



# Defense Health Agency (DHA) Institutional Review Board (IRB) Health Insurance Portability and Accountability Act (HIPAA) Compliance Review Findings on Data Requests

## A. TO BE COMPLETED BY RESEARCHER

**Principal Investigator (PI) Name and Rank (if applicable):** [Click here to enter text.](#)

**Corps and Service/Organization:** [Click here to enter text.](#)

**Title of Research Study:** [Click here to enter text.](#)

**Researcher Status: Indicate your status using the below definitions**

- MHS workforce member or MHS business associate
- Not an MHS workforce member or business associate

The *Military Health System* is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by the DHA.

*MHS workforce members* are employees, volunteers, trainees, and other persons whose conduct, in the performance of work for the MHS, is under the direct control of the MHS, whether they are paid by the MHS or not.

*MHS business associates* are contractors providing a service on behalf of an MHS health care provider or an MHS health plan and require DHA protected health information (PHI) to provide the service.

## 1. DATA SOURCE

**NOTE: Under the Privacy Act of 1974, as amended, 5 USC §552(a), and the HIPAA Privacy Rule requirements, Researchers may only receive the minimum amount of data needed to accomplish the intended purpose for the use of data managed by DHA (DHA data).**

- a.  Researcher agrees that the data requested is the minimum necessary to accomplish the purpose of the study as described in the Protocol
- b. **FORMAT OF DATA:** Indicate all the ways in which you will obtain data managed by DHA (DHA data) for this project.
  - Verbal–Talking with MHS health care providers or health care plans about patient cases or history
  - Hard Copies–Obtaining DHA hard copy records
  - Digital–Accessing or obtaining data from an information system(s) managed by DHA

**NOTE:** *Digital data managed by DHA is data maintained on DHA information systems or information systems that are determined to fall under the DHA Chief Information Officer. The DHA Privacy Office has a list of systems that contain DHA data to assist Researchers in determining whether data is DHA data. If the system is not on the list, then the Researcher or the DoD Sponsor should contact the DHA Privacy Office for assistance at [DHA.PrivacyBoard@mail.mil](mailto:DHA.PrivacyBoard@mail.mil).*



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c. **DIGITAL DHA DATA:** If you are obtaining digital DHA data, indicate ALL the ways you plan to receive digital DHA data.

- Researcher will view DHA data by directly logging into the source and will **not** download data
- Researcher will obtain DHA data by downloading data after logging into the source
- Researcher will receive DHA data as an extraction provided by the following DoD program:  
[Click here to enter text.](#)

d. **NON-DHA DATA:** Indicate if the DHA data will be merged, linked, or otherwise associated with data from any other sources outside of DHA, including but not limited to non-DHA hardcopies, other digital DoD data that is not managed by DHA, and digital non-DoD data

- Yes, will merge data
- No, will not merge data

e. **DHA SYSTEMS THAT WILL BE ACCESSED:** In the space below, enter the names of the information system(s) that will be accessed for digital DHA data.

***NOTE:** For non-MHS business associates or non-MHS employees with access rights to an information system, the determination of the type of data you are requesting through access will depend upon the type of information in the system you are accessing. For example, if the information system has PHI, the determination of the type of data requested through access will be PHI. If you intend to access more than one information system, the determination of the type of data requested through access will be the most sensitive data type on the information systems to be accessed. For example, if one information system has personally identifiable information (PII) excluding PHI and the other information system has PHI, the data access request will be considered a request for PHI.*

*For MHS business associates and MHS employees, the data determination will be based on the data elements accessed for the project as indicated below in Section 2.*

Section 1.e is not applicable because not accessing a DHA information system

### List the Names of DHA Information Systems

[Click here to enter text.](#)

f. **DHA SYSTEMS FROM WHICH DHA DATA WILL BE DOWNLOADED FOR STORAGE:** In the space below, enter the names of the information system(s) from which digital DHA data will be downloaded to be stored on another federal or non-federal information system.

Section 1.f is not applicable because not downloading DHA data.

### List the Names of DHA Information Systems



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Click here to enter text.

- g. **DHA SYSTEMS FROM WHICH DHA DATA WILL BE EXTRACTED:** In the space below, enter the names of the information system(s) from which digital DHA data will be extracted and provided to the Researcher.

Section 1.g is not applicable because not requesting an extract of digital DHA data

**List the Names of DHA Information Systems**

Click here to enter text.

