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# TRICARE MANAGEMENT ACTIVITY (TMA) PRIVACY BOARD: 2012 ANNUAL REPORT

**TMA Privacy and Civil Liberties Office** 

#### MESSAGE FROM THE TMA PRIVACY BOARD CHAIR

I am pleased to present the Calendar Year 2012 (CY12) TMA Privacy Board Annual Report. CY12 was truly a year of growth for the TMA Privacy Board (Board). With the introduction of two new Board members, including myself, the Board's membership grew, increasing the Board's efficiency and capacity to conduct reviews. In addition, the Board's focus on educating the research community expanded from developing a TMA Privacy Board webpage to initiating a pilot project with the Walter Reed National Military Medical Center (WRNMMC) to conduct Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule reviews on behalf of TMA. As part of the pilot project, the TMA Privacy Board is training WRNMMC on how to conduct HIPAA Privacy Rule reviews using new HIPAA compliant templates, developed from the current TMA Privacy Board templates.

In establishing this Annual Report, my intent is to establish a forum where I can present the achievements of the Board, share information about the direction of the Board in the upcoming year, and recognize the Board members who volunteer their expertise and time to TMA, thus providing guidance and a means for measuring progress. I believe that this report is consistent with that intent and, in and of itself, fulfills one of the Board's main goals in the strategic plan this past year - to capture metrics on the Board's performance and report progress on them.

Linda Thomas

Director, TMA Privacy and Civil Liberties Office

Linda Thomas

Chair TMA Privacy Board TMA Privacy and Civil Liberties Office

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### **Executive Summary**

The TMA Privacy and Civil Liberties Office (TMA Privacy Office) oversees the protection of personally identifiable information (PII) and protected health information (PHI) within the Military Health System (MHS) for over 9.7 million beneficiaries worldwide. Due to the nature of the beneficiary data managed by TMA, researchers often submit requests for MHS data to the TMA Privacy Office. Reviewing these requests and authorizing the permissible use and/or disclosure of MHS data managed by TMA in compliance with



federal privacy and security laws and Department of Defense (DoD) regulations and guidelines is one of many TMA responsibilities. To ensure compliance with the HIPAA Privacy Rule and DoD Health Information Privacy Regulation (DoD 6025.18-R) in the protection of MHS PHI, the TMA Privacy Office established a HIPAA Privacy Board, known as the TMA Privacy Board. On August 13, 2009, the Assistant Secretary of Defense for Health Affairs approved the TMA Privacy Board in the "Memorandum for the Establishment of the TMA Privacy Board and Revision of Section C7.9.1 of Department of Defense (DoD) Health Information Privacy Regulation (DoD 6025.18-R)." Following approval, the TMA Privacy Board enlisted members, instituted procedures and commenced operations on August 25, 2009.

Prior to the establishment of the TMA Privacy Board, the TMA Privacy Office relied on Institutional Review Boards (IRBs) and external Privacy Boards to review for HIPAA Privacy Rule compliance and to provide waivers of HIPAA Authorizations and/or altered HIPAA Authorizations to satisfy compliance with HIPAA. However, at that point in time, it came into question whether the reviews were being conducted consistently and in compliance with the requirements under the HIPAA Privacy Rule. As a result, the TMA Privacy Board was formed as a means for researchers to receive waivers of HIPAA Authorizations not otherwise provided by their IRBs. Remaining true to its purpose, the Board has greatly improved the process for ensuring compliance with the requirements of the HIPAA Privacy Rule and DoD 6025.18-R, while helping to clarify the complex intersection of the HIPAA Privacy Rule and the Federal Framework for the Protection of Human Subjects (45 CFR 46). The TMA Privacy Board continues in natural alignment with its mission to focus its efforts on enhancing compliance through process improvements, education and outreach efforts, and service as a resource for the research community on HIPAA-related research topics and data sharing concerns.

