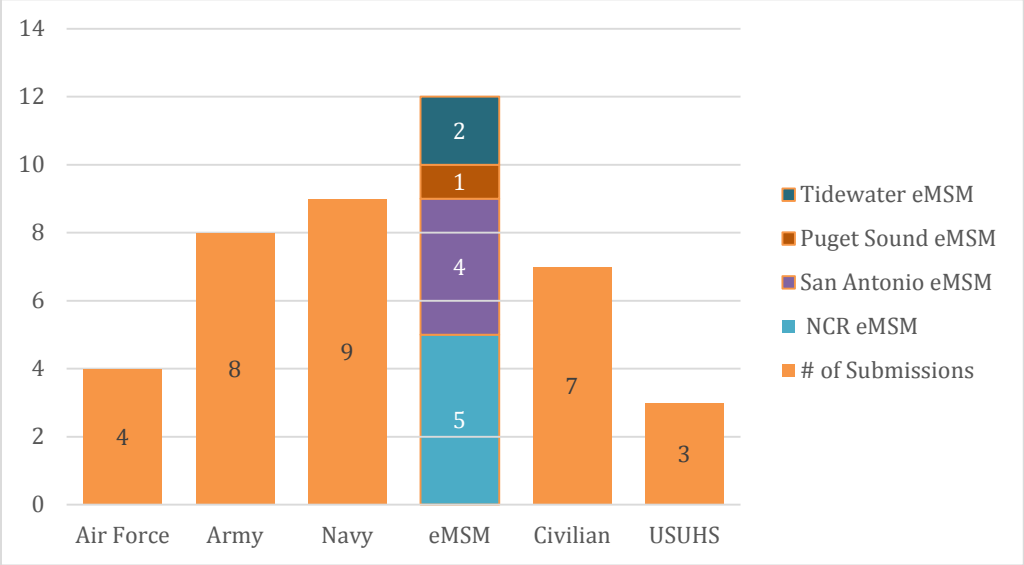
In developing the SOP, support staff considered how to make the DHA Privacy Board process as easy as possible for researchers. Many researchers have expressed confusion about the Board process – namely, how their study was referred to the Board and what happens once they obtain Board approval. Recognizing this, the Board implemented an initial phone call with the researchers during which Board support staff review the Board process, learn about the research study, and answer any questions the researchers may have. This approach is emblematic of the Board's focus on customer service and education.

Served 16 different healthcare and research-related Centers and Institutions with HIPAA compliance reviews for Air Force, Army, Navy, eMSMs, Civilian sites, and USUHS

During FY15, the DHA Privacy Board served 16 different research Centers and Institutions for the Army, Navy, Air Force, eMSMs, USUHS, and Civilian sites, with the Naval Health Research Center being the greatest single requestor. eMSMs are Multi-Service Markets that have been provided with "enhanced" authorities that include the authority to manage the allocation of the budget for the market, direct the adoption of common clinical and business functions for the market, optimize readiness to deploy medically ready forces and ready medical forces, and direct the movement of workload and workforce between or among the medical treatment facilities.

The Board supported these centers and institutions by conducting efficient HIPAA Privacy Rule reviews and offering reviews of waivers of HIPAA Authorizations that the Centers and Institutions may not otherwise have been able to obtain. In addition, the Board provided HIPAA guidance and responded to research-related inquiries. See Appendix A for a complete listing of specific research Centers and Institutions.

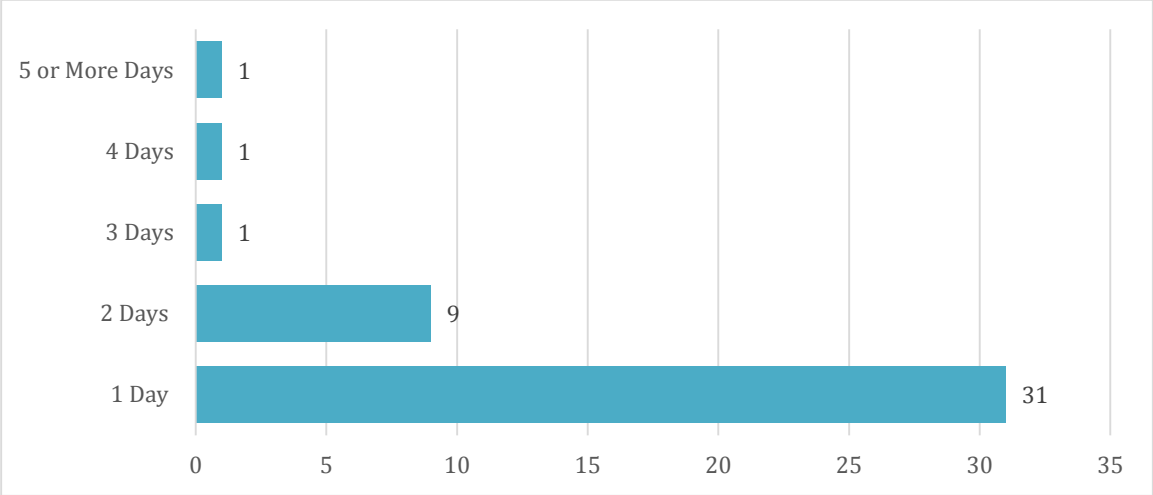
Figure 3: Submissions by Type of Centers & Institutions in FY15



Achieved an average review completion rate of fewer than two days from the date of perfection

The Board uses the date "perfected" as the official start of a review, which is when compliant necessary documentation for review has been submitted. The Board support staff coordinates with researchers and Board members to assist with any delays due to incomplete submissions or questions regarding the protocol or data requests. Per the SOP, the Board has up to five days to complete review of a perfected submission. One review of a DHA Privacy Board Waiver exceeded the five day benchmark due to the combination of longer than usual review and approval times, however, using the date of perfection and date of approval, the average time for review of a submission was still less than two days in FY15. **A significant majority of reviews, 31 out of 43, were completed in only one day.**

Figure 4: FY15 Review Times



Successfully continued to advance the work of the Board through quarterly meetings and provided a platform for discussion and expertise from Board members to guide and enhance the mission of the DHA Privacy Board

The DHA Privacy Board held quarterly meetings throughout FY15, one of which was a special meeting dedicated to reviewing and implementing the new Board templates. This meeting allowed the Board to review each of the new templates and to ask questions and provide feedback before approving their use by the Board. Another Board meeting was primarily focused on reviewing the Board's revised SOP. In FY15, the Board revised the previously high-level SOP to capture step-by-step detail about the conduct of each type of review and a collection of standardized email templates. The SOP also describes how the Board will handle scenarios that the Board has not yet faced, such as denials. This detailed SOP, approved by the Board in April, will ensure consistent reviews across different Board support staff and members and will provide for more robust and uniform procedures.

