

Military Health System
DHA Privacy & Civil Liberties Office

DHA PRIVACY BOARD ANNUAL REPORT

FISCAL YEAR 2014

DECEMBER 2014



Table of Contents

Message from the DHA Privacy Board Chair	3
Executive Summary	5
Board Operations and Process Improvements Accomplishments	7
Research Community Outreach Effort Accomplishments.....	16
DHA Privacy Board Trends.....	22
Future Vision for the Privacy Board.....	27
Appendix A: DHA Privacy Board Members	29
Appendix B: Centers and Institutions Served by the DHA Privacy Board in FY14	30
Appendix C: The Research Data Sharing Review Process.....	31
Appendix D: DHA Privacy Board Review Process for Research Related Data Requests .	33
Appendix E: Differences between the Common Rule and the HIPAA Privacy Rule	34

List of Figures

Figure 1: Frequency of Types of Submissions	7
Figure 2: Number of Research Subjects Affected as Specified in 19 Studies	8
Figure 3: Submissions by Type of Centers & Institutions in FY14.....	9
Figure 4: 100% Compliance with Review Times in FY14.....	10
Figure 5: Number of Individuals' Records Requested	23
Figure 6: Types of Submissions in FY12, 13, and 14.....	24
Figure 7: Centers & Institutions Served in FY12, 13, and 14.....	25
Figure 8: Continued 100% Compliance with Review Times	26

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 2014 (FY14) DHA Privacy Board Annual Report. The Board continued to make tremendous achievements during FY14, 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 data owned or managed by the DHA, it advanced its privacy work by staying abreast of current trends and topics in research, including the privacy and HIPAA related challenges associated with the evolution of Big Data and debates surrounding the de-identification of data. Board members are experts in both the research and privacy fields and are involved in workgroups, research initiatives, and events from which they bring a wealth of relevant experience.

The Board's FY14 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. A significant amount of the Board's work in FY14 focused on laying the foundation for the Research Data Sharing Streamlining Initiative ("Streamlining Initiative") within the MHS.

The Streamlining Initiative was established about two years ago in recognition of the fact that the MHS, including the DHA, where corporate level tri-service data is housed, holds a wealth of valuable information heavily sought after by the research community. This is evidenced by the fact that the majority of all data requests are for research-related purposes. The initial work of the Streamlining Initiative took a focused look at DoD's organizational structure under HIPAA. Through work with the DHA Privacy and Civil Liberties Office (DHA Privacy Office) and Office of General Counsel, we were able to first identify ways to increase efficiency in the provision of HIPAA Privacy Rule reviews within the MHS, as a "single covered entity," and second, enhance HIPAA research-related compliance across the MHS.

In FY13, we focused on establishing and developing five essential streamlining measures for reaching the goal of efficiently and effectively conducting HIPAA reviews of research studies. We further socialized the Streamlining Initiative and focused on identifying a Human Research Protection Program to work closely with as pilot site for testing recommended templates and processes. With the establishment of the DHA on October 1, 2013, site selection was made easier



with more programs, including those with an established IRB, coming under the purview of the DHA.

In FY14, our attention focused on the foundational work needed to launch the Streamlining Initiative, including: the development of MHS-wide standard HIPAA templates; the development of a data determination guide to assist reviewers with properly categorizing the type of requested data; the creation and negotiation of a policy setting forth the terms and conditions for delegating responsibility for HIPAA Privacy reviews of research projects to IRBs and HIPAA Privacy Boards; and, the development of the training protocol slides and scenarios for training DoD IRBs and HIPAA Privacy Boards on HIPAA compliance within the MHS and the various HIPAA-research reviews. FY14 was ideal for the foundation work because of the issuance of the HIPAA Omnibus Final Rule by the Department of Health and Human Services (HHS), effective September 23, 2013, made positive changes to HIPAA's research provisions – provisions that we will be able to incorporate prior to launching the Streamlining Initiative.

As we begin FY15, efforts are underway to fully implement the Streamlining Initiative, including training that was successfully delivered to our pilot site's IRB and Department of Research Program (DRP) staff. The ultimate and overwhelming benefit provided by the Streamlining Initiative will be the ability to take the work and lessons learned of the DHA Privacy Board and to expand its operations and processes to the DoD IRBs and HIPAA Privacy Boards for providing HIPAA reviews in research studies involving all MHS data.

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



Executive Summary

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 routine and appropriate HIPAA research reviews and required documentation were not in place. The DHA Privacy Office consulted with the Office of General Counsel and 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 have appropriate HIPAA documentation. 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 or on how the HIPAA requirements differed in important ways from reviews required under the Federal Policy for the Protection of Human Subjects, commonly referred to as the "Common Rule." Furthermore, at that time, TMA did not have an IRB. In order to quickly resolve the matter, the DHA 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 DHA 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 FY14 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 FY15, continuing its mission to increase the efficiency of research-related compliance reviews and to enhance HIPAA compliance within the MHS.



DHA PRIVACY BOARD 2014 ACCOMPLISHMENTS

BOARD OPERATIONS & PROCESS IMPROVEMENT

1. Completed reviews of 36 submissions requesting DHA-managed data and protected the privacy of about 9.5 million beneficiaries in adherence to the HIPAA Privacy Rule standards (See page 7)
2. Served 21 healthcare and research-related Centers and Institutions with HIPAA compliance reviews for the Army, Navy, Air Force, Enhanced Multi-Service Markets (eMSMs), and Civilian sites (See page 8)
3. Achieved 100% percent compliance with review period mandates, resulting in an average completion of reviews within two days from the date of perfection¹ (See page 10)
4. Conducted a comprehensive analysis, reported on Board trends, and projected future figures to monitor and improve Board operations and processes (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 that all information necessary to review the application has been submitted

Board Operations and Process Improvements Accomplishments

Completed reviews of 36 submissions requesting DHA managed data and protected the privacy of about 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 owned or managed by the DHA 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 which guide the reviewers through making and documenting their findings. Details on the Board’s review process can be found in Appendix C.

In FY14, the DHA Privacy Board received and completed the review of 36 submissions, including seven DHA full waivers, two DHA partial waivers, 25 IRB full waivers, and two Authorizations. In these submissions, researchers requested access to or data extracts from MHS systems containing the information on approximately 9.5 million beneficiaries.