**2. DATA TYPE**

- a. Indicate data elements about individuals or relatives, employers, or household members of individuals that you will receive from: 1) DHA hard copies; 2) accessing digital DHA data; 3) extracted digital DHA data; or 3) downloaded digital DHA data after accessing an information system. If you indicated above that you plan to merge the DHA data with other data, also indicate non-DHA data elements about individuals or relatives, employers, or household members of individuals that you will access or receive in any medium. **Select all categories even if you are replacing the data element with a quasi-ID (replacing an identifier with another code or ID to minimize identification).**

**NOTE:** For MHS business associates and MHS employees, the type of DHA data requested will be based on the data elements requested for the project and whether health information is included in the data request, regardless of whether the DHA data is obtained through access or received as an extraction. If health information is requested and you indicate data elements in rows 2, 4, 5, or 20 only, the data determination type is a limited data set (LDS). If you indicate data elements in rows more than 2, 4, 5, or 20, the data determination type is PHI greater than an LDS. If health information is not requested, then a data request that includes any data elements listed in the table is PII excluding PHI, **unless the data elements requested from the table are health information as explained below.**

For non-MHS business associates or non-MHS employees who access an information system to obtain DHA data and/or receive DHA data through an extraction, the data determination will be based on either the type of data in the information system accessed or the data elements received by the DHA through an extraction of data from an information system, depending on which data type is most sensitive based on the following order: PHI, LDS, PII excluding PHI, De-identified data.



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<i>Direct and Indirect Identifiable Data Elements</i>	<i>DHA Hard Copies</i>	<i>DHA Data Elements to be Accessed</i>	<i>Extracted DHA Digital Data</i>	<i>Downloaded DHA Digital Data</i>	<i>Non DHA Hard Copies or Digital</i>
1. Names	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Postal address with <i>only</i> town, city, state, and zip code	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Postal address with all geographic subdivisions smaller than state, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of Census: 1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and 2) the initial three digits of a zip code from all such geographic units containing 20,000 or fewer people is changed to 000	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Dates including all elements (except year) directly related to an individual, including birthdate, admission date, discharge date, and date of death	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Ages over 89 and all elements of dates ( <i>including year</i> ) indicative of such age, unless you will only request a single category of "age 90 or older"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Telephone Numbers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Fax Numbers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Email Addresses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Social Security Numbers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Medical Record Numbers (MRN) ( <i>including record ID</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Health Plan Beneficiary Numbers ( <i>including DEERS ID, Electronic Data Interchange Personal Identifier (EDIPI) or Number (EDIPN)</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Account Numbers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Certificate/License Numbers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



## Defense Health Agency (DHA) Institutional Review Board (IRB) Health Insurance Portability and Accountability Act (HIPAA) Compliance Review Findings on Data Requests

<i>Direct and Indirect Identifiable Data Elements</i>	<i>DHA Hard Copies</i>	<i>DHA Data Elements to be Accessed</i>	<i>Extracted DHA Digital Data</i>	<i>Downloaded DHA Digital Data</i>	<i>Non DHA Hard Copies or Digital</i>
14. Vehicle identifiers and serial numbers, including license plate numbers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Device identifiers and serial numbers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Web Universal Resource Locators (URLs)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Internet Protocol (IP) address numbers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Biometric identifiers, including finger and voice prints	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Full-face photographic images and any comparable images	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Any other unique identifying number, characteristic, or code ( <i>including non-military provider IDs</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Free Text Fields	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

b. Will you receive or obtain health information?

- Yes, I will receive or obtain health information
- No, I will not receive or obtain health information

**Note:** If you indicate you are not receiving health information, the answer must be consistent with the DHA data source. For a non-health information data request, if you are a non-MHS employee or non-MHS business associate, you may not access an information system that has PHI or LDS. For both MHS and Non-MHS employees and MHS business associates, you may **NOT** include data elements in the above table on: 1) lines 10 or 11, 2) line 21 if the free text field comes from a PHI or LDS system, and 3) lines 12, 13, or 18 if the account numbers, certificate and license numbers, biometric data, or any other data elements are health information created or received by an MHS health care provider, health plan, or business associate in relation to the physical or mental health or condition of an individual or payment for health care.

c. If no data elements were checked in the above table, is it possible that the requested DHA data is or will be identifiable because of any unique data elements, triangulation, or small cell size?

