Military Health System
DHA Privacy & Civil Liberties Office

DHA PRIVACY BOARD ANNUAL REPORT

FISCAL YEAR 2018

NOVEMBER 2018

Defense Health Agency

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Message from the Defense Health Agency (DHA) Privacy Board Co-Chairs

On behalf of the DHA Privacy Board (also referred to as the "Board"), we are pleased to present the Fiscal Year 2018 (FY18) DHA Privacy Board Annual Report. The Board continued to serve as a valuable resource to the research community and the Military Health System (MHS) during FY18 by providing clear guidance regarding the interpretation, application, and implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to research studies and initiatives.

During FY18, the Board continued to enhance HIPAA compliance across the MHS through the launch of its online training course, *HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards*, on Joint Knowledge Online (JKO) and the distribution of updated DHA HIPAA research templates that correspond with the training content. The Board continues to coordinate with the Research Regulatory Oversight Office (R2O2) to assist with updating the data section in the Protocol Application on the electronic protocol management system (eIRB) and with ensuring the revised HIPAA research templates are uploaded on eIRB for use across the MHS research community. The Board is also prepared to finalize the updates to the DHA Privacy Board webpages after the release of the soon-to-be published Department of Defense (DoD) Manual, *Implementation of the HIPAA Privacy Rule in DoD Health Care Programs* (DoD Manual 6025.18), which incorporates the HIPAA Omnibus provisions and the DoD hybrid entity structure and will replace the current *DoD Health Information Privacy Regulation* (DoD 6025.18-R). These efforts reaffirm the DHA Privacy Board's ongoing commitment to educate the research community and to standardize HIPAA Privacy Rule reviews throughout the MHS.

As predicted in the FY17 annual report, research repositories became a focal point for the DHA Privacy Board in FY18. Due to concerns about the proliferation of repositories throughout the MHS, the DHA Privacy Board collaborated with DHA's Strategy, Planning, and Functional Integration Directorate (J-5) and Health Information Technology Directorate (J-6) Enterprise Intelligence and Data Services (EIDS) Program Management Office (PMO) to develop a draft DHA-Procedural Instruction (DHA-PI), *Use of Defense Health Agency's (DHA's) Enterprise Data Warehouse as the Primary Source of DHA Data and the Establishment of Centralized Approval and Monitoring of Repositories* (the DHA Enterprise Data Warehouse and Repository Policy). This draft policy addresses the general use of DHA data through virtual access to the DHA Enterprise Data Warehouse and focuses on the requirements for creating and maintaining a repository outside of the data warehouse.

Although the need for this policy remains urgent, after addressing compliance concerns related to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system, the immediacy of the repository issue required the Board to implement procedural mechanisms of its own. To ensure HIPAA compliance reviews are conducted on DHA data requests where the requestor intends to put the data into a repository and to disclose the data from the repository for future research, the Board developed a Research Repository Template (RRT) to help identify and track repositories. The use of the RRT aids in HIPAA compliance, but the high number of requestors putting data into repositories has caused backlog both on Board submissions and on Data Evaluation Workgroup (DEW) considerations of the type of data being put into the repository and disclosed from the repository for future research. To resolve the backlog issue, the Board developed an information paper explaining to DHA leadership the acute concerns raised by

repositories and seeking leadership's support for addressing the compliance issues created by the number of research repositories. The information paper provides recommendations, including delegating to select DoD Institutional Review Boards (IRBs) the HIPAA compliance reviews of DHA data, which the IRBs can conduct in conjunction with the IRB reviews under the Federal Policy for the Protection of Human Subjects (known as the "Common Review"). The number of selected DoD IRBs able to independently perform HIPAA reviews on research studies using DHA data without DHA Privacy Board administrative review will increase over time, as more DoD IRBs are trained and delegation is formally arranged and documented.

Finally, the DHA Privacy Board continued to provide in-depth HIPAA Privacy Rule subject matter expertise and guidance on issues related to the privacy of research subjects through responses to requests for assistance, meetings, presentations, and online materials. The Board also continued to meet quarterly to review the status of compliance reviews and to address the evolving trends in the DHA and research.

In FY19, the DHA Privacy Board will continue outreach and compliance efforts across the MHS including: finalizing the DHA Enterprise Data Warehouse and Repository Policy; defining the DHA Privacy Board's role under the National Defense Authorization Act (NDAA), including potentially changing its role to auditing and monitoring IRB HIPAA compliance reviews after they have been trained and delegated the authority to provide review of DHA data; finalizing coordination with R2O2 to ensure the DHA HIPAA research templates are included on eIRB; developing a training to assist researchers using eIRB with understanding the HIPAA Privacy Rule requirements and when and how to use HIPAA research templates on eIRB; collaborating to update the DHA Privacy Board webpages after the publication of DoD Manual 6025.18; and updating the DHA Privacy Board standard operating procedure (SOP) to incorporate the new changes in procedures.

We look forward to your continued support and collaboration.

Rahwa Keleta
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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. The Board also provides in-depth HIPAA Privacy Rule subject matter expertise and guidance on issues related to the privacy of research subjects through technical assistance, meetings, presentations, and online materials. This report captures the FY18 operational and outreach accomplishments of the DHA Privacy Board and tracks operational trends.

Highlights of the DHA Privacy Board's operational and outreach accomplishments include:

- Completed reviews of 40 submissions requesting DHA data, through which the DHA Privacy Board protected the privacy of beneficiaries' data contained in MHS systems in strict adherence with HIPAA Privacy Rule standards. These reviews included 13 DHA Privacy Board Waivers of Authorization, 15 IRB-approved Full Waivers of Authorization, 3 IRB-approved Partial Waivers of Authorization, 6 IRB Authorization Templates, and 3 Non-DHA IRB Waiver Certifications.

- Achieved an average review completion rate of 1.2 business days from the date of perfection, with 22 reviews completed on the same day the submission was perfected and 10 reviews taking only one day.[1]

- Launched the online course, *HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards*, along with corresponding updated HIPAA research templates, to address the increased demand for HIPAA Privacy Rule training for DoD IRB members and staff in offices overseeing human research protection and to ensure standardized compliance documentation across the MHS.

- Facilitated collaboration with J-5 and J-6 to create a draft DHA-PI to address the general use of DHA data through a data warehouse maintained by J-6, the tracking and approval of repositories by J-5, and the process for compliance review by the DHA Privacy Office.

- Addressed concerns raised by questions from the U.S. Medical Research and Materiel Command regarding the FITBIR repository, closed without incident an investigation into possible violations of

- [1] Although the Board experienced a backlog due to the need to conduct additional data evaluations and compliance reviews associated with data going into repositories, the time for "perfection" (at which point a submission is ready for HIPAA review) remains the date on which the Board receives all necessary documentation for conducting the compliance review and making a determination. One of the issues with the compliance reviews associated with the data repositories is the amount of time it takes to work with researchers to get the correct documentation for getting a data evaluation from the data experts on the data going into and out of the repository and for making the final HIPAA compliance determination related to the repositories. The Board must wait for both the data determination from the data experts as well as the researcher's submission of the required compliance documentation before the Board can make a final determination. Furthermore, agreements often need to be reached between the principal investigator (PI) or organization hosting the repository and the DHA Privacy Office and documented within the RRT and/or Data Sharing Agreement (DSA) prior to concluding the HIPAA review.