Standard quarterly Board meetings commence with an update on the status of the Board's operations, including review of the Board submission-tracking spreadsheet setting forth all active and inactive submissions and the log of pending research-related DSAAs. Support staff also review the technical assistance requests and consultations with researchers for the fiscal year quarter leading up to the meeting. Each meeting also routinely provides updates on the Streamlining Initiative and outreach efforts, as well as an update on any research-related breaches posted on the OCR "Wall of Shame" for breaches of PHI affecting more than 500 individuals.

All quarterly meetings include presentations and open discussion about topics and articles related to or of interest to the Board; for example, in FY15, discussions included:

Big Data Recommendations, Office of the National Coordinator, Health Information Technology Federal Advisory Committee, Privacy and Security Workgroup, Final, August 11, 2015

21st Century Cures Act, House of Representatives

"Should HIPAA Compliance Let Researchers Access Patients' PHI?: AMIA recommended that HIPAA compliance should allow researchers to gain access to patients' PHI without their permission," Elizabeth Snell, December 8, 2014

Each quarterly meeting closed with a discussion about the Board's next steps, upcoming meetings or events of interest, and the timing of the next Board meeting. The Board members' insights continue to direct the efforts of the DHA Privacy Board and contribute to new strategic considerations.

1. Delivered *HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards* to 72 WRNMMC IRB members and DRP staff, FBCH DRP staff, and others with research oversight responsibilities in six intensive sessions provided as part of the Streamlining Initiative (See page 15)

2. Presented on HIPAA Privacy and the DHA Privacy Board process to approximately 131 members of the USUHS and WRNMMC research communities at three Researcher Roundtables (See page 17)

3. Expanded the scope of the Streamlining Initiative to further consolidate regulatory reviews of research studies and made significant updates to the DHA-AI (See page 18)

4. Provided in depth HIPAA Privacy subject matter expertise and guidance to the public and stakeholders in the research community in order to protect the privacy of research subjects within the MHS and to enhance the HIPAA compliance (See page 19)

Research Community Outreach Effort Accomplishments

Delivered HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards to 72 WRNMMC IRB members and DRP staff, FBCH DRP staff, and others with research oversight responsibilities in six intensive sessions provided as part of the Streamlining Initiative

Effective training is an essential component of the Streamlining Initiative and critical to its success. To ensure WRNMMC and FBCH are able to perform compliant HIPAA Privacy Rule reviews of research studies upon approval of the Administrative Instruction delegating this responsibility to them, the DHA Privacy Board provided specific research-related HIPAA Privacy training. In FY 2015, the DHA Privacy Board and support staff provided three HIPAA Privacy trainings events, consisting of six training sessions, for the WRNMMC and FBCH IRB members, DRP staff, and other individuals with research and privacy oversight responsibilities.

Figure 5: HIPAA Privacy Rule Training Attendance

October 2014 Training Registration and Attendance	
Total Registered	50
Total Attended	57
October 28th 8:00am – 12:00pm	20
October 28th 1:00pm – 5:00pm	10
October 29th 8:00am – 12:00pm	14
October 29th 1:00pm – 5:00pm	13
June 2015 Training Registration and Attendance	
Total Registered	8
Total Attended	15
June 2nd 8:00pm – 12:00pm	9
June 2nd 1:00pm – 5:00pm	6
	Total Attended 72

This training was designed to educate IRB members and other research oversight staff about HIPAA Privacy Rule requirements and to familiarize them with the new standardized templates they will use to perform HIPAA Privacy Rule reviews of research studies. Highlights of the training were:

- Quick review of HIPAA fundamentals, including key terminology and an overview of the structure of HIPAA – specifically the HIPAA Privacy Rule – in order to orient learners to the specific research-related areas addressed in the training
- Explanation of the Streamlining Initiative, how and why it was established and its impact on DoD IRBs and HIPAA Privacy Boards
- In-depth discussion of the HIPAA Privacy Rule's research provisions
- Review of the HIPAA Privacy Rule's relationship to the Common Rule
- Review of and practice with the HIPAA research-related templates available to: (1) collect necessary information from researchers for compliant reviews, and (2) properly conduct and document HIPAA Privacy Rule reviews
- Opportunity to practice using the templates and address HIPAA related technical questions through the use of realistic scenarios

Participants were asked to provide feedback on the training presentation and materials both during and after the events. Any IRBs that wish to take responsibility for HIPAA Privacy Rule Reviews via the Streamlining Initiative will be required to first complete this training to ensure they have a sufficient understanding of the HIPAA Privacy Rule, so receiving feedback is essential to ensure that the training is effective. Figure 6 below shows the average evaluation scores for each training, along with the overall average score for each evaluation factor. As demonstrated by the evaluation scores and participant feedback, the trainings have been well-received. The Board updates the training materials in response to participant feedback, as appropriate, in order to ensure that the trainings continue to meet the needs of the particular training audience.

Participant Feedback:

- "The templates are extremely helpful! Going through the examples of cases was great."
- "The education packages were well written and provide an abundance of information that will be an excellent resource and reference guide."
- "Fantastic job, instructor was very knowledgeable about topic; fielded questions well."
- "The relevance of the training to my daily work made the course enjoyable and useful."
- "Style of presentation; highly approachable even though material is very technical. Thanks!"

Figure 6: Participant Evaluation Scores

	Evaluation Factor (Scores out of 5)			
	The content was useful to my job	The length and pace of the content was appropriate	I will be able to apply the knowledge learned to my job	The facilitator had sound knowledge of the subject
October 28th 8:00am – 12:00pm	4.9	4.9	4.7	4.9
October 28th 1:00pm – 5:00pm	4.7	4.7	4.4	4.9
October 29th 8:00am – 12:00pm	4.9	4.8	4.9	4.9
October 29th 1:00pm – 5:00pm	4.6	4.4	4.7	5
June 2nd 8:00am – 12:00pm	4.5	4.7	4.7	5
June 2nd 1:00pm – 5:00pm	5	4.8	5	5
Average Score *(Out of 5)*	4.8	4.7	4.7	5

Once fully implemented, the Streamlining Initiative will allow researchers to receive Common Rule and HIPAA Privacy Rule approvals via one review, rather than waiting for reviews by both their local IRB and the DHA Privacy Board. In order for IRBs to assume responsibility for DHA Privacy Board HIPAA Privacy Rule reviews, they will need to use standardized templates and take the training provided by the DHA Privacy Office through its Privacy Board. DoD IRBs and HIPAA Privacy Boards will also be subject to assessments to monitor their adherence to the terms and conditions established as part of the Streamlining Initiative and the proper use of templates for documenting reviews compliant with the HIPAA Privacy Rule.

