

Military Health System
DHA Privacy & Civil Liberties Office

DHA PRIVACY BOARD ANNUAL REPORT

FISCAL YEAR 2016

DECEMBER 2016



Contents

Message from the DHA Privacy Board Co-Chairs.....	2
Executive Summary	3
Board Operations and Process Improvements Accomplishments	6
Research Community Outreach Accomplishments	14
DHA Privacy Board Trends.....	21
Future Vision for the Privacy Board.....	26
Appendix A: Centers and Institutions Served by the DHA Privacy Board in FY16.....	28
Appendix B: The Research Data Sharing Review Process.....	29
Appendix C: DHA Privacy Board Review Process for Research Related Data Requests .	30
Appendix D: Differences between the Common Rule and the HIPAA Privacy Rule.....	31
Appendix E: Acronym List.....	32

List of Figures

Figure 1: Number of Types of Submissions	6
Figure 2: Number of Individual's Records Requested as Specified in 15 Studies	7
Figure 3: Number of Submissions by Type of Center & Institution in FY16	9
Figure 4: FY16 Review Times.....	10
Figure 5: HIPAA Privacy Rule Training Attendance	14
Figure 6: Participant Evaluation Scores.....	16
Figure 7: Total Number of Reviews Each Year.....	21
Figure 8: Types of Submissions in FY12, 13, 14 and 15.....	22
Figure 9: Submissions from Each Type of Center & Institution Served in FY12 – FY16.....	23
Figure 10: Continued Efficient Review Times	24
Figure 11: Number of Individuals' Records Requested	25

Message from the DHA Privacy Board Co-Chairs

On behalf of the Defense Health Agency (DHA) Privacy Board (Board), we are pleased to present the Fiscal Year 2016 (FY16) DHA Privacy Board Annual Report. The Board continued to make tremendous achievements during FY16, 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 through the implementation of DHA Administrative Instruction (AI) 83, *Regulatory Reviews of Research Studies*, delegating HIPAA reviews, as well as other data sharing regulatory compliance reviews to the National Capital Region Medical Directorate (NCR-MD) Military Treatment Facilities (MTFs), Walter Reed National Military Medical Center (WRNMMC) and Fort Belvoir Community Hospital (FBCH). We also said farewell to one of our valued members, Dr. Eve Powell-Griner, and welcomed Ms. Robbi Watnik to the Board.

The Board's FY16 accomplishments further extend to its strong outreach efforts. The Board updated and expanded its provision of the *HIPAA Privacy Rule Compliance Training for Institutional Review Boards (IRBs) and HIPAA Privacy Boards* to new organizations, including implementing a webinar format to reach remote audiences. The Board continued to provide in-depth HIPAA Privacy Rule 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. As we begin FY17, we look forward to enhancing HIPAA compliance across the MHS through developing an online training course and 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.

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

Rita DeShields
Data Sharing Compliance Manager
Co-Chair, DHA Privacy Board

Executive Summary

The DHA Privacy Board provides HIPAA Privacy Rule compliance reviews for research studies requesting DHA data. This report captures the fiscal year 2016 (FY16) operational and outreach accomplishments of the Board. It also tracks trends in Board operations since FY12. These accomplishments include:

- Completed reviews of 54 submission, a 26% increase from FY15, requesting DHA data, through which the Board protected the privacy of approximately 9.4 million beneficiaries' data contained in MHS systems in strict adherence to the HIPAA Privacy Rule standards. These reviews included 11 DHA Privacy Board waivers of authorizations, 34 IRB-approved waivers of authorizations, one IRB-approved waiver of authorizations, and eight IRB-approved authorizations.
- Implemented an IRB Waiver Certification Template to improve HIPAA compliance and efficiency of Board administrative reviews of IRB-approved waivers, the most common type of submission to the Board
- Achieved an average review completion rate of two days from the date of perfection, with 31 reviews taking only one day
- Welcomed the Board's first new member since its establishment, Robbi Watnik, and celebrated the retirement of founding member Eve Powell-Griner
- Delivered HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards to 90 IRB members and others with research oversight responsibilities at Walter Reed National Military Medical Center (WRNMMC), Fort Belvoir Community Hospital (FBCH), Uniformed Services University of Health Sciences (USUHS), and Naval Medical Center San Diego (NMCS D)
- Supported the implementation of Administrative Instruction (AI) 83, Regulatory Reviews of Research Studies, at the National Capitol Region Medical Directorate (NCR-MD) Military Treatment Facilities (MTF). This AI delegates data sharing compliance reviews for research studies requesting DHA data, including HIPAA Privacy Rule reviews, to the NCR-MD MTFs
- Provided in depth HIPAA Privacy subject matter expertise to researchers in a variety of areas, including the use of online authorizations



- Researched and collaborated on the HIPAA and Common Rule protections required when developing and using research repositories and data banks for the purposes of future research. Over FY16, the Board received an increasing number of requests related to the requirements for creating data repositories and using data for future research. The Board anticipates seeing a continued increase in these requests.

Trends in Board submission data include:

- Experienced a continued increase in submissions. The Board has seen an increase in submissions each year since FY12. Specifically, FY16 saw an increase in IRB-approved waivers of authorizations and authorizations. The Board has seen an increase in these categories each year since FY12
- Realized a significant increase from FY15 to FY16 in submissions from USUHS and Navy institutions (300% from USUHS and 111% increase for Navy institutions) due to increased outreach and training to these institutions
- Continued to maintain efficient review times with 31 of the 54 submissions in FY16 completed in one day. Since FY13, the Board has completed reviews of 95% of its submissions within five days