DHA Privacy Office DSAs due to DHA protected health information (PHI) being placed into the FITBIR, and developed and communicated to the Walter Reed National Military Medical Center (WRNMMC), as well as the DHA Privacy Office Data Sharing team and data experts, necessary corrective processes for reviewing DHA data being put into and used or disclosed from repositories.

- Developed the RRT and DHA Privacy Board repository log to track data requests involving existing and newly established research repositories and to ensure compliance reviews of DHA data being put into the repositories as well as DHA data being disclosed from the repositories for future research purposes.

- Through the use of the RRT to identify DHA data going into research repositories, resolved compliance issues through the creation of terms and conditions for permitting DHA PHI – limited data set (LDS) and PHI greater than an LDS - to be put into a research repository and to be used and disclosed from the repository with the intent that the terms and conditions be standardized to meet compliance requirements for any well-established repositories that collect DHA PHI and uses and discloses the PHI for future research.

- Worked with R2O2 to update the data section of the new Protocol Application on eIRB and to upload the recent versions of the HIPAA research templates that incorporate the hybrid entity structure requirements for data determination and clarify the compliance review requirements in the HIPAA Authorization Checklist and in the distinction between the review of an application for a waiver of authorization and an application for an altered authorization.

- Developed an information paper asking for DHA leadership support and guidance on compliance issues raised by the rapid growth of research repositories, including an explanation of the challenges of identifying and containing the creation of repositories, the difficulties faced by the DHA Privacy Office in ensuring proper compliance reviews of data going into the repository and of data being used and disclosed from the repository, and recommendations for addressing the issues related to research repositories.

- Provided in depth HIPAA Privacy subject matter expertise to researchers in a variety of areas.

Trends in FY18 DHA Privacy Board submission data include:

- Experienced a small increase in submissions from FY17.

- Continued to maintain efficient review times with 22 of the 40 submissions in FY18 completed on the same day as perfected and 10 reviews completed within one day of perfection. All reviews were completed well within the five-day goal set forth in the DHA Privacy Board's SOP.

1. Completed reviews of 40 submissions requesting DHA data, protecting the privacy of beneficiaries' data contained in MHS systems in strict adherence to the HIPAA Privacy Rule standards. (See page 7)

2. Served 21 different health care and research-related centers and institutions with HIPAA compliance reviews for Air Force, Army, Navy, U.S. Marines, Uniformed Services University of the Health Sciences (USUHS) and Civilian Sites. (See page 8)

3. Achieved an average review completion rate of 1.2 business days from the date of perfection[2].(See page 8)

4. Developed the RRT to track data requests involving existing and newly established repositories to ensure appropriate compliance reviews are conducted prior to any use or disclosure of such data. (See page 9)

5. Continued to advance the work of the DHA Privacy Board through quarterly meetings and provided a platform for discussion to guide and enhance the DHA Privacy Board's mission. (See page 10)

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

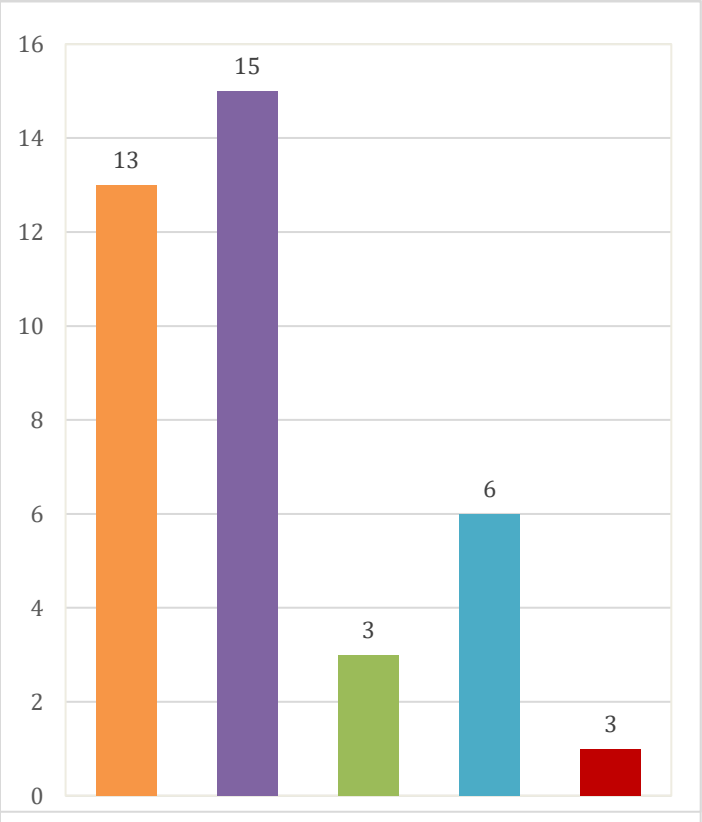
DHA Privacy Board Operations and Process Improvements Accomplishments

Completed reviews of 40 submissions requesting DHA data, protecting the privacy of 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 PHI of MHS beneficiaries from systems managed by the DHA to ensure compliance with the HIPAA Privacy Rule and the DoD 6025.18-R. The DHA Privacy Board maintains templates that request the information necessary to conduct HIPAA compliance reviews and that guide the reviewers through making and documenting their findings. Details on the DHA Privacy Board's review process can be found in Appendix C.

In FY18, the DHA Privacy Board received and completed reviews of 40 submissions, including 13 DHA Full Waivers of HIPAA Authorization, 15 IRB Full Waivers of HIPAA Authorization, 3 IRB Partial Waivers of HIPAA Authorization, and 1 DHA Full Waiver of Authorization denial. The submission that was denied for a DHA Full Waiver of Authorization is the first in DHA Privacy Board history and involved a researcher seeking a waiver to retroactively mitigate a defective authorization where interaction with the participants would continue throughout

Figure 2: Number of Types of Submissions



- **DHA FULL WAIVER:** Based on review of an application and specific circumstances, the need for individual Authorizations was waived for the entire research study.
- **IRB FULL WAIVER:** Based on an administrative review, the DHA Privacy Board support staff confirmed that all required regulatory criteria for a full waiver were documented by the IRB.
- **IRB PARTIAL WAIVER:** Based on an administrative review, the DHA Privacy Board support staff confirmed that all required regulatory criteria for a partial waiver were documented by the IRB.
- **AUTHORIZATION TEMPLATES:** Based on administrative review, the DHA Privacy Board support staff confirmed that all regulatory required statements and elements were present in the authorization template.
- **NON-IRB FULL WAIVER CERTIFICATION:** Based on an administrative review, the DHA Privacy Board support staff confirmed that all required regulatory criteria for a full waiver were documented by the approving entity.

the study. The DHA Privacy Board determined that due to the small number of study participants that required re-authorization and the fact that there would be interaction with each participant throughout the study, a waiver would be inappropriate. The denial reflects the DHA Privacy Board's commitment to comply with regulatory requirements and the specific needs of each study.

Served 21 different health care and research-related centers and institutions with HIPAA compliance reviews for Air Force, Army, Navy, U.S. Marines Corps, USUHS, and Civilian sites

During FY18, the DHA Privacy Board served 21 different research centers and institutions from the Army, Navy, Air Force, USUHS, and Civilian sites, with USUHS submitting the highest number of requests. The DHA Privacy 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 DHA Privacy Board provided HIPAA guidance and responded to research-related inquiries. The DHA Privacy Board tracks centers and institutions by Service, USUHS, or Civilian and Partnership categories. See Appendix B for a complete listing of specific research centers and institutions.