Presented on HIPAA Privacy and the DHA Privacy Board process to approximately 131 members of the USUHS and WRNMMC research communities at three Researcher Roundtables

Researchers are often confused about how the DHA Privacy Board review process and HIPAA requirements fit into the larger Data Sharing Agreement (DSA) process. To help address this, DHA Privacy Board Support Staff joined Ms. Rita DeShields, DHA Data Sharing Compliance Manager and DHA Privacy Board Co-Chair, and Data Sharing Analysts at presentations for the WRNMMC and USUHS research communities. The presentations covered:

- What is a Data Sharing Agreement Application (DSAA)
- How does the Privacy Office use the DSAA
- Who are the parties involved in a DSAA
- What is the DHA Privacy Board
- Why does the DHA Privacy Board exist
- What are the differences between the Common Rule and the research-related provisions of the HIPAA Privacy Rule
- What are the four different types of HIPAA reviews and when do they apply

The presentations were well attended, with 41 attending the WRNMMC Roundtable, and approximately 30 and 60 attending the USUHS IRB and USUHS Infectious Disease IRB Roundtables, respectively. Although formal feedback was not requested, the organizations provided favorable feedback and expressed interested in future sessions on the same or related topics. A follow-up article was also drafted and distributed by WRNMMC highlighting the key take away points from the Roundtable.

Expanded the scope of the Streamlining Initiative to further consolidate regulatory reviews of research studies and made significant updates to the DHA-AI

Throughout, the DHA Privacy Office and Privacy Board continued work on the DHA-AI for the Streamlining Initiative: *Regulatory Reviews of Research Studies*. Comments from the DHA Office of General Counsel (OGC) and the DHA Publications Office were adjudicated and further streamlining opportunities were brainstormed with and approved by the DHA Data Sharing Compliance Manager. The Streamlining Initiative was expanded to not only delegate HIPAA Privacy Rule reviews of research studies to DHA's NCR-MD MTFs, but to also delegate all other types of regulatory compliance reviews currently conducted by the DHA Privacy Office for research-related data requests. Significant thought went into articulating the different types of regulatory compliance reviews conducted for research-related DSAAs, and whether and how DHA's NCR-MD MTFs could take on these additional compliance reviews. The major advantage of this expansion is that enabling the DHA's NCR-MD MTFs to conduct all of the regulatory compliance reviews currently conducted by the DHA Privacy Office will allow researchers to obtain all necessary compliance reviews at the NCR-MD-level without the need for second-tier reviews within the DHA Privacy Office. Once approved, the DHA-AI will eliminate the need for researchers to submit a DSAA when using DHA data in order to obtain regulatory review, and from having to obtain administrative or secondary review by DHA's Privacy Board for HIPAA

reviews conducted by WRNMMC and FBCH's DRP or by WRNMMC's IRB. The DHA-AI was updated to include the expanded scope and was submitted again for review and comment by DHA OGC and DHA Publications and all comments were adjudicated, Toward the end of FY15, the updated DHA-AI was further socialized and updated with the Chief of WRNMMC's DRP, WRNMMC's General Counsel, Director of WRNMMC's IRB Operations, Chief of WRNMMC's Business Office-Office of Research and Technology Applications, Chief of FBCH's DRP, and DHA's General Counsel, and requirements and responsibilities under the DHA-AI were thoroughly discussed. Meetings were also held with representatives at WRNMMC and FBCH to discuss and plan needs associated with implementing the requirements.

The Board also joined our efforts on the Streamlining Initiative with the Unity of Effort initiative, as WRNMMC, FBCH and USUHS work to streamlining their Common Rule templates. This opened the opportunity to make standard HIPAA templates part of the effort, and the Board helped to address and update HIPAA references in the proposed common protocol application. The Board also met with WRNMMC, FBCH, and USUHS the later part of FY15 in order to further discuss ways to integrate HIPAA reviews into their existing Common Rule review practices.

WRNMMC and FBCH have served as the pilot programs for launching the Streamlining Initiative and testing the requirements and implementation needs. The DHA-AI developed to effectuate the Streamlining Initiative with them will ultimately serve as the model that will be used in other types of issuances developed as the Streamlining Initiative further expands across the MHS. Efforts to expand the initiative to USUHS are currently underway for FY16.

Provided in-depth HIPAA Privacy subject matter expertise and guidance to the public and a variety of stakeholders in the research community in order to protect the privacy of research subjects within the MHS and enhance the HIPAA compliance

The Board continued to provide in-depth HIPAA Privacy subject matter expertise and guidance through requests for technical assistance, meetings and presentations, and its website to stakeholders in the research community and the general public. For example, in FY15, the Board was asked to provide input regarding student access to DoD population data, including MHS data, for research that is not sponsored, funded or supported by DoD. The MHS holds a wealth of data that many student researchers seek access to in order to complete projects in support of their degree. Providing this information can be resource-intensive; in some cases the DoD may need to develop new query tools or de-identify the data before it can be provided to the researchers. In addition, there were concerns related to vetting and performing oversight over such requests. The Board participated in conversations regarding the restrictions on providing this information, whether there are obligations to provide the information, and related compliance concerns. The

Board shared that HIPAA does not obligate the DoD to provide information to a researcher and concurred that any data sharing would need to be HIPAA-compliant. Because there are many advantages to sharing DHA data for research purposes, HIPAA-compliant ways of sharing DHA data with students for research purposes were also discussed.

As part of the development of the Streamlining Initiative DHA-AI, the Data Sharing Compliance Manager and DHA Privacy Board support staff recognized the need for a definition of DHA data. Throughout the development of the AI, there was confusion on the part of the NCR-MD research community as to when a DSAA is needed and when it is not. In order to clarify the requirements and responsibilities of the AI, the Board worked with the DHA OGC, the Health Information Technology Directorate, DHSS Acquisition Support, and the DHA Privacy Office's DSA team to develop a workable definition of DHA data. The definition, provided above, removes the previous distinction between DHA and service-level data in DHA-managed systems and clarifies that all data on DHA-managed systems is DHA data. Although it is recognized that the definition will increase the number of regulatory compliance reviews conducted the DHA Privacy Office – and by extension the DHA Privacy Board – the benefit of introducing greater clarity as to when requests for DHA data must be submitted to the DHA Privacy Office and further enhancing HIPAA and Privacy Act compliance is significant. Through well thought-out and deliberate approaches like the Streamlining Initiative, delegations of data sharing regulatory compliance reviews can help manage the workload for the DHA Privacy Office and increase efficiency for researchers at the local level, while also ensuring and enhancing compliance with HIPAA and the Privacy Act across the MHS.