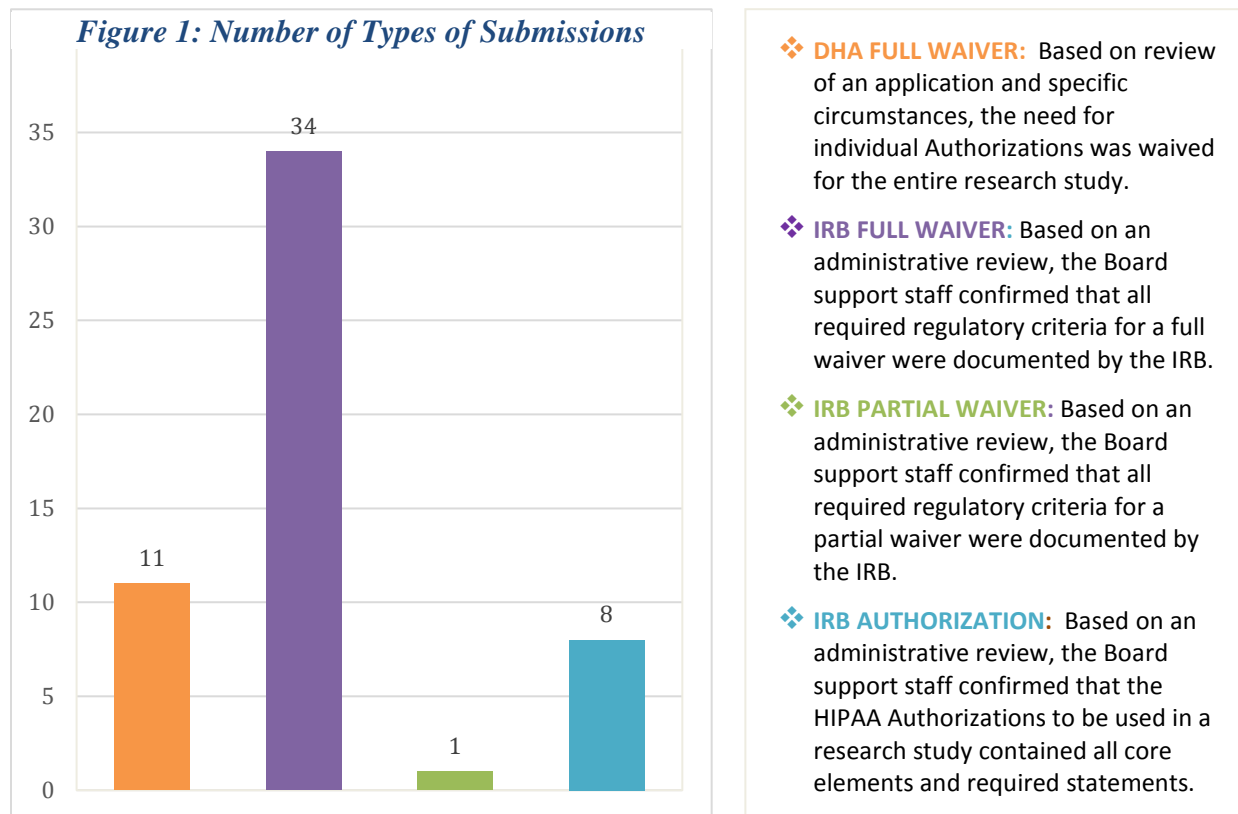
1. Completed reviews of 54 submissions requesting DHA data, through which the Board protected the privacy of approximately 9.4 million beneficiaries' data contained in MHS systems in strict adherence to the HIPAA Privacy Rule standards (See page 6)
2. Implemented an IRB Waiver Certification Template to improve HIPAA compliance and efficiency of Board operations (See page 8)
3. Served 19 different healthcare and research-related Centers and Institutions with HIPAA compliance reviews for Air Force, Army, Navy, Enhanced Multi-Service Markets (eMSMs), Civilian sites, and Uniformed Services University of the Health Sciences (USUHS) (See page 9)
4. Achieved an average review completion rate of two business days from the date of perfection¹ (See page 10)
5. Welcomed a new Board member, as one of our established Board members retired (See page 11)
6. 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 11)

¹ Date of perfection is the date on which a researcher's submission is ready for review (i.e., all of the necessary information has been submitted and is compliant)

Board Operations and Process Improvements Accomplishments

Completed reviews of 54 submissions requesting DHA data, through which the Board protected the privacy of approximately 9.4 million beneficiaries' data contained in MHS systems 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 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 B.²



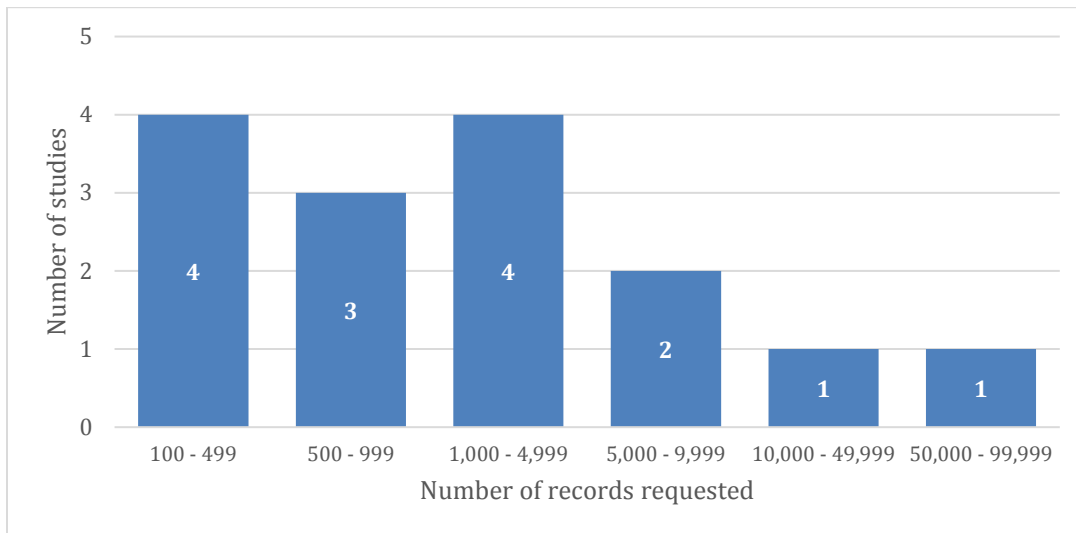
In FY16, the DHA Privacy Board received and completed reviews of 54 submissions, including 11 DHA full waivers of HIPAA authorization (two of which were continuing approvals), 34 IRB

² There were no DHA Privacy Board Partial Waivers of Authorization or IRB Altered Authorizations in FY2016.

full waivers of HIPAA authorization, one IRB partial waiver of HIPAA authorization, and eight IRB Authorizations. In these submissions, researchers requested access to or data extracts from MHS systems that contain information on approximately 9.4 million beneficiaries.

The exact number of subjects 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, the Board now uses a certification template for reviews of IRB waivers of authorization as opposed to reviewing IRB documentation, so reviewers do not receive study documentation that would include information about the number of research subjects. During FY16, the actual or approximate number of research subjects was specified for 15 of the 54 submissions. As illustrated in the graph below, four of those 15 studies had fewer than 500 subjects and seven studies had fewer than 1,000 subjects. A majority of the 15 studies (11) involved fewer than 5,000 subjects, however, one study had more than 50,000 subjects.

Figure 2: Number of Individual's Records Requested as Specified in 15 Studies



Implemented an IRB Waiver Certification Template to improve HIPAA compliance and efficiency of Board operations

The HIPAA Privacy Rule allows covered entities to rely on an IRB's independent review and determination in HIPAA Privacy reviews of research studies as long as the covered entity receives documented assurance from the IRB that it has reviewed all elements required to approve the

waiver. When an IRB-approved waiver is accepted by DHA, an administrative or secondary review is conducted in order to ensure all required elements are documented. The DHA Privacy Board is not required to perform its own HIPAA review in these cases.

In FY16, the Board introduced the IRB Waiver Certification template. This template, which is unique to the Board, was developed in response to increasingly complex administrative reviews of IRB-approved waivers. IRBs document their HIPAA reviews and approvals in varying ways. Some IRBs document their waiver approvals by indicating approval on a waiver application, while other IRBs simply document a waiver approval through the overall study approval letter. Board Support Staff were spending significant amounts of time reviewing the documentation for each study in order to identify whether the IRB had considered all required elements for a HIPAA waiver. Often the required elements would be found in different documents, leading to complex approval packages, or, more commonly, not all of the requirements would be present and the Board would have to work with the researcher and IRB to update the documentation. This led to confusion on the part of researchers and IRBs, repetitive back and forth, and lengthy wait times while researchers waited for the IRBs to document necessary updates.