With this brief introduction to the TMA Privacy Board, the primary focus of this report is to highlight the major accomplishments of the TMA Privacy Board for CY12. In addition, this report provides a snapshot of the Board's vision for 2013, a summary of the regulations significant to Board operations, a brief description of the TMA Privacy Board's review process and an overview of the Board members' backgrounds.

### TMA Privacy Board 2012 Highlighted Accomplishments Board Operations and Process Improvements

- 1. Successfully completed reviews of 39 submissions requesting TMA managed data and protected the privacy of that data totaling records for up to 9 million beneficiaries in strict adherence to the HIPAA Privacy Rule standards (See Figure 1 on page 4 and Figure 2 on page 5.)
- 2. Completed HIPAA compliance reviews from 29 different agencies, including agencies from DoD, Air Force, Army, Navy, TMA and several civilian medical research institutions (See Figure 3 on page 6.)
- 3. Achieved 100% compliance with review period mandates in the fourth (4<sup>th</sup>) quarter of CY 2012, with an average completion of reviews within one day from the date of perfection (Note: The Privacy Board began to capture "perfection date" at the start of the 4<sup>th</sup> quarter.) (See Figure 4 on page 7.)
- Established and adopted the <u>TRICARE Management Activity Privacy Board Standard Operating Procedures</u> (SOP) allowing for 1) transparency of Board operations;
   consistency, accuracy and efficiency of reviews; and 3) effective training and onboarding of new Board members and support staff
- 5. Created and implemented the use of standardized, user-friendly fillable PDF templates that guide researchers through the request process and aid in ensuring compliance with the requirements of the HIPAA Privacy Rule and DoD 6025.18-R
- 6. Launched an all new <u>TMA Privacy Board webpage</u> on the TMA Privacy Office website, creating a centralized repository of information for researchers on how to obtain TMA managed data and providing transparency into Board procedures to allow for the proactive planning and submission of compliant data requests
- 7. Strengthened the Board review process by onboarding new Chair and Board member with training on HIPAA, Privacy Board and business processes, thereby increasing capacity for reviews and infusing new insights into the Board
- 8. Streamlined required file maintenance by developing and maintaining TMA Privacy Board email and electronic document files, freeing up resources to focus on upfront processing and review efforts
- 9. Successfully met the goal of conducting quarterly meetings to address issues related to Board processes, research issues, and the education of IRBs and researchers on compliance requirements

### TMA Privacy Board 2012 Highlighted Accomplishments (Cont.) Research Community Outreach Efforts

- 1. Initiated major process improvements expected to impact 1,100 MHS HIPAA Privacy Rule reviews during the pilot phase and more than 10,000 MHS HIPAA Privacy Rule reviews after full rollout
- 2. Increased protection of TMA managed data and reduced the processing time of research requests by providing forums for fluid communications between TMA Privacy Board staff with in-depth knowledge of HIPAA and the Common Rule and stakeholders in the researcher community, including researchers, IRBs and Human Research Protection Programs (HRPP)
- 3. Contributed to developing the <u>Guide for DoD Researchers on Using MHS Data</u>, a comprehensive resource available to researchers to facilitate the efficient submission and review of data requests for TMA managed data

### **TMA Privacy Board Major Accomplishments**

### 1. Protected the privacy of millions of individuals whose PHI is managed by TMA and is requested for use and disclosure for research projects

In CY12, the number of individuals whose PHI was requested for a single research project ranged from 70 individuals to 9,000,000 individuals. This wide range in the number of individuals was due in part to how the researchers identified the number of individuals whose information they expected to access. For example, some researchers provided the actual number of research subjects whose PHI they expected to collect, while others provided the approximate number of individuals whose PHI is contained in the database they intended to access to locate their research subjects. The TMA Privacy Board's efforts to ensure HIPAA Privacy Rule and DoD 6025.18-R compliance protected the data for all of these individuals.