Definition of 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).

Through its website, the Board provides information about its processes and the research-related requirements of the HIPAA Privacy Rule. In FY15, the DHA transitioned to a SharePoint infrastructure for its intranet. The Board support staff provided content to serve as a reference for members of the MHS workforce interested in learning more about Board operations and research-related HIPAA Privacy Rule requirements. The intranet site includes Board annual reports and unfillable versions of the Board templates for reference. The Board also reached out via the Privacy Post, a monthly DHA Privacy Office electronic newsletter that is distributed throughout the MHS

on privacy and civil liberties topics. The Board's article, *"Developments in the Research Data Sharing Streamlining Initiative,"* was published in the January 2015 issue.

Through its review process, the Board continued to provide significant guidance to researchers new to the Board regarding the similarities and differences between the Common Rule and the HIPAA Privacy Rule, as outlined in Appendix D. Common misconceptions include thinking that an informed consent under the Common Rule meets HIPAA Authorization standards. The Board and support staff explain that HIPAA Authorizations, unlike informed consents under the Common Rule, must be in writing and signed by the research participant and must include all of HIPAA's core elements and required statement to be valid. Although HIPAA allows for combining an informed consent with a HIPAA Authorization in a "Compound Authorization," the HIPAA-specific core elements and requirements statements are still required. Another misconception is that research projects that are exempt from IRB review under the Common Rule are also exempt from HIPAA Privacy Rule review. All research studies seeking PHI from DHA are required to undergo HIPAA Privacy Rule review by an IRB or HIPAA Privacy Board; there are no exemptions.

Several other requests for HIPAA-related technical assistance were received and addressed as part of the Streamlining Initiative. The nature of the inquiries received this year demonstrated an increase in concerted efforts to properly conduct HIPAA Privacy Rule reviews of research studies than had been seen in prior years, and a genuine intent to clearly understand and apply the HIPAA regulations. For example, inquiries within FY15 included issues as to whether and what HIPAA protections apply to derivative data in a research study, whether specific language in a researcher's template authorization truly addressed core elements of a HIPAA Authorization, and HIPAA requirements for research conducted solely on decedents in studies that were not required to undergo IRB review by the Common Rule.

The Board also provided guidance to the Naval Medical Research Center (NMRC), explaining that DoD IRBs do not need to receive approval from DHA or the DoD in order to perform HIPAA privacy reviews of research studies. In the short-term, the Board was able to provide general HIPAA education and, because the specific study at issue will be using DHA data, the Board will be able to provide the necessary HIPAA review if it is determined to be PHI by the Data Evaluation Workgroup (DEW). In the long-term, Board support staff is working with Commander Ramiro Gutierrez, IRB Chair, to further expand the Streamlining Initiative within the Navy and potentially schedule HIPAA privacy trainings for the NMRC IRB and Office of Research Administration (ORA). The participants would receive training on HIPAA's research-related requirements and the standard HIPAA templates. As a significant percentage of the Board's FY15 submissions were

from Navy institutions, this will help reduce the Board's workload by increasing the number of Navy IRBs performing HIPAA reviews and the quality of the documentation of those reviews.

In the latter part of FY15, the DHA Privacy Office and Board was given the opportunity to perform a preliminary review of the draft Notice of Proposed Rulemaking (NPRM) pertaining to proposed changes to 42 CFR Part 2, currently entitled "the Confidentiality of Alcohol and Other Drug Abuse Patient Records" and proposed to be revised to "Confidentiality of Substance Use Disorder Patient Records." Significant revisions are needed in order to modernize the regulations to better align to advances in the health care system, while still maintaining important protections to protect against the stigma associated with substance abuse treatment. The Board will monitor the NPRM for publication in the Federal Register and the open comment period.

DHA Privacy Board Trends

The DHA Privacy Board tracks trends in data in order to make adjustments, as needed, to provide better service to its customers and to analyze the impact of its education and outreach efforts. Where possible, the Board has collected metrics about its activities, which are then organized by fiscal year, to enable appropriate comparison and trending.

The DHA Privacy Board tracks, to the extent possible, the number of individuals whose records are requested for a research study

The number of research participants whose PHI is requested in a research study is not always known at the time the study comes to the DHA Privacy Board for HIPAA Privacy Rule review. In some cases, researchers provided the approximate number of individuals whose PHI is contained in the MHS information systems they intended to access in order to locate their research subjects, as opposed to providing the actual number of anticipated research participants. When providing administrative reviews of IRB-approved HIPAA documentation, the Board usually does not receive documentation that includes the number of research participants; these types of reviews are consistently the majority of Board reviews each year (for example, 27 out of 43 in FY15). In FY15, 20 of the 43 total submissions included the number or estimated number of research participants. Although the data on research participants is limited, the Board uses it to estimate trends in order to increase its understanding of the research community it serves.