The certification template simply asks the IRB to document that it considered all of the required elements as part of its determination. It was designed to minimize any potential burden on reviewers by using checkboxes where possible and by only collecting the information required under HIPAA. The template also ensures the Board's documentation is consistent across studies, making record-keeping and any internal audits or compliance reviews more efficient. Board Support Staff explain the template and the reasons the Board uses it in the initial phone call with the researchers, take time to answer any questions they may have in order to reduce confusion, and remain available to answer any questions from researchers or IRBs throughout the process. Overall, implementation went smoothly and the response to the template has been positive.

Served 19 different healthcare and research-related Centers and Institutions with HIPAA compliance reviews for Air Force, Army, Navy, eMSMs, Civilian sites, and USUHS

During FY16, the DHA Privacy Board served 19 different research centers and institutions for the Army, Navy, Air Force, eMSMs, USUHS, and Civilian sites, with USUHS being the greatest single requestor. eMSMs are Multi-Service Markets that have been provided “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: Number of Submissions by Type of Center & Institution in FY16³

Type of Center/Institution	Number of FY16 Submissions
Air Force	4
Army	5
Navy/Marine Corps	19
eMSM	13
USUHS	12
Civilian/Other	1

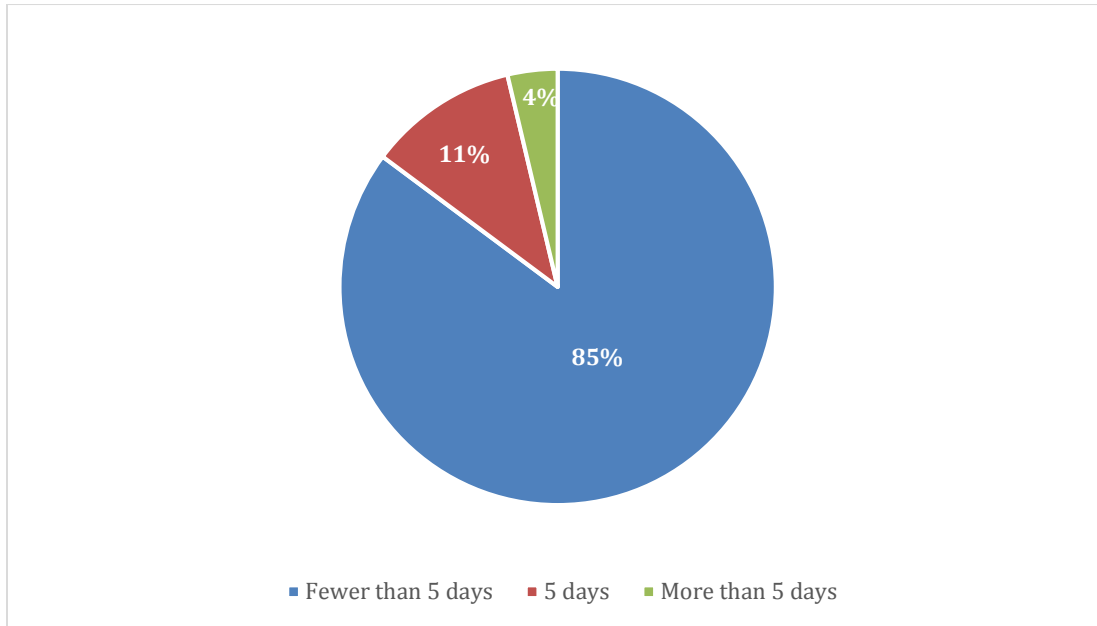
Achieved an average review completion rate of two business days from the date of perfection

Although the Board tracks the date on which a submission is received for internal monitoring purposes, the Board uses the date in which a submission is “perfected” as the official start of a review. “Perfection” is when all necessary documentation has been received by the Board to be able to perform its HIPAA Privacy Rule review. The date of perfection is largely driven by the responsiveness of the researcher in providing all required completed templates and supporting documents to the Board. 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

³ Of the eMSMs, one submission was received from Puget Sound, one from Hawaii, five from National Capital Region (NCR), and six from Tidewater.

requests. FY16 saw a significant increase in complicated submissions from organizations that had limited experience with the Board and HIPAA requirements, resulting in longer review times and required follow-up with the researcher. A significant majority of reviews, 31 out of 54, were completed in only one day.⁴

Figure 4: FY16 Review Times



Welcomed a new Board member, as one of our established Board members retired

In FY16, the Board said farewell to one of its founding members, Dr. Eve Powell-Griner. Dr. Powell-Griner was a valued member of the Board who oversaw the implementation of its processes and its evolution from a focus on performing reviews, to a more proactive Board with a focus on outreach across the MHS. Her expertise and insights will be sorely missed.

Ms. Robbi Watnik, Deputy Chief Officer/Executive Director for the Office of Compliance and Business Integrity (CBI) at the Department of Veterans Affairs (VA), was selected to join the

⁴ Longer than usual review times were primarily related to institutional research-related HIPAA compliance issues associated with a single requesting entity. After training and process improvements, the Board does not anticipate a recurrence of these delays.

Board in late FY16. She was an ideal candidate, given her previous experience as the HIPAA Compliance Officer in the TMA Privacy Office, and her career in compliance. As all Board members do when potential conflicts of interest arise, she will recuse herself from the review of any VA-related studies.

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 FY16, as well as a special additional meeting dedicated to reviewing procedures for studies where the researchers had already obtained what is now considered DHA data.⁵ This meeting allowed the Board to discuss how organizational changes within the MHS and changes in data sharing practices affect the DHA Privacy Board process and how it can best ensure ongoing HIPAA compliance while enabling research in the MHS.

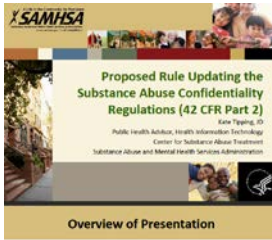
Standard quarterly Board meetings begin with an update on the status of the Board's operations, including a review of Board submission metrics and pending research-related data sharing agreement applications (DSAAAs). Support staff also review the technical assistance requests and consultations with researchers for the fiscal year quarter leading up to the meeting. Each meeting also routinely provides updates on the Streamlining Initiative and outreach efforts.

All quarterly meetings include presentations and open discussion about topics and articles related to or of interest to the Board; for example, in FY16, discussions included:



National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Privacy, Confidentiality and Security hearings on the Minimum Necessary Standard, June 16, and De-identification, May 24 - 25

⁵ As DHA continues to expand and new systems and organizations come under DHA, the associated information becomes DHA data.