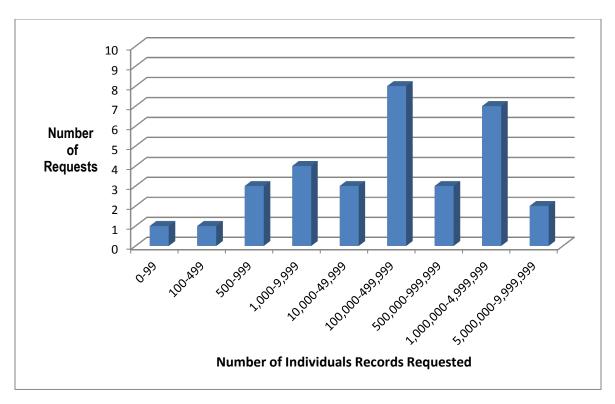


Figure 1: Frequency of Number of Individuals Records Requested

## 2. Successfully facilitated and completed 39 reviews of submissions related to research requests for PHI with strict adherence to the HIPAA Privacy Rule standards

By offering researchers the service of HIPAA Privacy Rule reviews, the TMA Privacy Board ensures HIPAA compliance through its templates that 1) ask for documentation necessary to meet HIPAA requirements, and 2) guide the reviewers in making the proper findings to meet HIPAA standards. Thus, the reviews enhance the privacy protections of the individuals in the MHS whose PHI is part of a research request. For CY12, these reviews and approvals included submissions of 20 applications to the TMA Privacy Board for waivers of HIPAA Authorization, including one partial waiver, and 19 IRB waivers of HIPAA Authorization. The Board did not review any HIPAA Authorizations with the accompanying TMA Privacy Board templates.

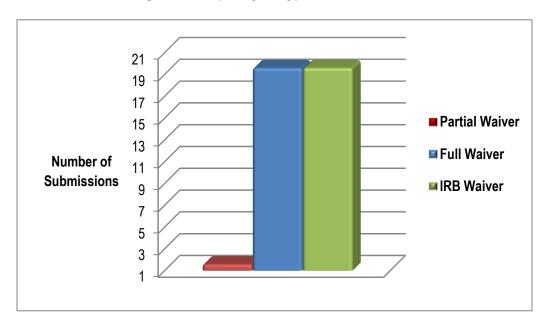


Figure 2: Frequency of Types of Submissions

### 3. Served a wide range of healthcare and research related offices within DoD, Air Force, Army, Navy, TMA, and civilian medical research centers

In CY12, the TMA Privacy Board served 29 institutions and agencies through its HIPAA compliance reviews. (See appendix for listing of specific agencies.) By conducting efficient and compliant HIPAA Privacy Rule reviews, the TMA Privacy Board supported these institutions, if necessary, by offering reviews for waivers of HIPAA Authorizations that they may not otherwise have been able to obtain. Also, the TMA Privacy Board helped these organizations meet the compliance requirements necessary for them to receive data managed by TMA.