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

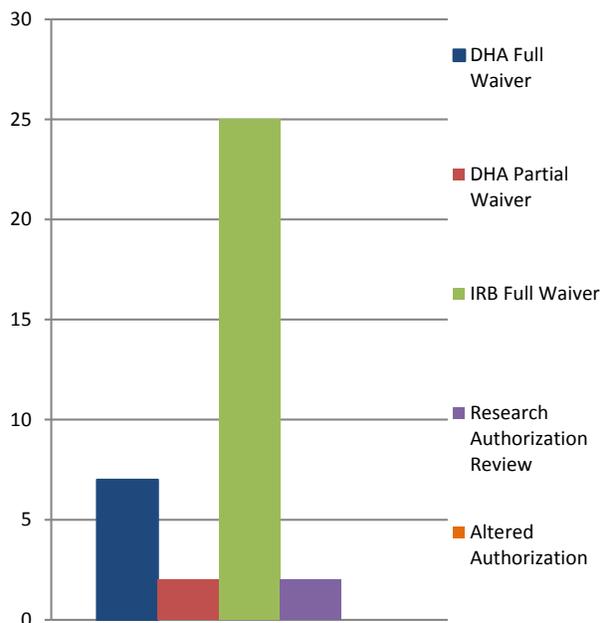
DHA Partial Waiver: Based on review of an application and specific circumstances, the need for an Authorization was waived for part of the research study, at which point Authorizations could be obtained for any further use/disclosure of PHI or PHI was no longer required for the study.

IRB Waiver: Based on an administrative review, the Board support staff confirmed that all required regulatory criteria were contained in a HIPAA waiver document provided by an IRB.

Research 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 required statements.

Altered Authorization: Based on review of an application and specific circumstances, an altered HIPAA Authorization was approved.

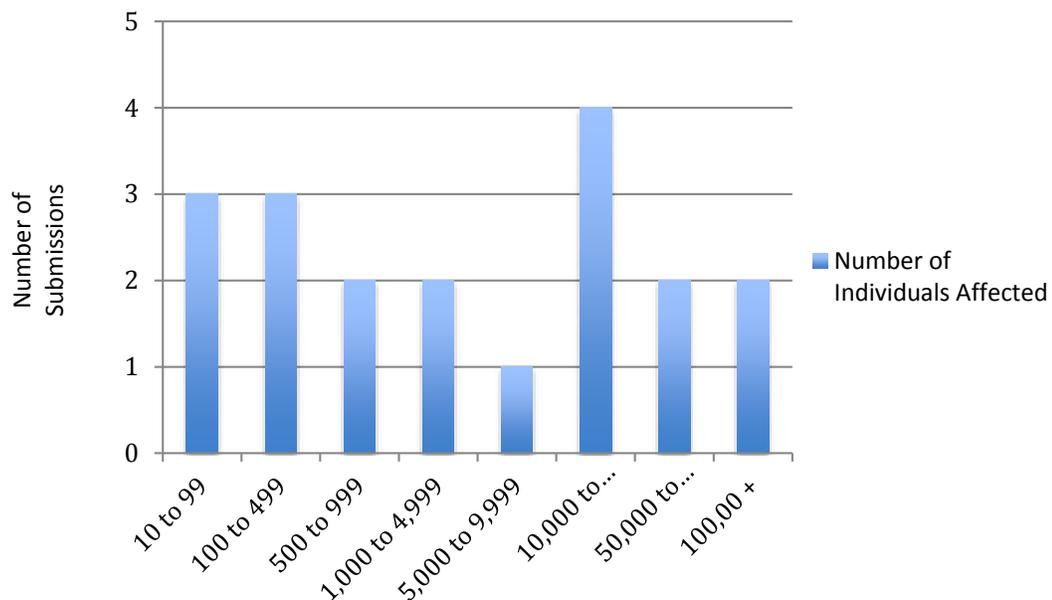
Figure 1: Frequency of Types of Submissions



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. For example, one study submitted for review in FY14 sought data about all tri-service women whose records reflected that they had cystic ovarian cancer between January 2002 and December 2012. At the time of the DHA Privacy Board's review, the number of study participants was not known. Waivers of Authorization are often requested in studies where it is anticipated that the study population will be extremely large and, together with other issues, it is believed to be impossible or impractical to obtain a written and signed authorization from each and every research participant.

During FY14, the actual number of research participants was specified for 19 of the 36 submissions. Of those 19 studies, the number of research participants ranged from 15 to 100,000 individuals. As illustrated in the graph below, only three of those 19 studies had fewer than 100 participants and six studies had fewer than 500 participants. A majority of the 19 studies involved over 500 participants, with eight studies reporting over 10,000 research participants.

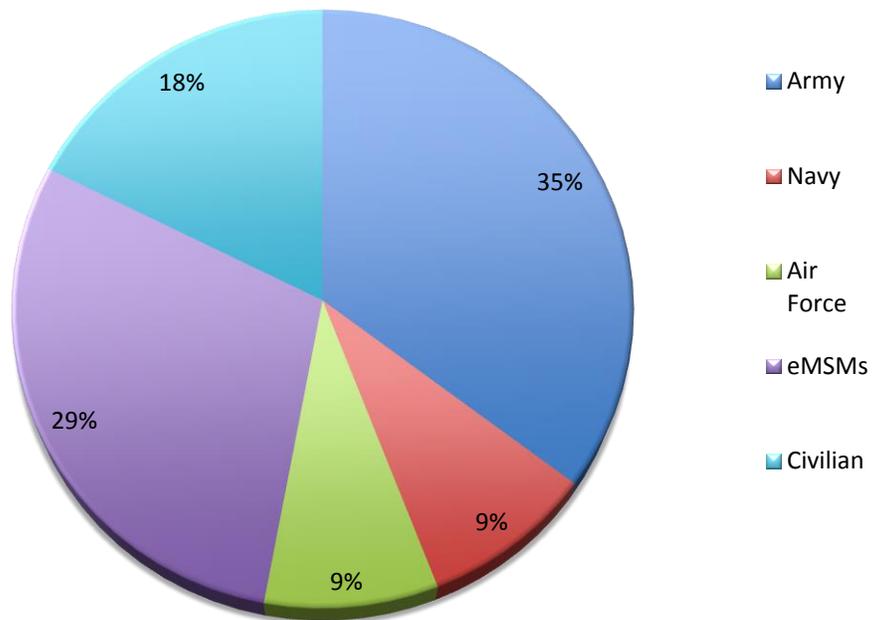
Figure 2: Number of Research Subjects Affected as Specified in 19 Studies



Served 21 different healthcare and research-related Centers and Institutions with HIPAA compliance reviews for the Army, Navy, Air Force, eMSMs, and Civilian sites

During FY14, the DHA Privacy Board served 21 different research Centers and Institutions for the Army, Navy, Air Force, eMSMs and Civilian sites. 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 B for a complete listing of specific research Centers and Institutions.