Figure 7: Number of Individuals' Records Requested

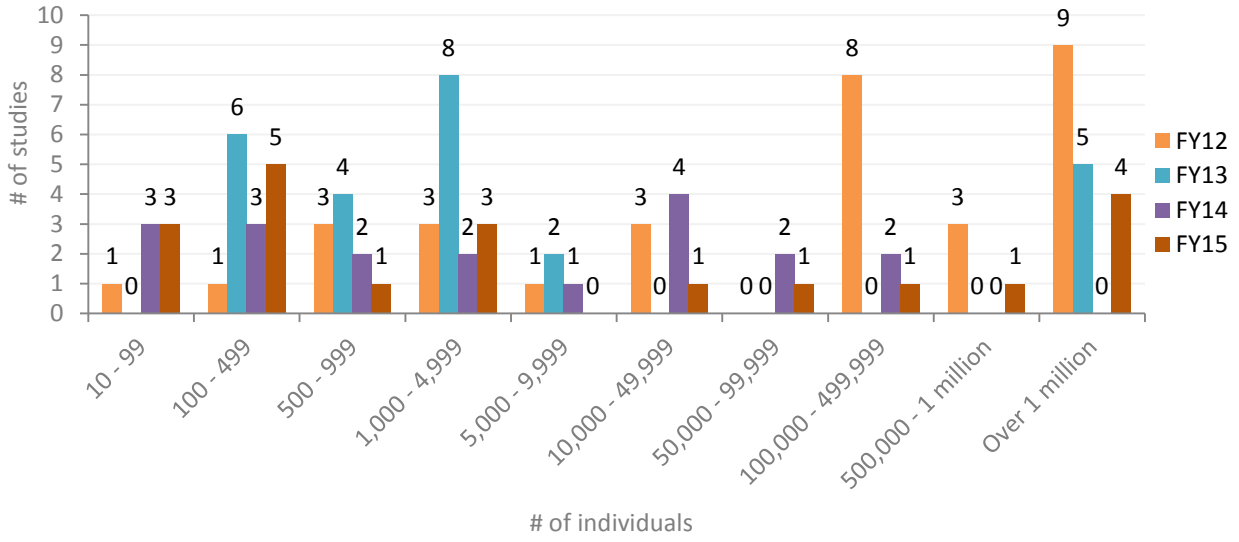
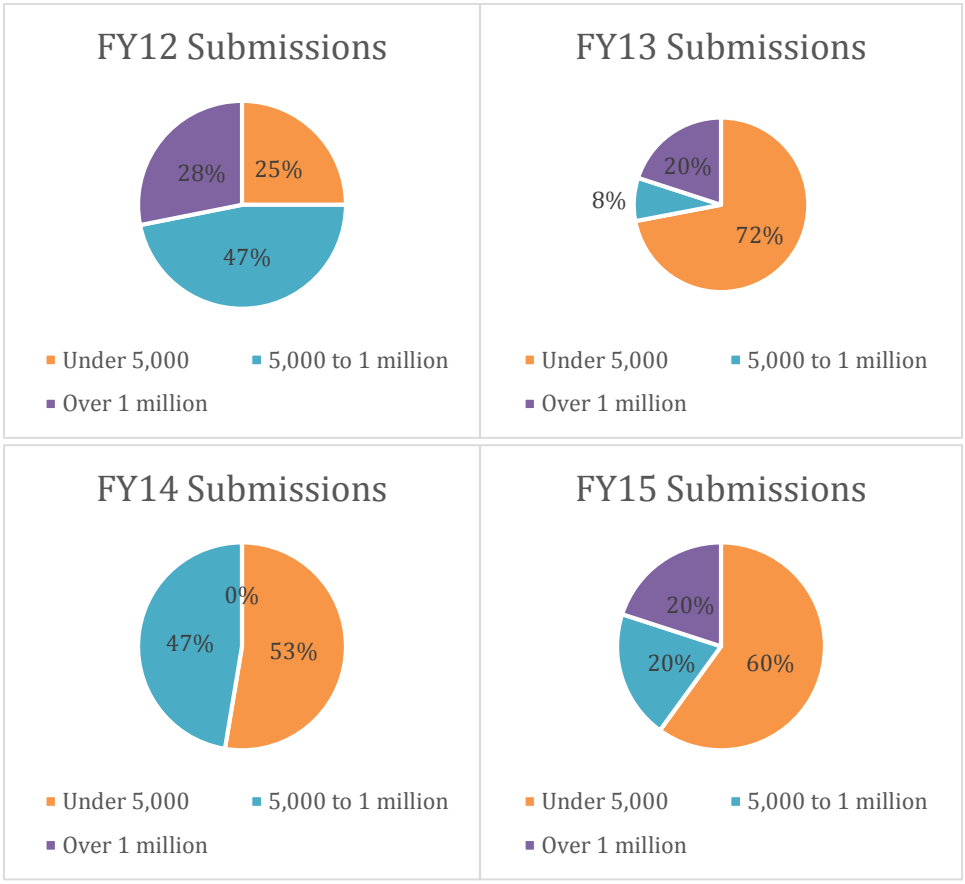


Figure 8: Annual Comparison of the Size of Study Populations



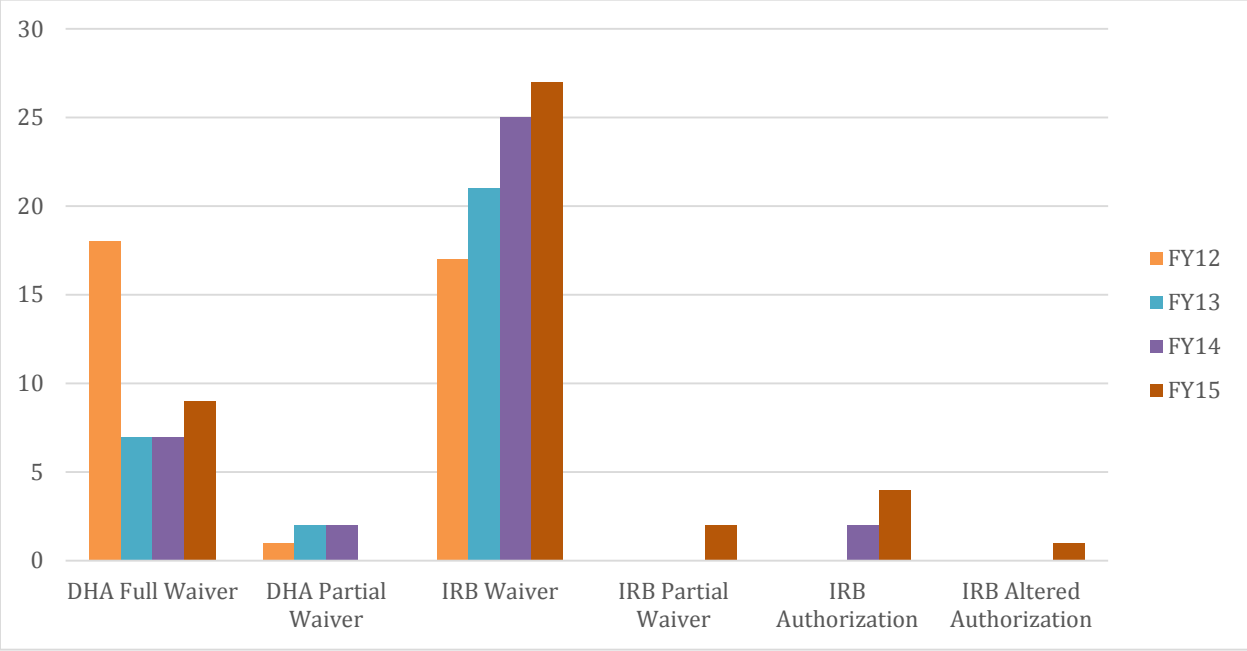
The graphs above show that since FY13, the majority of studies each year have had 5,000 or fewer participants – in contrast, 75% of the studies in FY12 had more than 5,000 participants. The Board believes this change is due, in part, to its efforts to educate researchers about narrowing their access requests to only the minimum number of individual records necessary for the study. The Board is encouraged by this continuing trend, which lowers the overall privacy and security risks to research participants.