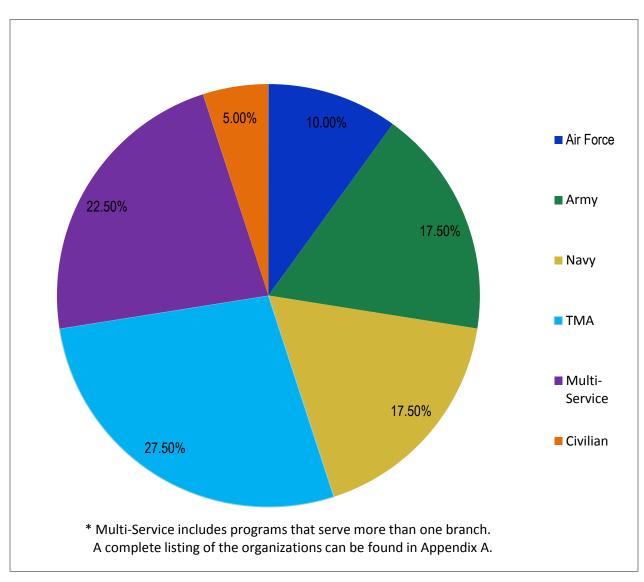


Figure 3: Types of Organizations Served by the TMA Privacy Board

### 4. One hundred percent compliance with review time requirements in the last quarter

The TMA Privacy Board's SOPs provide Board members with five days to respond to the principal investigator (PI) or government sponsor (Sponsor) named in a submission with the results of the review or follow-up questions, as necessary. This metric for review time counts the number of days from the day after the review is perfected, or all of the necessary documentation for review has been submitted. The TMA Privacy Board started tracking the time for review at the end of May 2012 and the date of perfection in October 2012. Using the date of perfection and date of approval, during the last quarter of CY12, the average time for review of an application for waiver of HIPAA Authorization was 1.4 days. Only one day was needed for review and approval of IRB waivers of HIPAA Authorization once the submission was perfected by the PIs and Sponsors. Due to the funding time limits imposed on research projects. researchers appreciate quick and timely reviews. The support staff works with the researchers and reviewers to assist in any delays due to incomplete submissions or the need for understanding by the reviewers or researchers.

Figure 4: 100% Compliance with Review Times in Final Quarter of CY12





# 5. Established and adopted TRICARE Management Activity Privacy Board Standard Operating Procedures (SOPs) that enable quick responses within a stated time frame

At the fourth quarterly Board meeting in December 2012, the TMA Privacy Board voted on the *TRICARE Management Activity Privacy Board Standard Operating Procedures* (SOP) to govern the Board operations, thus, improving business process through standardization, consistency, and established metrics. The SOPs direct the training of new Board members and allow for a seamless transition of Board members and support staff without interruption in Board operations. The SOPs also inform the research community and public about the detailed operations of the TMA Privacy Board.

### 6. Created easy fillable PDF templates that ensure compliance with the requirements of the HIPAA Privacy Rule and DoD 6025.18-R

The TMA Privacy Board converted the previous seven TMA Privacy Board templates from Microsoft Word documents to fillable PDFs in accordance with the federal regulation requiring accessible public documents for people with disabilities. The templates also improve the efficiency of the review process by allowing an electronic signature from those who have DoD common access cards (CACs). Previously, all of the Board members and researchers had to print a document, sign, and scan it to create an executed electronic document for submission and filing.

#### 7. Created a webpage on the TMA Privacy Office website containing:

- Background on the establishment of the TMA Privacy Board
- Board member bios
- Educational information, including an explanation of the differences between the Common Rule and the HIPAA Privacy Rule
- Flowcharts illuminating the pre-requisite requirements to TMA Privacy Board review
- Details of the Board processes
- Watermarked Board templates
- Additional resources

The webpage will have significant impact as it will address frequently asked questions from the research community (including researchers, IRBs and HIPAA Privacy Boards) and provide indepth information about the HIPAA Privacy Rule; DoD 6025.18; DoDI 3216.02, the DoD implementation of the Common Rule; and the review process within TMA required for regulatory compliance. The webpage also provides additional resources for further understanding of HIPAA and related considerations.

### 8. Incorporated new Chair and Board member with training on HIPAA and review process

The addition of a new Chair and Board member has increased the speed and efficiency of reviews. The new Chair has also provided ideas, such as tracking metrics and the expansion of the Board's role to include the support of, and integration with, IRBs and other HIPAA Privacy Boards within the MHS multi-service markets.