Figure 3: Number of Submissions by Type of Center & Institution in FY18

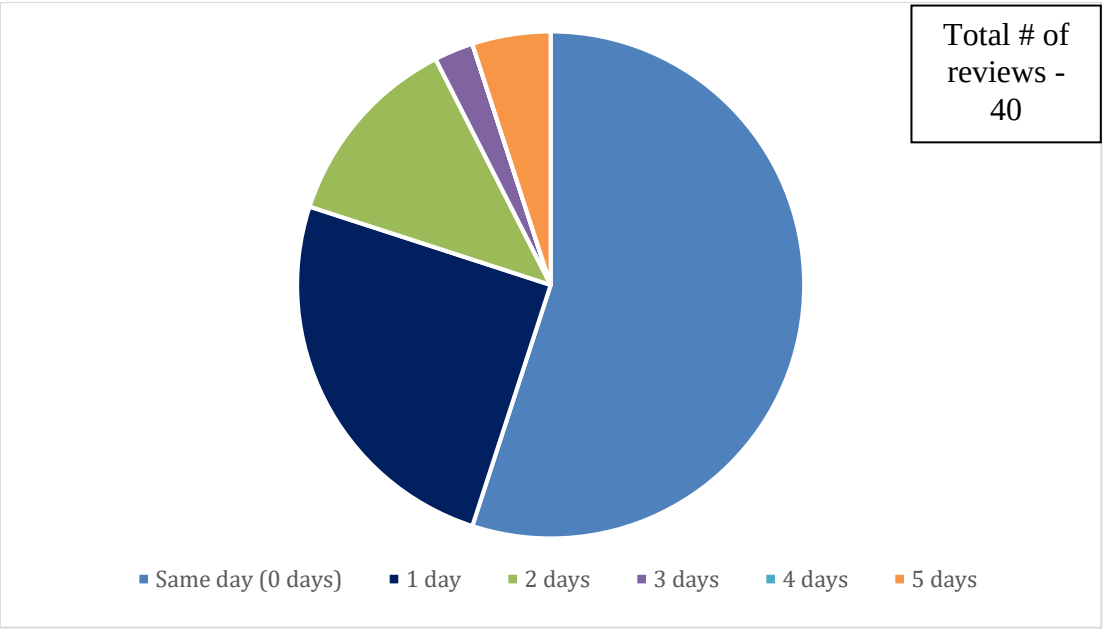
Type of Center/Institution	Number of FY18 Submissions
Air Force	4
Army	6
Navy/Marine Corps	12
USUHS	12
Civilian and Partnerships	6

Achieved an average review completion rate of 1.2 business days from the date of perfection

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

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. In FY18, all submissions were reviewed in 5 days or less, which meets the Board's internal goal. Most reviews, 32 out of 40, were completed in one day or on the same day the review was perfected.

Figure 4: FY18 Submission Review Times



Developed a RRT to track data requests involving existing and newly established repositories and to ensure compliance reviews where appropriate.

To address the regulatory implications posed by the establishment and maintenance of research repositories, the DHA Privacy Board developed the RRT to assist in determining whether the researcher receiving DHA PHI or a LDS for a research study intends to put the data in a research repository for future research. The RRT defines the term "repository" as either: 1) the physical or virtual collection and storage of data for future use and disclosure, or 2) any collection of data without an explicit plan to destroy the data when the purpose for which the data was collected ends. The definition is purposefully broad to capture all mechanisms of how and where data are collected and stored for future research use. A repository may include, but is not limited to, copies of a data set and small data collections created by individuals in a document, such as an Excel spreadsheet, or in a program or application.

The RRT begins with the question: "Do you intend to disclose the DHA data received for the purposes of a research study into any type of research repository?" If the PI answers no, then the PI merely initials assurances and signs, indicating that no data will be placed in a research repository. The PI then signs the RRT. If the PI answers yes, indicating an intent to put DHA data into a repository for future research, then the researcher must provide additional information, such as: the name of the repository; what data elements will be placed into the repository; who will have access to the data; and under what authority data can be accessed or disclosed from the repository. The information provided in the RRT helps the Board to ensure that the use and disclosure of the DHA data meets the requirements of HIPAA.

The DHA Privacy Board decided not to use the RRT to identify whether researchers who receive de-identified data or personally identifiable information (PII) that is not PHI intend to place the data into a research repository. Although the Board would like to track all new or existing repositories, repositories with PII or deidentified data do not have to comply with HIPAA. Requiring researchers to complete the RRT would add an unnecessary burden on the researcher and create more delay in the DHA Privacy Board and Data Sharing Agreement Application (DSAA) approval processes. The draft DHA-PI, however, considers a streamlined means of inventorying all repositories, including those used for purposes other than research and those containing de-identified data and PII excluding PHI.

Continued to advance the work of the DHA Privacy Board through quarterly meetings and provided a platform for discussion and expertise to guide and enhance the DHA Privacy Board's mission

The DHA Privacy Board held quarterly meetings throughout FY18. Each meeting began with an operations status update, including a review of submission metrics and pending research-related DSAAs. Support staff reviewed the technical assistance requests and consultations with researchers and IRBs from the previous quarter. The meetings included updates on outreach efforts.

DHA Privacy Board meetings also included presentations and open discussion about topics and articles related to issues that impact the Board's data operations and review procedures. In FY18, presentations and discussions included:

- U.S. Department of Health and Human Services (HHS) Office for Civil Rights' (OCR) ongoing response to the opioid crisis, while implementing the 21st Century Cures Act.
- HHS Symposium: "Data Privacy in the Digital Age," October 26, 2017, Washington, DC.
- Briefing on the Federal Privacy Summit, December 12, 2017, Washington, DC.

- HIPAA Research-Related Clarifications: Remote Access and Future Use Authorizations of Protected Health Information (National Law Review Article).

- The 27th National HIPAA Summit, March 27 – 28, 2018, Arlington, Virginia.

- The FITBIR - Memorandum of Agreement between DHA and U.S. Army Medical Research and Materiel Command/National Institutes of Health (NIH).

- NIH Briefing on the *All of Us* Research Program National Launch, April 3, 2018.

- OCR Guidance on HIPAA and Individual Authorization of Uses and Disclosures of PHI for Research, issued on June 14, 2018.

- Federal Register Notice Delaying the General Compliance Date for 2018 requirements under the Federal Policy for Human Research Protections (known as the "Common Rule" to January 21, 2019.

- New Guidance from the Food and Drug Administration on Using Electronic Health Records for Clinical Trials, July 2018.

- Precision Medicine Initiative and Precision Care Advisory Panel (PCAP), continuing updates on participation in the PCAP meetings.

Each quarterly meeting concluded with a discussion about the DHA Privacy Board's next steps and upcoming meetings or events of interest. The Board members continued to direct the efforts of the DHA Privacy Board and contributed to strategic research-related privacy considerations.

