



Date of Request:	Principal Investigator (PI):
Title of Research Project:	
Number of Related Data Sharing Agreement Application (DSAA):	
Business Address:	
PI's Phone:	PI's Email:
Government Sponsor:	
Sponsor's Phone:	Sponsor's Email:

I. Purpose of this Document

An Authorization is an individual's signed permission allowing TMA to use or disclose the individual's Protected Health Information (PHI) that is described in the Authorization for the purpose(s) and to the recipient(s) stated in the Authorization. The HIPAA Privacy Rule, as implemented by Department of Defense (DoD) Health Information Privacy Regulation (DoD 6025.18-R), requires that an Authorization contain certain elements. This document facilitates the submission and review of the Authorization to use or disclose PHI for research purposes (referred to herein as a "Research Authorization") by the TMA Privacy Board to ensure that the above-referenced regulatory requirements are met. This review is limited to the research project indicated on this form. Authorizations for use in separate or different research projects must be submitted for a separate review.

IMPORTANT NOTICE: The TMA Privacy Board's approval of a Research Authorization Review signifies that TMA will accept the proposed Authorization as meeting the HIPAA Privacy Rule and DoD 6025.18-R requirements for the research project indicated on this form. To obtain the requested PHI, a DSAA must be submitted to the TMA Privacy Office, and the PI must certify that he/she has a signed and dated Authorization, as approved by the TMA Privacy Board, from every individual research participant before the individual's PHI is accessed, obtained and/or used.



II. Required Information

1. Provide a brief description of the research project.

Attach a copy of the Authorization you plan to have every individual research participant sign in order to obtain their PHI from TMA.

NOTICE: *Any and all attachments to this Application must include the name of the research project indicated on this form, the date of request indicated on this form, and the name of the PI.*

2. Indicate whether the Authorization you plan to have research participants sign to obtain their PHI from TMA contains each of the following required elements and statements required by the HIPAA Privacy Rule and DoD 6025.18-R.

[If you are missing any of the following core elements or required statements, you need to revise the Authorization prior to submission, or the review will be denied.]

Core Elements

- Description of PHI to be used or disclosed (identifying the information in a specific and meaningful manner).
- A statement indicating that the individual authorizes TMA to make the requested use or disclosure.
- The name(s) or other specific identification of the person(s) or class of persons to whom TMA may make the requested use or disclosure.
- Description of each purpose of the requested use or disclosure. Researchers should note that this element must be research study specific, not for future unspecified research.
- Authorization expiration date or event that relates to the individual or to the purpose of the use or disclosure (the terms "end of the research study" or "none" may be used for research, including for the creation and maintenance of a research database or research repository).
Signature of the individual and date. If the Authorization is signed by an individual's personal representative, a description of the representative's authority to act for the individual must be provided.



Required Statements

- The individual's right to revoke his/her Authorization in writing and either (1) the exceptions to the right to revoke and a description of how the individual may revoke the Authorization or (2) reference to the corresponding section(s) of the Military Health System's Notice of Privacy Practices (applicable to TMA).
- Notice of TMA's or DoD's ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and, if applicable, any consequences of refusing to sign the Authorization.
- The potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule. This statement does not require an analysis of risk for re-disclosure; rather, it may be a general statement that the Privacy Rule may no longer protect health information.

III. Required Representations

As PI of the research project indicated on this form, I make the following assurances to the TMA Privacy Board: **(initial each assurance and sign below)**

_____ I will maintain, electronically and/or in hard copy, the signed Authorization for every individual research subject whose PHI is used or disclosed in the research project.

_____ I will provide every individual research participant with a copy of the signed Authorization.

_____ I will provide any and/or all of the signed Authorizations to the TMA Privacy Board immediately upon request.

_____ I will provide the TMA Privacy Board with written notification if any of the responses to the above questions change.

_____ I understand that the TMA Privacy Board is NOT an Institutional Review Board and is not authorized to review and/or approve human subjects' research regulated under the Common Rule.

_____ I understand that this Research Authorization Review is binding upon and will inure to the benefit and obligation of the PI of the research project indicated on this form and his/her respective successors and/or assigns.

In accordance with DoD 8520.02, only Principal Investigators with a CAC card may provide an electronic signature as permitted on this template. For Principal Investigators who do not have a CAC card, please print the completed application, provide a handwritten signature, and scan the document so that it may be attached to an email for submission.

PI Signature

Date

PI Printed Name



TMA PRIVACY BOARD

RESEARCH AUTHORIZATION REVIEW

FOR TMA PRIVACY BOARD USE ONLY

Privacy Board Request #: _____

The Research Authorization Review is:

- APPROVED**, with a finding that the Research Authorization satisfies the requirements of the HIPAA Privacy Rule and DoD 6025.18-R required criteria.
- DENIED**

In accordance with DoD 8520.02, only TMA Privacy Board members with a CAC card may provide an electronic signature as permitted on this template. For board members who do not have a CAC card, please print the completed application, provide a handwritten signature, and scan the document so that it may be attached to an email for submission.

Signature of a Designated TMA Privacy Board Member

Date

Printed Name of Designated TMA Privacy Board Member