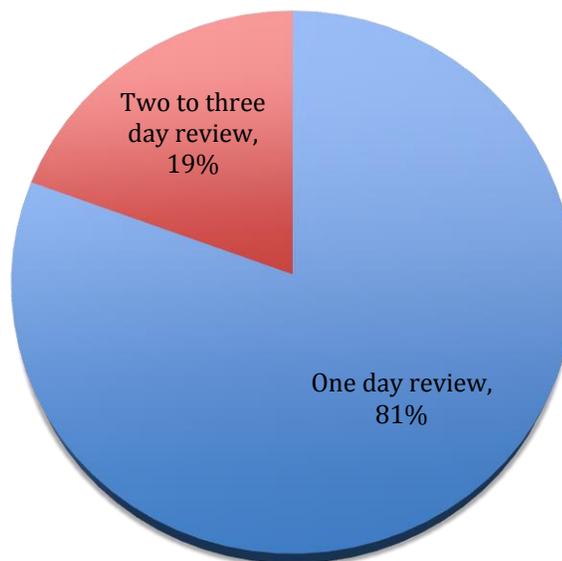
Figure 3: Submissions by Type of Centers & Institutions in FY14



Achieved 100% percent compliance with review period mandates, resulting in an average completion of reviews within two days from the date of perfection

The DHA Privacy Board’s Standard Operating Procedures (SOP) provides Board members with up to five days after the perfection of a submission to respond to the principal investigator (PI) and/or government sponsor (Sponsor) with the results of the review or follow-up questions. For all 36 submissions, the Board responded to a PI’s submission within three days or fewer after perfection, which is 100% compliance with the standard set in the SOP. The Board uses the date “perfected” as the official start of a review, which is when all of the 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. Using the date of perfection and date of approval, the average time for review of a submission was two days for FY14. A majority of reviews were completed in only one day. All reviews of perfected submissions within FY 14 were completed within three days, well under the five day limit.

Figure 4: 100% Compliance with Review Times in FY14



Conducted a comprehensive analysis, reported on Board trends, and projected figures for the future to monitor Board operations and processes

At the beginning of FY14, the DHA Privacy Board conducted an in-depth analysis of the Board's metrics to investigate trends and submission data in more detail and to identify future considerations that could impact the Board in order to forecast and plan ahead. The analysis began with a look at the number of research studies requesting data from DHA-managed systems and the number of submissions requiring Board review. These numbers were pulled by Privacy Board support staff who sit on the Data Evaluation Workgroup (DEW), which was set up by the Board in order to track and monitor research related requests for MHS data managed by DHA. (See Appendix C for more information about the relationship between the DEW and the Privacy Board.) It was determined that total number of research studies requesting DHA-managed data remained consistent over the years, however, there has been a slight increase in requests for Limited Data Sets (LDS) as opposed to data sets containing full PHI.

Of the requests for full PHI that are sent to the DHA Privacy Board for HIPAA Privacy Rule review, there was a shift in the types of reviews required. More submissions were able to be reviewed by Board support staff and fewer submissions required Board member review. Privacy Board support staff are able to perform administrative reviews of Authorizations and waivers approved by an IRB. DHA Board members, however, are required to conduct the reviews of waiver applications. The Board attributed this shift to the Board's outreach to DoD IRBs and the MHS research community. More DoD IRBs have started to conduct HIPAA Privacy Rule reviews and to generate HIPAA documentation. This documentation can be reviewed by the DHA Privacy Board support staff as an administrative review in order to ensure the documentation includes all HIPAA required criteria.

The Board identified two primary future considerations. The first was that, as more information systems come under the management of DHA, requests for Data Sharing Agreement Applications (DSAs), including research-related DSAs, will increase significantly. This increase will likely result in an increase of overall DEW submissions and the total number of DHA Privacy Board reviews. The second consideration focused on the goal of the Streamlining Initiative to provide efficient and uniform HIPAA reviews and to enhance HIPAA compliance within the MHS. As the Streamlining Initiative expands, the Board anticipates more submissions from eMSMs and more administrative IRB waiver reviews, as opposed to waiver applications for the DHA Privacy Board's review. Ultimately, once official policies are put in place for the Streamlining Initiative, the administrative reviews by the DHA Privacy Board will no longer be required for eMSMs bound by this policy. The Board will, however, continue to be required to maintain uniform MHS-wide

HIPAA research templates and addressing HIPAA research–related questions, and the DHA Privacy Office will be responsible for providing HIPAA assessments of IRBs and HIPAA Privacy Boards.

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 FY14. Each meeting commenced with an update on the status of the Board’s operations, including review of; the Board tracker setting forth all active and inactive submissions; the log of pending research-related DSAAs; and specifics regarding submission type and the sponsoring service for the study. Discussion ensues, as necessary, about any specific issues related to submission reviews from the quarter. Each meeting also routinely provides updates on the Streamlining Initiative and outreach efforts. All quarterly meetings include presentations and open discussion about topics and articles related to or of interest to the Board; for example, in FY14, discussions included:



The Substance Abuse and Mental Health Services Administration (SAMHSA) Public Listening Session on June 11, 2014 about considerations for changes to the 42 CFR Part 2 regulations pertaining to the confidentiality of alcohol and drug abuse patient records



“[Court ruling in lost PHI case muddies HIPAA waters](#),” McCann, Erin, *mHealth News*, October 18, 2013



“[De-Identification: Getting it Right](#),” Mcgee, Marianne Kolbasuk, *HealthInfoSec*, August 8, 2014



“[Labs Must Protect Newly Portable Patient Data](#),” Diana, Alison. February 12, 2014

Board members also take time during these meetings to address highlights from the various workgroups they are involved in, such as the Safeguarding Personal Health Data Integration and U.S. Army Big Data In-Process Reviews (IPRs) groups. As noted by the topics and articles of

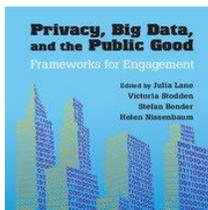
interest to the Board and Board Member workgroup involvement, Big Data has become an interesting topic in the federal and private sectors and the Board has taken a proactive approach by providing a platform for discussions and to share ideas and thoughts on this current topic and the related privacy implications. The Board members are involved with various Big Data initiatives, ranging from DoD and interagency work groups to non-profit stakeholder groups involved with discussing the implications of Big Data in society. In the last quarter of FY14, the Board began to hold roundtable discussions about Big Data in which all Board Members actively engage in discussion about the Big Data initiatives, groups, events, and research in which they participate. This is a lively discussion about recent developments and issues of great importance in the privacy and research communities, and helps identify and monitor challenges and solutions in this area.

Some of the Big Data articles and topics discussed include:

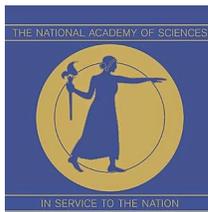


Health Affairs brief on Using Big Data to Transform Care summary

- [Creating Value In Health Care Through Big Data: Opportunities And Policy Implications](#)
- [Lessons Learned Bringing Big Data Analytics to Healthcare](#)
- [Using Big Data to Transform Care meeting video](#)



Follow up discussion and updates on the [Data Privacy Book](#)



Big Data initiatives updates from the National Academies conference



[“Should big data research override patient privacy needs?”](#),
Ouellette, Patrick

In FY14, DHA Privacy Board support staff also provided a full review and analysis of the HIPAA breaches posted on the HHS Office of Civil Rights (OCR) website, commonly referred to as the “Wall of Shame.” OCR is required by the Health Information and Technology Economic and



Clinical Health (HITECH) Act of 2009 to post breaches of unsecured PHI of 500 or more individuals publically. The analysis illustrated the formats involved in HIPAA breaches (e.g., paper, desktop computer, electronic medical records, email, laptop, network, and portable electronic devices) and the number of breaches per format. The analysis further looked at the number of breaches in relationship with the number of individuals affected, generally showing that the majority of breaches affect between 500-5,000 individuals. Although there were several breaches affecting significantly more individuals, they were not as common. Among the hundreds of reported PHI breaches for 2014, there was one research-related breach, which was caused by malware and affected 5,100 Kaiser Permanente research participants. The Board took a closer look to ascertain lessons learned for potential Privacy Board implications. DHA Privacy Board support staff continue to monitor OCR's HIPAA website in order to identify and report on HIPAA breaches that are specific to research activities.