# 9. Developed and maintained TMA Privacy Board email file and electronic document file on the TMA Privacy and Civil Liberties email and electronic document file stations

This past year the TMA Privacy Board converted its operations from paper files to electronic files, drastically reducing the amount of time for filing. In addition, the move to electronic files complies with the Federal Government Paperwork Elimination Act (Public Law 105-277 Title XCII) and the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

# 10. Successfully fulfilled the goal of conducting quarterly meetings to address new issues related to the Board processes, research issues, and the education of IRBs and researchers about the compliance requirements

Since its establishment in 2009, the TMA Privacy Board has met quarterly to update members on submissions received and to discuss projects related to education and collaboration in the MHS research community. This past year, the TMA Privacy Board again met quarterly, enabling initiation and robust discussion on the Board's new projects intended to improve the efficiency and effectiveness of the HIPAA Privacy Rule reviews. These discussion included topics such as: tracking new metrics for reviews, establishing de-identified databases, integrating the MHS HIPAA Privacy Rule reviews, and developing the TMA Privacy Board webpage.

# 11. Initiated major process improvements expected to impact 1,100 MHS HIPAA Privacy Rule reviews during the pilot phase and more than 10,000 MHS HIPAA Privacy Rule reviews after the rollout

The TMA Privacy Board, in conjunction with the TRICARE Management Activity Human Research Protection Program ("TMA HRPP"), is embarking on a pilot project – the Research Data Sharing Streamlining Initiative ("Streamlining Initiative") – with WRNMMC. As part of the pilot, the TMA Privacy Board will work with WRNMMC to develop universal templates to use for HIPAA



Privacy Rule compliance reviews and train the WRNMMC IRB on how to classify data under HIPAA and to conduct the reviews on research requests for PHI. Once the training is complete, the TMA Privacy Office intends to authorize WRNMMC, through a signed Memorandum of Understanding, to conduct the HIPAA Privacy Rule reviews for PHI managed by TMA. After

the initial pilot phase, the TMA Privacy Office will execute agreements to turn over HIPAA Privacy Rule reviews to other MHS multi-service market sites that meet the initial training requirements and agree to use the universal HIPAA templates. This process improvement will have a significant impact on the number of reviews and the processing time for reviews of research requests for PHI managed by TMA.

### 12. Provided in-depth expert guidance in responding to, and facilitating progress on, complex inquiries from members of the research community

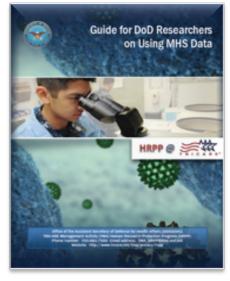
TMA Privacy Board support staff often receives questions, either by email or by phone, from researchers on the review process regarding how to apply HIPAA to their work activities. These inquiries require that the support staff possess a certain depth of expertise in order to respond in a comprehensive and timely manner. As an example, in June 2012, several TMA Privacy Board members and support staff held a teleconference with the Children's Hospital of Philadelphia (CHOP) IRB. The purpose of the meeting was to respond to CHOP IRB's question regarding the documentation that needed to be submitted to achieve compliance when a research study affecting approximately 1.5 million individuals is modified. As a result of the meeting, the TMA Privacy Board Chair and Director of the TMA Privacy Office drafted language for the CHOP IRB to submit to the TMA Privacy Board in order to meet the HIPAA Privacy Rule requirements for modifications, thus contributing to the efficiency of Board processing.

13. Collaborated with the TMA HRPP to prepare the Guide for DoD Researchers on Using MHS Data (Researchers' Guide), which is available on both the webpage for the HRPP and the TMA Privacy

weopage for the HRPF and the IMA Privac Board

The Researchers' Guide provides a quick overview of the MHS and TMA, describes the data and databases available at TMA, briefly explains the process for obtaining data and provides links to other informative sites. The guide is a novel document and provides an extensive appendix with details about all of the available databases.

14. Provided staff with expertise to assist the researchers, update documents, review submissions for compliance as needed, and support projects to educate and collaborate with researchers, IRBs and the HRPP



Subject matter experts in HIPAA and the Common Rule improve the efficiency of the reviews by delivering quick and reliable information to researchers and reviewers. In addition, experienced and knowledgeable staff members enhance the efforts and ability of the Board to complete projects related to research and HIPAA compliance.

