TMA PRIVACY BOARD

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APPLICATION FOR A WAIVER OF AUTHORIZATION OR AN ALTERED AUTHORIZATION

Privacy Board Request #

Date of Request:	**Principal Investigator (PI):**
Title of Research Project:	
Number of the 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

This document facilitates the submission and review of a request to use or disclose protected health information (PHI) for research purposes under a waiver or alteration by the TMA Privacy Board. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by "Department of Defense (DoD) Health Information Privacy Regulation" (DoD 6025.18-R), requires an Authorization that includes all core elements and required statements in order to use or disclose an individual's PHI, unless a permissible exception applies. Research is a permissible exception allowing use or disclosure of PHI without a HIPAA Authorization where it is impractical or impossible to obtain a HIPAA Authorization from every individual research participant and an Institutional Review Board (IRB) or Privacy Board approves a waiver or alteration of an Authorization.

Based on the information provided in this Application, the TMA Privacy Board will determine whether a full or partial waiver of a HIPAA Authorization or an alteration of the HIPAA Authorization is appropriate in a particular research project in accordance with the HIPAA Privacy Rule and DoD 6025.18-R. It is important that all questions are answered thoroughly and completely and that all required documents are provided as requested to avoid any delays in the review process.

If your project has been submitted to an IRB and the IRB conducts a HIPAA review, completion of this Application is not required. However, you are required to submit the IRB Approved Waiver to the TMA Privacy Board. The TMA Privacy Board will accept Approved IRB Waivers that satisfy all required elements under DoD 6025.18-R, C7.9.2, and the HIPAA Privacy Rule, 45 CFR § 164.512(i)(2).

NOTE: If additional space is required for your response, please use the blank pages at the end of this form. Please label any continued responses with the corresponding Part and Question number(s).

Any and all attachments to this Application, must include the name of the research project and the name of the PI. Acronyms should be defined the first time they are used.

II. Alteration of the Authorization

If you are requesting to alter any of the core elements or required statements that are contained in a HIPAA Authorization, explain what elements/statements you seek to alter and why. (**Note:** A list of the core elements and required statements in a HIPAA Authorization can be found in DoD 6025.18-R, C5.3 and 45 CFR Section 164.508(c).)

Attach a copy of the altered HIPAA Authorization(s) that you propose to use in the above-referenced research project.

III. Required Information

1. All PHI elements that you require in order to conduct your research must be requested in your Data Sharing Agreement Application (DSAA) . If you require any PHI that is not otherwise listed, you are required to modify your DSAA *before* submitting the Waiver Application. The Board will refer to the PHI elements you request in your DSAA when reviewing this Application.

2. *Attach* the research protocol so that the TMA Privacy Board may better understand the research project being conducted.

3. Provide the number of individuals whose PHI will be used or disclosed in your research project.

4. Provide a detailed explanation as to why your research could not practicably be conducted without access to and use of the PHI you requested in your DSAA.

   a. Indicate the page number(s) and section(s) in the protocol where information supporting your explanation can be found.

5. Please check any and all of the criteria outlined below which you believe make it impossible and/or impractical for you to obtain a written, signed Authorization from every individual research participant. Below each criterion that is checked, provide a detailed explanation as to how that criterion applies to this research and adds to the conclusion that the research could not practicably be conducted without the waiver or alteration.

   ☐ The number of research subjects

☐ Difficulty of obtaining individual written authorizations, including, but not limited to, cost and necessary resources

☐ Subjects are deceased making it impossible to determine who the personal representatives are or how to locate them; subjects are inactive military, and current contact information is unavailable in the system making it impossible to contact them

☐ Time constraints (i.e., Congressional mandates)

☐ Time since last contact with the individuals whose PHI will be used or disclosed (i.e., A long time has lapsed since last contact with the individual making it difficult to locate the individual to request the authorization.)

☐ Whether obtaining a written authorization for the use of PHI unnecessarily burdens or poses a new risk to the individual from whom the PHI was collected

☐ Whether informing practitioners or individuals from whom the PHI was collected could alter their behavior and, thus, bias the results of the study

Explain any other criteria not listed above making it impossible or impractical for you to obtain written authorizations.

a. Indicate the page number(s) and section(s) in the research protocol where information can be found supporting your justification for a waiver or alteration.