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 for the DHA Privacy Office.



DHA PRIVACY BOARD 2014 ACCOMPLISHMENTS
RESEARCH COMMUNITY OUTREACH EFFORTS

1. Conducted an initial HIPAA Privacy assessment of Walter Reed National Military Medical Center (WRNMMC) and Ft. Belvoir Community Hospital (FBCH), which were realigned under the DHA, and provided guidance on the application and implementation of the HIPAA Privacy Rule's research requirements (See page 16)
2. Finalized training slides and materials, completed draft MHS-wide standardized HIPAA - research templates, and successfully delivered training to WRNMMC IRB members and DRP staff as part of the Streamlining Initiative's Pilot Program (See page 17)
3. Supported DHA Privacy Office Data Sharing Analysts in the development of the overarching Data Sharing Agreement for the Henry M. Jackson and Geneva Foundations in order to reduce the number of DSAs submitted for a research study and expedite the Data Sharing Program's review process (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

Conducted an initial assessment of Walter Reed National Military Medical Center (WRNMMC) and Ft. Belvoir Community Hospital (FBCH), which were realigned under the DHA, and provided guidance on the understanding, application, and implementation of the HIPAA Privacy Rule's research requirements.

In January 2014, the DHA Privacy Board members and support staff met with Health Information Compliance staff at National Capital Region (NCR) Medical Directorate in order to include NCR in developing the DHA Privacy Office's Streamlining Initiative pilot program at WRNMMC. The Board provided guidance to WRNMMC regarding the application and implementation of HIPAA Privacy Rule requirements in research studies and worked with the WRNMMC's IRB throughout the year to understand its Common Rule procedures and processes and to help WRNMMC add HIPAA processes and procedures to its existing review framework.

The DHA Privacy Board was invited by the Office of the Undersecretary of Defense for Personnel and Readiness (OUSD (P&R)) Regulatory Research Oversight Office (R2O2) and the DHA Human Research Protection Program to participate in the March 2014 Common Rule audits of WRNMMC and FBCH, with the goal of gauging their understanding of the HIPAA Privacy Rule and evaluating their existing procedures and documents. DHA Privacy Board support staff created pre-assessment tools to help facilitate interviews and dialogue and to provide guidance, as needed. DHA Privacy Board support staff conducted conferences with Privacy Officers and IRB personnel and completed pre-assessment baseline evaluations of WRNMMC's IRB/HIPAA Privacy Board's Privacy Rule compliance reviews. In conjunction with the Human Research Protections Program Accreditation Site Visits, the DHA Privacy Board gave a presentation on the research-related compliance requirements of the HIPAA Privacy Rule and provided general guidance during a town hall meeting for researchers facilitated by the Army Human Research Protections Office (AHARPO) and R2O2. The town hall meeting was held to provide awareness and address questions about HIPAA compliance, the relationship and key distinctions between the HIPAA Privacy Rule and the Common Rule, DHA data sharing processes and procedures, and the DHA Privacy Board templates used for conducting HIPAA Privacy Rule reviews of research studies. DHA Privacy Board staff provided a "HIPAA Privacy Summary Report" to AHARPO and R2O2 for inclusion in the May 2014 final report on the site visits.

The DHA Privacy Board support staff used the information gathered during the WRNMMC and FBCH assessments to incorporate targeted guidance into the Streamlining Initiative training protocol for WRNMMC. Throughout FY14, DHA Privacy Board staff worked closely with

WRNMMC to solicit feedback on draft MHS-wide standard HIPAA templates, incorporating HIPAA language into existing IRB templates, and assisting in the restructure of IRB processes and procedures, as needed, in order to incorporate HIPAA review requirements into the existing Common Rule review processes. In FY14, it was determined that an Administrative Instruction (AI) was needed to implement the Streamlining Initiative; it will be completed in early FY15.

Finalized training slides and materials, completed draft MHS HIPAA research standardized templates, and successfully delivered training to WRNMMC IRB members and DRP staff as part of the Streamlining Initiative's Pilot Program.

During FY14, the DHA Privacy Board, through its members and support staff, who also serve the DHA Privacy Office, completed the development of the training slides, templates, and other materials, and coordinated with the WRNMMC Human Research Protection Administrator and DRP staff to plan the October 28th and 29th, 2014 *HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards*. This was an important accomplishment for the Streamlining Initiative, as it provided foundational HIPAA Privacy Rule knowledge to stakeholders and fulfilled one of the two requirements for WRNMMC to begin to perform its own HIPAA Privacy Rule reviews.



There were a total of four events, approximately four-hours each, held over two days. A total of 57 professionals attended the events, primarily IRB members, DRP staff, and other individuals with research and privacy oversight responsibilities. The training course focused on the requirements for providing HIPAA Privacy Rule reviews of research studies.

As a critical part of the Research Data Sharing Streamlining Initiative, 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
- An explanation of the Streamlining Initiative, how and why it was established and its impact on DoD IRBs and HIPAA Privacy Boards
- An in-depth discussion of the HIPAA Privacy Rule's research provisions
- A 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
- An opportunity to practice using the templates with realistic scenarios

Participants were asked to provide feedback on the templates and training presentation and materials both during and after the events. Their responses were used to revise the templates to ensure they are user-friendly. Any IRBs that wish to take responsibility for HIPAA Privacy Rule Reviews 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.

FEEDBACK FROM TRAINING PARTICIPANTS

- “The education packages were well written and provide an abundance of information that will be an excellent resource and reference guide.”
- “Good to know/understand changes that I will be encountering as part of the IRB and as a researcher.”
- “The relevance of the training to my daily work made the course enjoyable and useful.”
- “Interactive training scenarios were very helpful.”
- “Style of presentation; highly approachable even though material is very technical. Thanks!”

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.

Supported DHA Privacy Office Data Sharing Analysts in the development of the overarching Data Sharing Agreement (DSAA) for the Henry M. Jackson and Geneva Foundations in order to reduce the number of required DSAs submitted for a research study and expedite the Data Sharing Program’s review process.