#### **Future Vision for the Privacy Board**

To ensure compliance with the HIPAA Privacy Rule and DoD 6025.18-R and to bring quality service to our stakeholders, the TMA Privacy Office continually evaluates the legal and regulatory landscape, as well as Board processes and procedures, to make improvements, where necessary and appropriate. As part of these efforts, the Board continually assesses and strives for increased collaboration with the overall TMA Data Sharing Program, so as to improve the overall data sharing experience for researchers by making it as efficient and productive as possible.



This stakeholder-oriented focus is also apparent during Board meetings where the TMA Privacy Board considers areas where their expertise and experience may assist researchers in accessing data and, at the same time, ensuring compliance with laws that protect the privacy of the individuals whose data is accessed. In that regard, one of the most significant changes occurring in 2012 was the kickoff of the Research Data Sharing Streamlining Initiative ("Streamlining Initiative"). As noted above, once this initiative is fully launched, it will impact over 10,000 HIPAA Privacy Rule reviews. After fully implementing the pilot project with WRNMMC, the TMA Privacy Board will then move forward with other MHS multi-service markets. Eventually, the Board will adopt an additional role as the centralized body for monitoring ongoing activity related to the Streamlining Initiative through audits and compliance checks. That role will also include identifying and implementing necessary updates to universal templates, website content, and/or the Memorandum of Understanding, and, when necessary, conducting follow-up training and disseminating new information and resources relevant to the initiative.

In CY12, the TMA Privacy Board also developed a new webpage to educate researchers on the processes required for requesting data for research studies and to provide information and sample templates to IRBs. While the webpage will continue to be a significant resource for new and relevant updates and information, it will also serve as a conduit for opportunities to engage in dialogue with the HIPAA and research community. In doing so, the TMA Privacy Board hopes to encourage and promote continual compliance with the HIPAA Privacy Rule research provisions and to build an open forum where ideas can be shared and topics relevant to the research community can be discussed.

Finally, the TMA Privacy Board will continue serving the research community by providing efficient HIPAA Privacy Rule reviews for researchers who are outside the MHS multi-service markets. Consistent with this purpose, the TMA Privacy Board will update its own TMA Privacy Board templates to be consistent with the new, universal HIPAA templates, and will

continue to meet in order to discuss the primary goals of assisting researchers obtain reviews and documentation that are compliant with the HIPAA Privacy Rule.

# The Federal Framework for the Protection of Human Subjects (also known as the "Common Rule") and the Health Insurance Portability and Accountability Act of 1996 (also known as the "Privacy Rule")

Researchers seeking to access and/or obtain the MHS data for research purposes must adhere to the separate and distinct requirements within *both* the Common Rule and the HIPAA Privacy Rule. In acknowledgment of the already established IRBs as the bodies for reviewing research under the Common Rule, the HIPAA Privacy Rule authorized IRBs and newly defined HIPAA Privacy Boards, such as the TMA Privacy Board, to conduct HIPAA Privacy Rule reviews. As a result, many misconceptions have arisen among IRBs and researchers



regarding the type of review necessary for HIPAA compliance due to confusion between the Common Rule and the HIPAA Privacy Rule.

The chart and narrative on page 13 set forth the primary differences between the two applicable regulations. As indicated in the chart, although the Common Rule enables certain research projects to be exempt from IRB review, HIPAA Privacy Rule review and documentation is still required, even for exempt projects, before PHI can be used and/or disclosed. Furthermore, the requirements of informed consent are separate and distinct from those of a HIPAA Authorization. An informed consent can be joined with a HIPAA Authorization for research purposes, known as a "Compound Authorization" under the HIPAA Privacy Rule. HIPAA Authorizations or Compound Authorizations are required to be reviewed for compliance with the HIPAA Privacy Rule.