1. Launched the online course, *HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards*, along with corresponding HIPAA research templates, to address the increased demand for HIPAA Privacy Rule training for DoD IRB members and staff in offices overseeing human research protections. (See page 13)

2. Commenced the development of the DHA-PI regarding the DHA Enterprise Data Warehouse and Repository Policy in collaboration with J-5 and J-6. The DHA-PI establishes policy for the use of an enterprise data warehouse as the primary source for accessing data and for the creation of a centralized approval process for repositories that ensures regulatory compliance and the tracking of existing repositories. (See page 14)

3. Developed an information paper on research repositories addressing their rapid growth, challenges with identifying repositories and providing compliance reviews and processes for permitting PHI and LDS to be maintained in and used and disclosed from such repositories, and recommendations on centralizing the use of DHA data through a DHA data warehouse. (See page 15)

4. Continued to support the implementation of DHA Administrative Instruction (DHA-AI) 83, *Regulatory Reviews of Research Studies*, at the National Capital Region Medical Directorate Military Treatment Facilities (NCR-MD MTFs). (See page 16)

5. Provided HIPAA Privacy Rule subject matter expertise and guidance to DoD stakeholders and the research community to protect the privacy of research subjects within the MHS and to enhance HIPAA compliance. (See page 16)

Research Community Outreach Accomplishments

Launched the online course, HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards, to address the increased demand for HIPAA Privacy Rule training for DoD IRB members and staff in offices overseeing human research protections

Because of the increased demand for on-site training and webinars, the DHA Privacy Board launched its online comprehensive course, *HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards,* on JKO in November of FY18. The training can be found in the course catalog listed as: DHA-US096 HIPAA Privacy Rule Compliance Training for Institutional Review Boards and HIPAA Privacy Boards. The online training contains six modules and takes approximately four to five hours to complete. Modules may be taken separately; however, users are required to take the full training, following each module in sequential order, to obtain a certificate of completion. The online training course content is as follows:

- **Module 1**: reviews HIPAA basics and describes HIPAA's application within DoD.
- **Module 2**: highlights distinctions between the HIPAA Privacy Rule and the Common Rule.
- **Module 3**: discusses the HIPAA Privacy Rule provisions that impact research.
- **Module 4**: focuses on identifying various types of research data requests and demonstrates how to use the Data Determination Guides in conjunction with the Protocol Application Sections 10.0 through 10.11 to identify the type of data requested in a research study and the type of HIPAA Privacy Rule review, if any, required for a research study.
- **Module 5**: discusses the standard HIPAA research templates and how to conduct and document each type of HIPAA Privacy Rule review.
- **Module 6**: practices applying HIPAA concepts and reviewing submissions using the HIPAA research templates in several different scenarios.

As of this report's publication date, 731 human research protection staff and/or IRB members have completed the training. Although IRB training has experienced delays due to the number of IRBs and the size of the MHS, the DHA Privacy Board's long-term goal remains - that each IRB be equipped to conduct its own HIPAA compliance reviews and that the DHA Privacy Board eventually move to an oversight role, which would include auditing IRB HIPAA compliance reviews. To that end, the implementation of the NDAA changes the scope of the DHA Privacy Board's authority over IRBs and will assist with requiring IRBs to complete the IRB training and implementing the DHA standardized templates to perform HIPAA compliance reviews. In the interim, as the DHA Privacy Board moves to delegation of HIPAA compliance

reviews to the select DoD IRBs and to taking on an oversight role, the DHA Privacy Board will continue to provide reviews for those researchers whose IRBs do not conduct HIPAA compliance reviews. The Board will also continue distributing the HIPAA research templates to IRBs and researchers to help standardize HIPAA research compliance within the MHS.

In addition, the DHA Privacy Board will continue to track metrics on training attendance and encourage feedback and continue to update the training content, materials and templates as necessary. With the growth of research repositories, the Board plans to update the online training to include a new section on research repository compliance requirements and to develop a short training for researchers to help them understand the requirements for HIPAA compliance and the reviews and documentation needed.

Commenced the development of the DHA-PI regarding the DHA Enterprise Data Warehouse and Repository Policy in collaboration with J-5 and J-6.

As noted above, the FY17 annual report discussed the increasing interest in repositories. In FY18, the DHA Privacy Board began work with stakeholders to develop a high-level policy to centralize, monitor, inventory, and oversee the creation of new research repositories and the maintenance of existing research repositories. With the collaboration of J-5 and J-6, this DHA-PI became the DHA Enterprise Data Warehouse and Repository Policy. The intent of the policy is to require DHA data requestors to access DHA data through the DHA Enterprise Data Warehouse by being provided specific data sets on virtual "data islands." The data islands allow the requestor to access and manipulate the DHA data, but not download the data outside of the warehouse. In the event a data requestor requires a separate data repository outside of the warehouse, then the policy also provides the governance structure for requesting and getting approval for the creation of a new repository or maintenance of an existing repository. The policy requires the data requestor to get the necessary regulatory compliance reviews and approvals before obtaining DHA data. Finally, the DHA-PI requires that J-5 track all repositories within the DoD.

This policy is currently in draft form and has been temporarily stalled due to the need to immediately implement procedures addressing compliance requirements related to the numerous requests to put data into repositories and to disclose data from repositories. In FY19, the DHA Privacy Board will move to finalize the DHA Enterprise Data Warehouse and Repository Policy, as the need for it is increasingly evident.

Developed an information paper on research repositories addressing their rapid growth, challenges with identifying repositories and providing compliance reviews and processes for permitting PHI and LDS to be maintained in and used and disclosed from such repositories, and recommendations on centralizing the use of DHA data through a DHA data warehouse and delegating HIPAA compliance reviews to IRBs.

Although the FY17 Privacy Board report identified repositories as an area of interest to researchers, the extent of the issues surrounding research repositories became apparent after the development of the RRT as a corrective action in response to the concerns with the FITBIR repository. After becoming aware that researchers were placing DHA data into the FITBIR, the DHA Privacy Office investigated the DHA Privacy Board data requests and DHA research programs for studies that had put DHA data into FITBIR. The investigation revealed that some researchers who put DHA data into FITBIR never applied for a DSA to obtain DHA data, and other researchers who received approval from the DHA Privacy Office to obtain PHI for a particular research study did not disclose in the DSAA that the DHA data would be placed in a repository for future research purposes.

The resulting use of the RRT as a corrective action based on lessons learned from the FITBIR investigation revealed the previously unknown extent of research repositories containing DHA data. The DHA Privacy Office, in collaboration with the DHA Privacy Board, authored an information paper detailing the challenges associated with the research repositories as well as recommendations to address compliance concerns.

Challenges associated with the unfettered growth of research repositories include the following:

- Bypassing privacy and security compliance reviews and increasing DHA's exposure to risks and potential liability/penalties for regulatory non-compliance.

- Funding requirements for placing DHA data into a specified repository without an additional requirement for DHA privacy and security compliance reviews.

- Lack of IRB training on and understanding of HIPAA research compliance reviews and the failure to use HIPAA compliant templates, especially when DHA data will be maintained, used, and disclosed for future research studies.

- Misunderstanding HIPAA requirements for deidentified data, such that researchers claim that the data being put into the repository or taken out of the repository is deidentified, but the deidentification method does not meet HIPAA requirements.

- Mistakenly believing that an IRB approved protocol is sufficient for obtaining, using, and disclosing PHI, when in fact, a HIPAA compliance review and documentation is also needed.

Based on these identified challenges, the information paper provided the following recommendations to mitigate DHA's risk and potential liability:

- Utilize the DHA Enterprise Data Warehouse whenever possible to ensure that DHA data is only maintained and available on DHA accredited systems.

- Require that data requests for research purposes receive a HIPAA compliance review from a DoD IRB that has received DHA Privacy Office HIPAA training, uses DHA Privacy Office standardized templates, and is subject to DHA Privacy Office oversight through audits/assessments.