- Data elements were checked in the above table, STOP HERE.**

**NOTE:** A unique data element includes any unique features that alone are not identifiable but that could be used to identify an individual within the context of other information, such as any type of



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*code (such as diagnosis or procedural), rank of general or admiral, gender, or race. Triangulation means using different data elements that when combined can be used to identify an individual, such as including the above lists of unique data elements in a data set. Determining whether an individual is identifiable through triangulation requires consideration of all data elements in combination. Within the military, the use of rank and/or diagnosis code, procedural codes, or any other code that changes on a predictable basis, increases the possibility of identification. Small cell size means that there is only a small number of eligible individuals that satisfy the category description. Department of Defense Manual 6025.13, Medical Quality Assurance and Clinical Quality Management in the Military Health System (MHS), provides that the threshold for de-identifying data within the MHS requires a cell size of three, but also states that the de-identification standards must meet the DoD implementation of the HIPAA Privacy Rule. Centers for Medicare and Medicaid also gives guidance on small cell size stating that no data cell less than 11 may be published or displayed. However, the Office for Civil Rights' (OCR), which is the official regulatory office for the HIPAA Privacy Rule, provides that OCR does not designate a universal value for small cell size in accordance with the de-identification standard; instead, the cell size should be set at a level that is appropriate to mitigate risk of identification by the anticipated recipient of the data set. This means that a cell size of 3 or 11 may not meet the HIPAA Privacy Rule requirements if the cell size level does not appropriately mitigate risk of identification by the anticipated recipient of the data set.*

**Note: If dates are altered as a means of de-identifying the data, diagnosis and procedural codes need to be rolled-up or collapsed. If dates are provided "as time between events," the roll-up is not necessary.**

- Yes, the DHA data will become identifiable
- No, the DHA data will not become identifiable table

d. If you checked that the DHA data will not become identifiable in Section 2c, explain below how unique data elements, triangulation, and small cell size are addressed or are not applicable. If you are requesting rank and/or diagnosis or procedural codes, explain how these data elements in combination with other data elements will not make the data identifiable.

**Data elements will be identifiable due to unique data elements, merging, and triangulation STOP HERE.**

*A sample statement for cell size is included below.  
"If individual level data sets or summary tables contain cells with less than 11 counts, the data is either deleted and instead an asterisk will indicate that the count was too small, or the data will be re-categorized so that the new cell size will no longer contain counts of 11 or less."*

Click here to enter text.

**STOP HERE, the IRB will complete the next Section.**





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## B. TO BE COMPLETED BY AN IRB

IRB Name: Choose an item.

## NON-REPOSITORY DATA REQUEST

<input type="checkbox"/> <b>Not Applicable Requesting DHA Data to Put into a Repository Only</b>	
<i>IRBs should complete this section for both Non-Repository (specific study) data requests and Combined Non-Repository and Repository data requests by using the information provided by the researcher in the above responses and in the Research Repository Template (RRT). For assistance with the type of data in an information system, use the categorized list of information systems (List).</i>	
<b>I. Minimum Necessary: The data requested is the minimum necessary to accomplish the purpose of the study as described in the Protocol:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>II. Form and Type of DHA Data Requested—Indicate ALL that apply</b>	
<input type="checkbox"/>	Verbal—PHI
<input type="checkbox"/>	Hard Copies
	Type of hard copy DHA data based on section 2.a hard copy data elements and answers to sections 2.b-2.d <input type="checkbox"/> PHI <input type="checkbox"/> LDS <input type="checkbox"/> PII Excluding PHI <input type="checkbox"/> De-identified
<input type="checkbox"/>	Access Information System(s) to Obtain Digital DHA Data
	Type of digital DHA data in the information system accessed based on systems listed in section 1.e and the List <input type="checkbox"/> PHI <input type="checkbox"/> LDS <input type="checkbox"/> PII Excluding PHI <input type="checkbox"/> De-identified
	Type of accessed digital DHA data based on section 2.a accessed data elements and answers to sections 2.b-2.d <input type="checkbox"/> PHI <input type="checkbox"/> LDS <input type="checkbox"/> PII Excluding PHI <input type="checkbox"/> De-identified
<input type="checkbox"/>	Download digital DHA data to be stored for use for this study
	Type of downloaded digital DHA data based on section 2.a downloaded data elements and answers to sections 2.b-2.d <input type="checkbox"/> PHI <input type="checkbox"/> LDS <input type="checkbox"/> PII Excluding PHI <input type="checkbox"/> De-identified
<input type="checkbox"/>	Extract digital DHA data
	Type of digital DHA data in the information system from which data will be extracted based on systems listed in section 1.g and the List <input type="checkbox"/> PHI <input type="checkbox"/> LDS <input type="checkbox"/> PII Excluding PHI <input type="checkbox"/> De-identified
	Type of extracted digital DHA data based on section 2.a extracted data elements and answers to sections 2.b-2.d <input type="checkbox"/> PHI <input type="checkbox"/> LDS <input type="checkbox"/> PII Excluding PHI <input type="checkbox"/> De-identified
<b>III. Determination Type of DHA Data Requested for a Specific Study Using the Following Guidance</b> <i>For MHS business associates and MHS employees, the type of DHA data requested will be based on the combination of data elements requested for the project, regardless of whether the DHA data is obtained through access or received as an extraction, and the answer to question 2.b, whether the data will have health information. If the data request includes health information, then using the table in Section 2.a above, a data request for data elements in rows 2, 4, 5, or 20 only, is an LDS data request. A data request for any data elements in rows other than 2, 4, 5, or 20 is a PHI greater than LDS (PHI) data request. If health information is</i>	