Table 1: 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)
Department of Defense (DoD) Implementing Regulation	Protection of Human Subjects (32 CFR 219); Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research (DoDI 3216.02)	DoD Health Information Privacy Regulation (DoD 6025.18-R)
Primary Purpose	Protect individuals who are the subject of research projects. Consideration is given to how various aspects of the research project, including privacy, confidentiality, data collection, data maintenance and data retention, impact physical, emotional, financial, and informational harms	Protect individuals against informational harm while allowing the necessary flow of health information with specific rules pertaining to the privacy and security of PHI
Threshold Requirement	Informed consent from each research participant (oral and/or written)	HIPAA Authorization from each research participant (must be written and signed)
Enforcement	Office for Human Research Protections, United States Department of Health and Human Service (HHS), and DoD Assistant Secretary of Defense for Research and Engineering	Office for Civil Rights, HHS
Administration	IRBs	IRBs or HIPAA Privacy Boards
Exemptions	Human Research Protection Officials (HRPOs) and/or IRBs can exempt certain research projects from IRB review in accordance with 32 CFR 219.101(b)	None. All research projects seeking PHI from a HIPAA covered entity, including TRICARE Management Activity (TMA), must comply with the HIPAA Privacy Rule

#### The TMA Privacy Board Review Process

#### 1. Determining the Data Type

Prior to review by the TMA Privacy Board, researchers must submit a Data Sharing Agreement Application (DSAA) to the TMA Privacy Office. The TMA Privacy Office then considers the type of information needed by the research project. The TMA Privacy Office categorizes a research project's informational needs into one of four types for compliance review: 1) De-identified data; 2) PII excluding PHI; 3) Limited data set (LDS); or 4) PHI greater than an LDS. An explanation of the four types of informational categories is available on the TMA Privacy Board section of the TMA Privacy Office website.



A research project that seeks PHI greater than an LDS is sent to the TMA Privacy Board for HIPAA Privacy Rule review and documentation. Once the TMA Privacy Board receives a research project submission seeking PHI greater than an LDS, the Board will reach out to the PI and Sponsor and begin the HIPAA Privacy Rule review process.

This process is briefly described below and illustrated in the flowchart entitled "TMA Privacy Board Review Process for Research Related Data Requests," attached in Appendix B.

#### 2. Types of Privacy Board Reviews

In the initial email to the PIs and Sponsors regarding the need for documentation to demonstrate compliance with the HIPAA Privacy Rule and DoD 6025.18-R, the TMA Privacy Board outlines four possible types of submissions that the researchers may submit to meet the required standards, as appropriate. They include the following: 1) Required Representations for Research on Decedent's Information; 2) Required Representations for Review Preparatory to Research; 3) Research Authorization Review and sample HIPAA Authorization(s); and 4) Waiver of HIPAA Authorization or an Altered HIPAA Authorization from an IRB or HIPAA Privacy Board, including a TMA Privacy Board Application for a Waiver of Authorization or a request for the TMA Privacy Board to conduct an Altered Authorization review.

When reviewing the above-referenced documents, the TMA Privacy Board will contact the PI and Sponsor to complete its review, as necessary. Once the TMA Privacy Board completes the HIPAA Privacy Rule review, the TMA Privacy Office continues processing the DSAA for additional compliance requirements.

Detailed information about the TMA Privacy Board reviews, including the required documentation, standards for review and the TMA Privacy Board HIPAA compliant templates, is outlined in the TMA Privacy Board SOPs, available on the TMA Privacy Board section of the TMA Privacy Office website.

#### 3. Limits on the Use and Disclosures of PHI

Researchers are prohibited from using or disclosing PHI received for a specific research project(s) for other or future research projects. Requests for re-use or re-disclosure of PHI in an existing study or studies can take the form of a modification, extension, or renewal. When a data request is modified, extended and/or renewed, the TMA Privacy Board is contacted and will email the PI and Sponsor to determine if the study has changed and if the responses or representations in any documents/templates previously approved by the TMA Privacy Board remain the same. Any substantial changes in the previous information reviewed by the TMA Privacy Board will require further review in support of a modification, extension or renewal.