The DHA Privacy Board assisted in the development of an overarching DSAA specifically for the Henry F. Jackson and Geneva Foundations, which will allow researchers from these foundations



to request DHA-managed data without executing separate DSAs for each individual research protocol submission. The Henry F. Jackson and Geneva Foundations are two of the primary medical research contractors used by the DoD; both regularly submitted requests for MHS data and the need to streamline the process was identified. The overarching DSA will lead to a decrease in the number of DSAs from these organizations and will reduce the processing burden and time shared by the researchers and DHA Privacy Office data sharing analysts. This was a major collaboration effort with the DHA Data Sharing team to facilitate efficient and streamlined DSAs while ensuring HIPAA privacy compliance is achieved. As the DHA Privacy Office and Privacy Board work to streamline data sharing activities, the Board will work with data sharing analysts on any other overarching DSAs.

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 the public and a variety of stakeholders in the research community. A sampling of guidance provided by the DHA Privacy Board includes:

- Meeting with AHRPO to discuss streamlining Army research requests for data for research (Nov 2013)
- Meeting with researchers at Uniformed Services University of the Health Sciences (USUHS) to discuss the HIPAA requirements for de-identification and to provide contacts for assistance with data needs (Dec 2013)
- Providing HIPAA feedback to R2O2 in the development of the Privacy, Information Collection and Human Research (PICHR) tool for providing guidance on requirements related to collecting, using, and releasing information on individuals for research and related purposes (March 2014)
- Providing advice to the Office of Research Protections (ORP), US Army Medical Command (MEDCOM) on preparatory to research requirements for recruitment purposes and Waiver of HIPAA Authorization issues (May 2014)

Through its website, the Board provides information about its processes and the research-related requirements of the HIPAA Privacy Rule. With the formalization of the DHA, the DHA Privacy Board transitioned to the health.mil sites. The Board updated and streamlined its webpage to offer a plain language, user-friendly public-facing site. A new section was drafted and revised to align



with the structure used by the DHA Privacy Office on its other webpages in order to provide consistency. More detailed content is still available to DHA personnel on the intranet. 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, "*Ensuring Compliance with the HIPAA Privacy Rule Highlights Ongoing Contributions from the DHA Privacy Board,*" was published in the January 2014 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 E. Researchers and IRBs that have engaged with the Board in the past now have a solid understanding of the requirements, which is reflected in their well-documented submissions. New researchers and IRBs continue to have some misconceptions and misunderstandings regarding the distinctions between and requirements of the Common Rule and HIPAA Privacy Rule. Misconceptions include thinking that an informed consent under the Common Rule meets the HIPAA Authorizations 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 the MHS are required to undergo HIPAA Privacy Rule review by an IRB or HIPAA Privacy Board; there are no exemptions.

Throughout FY14, the DHA Privacy Board support staff were also heavily engaged in updating the DoD 6025.18-R as a new DoD Instruction (DoDI) in response to developments within the MHS and the modifications to the HIPAA Privacy Rule created by the Final HIPAA Omnibus Rule. The relevant modifications are primarily focused in two key areas: (1) authorizations may be used for future research if the intent to use the PHI for *future studies* is made clear in the authorization, and (2) a single authorization can now cover both conditioned and unconditioned research-related activities. However, for unconditioned research activities, such as inclusion of PHI in a database for use in future studies, the participant must opt-in for their information to be used. Based on the questions from the research community in this regard, the DHA Privacy Board is drafting an MHS-wide standard HIPAA Authorization template in order to help facilitate reviews and provide clear guidance in this area. Previously, the DHA Privacy Board did not provide Authorization templates in order to give the research community more flexibility and accepted Authorizations as long as all core elements and required statements were included. Now,



however, the confusion about the changes in the Final HIPAA Omnibus rule makes it so that having a MHS-standard template will help researchers ensure they know how to incorporate the new requirements and will facilitate efficient DoD IRB and HIPAA Privacy Board reviews.

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. The Board started collecting and reporting on this data in Calendar Year 2012 (CY12); however, it transitioned to analyzing Fiscal Year (FY) data in 2013. Trend data in the FY13 Annual Report was slightly skewed, as its comparisons were made against part of the CY12, rather than FY12 reporting period. To improve trend analysis going forward, in FY14, the Board went back and, where possible, collected data about its activities throughout FY12 to allow consistent comparisons between all years. Unlike previous annual reports, this report uses the FY12 data in all cases, except for length of time it took to review a submission (Fig. 8), as this information is only for Q4 CY12, which falls within FY13.



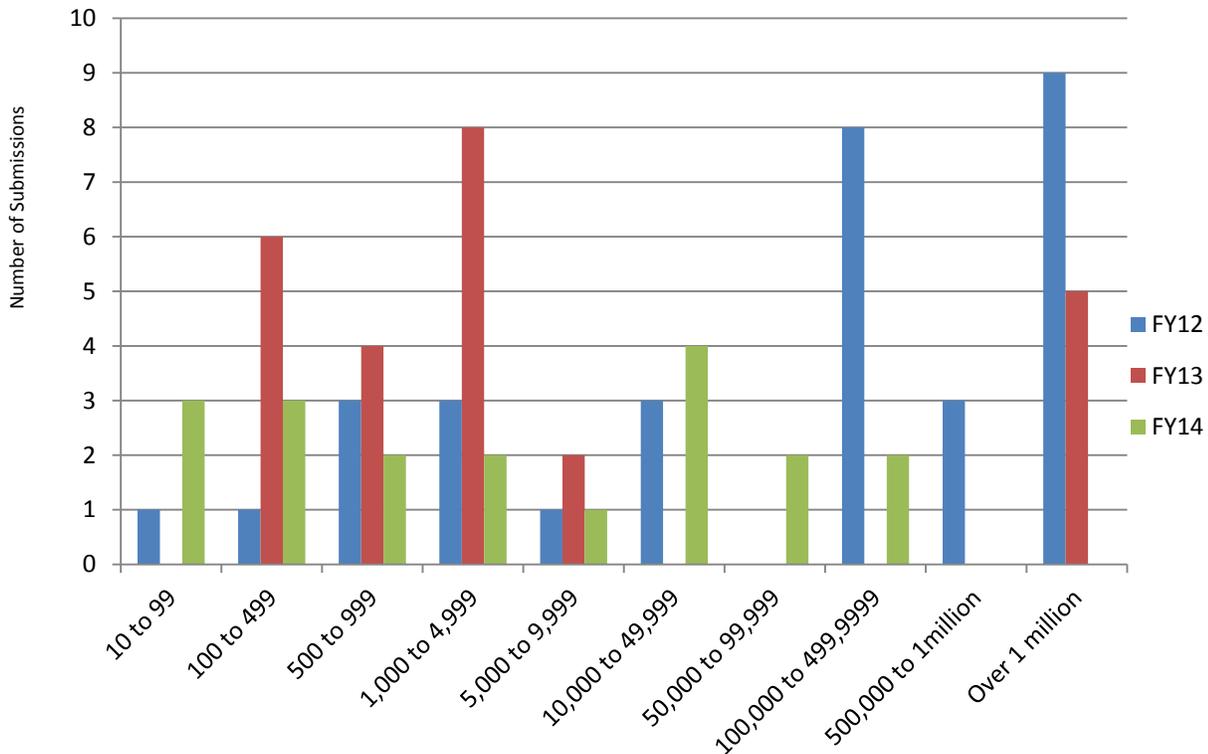
The DHA Privacy Board tracks, to the extent possible, the number of individuals whose records are requested for a research study

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 addition, 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. In FY14, the Board attempted to identify whenever possible, the approximate number of research participants in order to begin to monitor trends in this regard and to see how this trend relates the trend in the types of submissions for each FY. Although there is limited relevant data at this point, the graph below shows an apparent decrease in the number of individual records requested for research studies over the past two years. Since FY12, it appears researchers are requesting records for a smaller number of individuals in their studies. The Board believes this 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 and to more accurate reporting of the number of requested records.