- Require that data requestors who cannot use the DHA Enterprise Data Warehouse seek approval for the creation or continued use or maintenance of a repository from J-5 and J-6 EIDS PMO and obtain approval from the DHA Cybersecurity Division for adherence to the DoD cybersecurity policy and the DoD Risk Management Framework.

The DHA Privacy Board will continue to collaborate with other DoD components to develop and effectively implement policy and processes to identify, centralize, review, and monitor all repositories, which have been established and maintained using DHA data.

Continued to support the implementation of DHA-AI 83, Regulatory Reviews of Research Studies, at the NCR-MD MTFs

DHA Privacy Board assisted WRNMMC in providing HIPAA compliance reviews by responding to several questions pertaining to implementation of the HIPAA research provisions, updating the WRNMMC HIPAA and Privacy Board policy, and providing comments on the WRNMMC Research Database, Registry and Repository Policy. However, due to several data sharing related concerns and the long-term vision of the DHA Privacy Office as to how data sharing requests and HIPAA research reviews will be conducted under the NDAA, the DHA Privacy Office is contemplating rescinding the DHA-AI 83 at some point to ensure uniformity and consistency for all MTFs that are subject to DHA oversight. If the policy is rescinded, the DHA Privacy Board will encourage the continued delegation of HIPAA compliance reviews by WRNMMC with greater DHA Privacy Board oversight through a developed process for providing assessments, audits, and corrective actions.

Provided HIPAA Privacy subject matter expertise and guidance to DoD stakeholders and the research community to protect the privacy of research subjects within the MHS and enhance HIPAA compliance

The DHA Privacy Board continued to provide HIPAA Privacy subject matter expertise and guidance to DoD stakeholders and the research community by responding to requests for technical assistance, meetings,

presentations, and through information provided via its website. Below is a sampling of the expertise and guidance provided during FY18.

- The DHA Privacy Board provided guidance on a variety of privacy related topics, including:
    - Assisted with the updating of the WRNMMC HIPAA and Privacy Policy as well as reviewed the WRNMMC Database, Registry, and Repository Policy.
    - Met with the Joint Trauma Analysis and Prevention of Injury in Combat Program to discuss how they can obtain DHA PHI for their military mission and assisted through legal research and consultation with the DHA Office of General Counsel (OGC) to obtain approval to release DHA PHI through the military command authority exemption.
    - Reviewed the DSAs between DHA and the Joint Pathology Center (JPC), researched JPC's authorizing statutes, and consulted DHA OGC in the determination that JPC acts as a public health authority and may obtain DHA PHI in the maintenance of the DoD cancer registry and the DoD tissue repository. Drafted a decision memorandum designating JPC as a public health authority. The decision memorandum was submitted into the Correspondence and Task Management System review and approval process but has since been placed on hold to address further questions and information from the JPC.
    - Reviewed the agreements with the Defense Manpower Data Center (DMDC) and determined, in consultation with the DHA OGC, that DMDC acts as a business associate in maintaining PHI in the Defense Enrollment Eligibility and Reporting System and the Automated Central Tumor Registry databases. Drafted an informal memorandum to notify DMDC that, as a DoD business associate, DMDC must comply with HIPAA and DoD 6025.18-R.
    - Responded to several questions from the WRNMMC IRB Chair regarding the need for HIPAA authorizations to conduct research surveys, the use of the representations for review preparatory to research compared to the use of a partial waiver of authorization, the written designation of the research component of WRNMMC as a non-HIPAA covered entity, as well as reviewed the WRNMMC IRB Chair's presentation on the HIPAA research provisions.
    - Responded to researcher questions regarding the need to include, as a purpose of use in a research authorization, the intent to de-identify the PHI and to provide the de-identified data to other researchers for future research use.
- The DHA Privacy Board assisted several data requestors by preparing agreements with terms and conditions under which DHA data could be placed in and disclosed from a repository where the requestor's intent was to maintain and disclose DHA data from established research repositories to

researchers for future use. These data requests came from Stanford University's Technology Consulting Group for the Stanford Military Data Repository; Naval Health Research Center (NHRC) for the Expeditionary Medical Encounter Database; and U.S. Medical Research and Materiel Command for the FITBIR.

- The DHA Privacy Board prepared to send the media team updates to the DHA Privacy Board webpages in anticipation of the soon-to-be published DoD Manual 6025.18. These updates will incorporate changes in the references from the DoD 6025.18-R to the DoD Manual 6025.18 and will add the information paper on the designation of the DoD as a hybrid entity structure. The changes will also include recent modifications in the DHA HIPAA research templates and updated guidance related to the final Common Rule that will go into effect in January 2019.

- The DHA Privacy Board coordinated with R2O2 to update the eIRB Protocol Application section on data collection to ensure PIs provide the information needed to assist IRBs in making the correct determinations on the type of data being requested. The Board continues to work with R2O2 to launch the DHA HIPAA research templates, which will assist IRBs in reviewing research requests for DHA PHI.

DHA Privacy Board Trends

The DHA Privacy Board tracks trends in its operations and makes necessary adjustments to provide the best service possible to its customers, while maintaining regulatory compliance and the protection of beneficiary data sought for use in research studies. The DHA Privacy Board analyzes the impact of its education and outreach efforts. Where possible, the DHA Privacy Board has collected metrics about its activities, which are then organized by FY, to enable appropriate comparison and trending.

The DHA Privacy Board realized a small increase from FY17 in the total number of reviews performed. However, the FY18 submissions numbers remain on par with previous years.

As in every past year, except FY17, the total number of reviews performed by the Board increased in FY18. 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 5: Total Number of Reviews Each Year

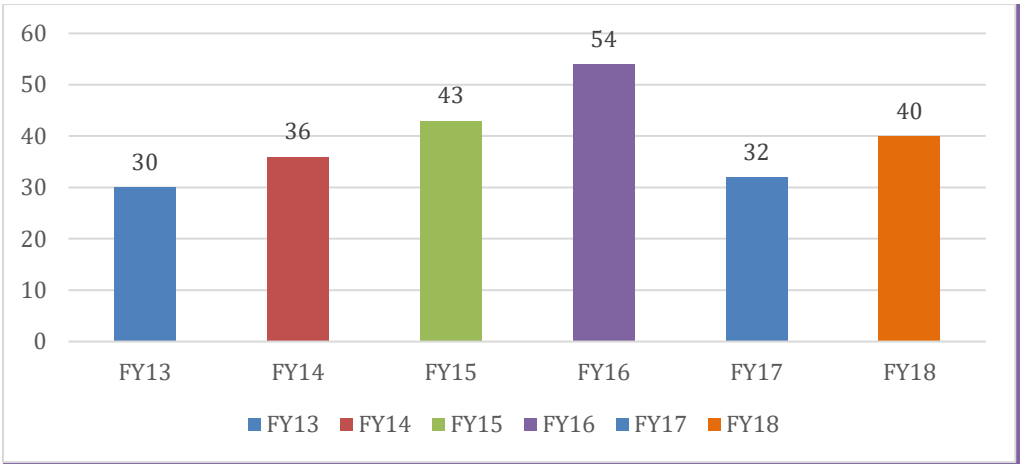


Figure 5 shows the types of submissions that the DHA Privacy Board received from FY12 through FY18. During FY18, IRB Waiver reviews remained the largest type of submissions to the DHA Privacy Board. For the first time in the DHA Privacy Board's history, the Board denied an application for a full waiver of authorization. The denial firmly establishes the DHA Privacy Board's commitment to regulatory compliance and study specific needs.