On January 25, 2013, the final regulations implementing the statutory amendments to the Health Insurance Portability and Accountability Act (HIPAA) found under the Health Information Technology for Economic and Clinical Health Act ("HITECH Act") were published in the Federal Register (the "Omnibus Rule"). The changes to the research provisions therein may serve as the basis for future changes to Board operations and policies. One such potential change may revolve around the use of PHI for future unspecified research.

Source: Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Department of Health and Human Services, Office of the Secretary (45 C.F.R. Parts 160 and 164). 78 Fed. Reg. 5566 (Jan. 25, 2013).

#### **Summary**

The TMA Privacy Board continues to provide HIPAA Privacy Rule reviews that serve the research community and ensure the privacy of the individuals whose health information is managed by TMA. In CY12, the Board completed many new projects and tasks that increased the speed of the HIPAA Privacy Rule reviews, educated the research community and improved the efficiency of compliance within the MHS, while enhancing the understanding of the HIPAA Privacy Rule requirements. The Board continues to move forward on its initiatives, in particular the roll-out of the pilot project with WRNMMC. The next steps involve engaging the MHS multi-service markets in executing Memorandums of Agreements to assume responsibility for HIPAA Privacy Rule reviews, adopting the universal HIPAA Privacy Rule compliant templates, training on the classification of data requests, and meeting HIPAA requirements through the use of approved templates.

#### **Board Members**

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

- Linda Thomas, J.D., M.S., M.A., P.M.P., CIPP/G, Director, TMA Privacy Office and TMA Privacy Board Chair
- **Rita DeShields,** B.A., TMA Data Sharing Compliance Officer, TMA Privacy Office and TMA Privacy Board Co-Chair
- **Jacob Bournazian,** J.D., M.A., Confidentiality Officer for the Energy Information Administration, Department of Energy
- **Dr. Kenneth Cox,** M.D., M.P.H., retired Colonel and civilian at the United States Army Public Health Command
- CAPT John Eckert, PhD, Program Manager, Human Research Protection Program, DoD/Office of the Assistant Secretary of Defense for Health Affairs/TMA Privacy Office
- **Eve Powell-Griner,** PhD, CIPP/G, Confidentiality Officer for the National Center for Health Statistics, Centers for Disease Control and Prevention

### **Appendix A: Organizations Served by the Privacy Board in CY12**

Air Force Mobility Command, Travis Air Force Base
Air Force Research Lab, Wright Paterson Air Force Base
AMEDD
CDMRP/Army (Army Medical Research and Materiel Command)
Center for Naval Analysis/ Office of the Chief Medical Officer for Behavioral Health in Primary Care
Children's Hospital of Pennsylvania
DoD Pharmacoeconomic Center*
DoD/DHCAPE*
DoD/TMA HPA&E
Infectious Disease Clinical Research Program*
John Hopkins HealthCare
Keesler AFB 81st MDG, PT Department
National Naval Medical Center
Naval Health Research Center
Naval Hospital Camp Lejeune
Navy Submarine Medical Research Laboratory
Surgeons Generals of US Army, Navy, Air Force and DoD Health Affairs*
TMA Office of Chief Medical Officer; TMA Scientific Advisory Panel
TMA Scientific Advisory Panel; DoD Senior Leadership
U.S. Air Force School of Aerospace Medicine
U.S. Army TATRC
United States Navy Bureau of Medicine and Surgery
Uniformed Services University of Health Sciences*
US Army Institute of Surgical Research
US Army Pharmacovigilance Center
US Military Cancer Institute*
William Beaumont Army Medical Center
Walter Reed National Medical Military Center*

<sup>\*</sup>Represents the organizations referred to in the "Multi-Service" category on Figure 3, page 6