The nature of studies also appear to have affected the number of records requested. Historically, research studies commonly requested data about all service members; however, in FY14, more

studies were focused on specific medical treatments or injuries, which translated to requests for smaller datasets. The Board is encouraged by this trend, which lowers the overall privacy and security risks to research participants.

Figure 5: Number of Individuals' Records Requested

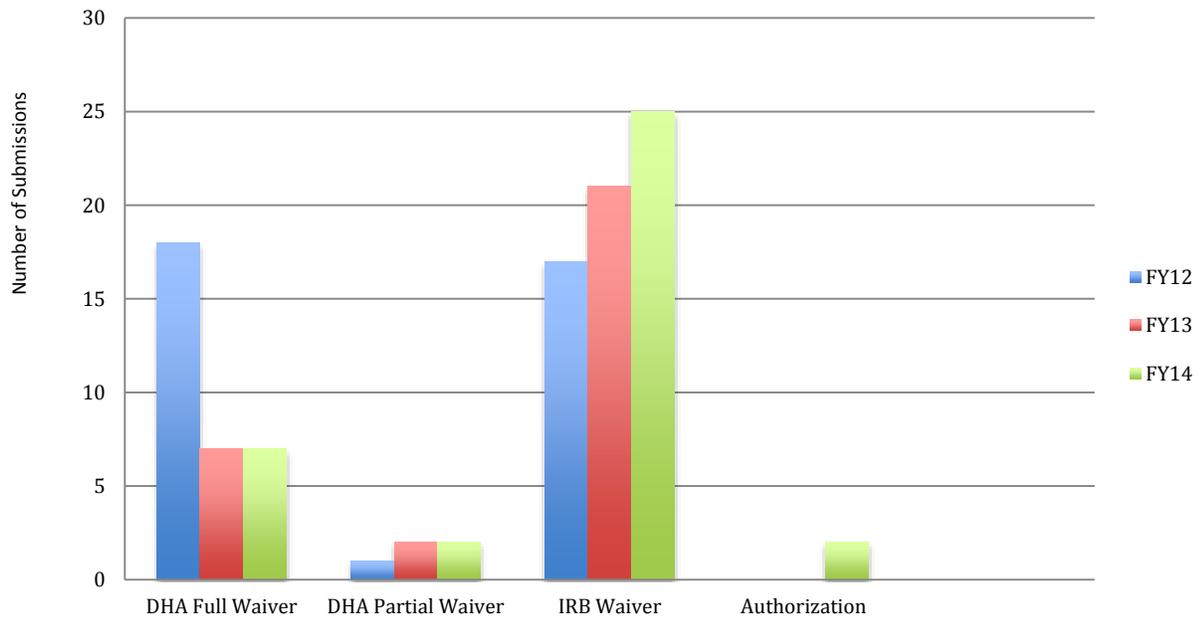


The Board saw a continued increase in the number of IRB Waivers obtained in FY14. The Board performed its first Authorization reviews as HIPAA compliance outreach and education increased

During FY14, IRB Waiver reviews continued to increase, while the number of Full Waivers decreased and Partial Waivers stayed consistent. The decrease in Full Waiver reviews was due to continued education and outreach to IRBs on HIPAA requirements and reviews. As the IRBs conduct their own HIPAA Privacy Rule reviews, the DHA Privacy Board only requires administrative reviews of the IRB approval documentation to ensure that the documentation is compliant with HIPAA. The Board expects to see a slight increase in the number of submissions for Partial and Full Waivers due to the growing number of Centers and Institutions that fall under

the purview of the DHA, as well as the increasing number of information systems coming under the management of the DHA. During FY14, the Board conducted two Authorization reviews, in contrast with none in FY12 and 13, which further shows the impact of the DHA Privacy Board’s outreach efforts in educating the research community on using Authorizations whenever feasible.