Figure 6: Types of Submissions FY12 – FY18

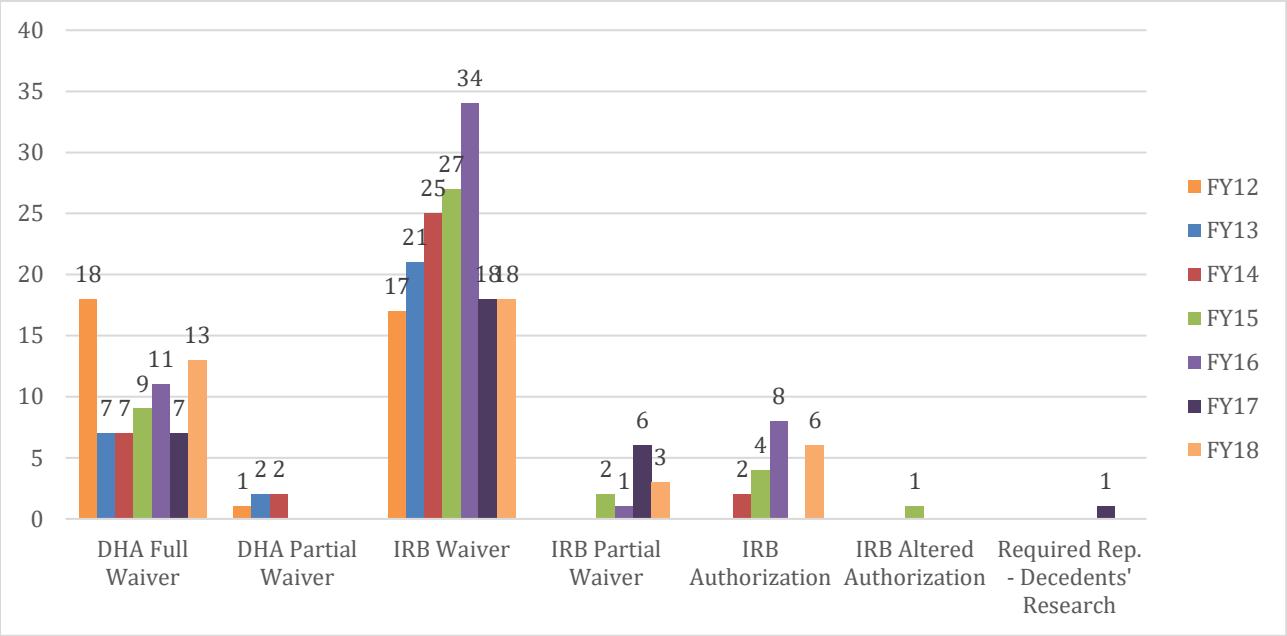
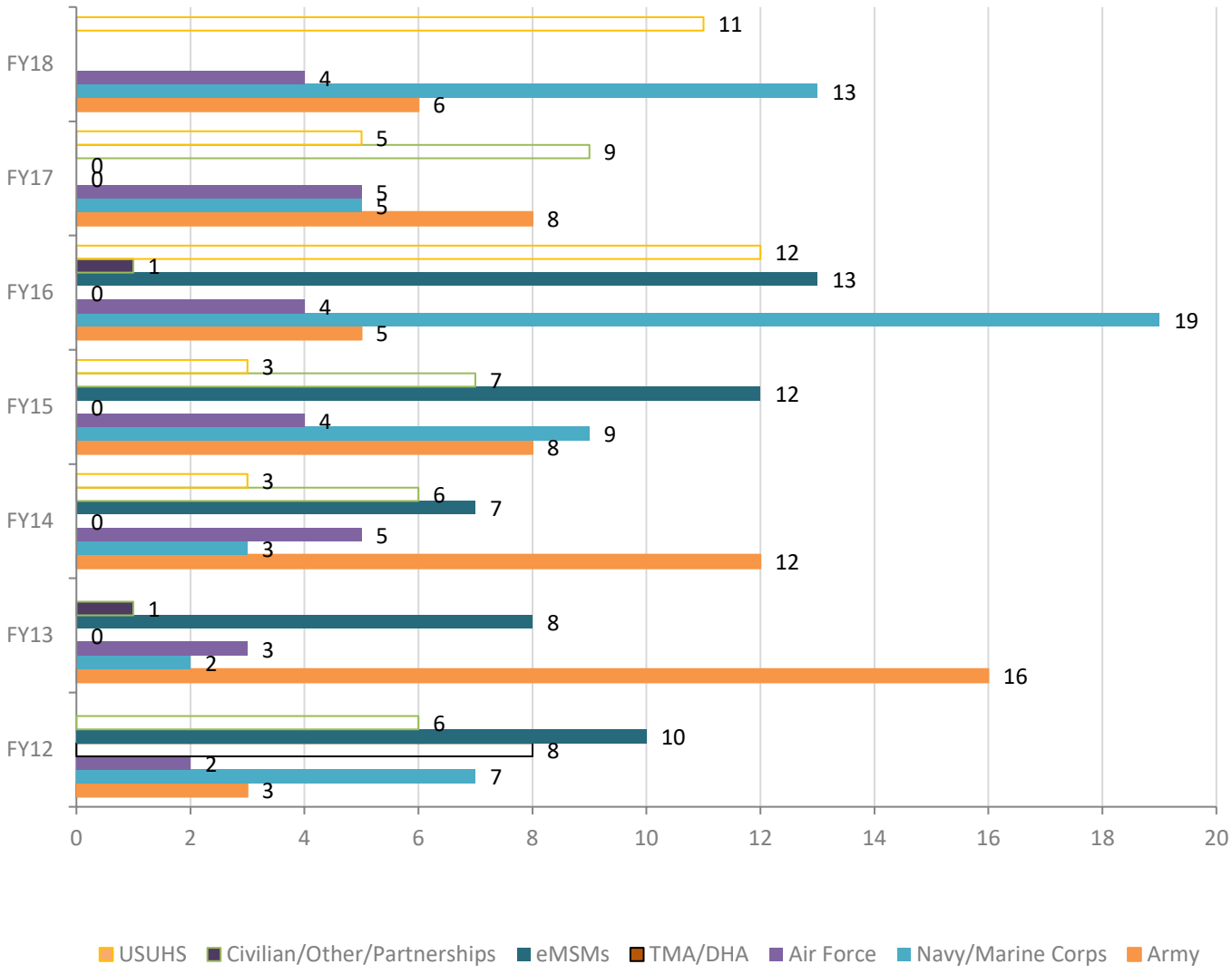


Figure 7: Submissions from Each Type of Center & Institution Served in FY12 – FY18[3]