The Board saw a continued increase in the number of IRB Waivers obtained in FY15. The Board performed its first IRB Partial Waver and IRB Altered Authorization reviews as HIPAA compliance outreach and education increased

During FY15, IRB Waiver reviews continued to increase and, in a divergence from previous years, the number of Board Full Waivers also increased. The Board hypothesizes that the rise in DHA

Full Waivers is due to new organizations joining DHA as it neared Full Operational Capability (FOC) at the end of FY15. During FY15, the Board conducted four reviews of IRB-approved Authorization, in contrast with two in FY14 and none in FY12 and 13; and performed its first ever reviews of IRB-approved Partial Waivers and IRB-approved Altered Authorization. These increases demonstrate the impact of the DHA Privacy Board's efforts to educate the research community on using Authorizations whenever feasible. The use of Partial Waivers and Altered Authorizations means that IRBs are performing in-depth HIPAA reviews; truly assessing the feasibility of obtaining Authorizations at any point during the study; and using all of the review options available to them under HIPAA.

Figure 9: Types of Submissions in FY12, 13, 14, and 15



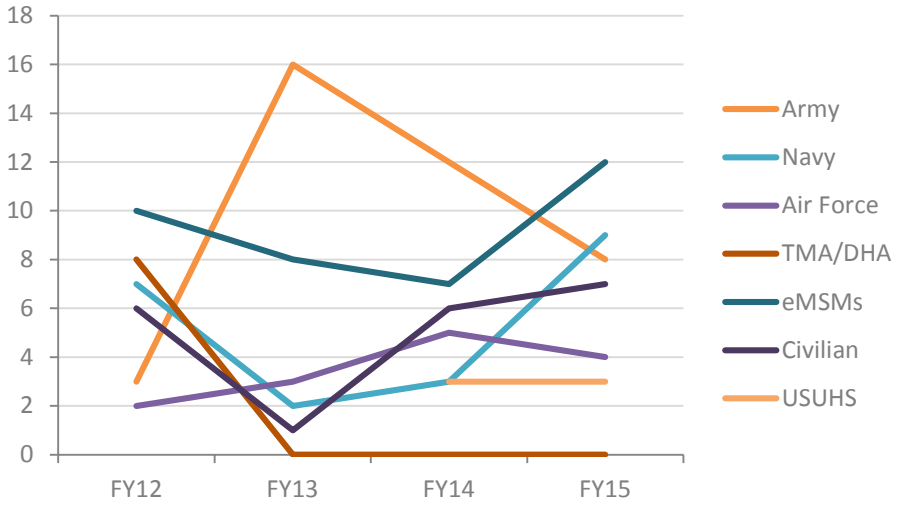
The types of organizations served by the DHA Privacy Board will change over time as streamlining efforts are implemented for HIPAA compliance

During FY15, there continued to be a general increase in participation from the Services and eMSMs, particularly eMSMS and the Navy. The number of Army submissions to the DHA Privacy Board continue to decrease; this appears to be because the majority of Army institutions making submissions to the Board are now part of eMSMs, particularly the San Antonio eMSM. Previously, USUHS was part of TMA, so its submissions were captured in that category; however, USUHS

was not made part of DHA when it was established in October 2013. Therefore, beginning with this report, USUHS submissions will be counted independent of the DHA as a separate Center and Institution served by the DHA Privacy Board. DHA and the MTFs that came under the DHA, including WRNMMC and FBCH, are counted within the eMSM category.

With the exception of the Army, Navy, and eMSMs, the numbers of requests from each type of organization remained consistent with the FY14 numbers, with difference of no more than two. The Board expects that the overall number of Centers and Institutions served will continue to increase over the next Fiscal Year with further outreach and education by the Board and through Streamlining Initiative in expanding compliance with the HIPAA Privacy Rule's research provisions.

Figure 10: Numbers of Submissions from Each Type of Center & Institution Served in FY12, 13, 14, and 15



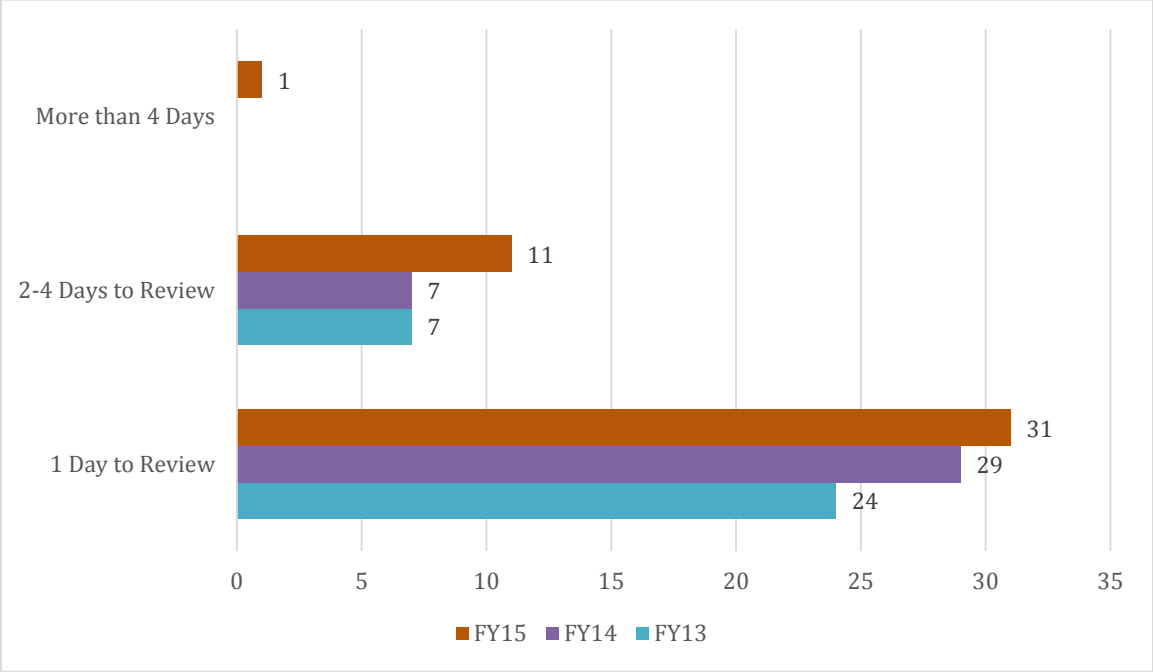
The DHA Privacy Board continues to provide efficient HIPAA compliance reviews; 31 of 43 FY15 reviews were completed in one day

There continues to be an increase in the number of reviews taking only one day to complete from the date of perfection; in FY15 the review of 31 of the 43 submissions to the Board were completed in one day. Longer review times are required for more in-depth administrative reviews of IRB Waivers, which are becoming increasingly common. As the standard templates are made available to more IRBs, administrative reviews will become more routine and efficient. Authorization

reviews by support staff and Full and Partial Waiver reviews by DHA Privacy Board members generally involve in-depth discussions with the PI and thus are more time consuming, but are still conducted efficiently.