Figure 6: Types of Submissions in FY12, 13, and 14

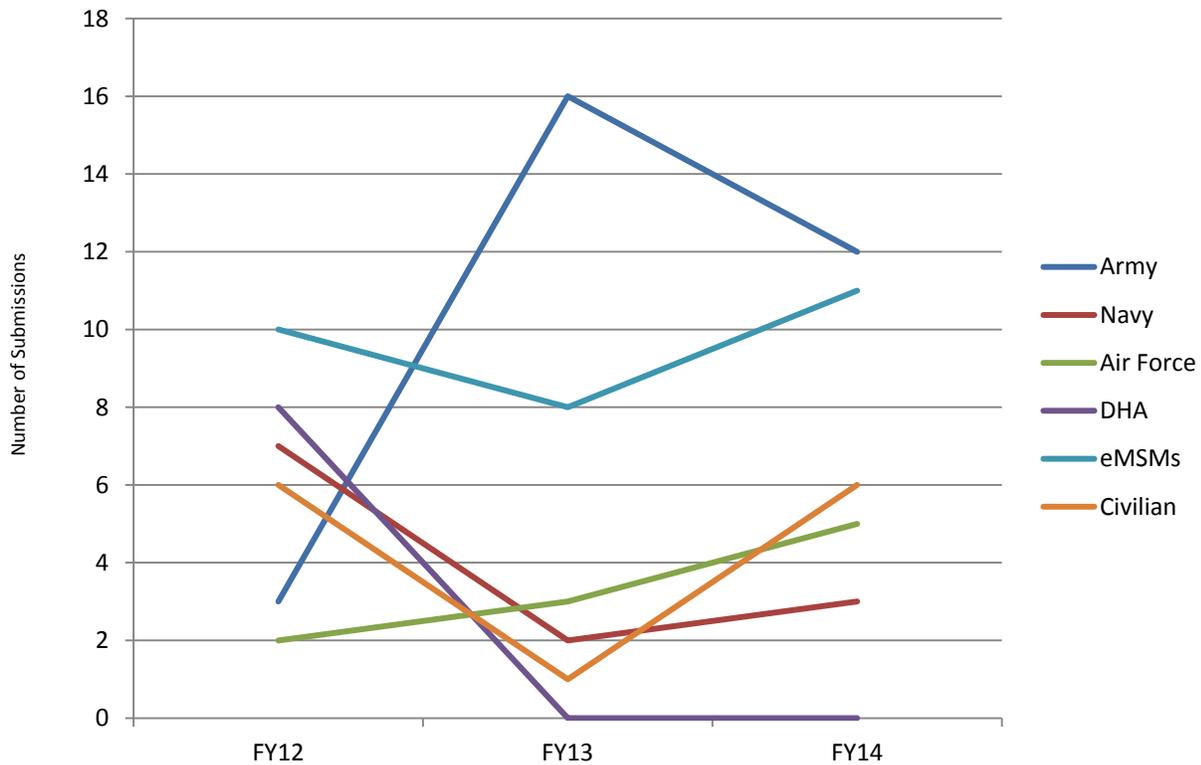


The types of organizations served by the DHA Privacy Board will change over time as streamlining efforts are implemented for HIPAA compliance

During FY14, there was an overall increase in participation from the Services and eMSMs. The number of Army submissions to the DHA Privacy Board decreased; the Board will monitor this trend, but anticipates that Army submissions will normalize over time. In FY14, the eMSMs and Civilian institutions showed the most significant increase in the number of submissions to the Board. The Navy’s and Air Force’s number of FY14 submissions remained relatively consistent with FY13. As in FY13, there were no research-related submissions from DHA to the Board in FY14. 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 7: Centers & Institutions Served in FY12, 13, and 14



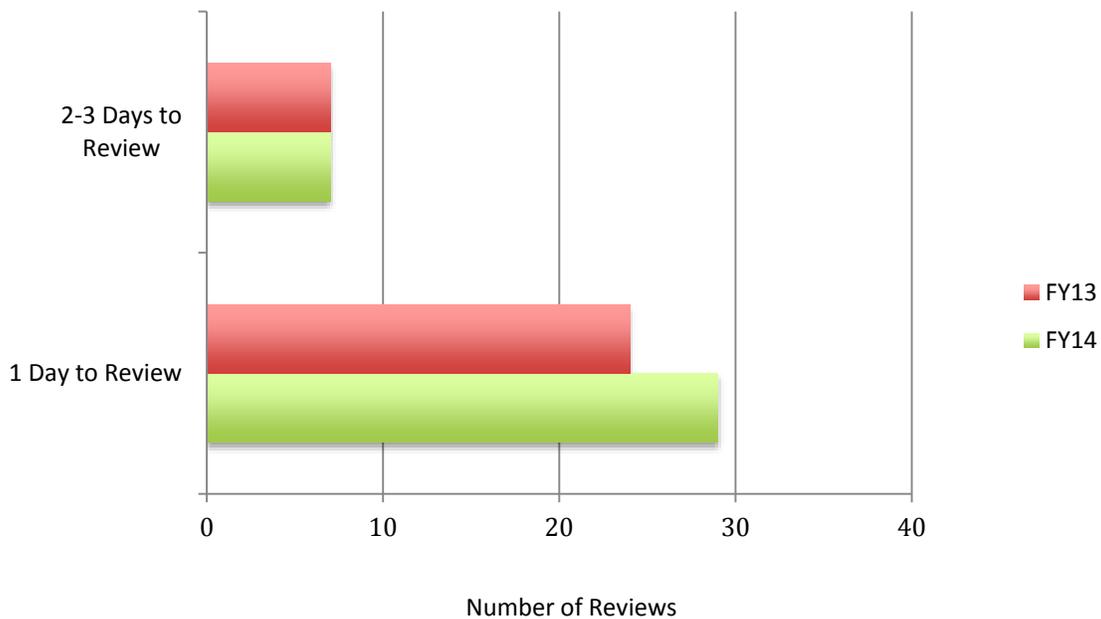
The DHA Privacy Board continues to exceed the efficiency measure for HIPAA compliance reviews

There continues to be an increase in the number of reviews taking only one day to complete from the date of perfection. The DHA Privacy Board is given five days from the perfection of the submission to complete its review. No reviews took longer than three days to complete. Administrative reviews of IRB Waivers conducted by DHA Privacy Board support staff can be completed relatively quickly, especially with IRBs that the Board has worked with in the past and who thus understand HIPAA requirements. Authorization reviews by support staff and Full and Partial Waiver reviews by DHA Privacy Board members may involve in-depth discussions with

the PI and thus be more time consuming, but are still conducted efficiently and within the five days provided by the SOP.

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

Figure 8: Continued 100% Compliance with Review Times





Future Vision for the Privacy Board

In a memo dated March 6th, 2012 to the Deputy Assistant Secretary Defense Force Health Protection & Readiness (DASD (FHP&R)), Dr. Woodson, Assistant Secretary of Defense for Health Affairs, directed R202 to "propose a series of potential reforms to the Department of Defense Institutional Review Board procedures to increase efficiencies and streamline processes." In the spirit of this challenge, the DHA Privacy Board will continue to expand its efforts to work with DoD IRBs and HIPAA Privacy Boards through the Streamlining Initiative and to strive to identify ways to reduce the perceived burden that HIPAA Privacy Rule reviews places on researchers. The ultimate success of the Streamlining Initiative will:



- Empower DoD Institutional Review Boards (IRB) 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 Federal Policy for the Protection of Human Subjects (also known as 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 the NCR eMSM 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, R202, 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 FY14, the Board increased its outreach activities to both research oversight professionals and DoD IRBs through participating in site visits and a Town Hall and by providing trainings, as well as ad hoc advice throughout the year. In FY15, 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.

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
<ul style="list-style-type: none"> • Continue outreach efforts to enhance HIPAA compliance in the research community and to expand the Streamlining Initiative within the MHS, and work with R2O2 and the Office of General Counsel to create appropriate agreements and issuances for implementing the Streamlining Initiative at new locations
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • Complete the final MHS-wide standard HIPAA templates and required processes for DoD IRBs and HIPAA Privacy Boards, which incorporate new provisions in the Final HIPAA Omnibus Rule and align to recent developments within the MHS as part of the Streamlining Initiative
<ul style="list-style-type: none"> • Update the DHA Privacy Board’s templates and processes in order to adopt the same look and feel as the MHS-wide standard templates, making adjustments as needed to accommodate necessary differences in procedures
<ul style="list-style-type: none"> • Complete the Administrative Instruction setting forth the terms and conditions and policy requirements for formally delegating HIPAA Privacy Rule compliance reviews to IRBs and/or HIPAA Privacy Boards within the National Capital Region eMSM
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • Continue to update and standardize the HIPAA Compliance Training for IRBs and HIPAA Privacy Boards, with ultimate possible goal of creating an online training in order to address turnover in IRB membership and to help further expand the Streamlining Initiative



Appendix A: DHA Privacy Board Members

HIPAA requires that a HIPAA Privacy Board: 1) has members of varying and appropriate professional competency; 2) includes at least one member who is not affiliated with the HIPAA covered entity (in this case MHS), not affiliated with any entity conducting or sponsoring the research, and not related to any person affiliated with any such entity; and 3) not have any member participating in a review for which the member has a conflict of interest. 45 CFR 164.512(i)(i)(B).