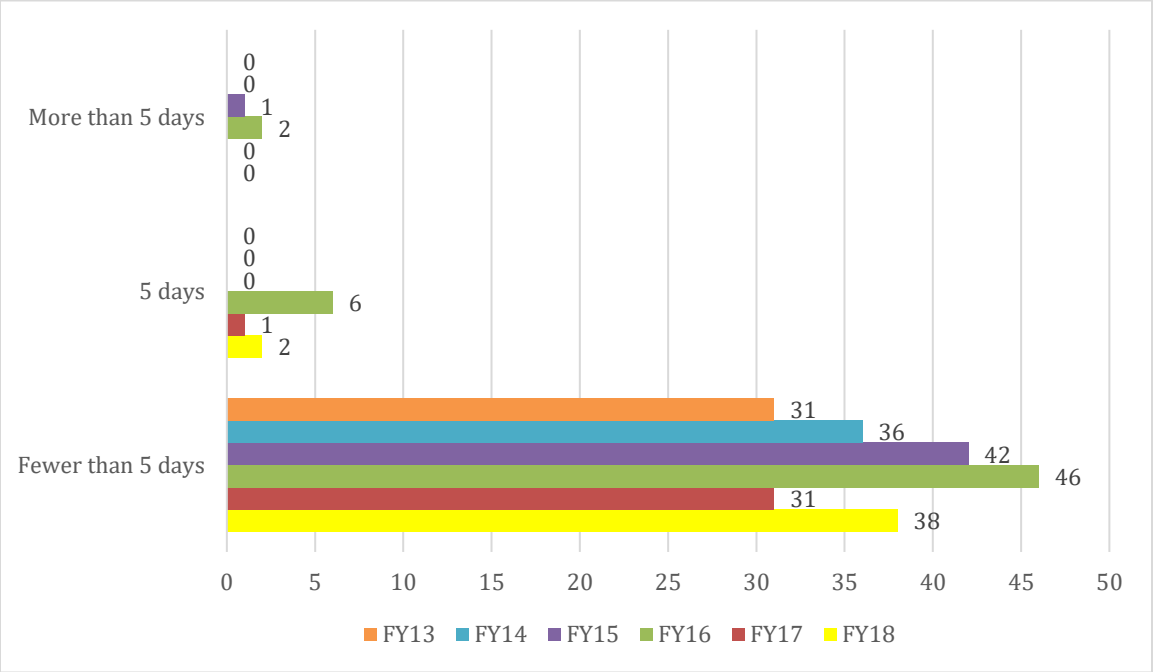
[3] USUHS was part of TRICARE Management Activity (TMA), so its submissions were previously captured in that category; however, when the DHA was established in October 2013, USUHS was *not* made part of DHA. Therefore, USUHS submissions are now counted independent of the DHA as a separate center and institution served by the DHA Privacy Board.

The DHA Privacy Board continues to provide efficient HIPAA compliance reviews; 32 of 40 (80%) FY18 reviews were completed in one day or less

The number of reviews increased, as did the percentage of reviews taking only one day or less to complete from the date of perfection (75% in FY 17 and 80% in FY18). Reviews that took less than one day were completed the day they were perfected.

The DHA Privacy Board did not begin to record review times until the fourth quarter of calendar year 2012, which falls in the government's FY13, so FY13 is used as the baseline in the graphic below.

Figure 8: Continued Efficient Review Times



Future Vision for the DHA Privacy Board

In FY19, the DHA Privacy Board will continue to provide compliance guidance and outreach across the MHS. However, with the centralization of privacy compliance in the DHA Privacy Office under the NDAA, the Board intends to further the NDAA goals by assisting with the standardization of HIPAA compliance reviews throughout the MHS research community. The Board plans to offer additional trainings in FY19 by adding a section on research repository compliance to the online JKO *HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards* and by creating a training on eIRB for researchers to learn about HIPAA research compliance. By providing researchers with a short HIPAA compliance training, researchers will know which HIPAA research templates to submit for review and documentation. In addition to these trainings, the DHA Privacy Board will ensure that IRBs and researchers use only the DHA Privacy Office standardized HIPAA research templates in submitting and reviewing documentation for HIPAA compliance.

The Board's effort to expand training furthers its pursuit of the Board's original long-term goal – to ensure each IRB is trained and able to conduct its own HIPAA compliance reviews. In FY19, the Board seeks to identify two or three DoD IRBs that will be delegated HIPAA compliance reviews of DHA data, similar to the delegation to WRNMMC authorized under the DHA-AI 83. The Board will work concurrently to develop an effective assessment and audit program and will begin to regularly assess or audit DoD IRBs as well as implement corrective actions, as necessary.

By training DoD IRBs, delegating HIPAA compliance reviews to DoD IRBs, and changing the DHA Privacy Board's role to one of oversight, the DHA Privacy Board will enhance HIPAA compliance in the DHA by addressing two critical issues: 1) research projects that do not receive HIPAA compliance reviews where researchers are unaware of the need to submit a DSAA when requesting DHA data; and 2) the DSAA backlog created by the need for compliance reviews on data placed in and disclosed from a repository. The objective is that these additional DoD IRBs will assist with these issues by ensuring researchers receive both Common Rule and HIPAA compliance reviews, thereby decreasing DSAA backlogs.

To further the above goals, the Board will continue to work with J-5 and J-6 EIDS PMO to finalize the DHA Enterprise Data Warehouse and Repository Policy. This policy will enable researchers to access DHA data through a virtual "island," while the data remains secure and protected on DHA authorized systems. In the event a repository is necessary in place of accessing DHA data through the data warehouse, the policy will establish an approval process for maintaining or creating repositories and a corresponding tracking mechanism of existing repositories. These processes will help to ensure that DHA data that is disclosed and used for research meets HIPAA compliance requirements.

Finally, the Board will complete the process of uploading the HIPAA research templates on to eIRB and will update the DHA Privacy Board webpages once the DoD Manual 6025.18 is published. Providing the HIPAA research templates to researchers and IRBs is crucial to the delegation of HIPAA compliance reviews to IRBs. In addition, updating the DHA Privacy Board webpages is necessary to ensure the research community has access to current guidance and tools.

DHA Privacy Board Future Activities
• Develop a new module regarding research repositories to the JKO online HIPAA Privacy Rule Compliance Training for IRBs and HIPAA Privacy Boards.
• Create a new training for researchers on HIPAA research compliance to provide guidance on the use of the standardized DHA HIPAA Research template and to be uploaded on to eIRB.
• Establish and facilitate a Privacy Board NDAA sub-workgroup to socialize and help effectuate the DHA Privacy Board's short and long-term goals.
• Delegate HIPAA research compliance reviews to at least two IRBs after training the IRBs and requiring the use of the DHA HIPAA research templates.
• Collaborate with J-5 and J-6 EIDS PMO to complete and finalize the DHA Enterprise Data Warehouse/Repository Policy.
• Establish and implement a formal assessment and audit program of DoD IRBs conducting HIPAA compliance reviews and develop corrective actions for DoD IRB and researcher noncompliance.
• Update the DHA Privacy Board SOP to incorporate changes in procedures developed in FY18.
• Continue to provide HIPAA research-related technical assistance and guidance to DoD IRBs and the research community.
• Establish an open forum for DoD IRB and Privacy Boards and ultimately the research community where HIPAA-related research questions can be addressed, ideas can be shared, and relevant privacy topics can be discussed.
• Continue to follow research and privacy trends, assessing potential impact on the DHA Privacy Board and MHS research community.