The Board did not begin to record review times until the fourth quarter of CY12, which falls in the government's FY13, so FY13 is used as the baseline here.

Figure 11: Continued Efficient Review Times



Future Vision for the Privacy Board

"[P]ropose a series of potential reforms to the Department of Defense Institutional Review Board procedures to increase efficiencies and streamline processes."— Dr. Woodson, Assistant Secretary of Defense for Health Affairs, in a memo dated March 6th, 2012 to the Deputy Assistant Secretary Defense Force Health Protection & Readiness (DASD (FHP&R)).

In the spirit of this challenge, the DHA Privacy Board developed the Streamlining Initiative with DoD IRBs and HIPAA Privacy Boards and continues to work on ways to reduce the perceived burden that that HIPAA Privacy Rule places on researchers and to integrate HIPAA reviews into the reviews required by the Common Rule. The ultimate success of the Streamlining Initiative will:

- Empower DoD IRBs that work with the DHA Privacy Office and agree to certain terms and conditions to conduct HIPAA Privacy Rule reviews of research studies seeking DHA data without the need for additional HIPAA review by the DHA Privacy Office; and
- Streamline separate and distinct reviews required by the Common Rule and the HIPAA Privacy Rule so that a single board can simultaneously conduct both reviews rather than requiring two separate reviews by two separate boards.

The implementation of the Streamlining Initiative in DHA's NCR-MD MTFs is just a first step in the ultimate vision of expanding the initiative throughout the entire MHS. As part of these efforts, the Board will maintain its ongoing dialogue and collaboration with the DHA Data Sharing Program, R2O2, DEW, DoD IRBs, and the research community to improve the data sharing experience for researchers by making the process as efficient and productive as possible while also enhancing HIPAA compliance within the MHS.

Relatedly, in FY15, the Board increased its outreach activities to both research oversight professionals and DoD IRBs through participating in site visits and Roundtables, as well as ad hoc advice throughout the year. In FY16, the Board will continue its dialogue with DoD IRBs and the research community and will focus on helping IRBs and researchers understand HIPAA Privacy Rule compliance. The DHA Privacy Board seeks to share its best practices in establishing and maintaining HIPAA Privacy compliance programs for research studies, and help DoD IRBs adopt similar practices that can readily incorporated into their existing operations.

Going into FY16 and looking forward, the Board recognizes the increased and tremendous advantage that the Streamlining Initiative has to offer to the DHA. As the DHA evolves, and more and more systems and organizations are coming under the overall management of the DHA, regulatory compliance reviews under the Privacy Act and HIPAA are being viewed as a "shared service." The workload and responsibilities of the DHA, including those of the DHA Privacy Office and DHA Privacy Board, are continually increasing. In that research related data requests are estimated to account for approximately half of all data sharing requests within the MHS, the true advantage of the Streamlining Initiative is being realized in that it will help manage the workflow, optimizing resources, and improve and enhance HIPAA compliance across the MHS. Developing policy and making profound changes takes time and persistence, and the Board has never faltered in ensuring a strong foundation for the Streamlining Initiative, built with stakeholder input and buy-in, to ensure its ultimate success. Current organizational changes and new challenges are creating new opportunity for leveraging and expanding the Board's work on the Streamlining Initiative as a data sharing and research solution-driven approach.

The Board is also excited to continue to explore privacy and research-related topics, such as Big Data, that raise new challenges and issues for protecting the privacy of research subjects in order to identify future concerns and to develop solutions for emerging issues.

DHA Privacy Board Future
• Socialize and expand the Streamlining Initiative within the DHA and MHS
• Create an open forum for the research community where HIPAA-related research questions can be addressed, ideas can be shared, and relevant privacy topics can be discussed
• Continue to identify possible process improvements in response to internal analysis and feedback from the research community in order to continue to enhance the Board's customer service
• Provide research-related HIPAA privacy expertise to the MHS researcher community
• Execute the DHA-AI setting forth the terms and conditions and policy requirements for formally delegating HIPAA and Privacy Act regulatory review to DHA's NCR-MD MTFs, namely WRNMMC and FBCH
• Complete tools for measuring and assessing compliance with the Streamlining Initiative and coordinate with R2O2 to align HIPAA Privacy Rule assessments of DoD IRBs and HIPAA Privacy Boards with Common Rule audits
• Engage in relevant research and privacy reviews of proposed rulemaking, including NPRM pertaining to the Common Rule and 42 CFR Part 2.
• Update the DHA Privacy Board webpage on the health.mil interface to create further awareness of and provide information about the Streamlining Initiative once it has been officially implemented
• Continue to update and standardize the HIPAA Compliance Training for IRBs and HIPAA Privacy Boards, with ultimate possible goal of creating a virtual training in order to address turnover in IRB membership and to help further expand the Streamlining Initiative
• Follow research and privacy trends, assessing potential impact on the DHA Privacy Board and MHS research community

Appendix A: Centers and Institutions Served by the DHA Privacy Board in FY15

Centers and Institutions Served by the DHA Privacy Board in 2015
Army
U.S. Army Reserve Medical Corps (USARMC)
U.S. Army Research Institute of Environmental Medicine (USARIEM)
William Beaumont Army Medical Center (WBAMC)
Air Force
Air Force Research Laboratory (4)
Navy
Naval Health Research Center
Naval Medical Center
eMSMs
Madigan Army Medical Center
Fort Sam Houston
Defense Health Agency
Naval Medical Center Portsmouth
Walter Reed National Military Medical Center (WRNMMC)
USUHS
Uniformed Services University of Health Sciences (USUHS)
Civilian
Rand Corp
University of Chicago
Battelle Memorial Institute
Department of Veterans Affairs

Appendix B: The Research Data Sharing Review Process

Determining the Type of Data Requested

Prior to review by the DHA Privacy Board, researchers must submit a Data Sharing Agreement Application (DSAA) to the DHA Privacy Office. All research-related data requests are sent by the DHA Privacy Office Data Sharing Analysts to the Data Evaluation Workgroup (DEW), which was set up by the Board in order to track and monitor research-related requests for DHA data. Privacy Board support staff are active participants in the DEW, along with DHA Privacy Office Data Sharing Analysts and MHS data experts. The DEW reviews the source and type of information requested by a researcher and categorizes the request into one of the four types set forth in the HIPAA Privacy Rule: 1) De-identified data; 2) Personally Identifiable Information (PII) excluding PHI; 3) Limited data set (LDS); or 4) PHI greater than an LDS. An explanation of each category is available on the DHA Privacy Board section of the DHA Privacy Office website.