42 CFR Part 2 Notice of Proposed Rulemaking (NPRM),
“Confidentiality of Substance Use Disorder Patient Records
Regulations”



Precision Medicine Initiative



The National HIPAA Summit: *The Leading forum on Healthcare
EDI, Privacy, Confidentiality, Data Security, and HIPAA
Compliance*

Each quarterly meeting closed with a discussion about the Board’s next steps and upcoming meetings or events of interest. 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 90 IRB members and others with research oversight responsibilities (See page 14)
2. Facilitated the implementation of AI 83, Regulatory Reviews of Research Studies, at the NCR-MD MTFs (See page 16)
3. 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 HIPAA compliance (See page 17)
4. Researched and collaborated on HIPAA and Common Rule protections required when developing and using research repositories and data banks for the purposes of future research (See page 20)

Research Community Outreach Accomplishments

Delivered HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards to 90 IRB members and others with research oversight responsibilities

Effective training is an essential component of ensuring HIPAA compliance throughout the research community. The *HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards* was originally developed in support of the Research Data Sharing Streamlining Initiative (Streamlining Initiative),⁶ but, in FY16, recognizing the value of this training to all audiences, the training was provided to organizations interested in improving their understanding of HIPAA Privacy Rule requirements even if they were not yet ready to sign onto the Streamlining Initiative. Audiences included IRB members and others with responsibilities for overseeing human research protections, reaching a total of 90 individuals at the Uniformed Services University of Health Sciences (USUHS), Walter Reed National Military Medical Center (WRNMMC), Fort Belvoir Community Hospital (FBCH), and Naval Medical Center San Diego (NMCS D) over four training events.

Figure 5: HIPAA Privacy Rule Training Attendance

Training	Organization	Participants
December 10 th 2015	USUHS	26
March 8 th 2016	USUHS	13
May 4 th 2016	WRNMMC, FBCH, USUHS	25
July 27 th and 28 th 2016	NMCS D	26
Total		90

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 included:

⁶ The Streamlining Initiative was initially developed in an effort to help the DHA Privacy Office delegate HIPAA Privacy Rule reviews to interested DoD components with IRBs and research oversight programs that agree to be trained by the DHA Privacy Office and use standard HIPAA templates developed by the DHA Privacy Office. Through the DHA Privacy Office's work on the NCR-MD pilot program, consideration was given to expanding the Streamlining Initiative to include the delegation of both HIPAA and non-HIPAA required data sharing compliance reviews.

- 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
- 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. With the planned addition of the standard HIPAA templates to the electronic protocol management system (eIRB) for all DoD IRBs to use, and growth of the Streamlining Initiative, receiving feedback is essential to ensure that the training continues to be effective and responsive to the HIPAA Privacy needs of the MHS research community. Figure 6 below shows the average evaluation scores for the FY16 trainings. 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

- Excellent materials. Scenarios were very informative
- The information given was helpful with my day to day duties.
- Very thorough and the ability to interact and ask questions during the presentation was very helpful
- The presenter really knew the information and responded to questions wonderfully.
- Great instructor – I am new to HIPAA compliance so this was very helpful.
- Interactive format – even from remote connection!

Figure 6: Participant Evaluation Scores⁷

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	The materials provided were useful and well explained
4.5	4.2	4.3	4.7	4.5

In FY16, the Board introduced the training in a webinar format in order to better serve the MHS’s dispersed workforce. The webinar covers the same content as the in-person training, but was modified to be more successful in a remote environment. The Board added role playing to the training’s knowledge checks and practice scenarios to maintain the pace of the training and to keep it dynamic for remote participants. Participants responded positively to hearing the different voices and seemed to also feel more comfortable actively participating. The in-person training is an intensive four-hour session; recognizing the difficulty of keeping participants engaged remotely for such a long period of time, the webinar is offered in a single 3.5-hour session or two 2-hour sessions. The Board also encourages hosting organizations to gather the participants in a single place for the training. This makes it easier for the host to distribute materials, take attendance, and collect feedback, and easier for participants to remain engaged and work collaboratively on the practice scenarios.

Facilitated the implementation of AI-83, Regulatory Reviews of Research Studies, at the NCR-MD MTFs

On April 1, 2016, Vice Admiral Bono signed DHA-AI 83, “Regulatory Reviews of Research Studies,” officially approving WRNMMC and FBCH’s participation in the Streamlining Initiative. Through the Streamlining Initiative, the DHA further enhances HIPAA Privacy Rule compliance by ensuring that IRBs and offices overseeing human research protections have the tools and necessary expertise to perform compliant HIPAA Privacy Rule reviews of research studies. Under the AI, WRNMMC and FBCH researchers will no longer need to submit DSAA to the DHA Privacy Office in order to use DHA data in their research. Instead, the compliance reviews normally performed as part of the DSAA process will be performed at the component level. The DHA Privacy Office worked closely with WRNMMC and FBCH as pilot sites to develop the Streamlining Initiative, including standard HIPAA templates, and will continue to work with them

⁷ Participants were asked to score the training on the following scale:
5: Strongly Agree, 4: Agree, 3: Neither Agree nor Disagree, 2: Disagree, and 1: Strongly Disagree

through implementation to provide technical assistance to ensure the success of the Streamlining Initiative.

To help WRNMMC and FBCH prepare for implementation, Ms. Rita DeShields, DHA Data Sharing Compliance Manager and DHA Privacy Board Co-Chair, and Data Sharing Analysts held a brownbag session to review the non-HIPAA review requirements of the AI. Representatives from WRNMMC and FBCH took advantage of the opportunity to ask questions and brainstorm different approaches for implementing the regulatory review processes in their organizations.

Data Sharing Analysts and Board Support Staff also collaborated to present the AI to the program offices in order to prepare them for the transition away from data sharing agreements (DSAs) for WRNMMC and FBCH researchers. This included developing a new data request template for WRNMMC and FBCH researchers to use when requesting data from the program offices. Creating a standard template allows the program offices to be confident that the required regulatory compliance reviews have been completed prior to releasing the data. The DHA Privacy Board looks forward to continuing to support the implementation of the AI, including responding to ad hoc inquiries and providing ongoing technical assistance.

Through its continued work on the Streamlining Initiative, the DHA Privacy Office determined in early FY16 that some DoD components were not in a position to take on all of the responsibilities for data sharing compliance, including both HIPAA and non-HIPAA reviews. For that reason, the focus for the remainder of FY16 for DoD components, other than the NCR-MD, was focused on enhancing HIPAA compliance and helping IRBs and research oversight programs to learn how to properly conduct HIPAA reviews and how to incorporate them into existing Common Rule reviews.

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.

- In FY16, the Board was asked to provide guidance regarding the use of online authorizations. The mobile and dispersed nature of the military community is one of the challenges researchers face in attempting to obtain signed authorizations. A researcher



contacted the Board because he was interested in using online authorizations in order to reach remote study participants. The researcher was interested in whether online authorizations are an accepted practice and what requirements would need to be met to allow their use. Board Support Staff found that online authorizations are increasingly common, allowing researchers to obtain authorizations from participants that they previously may have not been able to obtain them from. The potential challenge posed by online authorizations is the requirement that authorizations be signed by the participant, however, digital signatures offer an opportunity for participants to sign electronically. Digital signatures may not be possible for all study populations as technical savvy and resources vary, however, digital signatures are common in the MHS due to the Common Access Card (CAC), which every servicemember has and which allows for a high-degree of certainty.