Appendix B: Centers and Institutions Served by the DHA Privacy Board in FY14

Centers and Institutions Served by the DHA Privacy Board in 2014
Army
Brooke Army Medical Center
Madigan Army Medical Center
San Antonio Military Medical Center (SAMMC)
U.S. Army Institute of Surgical Research (USAISR)
William Beaumont Army Medical Center (WBAMC)
Air Force
Air Force 59 th Medical Wing
Air Force Research Lab, Wright Paterson Air Force Base
Air Force School of Aerospace Medicine (USAFSAM)
Navy
Naval Medical Center San Diego
Navy Bureau of Medicine and Surgery (BUMED)
eMSMs
Defense Center of Excellence for Psychological Health (PH) and Traumatic Brain Injury (TBI)
Defense and Veterans Brain Injury Center (DBVIC)
Uniformed Services University of Health Sciences (USUHS)
US Military Cancer Institute
Walter Reed National Medical Military Center (WRNMMC)
Civilian
CNA Analysis and Solutions
Deloitte
Henry M. Jackson Foundation
JXT Applications, Inc (JXTAI)
Mathematica Policy Research
RAND Corporation



Appendix C: The Research Data Sharing Review Process

Determining the Type of Data Requested

Prior to review by the DHA Privacy Board, researchers must submit a DSAA to the DHA Privacy Office. All research-related data requests are sent by the DHA Privacy Office Data Sharing Analysts to the DEW, which was set up by the Board in order to track and monitor research-related requests for data owned and/or managed by DHA. 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 they submit documentation to demonstrate compliance with the HIPAA Privacy Rule and DoD 6025.18-R. The email outlines five possible types of submissions that the researchers may submit to meet the required standards, as appropriate: (1) Required Representations for Research on Decedent's Information; (2) Required Representations for Review Preparatory to Research; (3) Research Authorization Reviews and the HIPAA Authorization(s) intended for use in the study; (4) Waiver of HIPAA Authorization or an Altered Authorization approved by an IRB or another HIPAA Privacy Board; or, (5) an Application for a Waiver of Authorization or Altered Authorization from the DHA Privacy Board. Privacy Board support staff assist researchers in understanding the HIPAA requirements and which submission(s) are appropriate for their study.

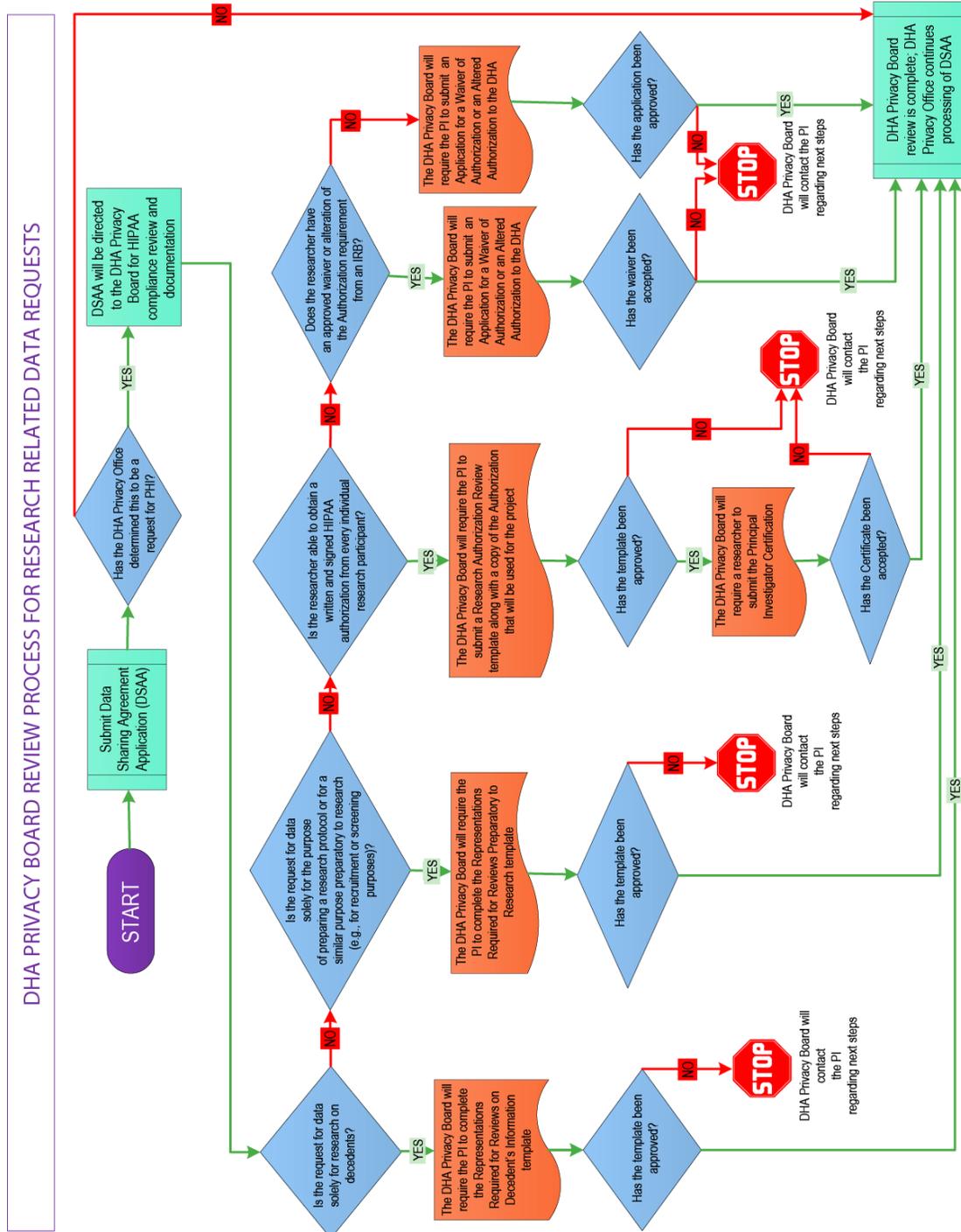


The Board maintains internal checklists to facilitate its HIPAA review and documentation procedures. When reviewing a submission, the Board will contact the PI and Sponsor with any questions or issues, if necessary. The Board notifies the DHA Privacy Office when it completes its HIPAA Privacy Rule Review 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 D: DHA Privacy Board Review Process for Research Related Data Requests



Appendix E: 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 (<i>must be written and signed</i>)
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

* The rows highlighted in blue describe the most significant differences between the Common Rule and the HIPAA Privacy Rule.