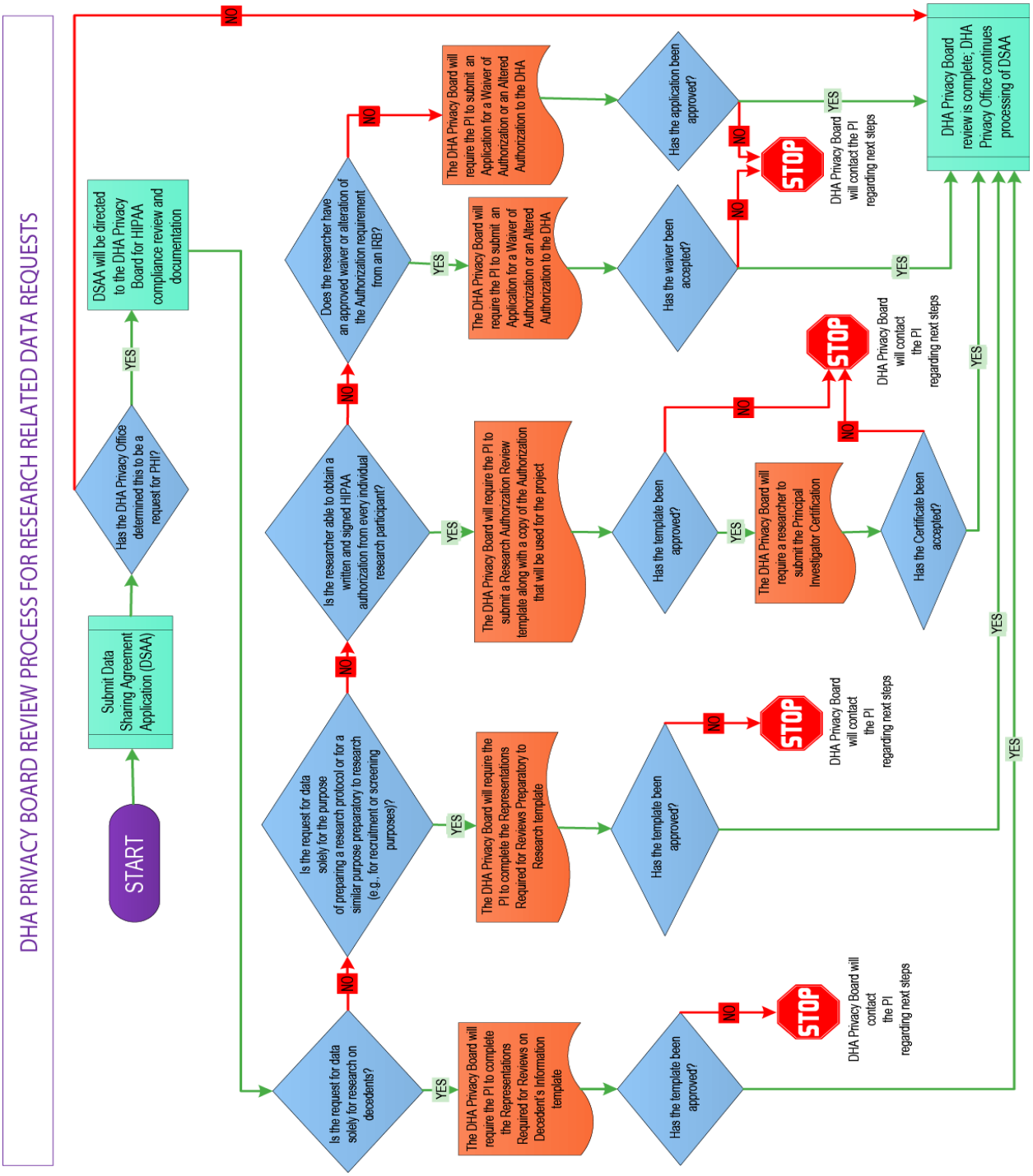
The DEW serves as a gate-keeper to ensure that only requests for PHI greater than an LDS are forwarded to the Board for further review. The DEW offers researchers direct consultation with MHS data experts in order to understand the data available in various MHS information systems, the quality of the data for purposes of their study, and the way in which data can be provided to meet their study requirements, as well as the minimum necessary requirements of HIPAA. Upon receiving a research-related DSAA seeking PHI greater than an LDS, the Board will reach out to the PI and Sponsor and begin the HIPAA Privacy Rule review process.

Types of Privacy Board Reviews

In the initial email to PIs and Sponsors, the DHA Privacy Board requests a short discussion with the PI to discuss the appropriate next steps for demonstrating compliance with the HIPAA Privacy Rule and DoD 6025.18-R. In this discussion, the Board identifies whether the PI's IRB performed a HIPAA review of the study, which can receive a secondary Privacy Board review, or whether a submission to the Board will be necessary. The Board maintains internal checklists to facilitate its HIPAA review and documentation procedures. When reviewing a submission, the Board will contact the PI and Sponsor with any questions or issues, if necessary. The Board notifies the DHA Privacy Office when it completes its HIPAA Privacy Rule Review so that the Data Sharing Analyst team can continue processing the DSAA for any additional compliance requirements.

More information about the Board reviews, standards for review and the DHA Privacy Board HIPAA-compliant templates is available on the DHA Privacy Board section of the DHA Privacy Office website.

Appendix C: DHA Privacy Board Review Process for Research Related Data Requests



Appendix D: Differences 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 informational 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, Department of Health and Human Services (HHS), and DoD Assistant Secretary of Defense for Research and Engineering	Office for Civil Rights, HHS
Administration	IRBs	IRBs or HIPAA PBs
Exemptions	The Human Research Protection Official (HRPO) and/or IRBs can exempt certain research projects from IRB review in accordance with 32 CFR 219.101(b)	None. All research projects seeking PHI from a HIPAA CE, including the MHS, must comply with the HIPAA Privacy Rule