6. Will there be contact or interaction with every individual research participant during the research project?

   ☐ Yes ☐ If No, go to Question 7.

   If Yes,

   a. What is the mode of contact or interaction with participants? (i.e., email, phone, face-to-face, mobile device, text messaging)

      i. Indicate the page number(s) and section(s) in protocol that describe any contact/interaction with participants.

   b. Does the contact or interaction provide the ability to obtain a written, signed authorization from every individual research participant?

      ☐ Yes ☐ No

      i. **If No**, provide a detailed explanation.

c. Is PHI required prior to making contact or interacting with participants?
☐ Yes ☐ No

i. **If Yes,** explain why you need the PHI you are requesting in your DSAA prior to making contact or interacting with participants. Include in your answer the page number(s) and section(s) in the research protocol where your explanation can be found.

ii. Will continued use of PHI and/or additional PHI be required *after* any contact or interaction with participants?
☐ Yes ☐ No

7. Is PHI needed for the entire project?
☐ Yes ☐ No

a. **If No**, state the time period when PHI is needed as indicated in the protocol.

b. Indicate the page number(s) and section(s) in the research protocol where information can be found supporting the time period indicated in Question 7a above.

8. If your list of PHI requested in the DSAA includes Social Security Numbers (SSNs), provide justification as to why SSNs are required and explain why a substitute cannot be used.

9. Describe your plan to protect identifiers contained in each of the following two types of documents from improper use and disclosure. [Your responses should include administrative, technical and physical safeguards that will be applied for each category of documents that will be maintained in your research project.]

a. Electronic documents

b. Hard copy documents

10. Describe your plan for destroying any and all records containing the identifiers at the completion of the research project. If the identifiers will not be destroyed, provide a health, research, or legal justification for retaining the identifiers. [Include the ***date and method*** for destruction in your response or a valid justification for retaining the identifiers.]

11. Pursuant to regulatory requirements, waiver approvals must document whether normal/full or expedited review procedures were used. The TMA Privacy Board's method of review for this waiver will be documented at the time of approval.

IV. Required Assurances

As Principal Investigator of the above-referenced research project, I make the following assurances to the TMA Privacy Board: (**initial each assurance and sign below**)

_____ The investigators and research staff who use and disclose PHI in connection with this research project will not reuse the PHI or disclose it to any person or entity other than those authorized to receive it, except: 1) as required by law; 2) for authorized oversight of the research project; or, 3) for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule [implemented by DoD 6025.18-R for DoD components].

_____ All information provided in this Application and the accompanying attachments are complete and accurate.

_____ If any responses in this Application change in any way during the course of the research project, I agree to terminate access and use of the PHI obtained from TMA until I resubmit this Application with updated information for further review and approval by the TMA Privacy Board.

_____ 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 waiver Application is binding upon and will inure to the benefit and obligation of the Principal Investigator of the above-referenced research project and his/her respective successors and/or assigns.

Signatures: 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

Additional Space: Please use the following blank pages for additional space to provide the required responses. Please label any continued responses with the corresponding Part and Question number(s).

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FOR TMA PRIVACY BOARD USE ONLY

Privacy Board Request #: _____ **EXPEDITED REVIEW CONDUCTED**

Pursuant to the HIPAA Privacy Rule and DoD 6025.18-R, this Application for a Waiver of Authorization or an Altered Authorization is:

☐ **APPROVED for a Partial Waiver of Authorization** (Check appropriate reason)

- ☐ A Research Authorization Review and PI Certification is also needed before completing the Board's review of this study

OR

- ☐ The Partial Waiver is all that is required for this study

☐ **APPROVED for Full Waiver of Authorization**

☐ **APPROVED for Alteration of Authorization**

☐ **DENIED** (Check appropriate reason)

- ☐ A waiver/alteration is not appropriate because written authorization can be obtained from every individual research participant
- ☐ The Application cannot be approved due to inadequate responses to question III 8, III 9 and/or III 10

Signatures: 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