Appendix B: Centers and Institutions Served by the DHA Privacy Board in FY18

Centers and Institutions Served by the DHA Privacy Board in FY18	
Army	**6 Submissions**
Army Public Health Center	
Brooke Army Medical Center (BAMC)	
Walter Reed Army Institute of Research (WRAIR)	
Womack Army Medical Center	
Air Force	**4 Submissions**
Air Force Medical Support Agency (AFMSA)	
David Grant USAF Medical Center	
Office of Under Secretary of the Air Force	
United States Air Force Academy	
59th Medical Wing IRB	
U.S. Marine Corp	**1 Submissions**
U.S Marine Corp IRB	
Navy	**12 Submissions**
Bureau of Medicine and Surgery (BUMED)	
Center for Naval Analyses (CNA)	
Naval Health Research Center (NHRC)	
Navy Medical Center Portsmouth (NMCP)	
Navy Medical Center San Diego (NMCSD)	
USUHS	**11 Submissions**
Uniformed Services University of the Health Sciences (USUHS)	
Civilian and Partnerships	**6 Submissions**
Children's Hospital of Philadelphia (CHOP)	
Diabetes Center of Excellence (DCoE)	
RAND	
University of Washington/Womack Army Medical Center (WAMC)	
Walden University	

Appendix C: The Research Data Sharing Review Process

Determining the Type of Data Requested

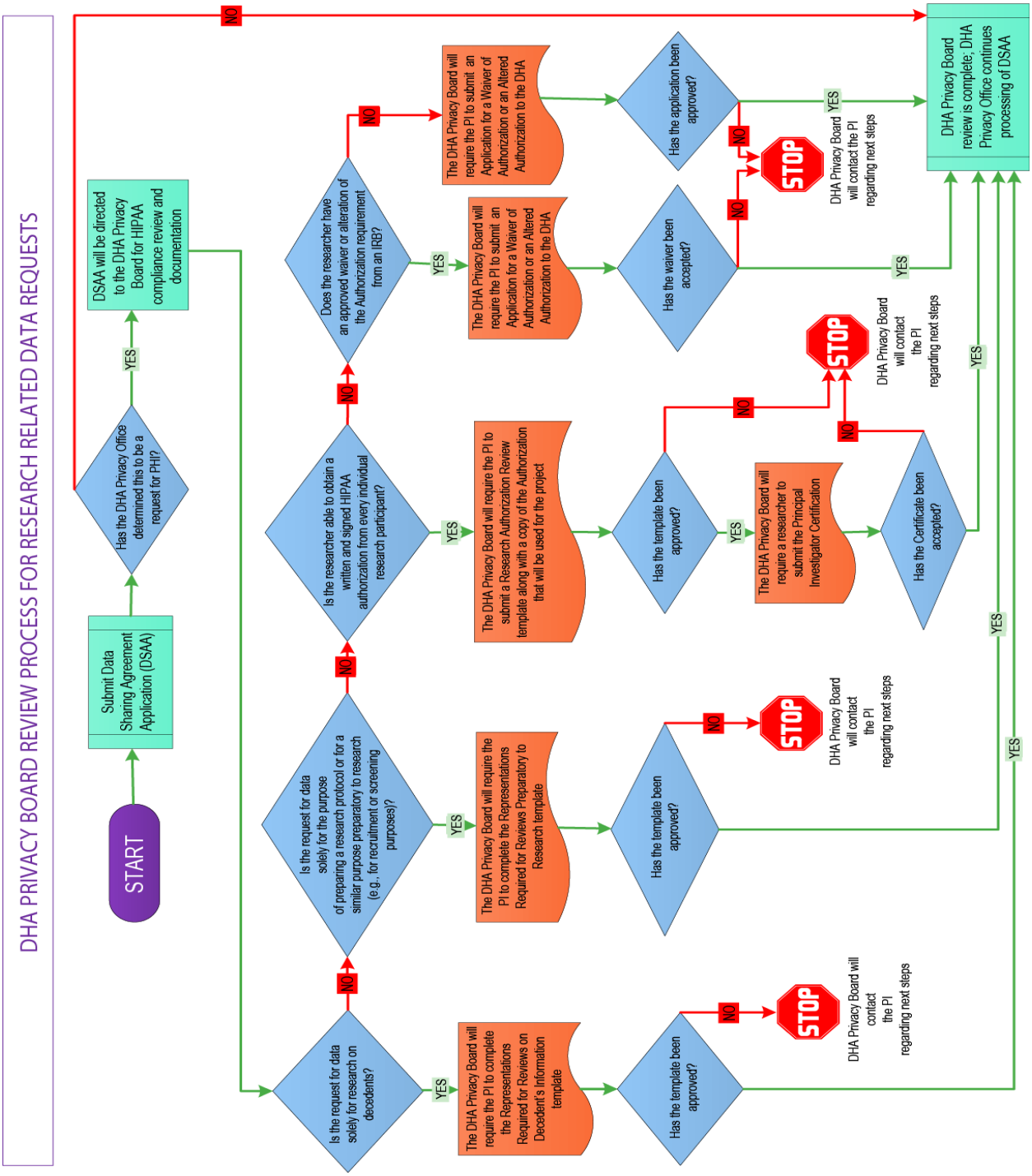
Prior to DHA Privacy Board review, researchers must submit a DSAA to the DHA Privacy Office. All research-related data requests are sent by the DHA Privacy Office Data Sharing Analysts to the Data Evaluation Workgroup (DEW), which was established by the DHA Privacy Board to track and monitor research-related requests for DHA data. 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: 1) De-identified data; 2) PII excluding PHI; 3) 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 DHA Privacy Board for further review. The DEW offers researchers direct consultation with MHS data experts 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 DHA Privacy Board will contact the PI and Sponsor and begin the HIPAA Privacy Rule review process.

Types of DHA Privacy Board Reviews

In the initial email to PIs and Sponsors, the DHA Privacy Board meets with the PI to discuss the next steps for demonstrating compliance with the HIPAA Privacy Rule and DoD 6025.18-R. In this discussion, the DHA Privacy Board identifies whether the PI's IRB performed a HIPAA review of the study, which can receive an administrative DHA Privacy Board review, or whether a full submission will be necessary. The DHA Privacy Board maintains internal checklists to facilitate its HIPAA review and documentation procedures. When reviewing a submission, the DHA Privacy Board will contact the PI and Sponsor with any questions or issues, if necessary. The DHA Privacy 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 DHA Privacy Board and its review process 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 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 F: Acronym List

AI	Administrative Instruction
DEW	Data Evaluation Workgroup
DHA	Defense Health Agency
DMDC	Defense Manpower Data Center
DoD	Department of Defense
DSA	Data Sharing Agreement
DSAA	Data Sharing Agreement Applications
EIDS	Enterprise Intelligence and Data Services
eIRB	MHS's Electronic Protocol Management System
FITBIR	Federal Interagency Traumatic Brain Injury Research
FY	Fiscal Year
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
JKO	Joint Knowledge Online
JPC	Joint Pathology Center
J-5	Strategy, Planning, and Functional Integration Directorate
J-6	Health Information Technology Directorate
LDS	Limited Data Set
MHS	Military Health System
MTF	Military Treatment Facility

NDAA	National Defense Authorization Act
NHRC	Naval Health Research Center
NIH	National Institutes of Health
OCR	Office for Civil Rights
OGC	Office of General Counsel
PCAP	Precision Care Advisory Panel
PHI	Protected Health Information
PI	Principal Investigator
PII	Personally Identifiable Information
PMO	Program Management Office
R2O2	Research Regulatory Oversight Office
RRT	Research Repository Template
TMA	TRICARE Management Activity
USUHS	Uniformed Services University of the Health Sciences
WRNMMC	Walter Reed National Military Medical Center