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*not requested, then the data request is PII excluding PHI if any data elements are checked in the table. If no data elements are checked in the table, the data request may be LDS, PII excluding PHI, or De-identified data depending on the answers to the questions in section 2.b-2.d above.*

*For non-MHS business associates or non-MHS employees who access an information system to obtain DHA data and/or receive DHA data through an extraction, the data determination will be based on either the type of data in the information system accessed or the combination of data elements received from the DHA through an extraction of data from an information system. The final data determination depends on which data type (data type in accessed information systems or data type of extracted data elements) is most sensitive based on the following order: PHI, LDS, PII excluding PHI, De-identified.*

- PHI       LDS       PII Excluding PHI       De-identified

**IV. Type of HIPAA Documentation Approved by IRB if PHI Request—Indicate ALL that apply**

<input type="checkbox"/>	MHS HIPAA Authorization and PI Certification
<input type="checkbox"/>	DoD IRB Waiver of Authorization or Altered Authorization: <input type="checkbox"/> Full <input type="checkbox"/> Partial
<input type="checkbox"/>	External IRB Waiver of Authorization or Altered Authorization: <input type="checkbox"/> Full <input type="checkbox"/> Partial
<input type="checkbox"/>	Representations for Review Preparatory to Research
<input type="checkbox"/>	Representations for Research on Decedent’s Information Only

**REPOSITORY DATA REQUEST**

**Not Applicable—Requesting data for Non-Repository Only (specific study only) and will destroy or return DHA data at completion of the study**

*IRBs should complete this section for both Repository Only data requests and Combined Non-Repository and Repository data requests by using the information provided by the researcher in the above responses and in the Research Repository Template (RRT). For assistance with the type of data in an information system, use the categorized list of information systems (List).*

**I. Minimum Necessary: The data requested is the minimum necessary to accomplish the purpose of the study as described in the Protocol:**     Yes     No

**II. Form and Type of DHA Data Requested—Indicate ALL that apply**

<input type="checkbox"/>	Hard copy DHA data including derivative data from verbal PHI
	Type of hard copy DHA data based on hard copy data elements and answers to sections 2.b-2.d <input type="checkbox"/> PHI <input type="checkbox"/> LDS <input type="checkbox"/> PII Excluding PHI <input type="checkbox"/> De-identified
<input type="checkbox"/>	Access information system(s) to obtain digital DHA data – <b>Note: For a Combined Non-Repository and Repository Data Request, the data determination regarding accessed digital DHA data should be the same as in the above Non-Repository Determination for accessed digital DHA data</b>
	Type of digital DHA data in the information system accessed based on systems listed in section 1.e and the List <input type="checkbox"/> PHI <input type="checkbox"/> LDS <input type="checkbox"/> PII Excluding PHI <input type="checkbox"/> De-identified
	Type of accessed digital DHA data based on section 2.a accessed data elements and answers to sections 2.b-2.d <input type="checkbox"/> PHI <input type="checkbox"/> LDS <input type="checkbox"/> PII Excluding PHI <input type="checkbox"/> De-identified