In order to document its determination to allow digital signatures, the Board determined that when this or future researchers seeking to use online authorizations come to the Board, they will be asked to complete an application for an altered authorization. HIPAA allows for altered authorizations in situations where it is possible and practicable to obtain authorizations from each participant but is not possible or appropriate to meet all of the requirements for a compliant authorization (for example, when explaining the purpose of a study could influence the results). The applications document what deviation the researcher is requesting and for what reasons. Using the altered authorization application allows the Board to document when it determines that the online authorization and digital signature are appropriate. The Board is heartened by the researcher's interest in online authorizations, as opposed applying for a waiver of authorization, as this demonstrates a growing understanding of the importance of authorizations and the presumption that authorizations should be obtained. The Board hopes to see other researchers consider the possibility of online authorizations for studies with dispersed research populations.

- The Board is also engaged in the Precision Medicine Initiative through broad discussions at its quarterly meetings and through inquiries received related to the Million Veteran Program (MVP). MVP is a VA research program whose goal is to partner with veterans to create one of the world's largest medical databases by collecting blood samples and other health information from one million veterans for research on diseases and military-related illnesses. The MHS is working with VA to introduce active duty servicemembers to the study. Support staff provided HIPAA-related feedback on the memorandum of agreement, research protocol, and authorization template and, through the Precision Care Advisory Panel (PCAP), will remain engaged and available to provide guidance on HIPAA-related issues as the relationship between the MHS and VA develops.





- 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 statements 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.
 - The stand-up of eIRB, the MHS’s new electronic protocol management system, provided an opportunity to integrate the protocol application section that was developed as part of the Streamlining Initiative into the MHS-wide protocol application. The protocol application section collects the information necessary for reviewers to complete the Data Determination Guide. To help researchers feel confident when completing the HIPAA-related section of the protocol application, it includes contact information for the DHA Privacy Board and MHS Data Experts. MHS Data Experts can provide guidance on de-identification, encryption, data quality, minimum necessary, and similar topics. As eIRB rolls out to more and more installations, the Board expects to continue to see an increase in requests for consultations with the data experts.
 - The DHA Privacy Board monitors developments in the research community, including proposed changes to the Common Rule. Board support staff attended the National HIPAA Summit and the National HIPAA Summit Special Fall Session, and reported back to the Board on hot topics related to research, Big Data, and non-covered entities.
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Researched and collaborated on HIPAA and Common Rule protections required when developing and using research repositories and data banks for the purposes of future research

With the increased interest in and development of research repositories and databases, as well as the desire to use data for a variety of future research purposes, the Board assessed both HIPAA and the Common Rule to ensure a full understanding of the protections that apply when collecting and using data for future research purposes. Privacy Board support staff developed an internal memo to help address these increasing inquiries. HIPAA provides limited protection through the requirements for authorizations that contemplate future research purposes and/or through waivers of authorization approved for either putting PHI into or taking PHI out of a repository or data bank for future research purposes. Waivers are increasingly used for this purpose, although the Board hopes to create awareness moving forward about the preference for using authorizations when there is the desire to use data for multiple future research purposes. The Board will continue to monitor proposed changes to the Common Rule and their potential impact on the use of data clearinghouses for research initiatives.

Ms. DeShields and CAPT Eckert, DHA Human Research Protection Program Manager and DHA Privacy Board member, along with Board support staff, also consulted with DHA's General Counsel to further discuss the emerging issues with respect to using repositories and data banks for future research purposes. In addition to considerations under HIPAA and the Common Rule, the Board will also need to take into account any positions that the DHA may wish to ultimately take with regard to the growing interest in research repositories and data banks within the DoD.

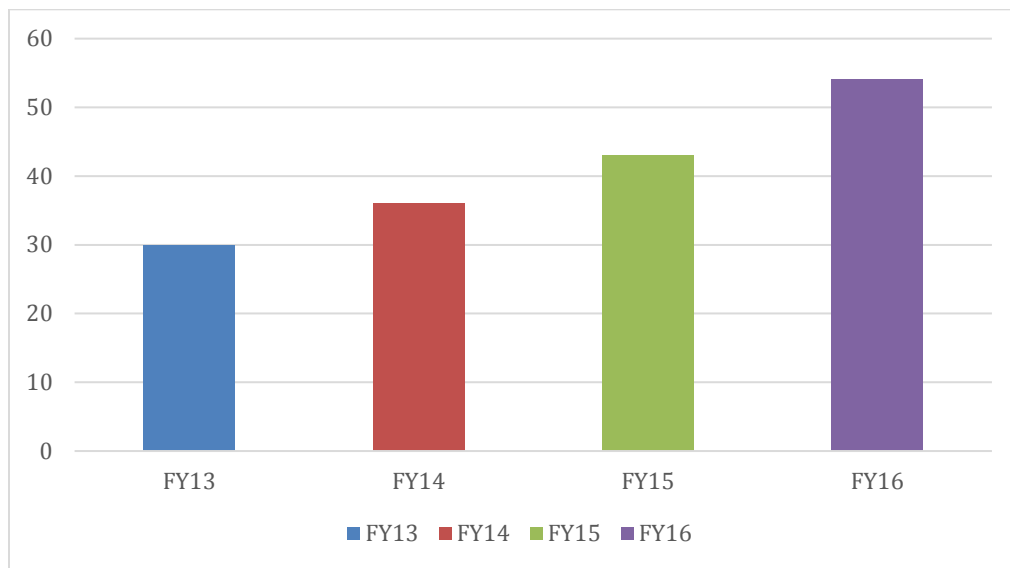
DHA Privacy Board Trends

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 Board saw a continued increase in the number of IRB Waivers obtained in FY16. The total number of reviews performed by the Board has continued to grow each year, with a 26% increase in the number of reviews performed from FY15 to FY16.

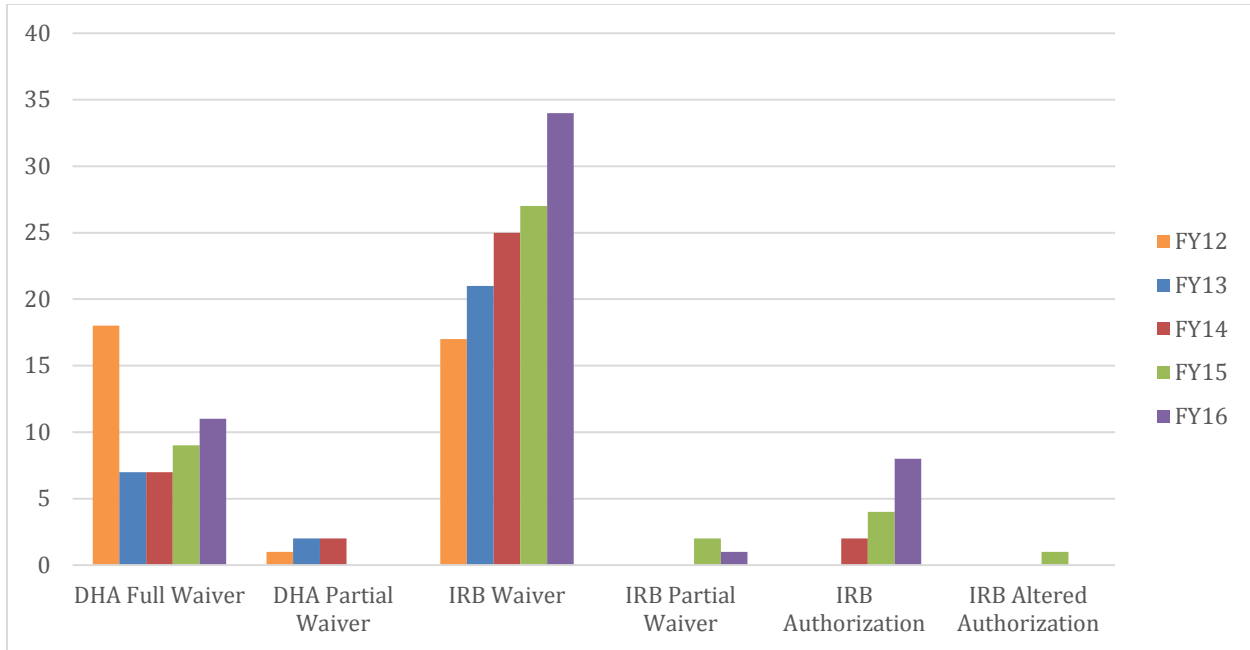
As in every past year, the total number of reviews performed by the Board increased in FY16. The increase in the number of reviews is due in large part to the Board’s continuing outreach across the MHS and a greater understanding of the requirements for obtaining DHA data for research purposes.

Figure 7: Total Number of Reviews Each Year



During FY16, IRB Waiver reviews continued to increase and, continuing last year’s new trend, the number of Board Full Waivers and IRB-approved Authorizations also increased. The increase in the number Authorizations is a heartening shift, meaning IRBs are truly operating from the assumption that Authorizations should be obtained from each participant.

Figure 8: Types of Submissions in FY12, 13, 14 and 15



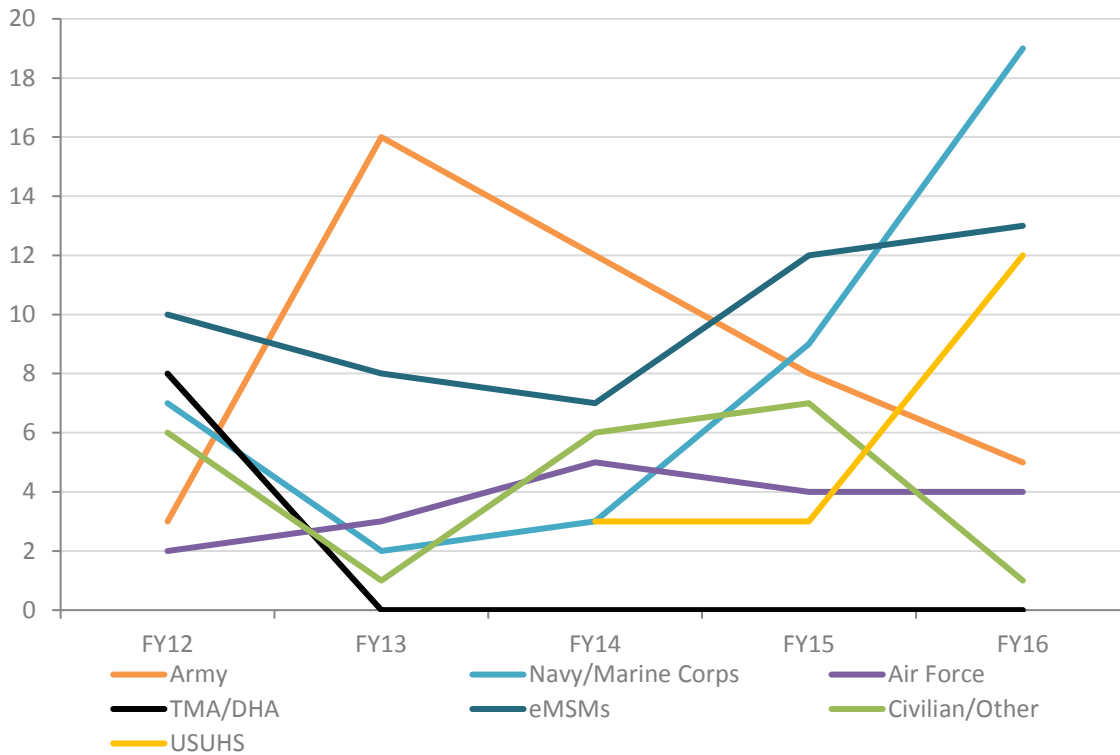
The types of organizations served by the DHA Privacy Board will change over time as streamlining efforts are implemented for HIPAA compliance

During FY16 there continued to be a general increase in participation from the Services and eMSMs, particularly eMSMs and the Navy. The Board believes that the increase in participation from the Navy is due to increased outreach to Navy organizations, particularly Naval Medical Center San Diego, and Navy-led eMSMS, specifically the Tidewater eMSM. The other significant increase came from USUHS, which the Board believes results from providing the HIPAA Privacy Rule Compliance Training to its IRBs and research oversight personnel. As more organizations receive the HIPAA Privacy Rule training, more will direct their researchers seeking DHA data to the Privacy Office.

TMA/DHA submissions have flat-lined over the last few fiscal years because of the stand-up of the NCR eMSM, of which DHA is part. The Board anticipates drop in the number of NCR-submissions in the coming years because of the implementation of the Streamlining Initiative at WRNMMC and FBCH, the largest NCR submitters. Through DHA AI-83, WRNMMC and FBCH handle their own HIPAA Privacy Rule reviews without the need for administrative or secondary

review by the DHA Privacy Office. It is not surprising, at least at the current time, that the Board is not seeing submissions from these programs, although the Board does continue to provide technical assistance as they implement their own HIPAA review programs and the standard HIPAA templates.

Figure 9: Submissions from Each Type of Center & Institution Served in FY12 – FY16⁸



The DHA Privacy Board continues to provide efficient HIPAA compliance reviews; 31 of 54 (57%) FY16 reviews were completed in one day