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<input type="checkbox"/>	Download digital DHA data to be stored for use for this repository
	Type of downloaded digital DHA data to be stored or put in the repository based on section 2.a downloaded data elements and RRT, sections 3.c–3.g <input type="checkbox"/> PHI <input type="checkbox"/> LDS <input type="checkbox"/> PII Excluding PHI <input type="checkbox"/> De-identified
<input type="checkbox"/>	Extract digital DHA data received from information systems
	Type of digital DHA data in the information system from which data will be extracted based on systems listed in section 1.g and the List <input type="checkbox"/> PHI <input type="checkbox"/> LDS <input type="checkbox"/> PII Excluding PHI <input type="checkbox"/> De-identified
	Type of extracted digital DHA data to be put into the repository based on section 2.a extracted data elements and RRT, sections 3.c–3.g – <b>Note: If the data to be put into the repository includes a free text field, and the information system from which data is obtained has PHI or LDS, then the data in the repository must be PHI or LDS.</b> <input type="checkbox"/> PHI <input type="checkbox"/> LDS <input type="checkbox"/> PII Excluding PHI <input type="checkbox"/> De-identified
<b>III. Existing or New Repository: Based on RRT, section 3.h, indicate whether the repository is existing or new</b>	
Existing repository and name: <a href="#">Click here to enter text.</a>	
New repository and name: <a href="#">Click here to enter text.</a>	
<b>IV. Determination Type of DHA Data Requested for a Repository Only Request Using the Above Guidance</b> Using the guidance for making a data determination for a specific study, indicate the determination of the type of DHA data requested for a Repository Only data request. <i>Note: This answer will be the same as in Section V, unless a non-MHS Employee or non-MHS Business Associate will access an information system to create and download a data set to store or put in a repository.</i> <input type="checkbox"/> PHI <input type="checkbox"/> LDS <input type="checkbox"/> PII Excluding PHI <input type="checkbox"/> De-identified <input type="checkbox"/> N/A–Not Repository Only	
<b>V. Determination Type of DHA Data to be Put into the Repository</b> <i>The type of DHA data in the repository will be based on: 1) the DHA Privacy Office data experts’ review of the de-identification plan if the researcher intends the repository to include de-identified data only in the repository; or 2) the DHA data elements to be put into the repository. If the answer to RRT, section 3.e indicates that the researcher intends to put the exact same DHA data elements received through extraction or obtained through downloading as indicated in the above section 2.a table, then the repository DHA data determination type depends on the data elements indicated in this table and the answer to question 2.b, whether the data will have health information. If the answer to RRT, section 3.e indicates that the researcher does NOT intend to put into the repository the exact same DHA data elements as in the above section 2.a table, then the repository DHA data determination type depends on the data elements indicated in RRT, section 3.f table and the answer to question 3.g, whether the data will have health information.</i>  <i>If the data repository will include health information, then using the appropriate table of data elements, a data repository with data elements in rows 2, 4, 5, or 20 only, is an LDS data request. A data repository that includes any data elements in rows other than 2, 4, 5, or 20 is a PHI greater than LDS repository. If health information will not be included in the repository, then the repository is PII excluding PHI if any data elements are checked in the table. <b>If the repository will have de-identified data, the IRB must get approval from the DHA Privacy Office data experts that the data meets compliance requirements for de-identification before determining that the repository has de-identified data.</b></i>	



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<input type="checkbox"/> PHI	<input type="checkbox"/> LDS	<input type="checkbox"/> PII Excluding PHI	<input type="checkbox"/> De-identified as Confirmed by Data Experts
<b>VI. Type of HIPAA Documentation Approved by IRB if PHI Requested to Be Put into a Repository</b>			
<input type="checkbox"/>	MHS HIPAA Authorization with Future Research Opt-in		
<input type="checkbox"/>	DoD IRB Waiver of Authorization or Altered Authorization		
<input type="checkbox"/>	External IRB Waiver of Authorization or Altered Authorization		

Upon completion, please send a copy of this document to the researcher, and send a copy of this document, along with the Research Repository Template submitted by the researcher to [DHA.PrivacyBoard@mail.mil](mailto:DHA.PrivacyBoard@mail.mil).

Reviewer's Name: [Click here to enter text.](#)

Date: [Click or tap to enter a date.](#)

X

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Reviewer's Signature