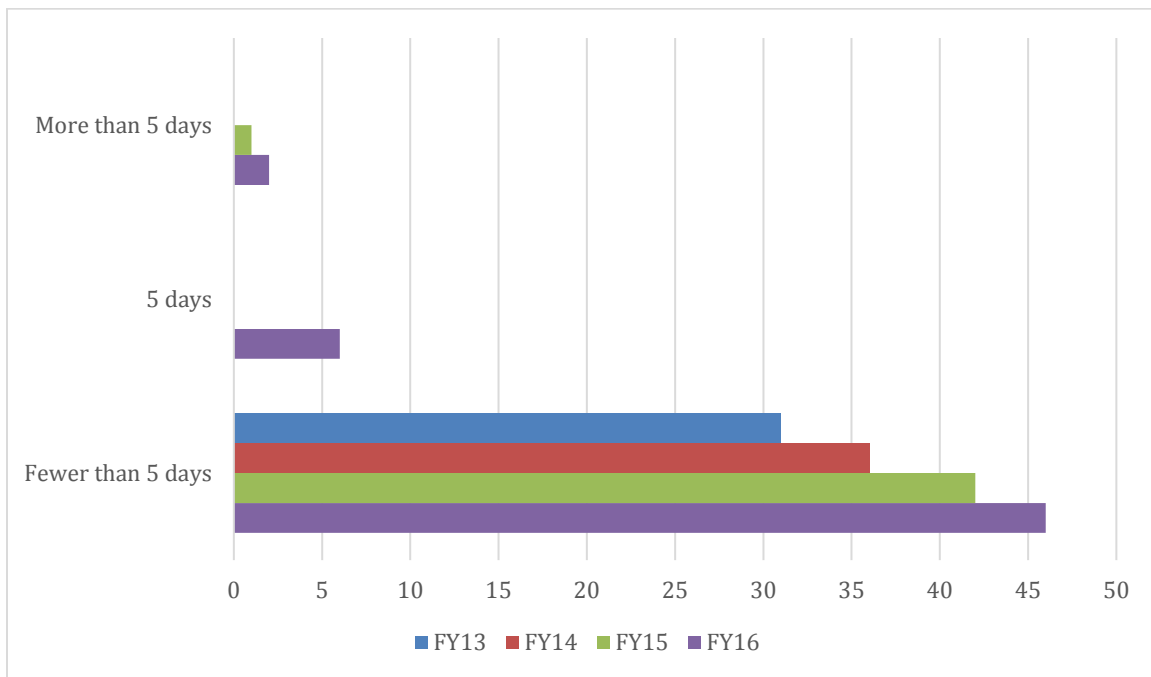
There continues to be an increase in the number of reviews taking only one day to complete from the date of perfection; in FY16 the review of 31 of the 54 submissions to the Board were completed

⁸ 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, USUHS submissions are now 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.

in one day. The increase in submissions from organizations who are unfamiliar with the DHA Privacy Board process resulted in more time consuming, but still efficient reviews.

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 10: Continued Efficient Review Times

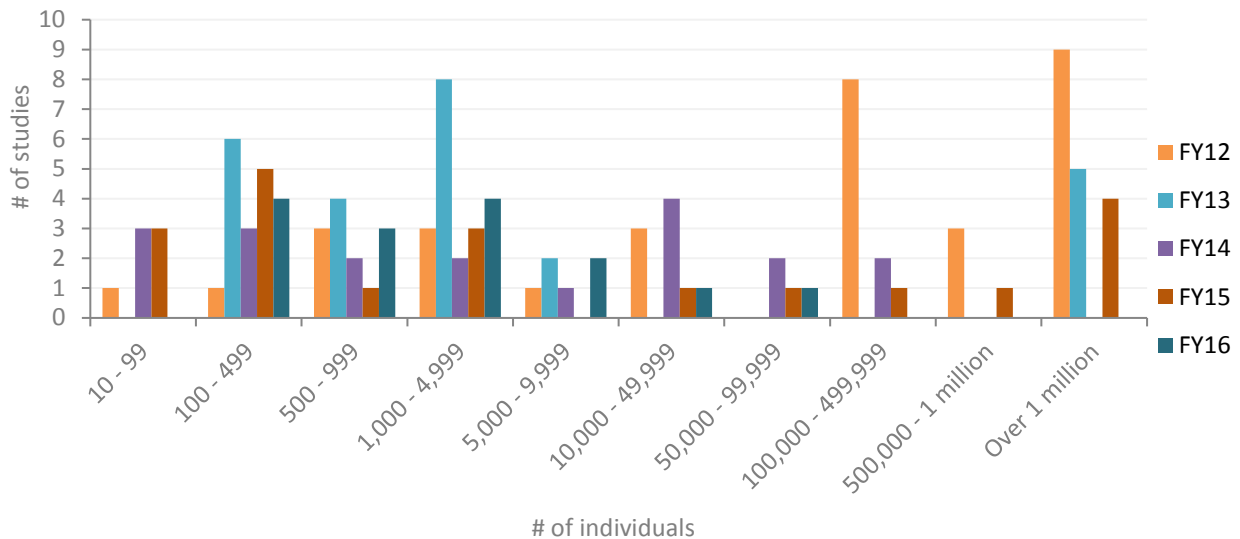


The DHA Privacy Board tracks, to the extent possible, the number of individuals whose records are requested for a research study

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 now uses the IRB Waiver Certification template and therefore does not receive any supplemental information, including the number of participants, for its most common type of review (for example, 34 out of

54 reviews in FY16 were for IRB-approved waivers). In FY16, 15 of the 54 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 11: Number of Individuals' Records Requested



There was not sufficient data regarding the number of research participants in FY16 and, as such, the Board is not able to make a definitive statement as to trending in this regard. However, through inquiries made to the Data Evaluation Workgroup (DEW) and DHA Privacy Board throughout FY16, it appears as though continued efforts are being made by researchers to narrow their access to only the minimum number of individual records necessary for the study. Through training and guidance, the Board continues to create awareness in the research community about the importance and value of limiting data requests to the minimum necessary in order to reduce the overall privacy and security risks to research participants.

Future Vision for the Privacy Board

The DHA Privacy Board seeks to promote health research to support our military and ensure the privacy protections provided under HIPAA are applied to safeguard the privacy interests of our military and their families



In recognition of this vision, the DHA Privacy Board strives to support and enhance research activity throughout the MHS, working to reduce any perceived burdens that that HIPAA Privacy Rule places on researchers through the development of tools, such as the IRB Waiver Certification template and other standard HIPAA templates, and strategies, such as the Streamlining Initiative. The distribution of the standard HIPAA templates and the Streamlining Initiative reflect an effort to integrate HIPAA into existing Common Rule reviews, increasing compliance without increasing barriers.

In FY16, the Board increased its outreach activities to both research oversight professionals and DoD IRBs through the HIPAA Privacy Rule Compliance Training, as well as ad hoc advice throughout the year. In FY17, the Board will continue its dialogue with DoD IRBs and the research community and will focus on expanding the HIPAA Privacy Rule Compliance training to even more audiences by developing an online training module. The DHA Privacy Board will also share its best practices, as well as best practices from other organizations, in establishing and maintaining HIPAA Privacy compliance programs for research studies, and help DoD IRBs adopt consistent 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 and the Precision Medicine Initiative, 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 to socialize and expand HIPAA Privacy Rule compliance across the MHS
<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"> • 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
<ul style="list-style-type: none"> • Provide research-related HIPAA privacy expertise to the MHS researcher community
<ul style="list-style-type: none"> • Engage in DHA’s Precision Medicine Initiative-related activities to provide HIPAA privacy expertise



- 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 the Common Rule and 42 CFR Part 2.
- Develop an online training for the HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards to address turnover in IRB membership and research oversight programs
- 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 FY16

Centers and Institutions Served by the DHA Privacy Board in FY16	
Army	5 Submissions
William Beaumont Army Medical Center (WBAMC)	
US Army Research and Material Command (USARMC)	
Walter Reed Army Institute of Research (WRARI)	
San Antonio Military Medical Center (SAMMC)	
Brooke Army Medical Center (BAMC)	
Air Force	4 Submissions
Air Force Research Lab (AFRL)	
Air Force Medical Operations Agency (AFMOA)	
Navy/Marine Corps	19 Submissions
Naval Health Research Center (NHRC)	
Bureau of Medicine and Surgery (BUMED)	
Naval Medical Center San Diego (NMCSD)	
Navy Research Medical Center (NRMCC)	
HQMC Behavioral Health Branch, Quantico	
eMSMs	13 Submissions
Naval Medical Center Portsmouth (Tidewater eMSM)	
Walter Reed National Military Medical Center (WRNMMC) (NCR eMSM)	
Tripler Army Medical Center (Hawaii eMSM)	
Madigan Army Medical Center (Puget Sound eMSM)	
Armed Forces Health Surveillance Branch (AFHSB) (NCR eMSM)	
USUHS	12 Submissions
Uniformed Services University of Health Sciences (USUHS)	
Civilian/Other	1 Submission
Defense Manpower Data Center (DMDC)	

Appendix B: The Research Data Sharing Review Process

Determining the Type of Data Requested

Prior to DHA Privacy Board review, 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 Data Evaluation Workgroup (DEW), which was established 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: 1) De-identified data; 2) Personally Identifiable Information (PII) excluding PHI; 3) Limited data set (LDS); or 4) PHI greater than a LDS. Definitions of these data types are 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 a 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 a LDS, the Board will contact the PI and Sponsor and begin the HIPAA Privacy Rule review process.

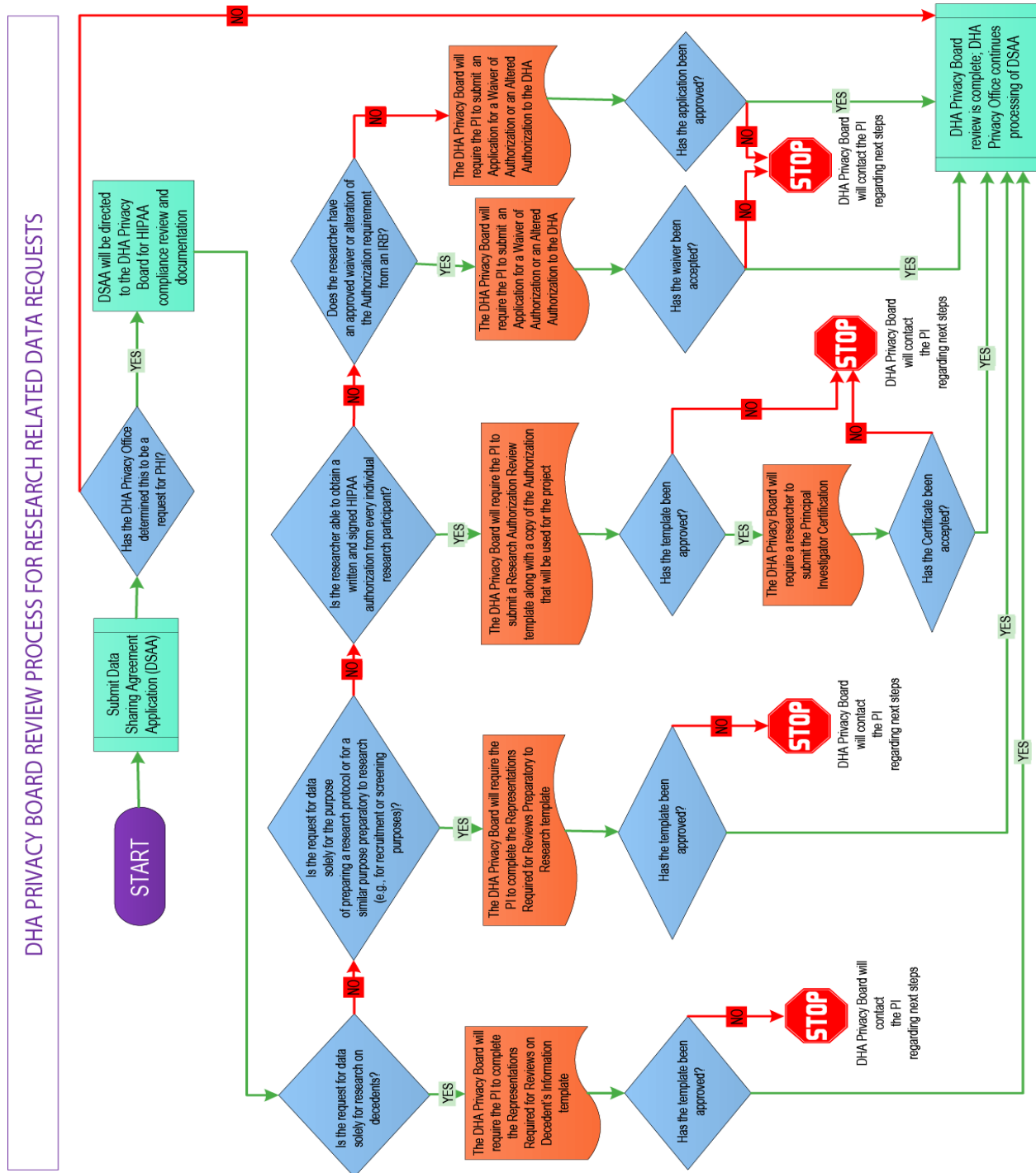
Types of Privacy Board Reviews

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 an administrative Privacy Board review, or whether a full 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 prerequisites to the Board and the Board's review process 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 of 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 living individuals who are the subject of research studies. Consideration is given to how various aspects of the research study (including privacy, confidentiality, data collection, data maintenance, and data retention) impact physical, emotional, financial, and informational harms	Protect living and deceased individuals against informational harm while allowing the necessary flow of health information with specific rules pertaining to the privacy and security of PHI. Deceased individuals are protected for 50 years following date of death
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	Institutional Review Boards (IRBs)	IRBs or HIPAA Privacy Boards
Exemptions	The Human Research Protection Official (HRPO) and/or IRBs can exempt certain research studies from IRB review in accordance with 32 CFR 219.101(b)	None. All research studies seeking PHI from a HIPAA CE, including the MHS, must comply with the HIPAA Privacy Rule



Appendix E: Acronym List

AI	Administrative Instruction
CAC	Common Access Card
DEW	Data Evaluation Workgroup
DSA	Data Sharing Agreement
DSAA	Data Sharing Agreement Applications
DHA	Defense Health Agency
DoD	Department of Defense
eIRB	MHS's Electronic Protocol Management System
eMSM	Enhanced Multi-Service Market
FBCH	Fort Belvoir Community Hospital
FY	Fiscal Year
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
LDS	Limited Data Set
MHS	Military Health System
MTF	Military Treatment Facility
MVP	Million Veteran Program
NCR MD	National Capital Region Medical Directorate
NPRM	Notice of Proposed Rulemaking
OGC	Office of General Counsel
PCAP	Precision Care Advisory Panel



DHA PRIVACY AND CIVIL LIBERTIES OFFICE

Defending Privacy

PII	Personally Identifiable Information
PHI	Protected Health Information
TMA	TRICARE Management Activity
USUHS	Uniformed Services University of the Health Sciences
WRNMMC	Walter Reed National Military Medical Center
VA	Department of Veterans Affairs

