Defense Health Agency (DHA)
Research Repository Template
For ALL Research Studies seeking DHA data

This template is designed to assist the Department of Defense Institutional Review Board with determining if DHA data disclosed to a research study will, in any form (de-identified or otherwise), be placed in a research repository and, if so, the type of data and whether any Health Insurance Portability and Accountability Act (HIPAA) compliance requirements are applicable. For purposes of this template, the term "**repository**" is defined as either: 1) the physical or virtual collection and storage of data or derivative data for future use and disclosure, or 2) any collection of data or derivative data without an explicit plan to destroy the data or derivative data when the purpose for which the data or derivative data was collected ends. A repository may include, for example, copies of a data set, a code key based on identifiable information, transcribed or digitized verbal data, and small data collections created by individuals in a document, such as an Excel spreadsheet, or in a program or application.

1. **Please provide answers to the questions below and certify your responses by signing where required.**

   Project Title:

   Principal Investigator (PI) Name and Rank/Title, as applicable:

   Service/Organization:

   E-Mail Address: Phone Number:

2. **Do you intend to use the received DHA data or derivative DHA data to put into a research repository?** *Note: A research repository may include DHA data or derivative data received, created, or downloaded for a particular research study that is later put into a new or existing research repository, or DHA data or derivative data received or downloaded for the sole purpose of putting the data into a new or existing research repository.*

   a.   **PI Initials** Yes - answer Section 3 below.
   b.   **PI Initials** No - skip to Section 4 below.

3. **Required information IF you intend to put DHA data or derivative data into a repository**
   NOTE: *The Institutional Review Board (IRB) must determine the type of data or derivative data to be put into the repository based on the requested data elements indicated in the "DHA Institutional Review Board HIPAA Compliance Review Findings on Data Requests (IRB Findings Document)," section 2.a table of data elements or on the table below. If you intend to put de-identified data into a repository, the IRB will submit your de-identification plan to the DHA Privacy Office data experts to verify that the de-identification plan meets compliance requirements.*

   a. Will you put DHA data into an existing repository or new repository?

   ☐
   ☐ Existing   ☐ New

b. Indicate the name of the repository: **Click here to enter text.**

c. Indicate ALL the types of repositories where DHA data will be stored:

 ☐ Hard Copy ☐ Information System

d. If you are creating an information system repository, will the digital DHA data for the repository be received through an extraction of digital DHA data provided to you, or will you download digital DHA data from an information system?

 ☐ Extraction ☐ Download ☐ N/A

e. Do you intend to put DHA data into a de-identified data repository?

 ☐ Yes, attach the de-identification plan to this template. **Continue to Question 3.i.**
 ☐ No, continue to next question.

f. Will the DHA data placed in the repository include the exact same data elements indicated in the *IRB Findings Document*, section 2.a table?

Hard Copies	☐ Yes	☐ No	☐ N/A
Extracted Data	☐ Yes	☐ No	☐ N/A
Downloaded Data	☐ Yes	☐ No	☐ N/A

g. **If yes** for all data types in Question 3(f) above, **continue to Question 3.i.**

 If no to any data type in Question 3(f) above, indicate the DHA data elements that you will put into the repository from hard copies or an information system in the below table.

 Note: *If the repository has health information and includes data elements 2, 4, 5, or 20 only, the repository is a limited data set (LDS) repository. If the repository includes data elements other than 2, 4, 5, or 20, the repository is a PHI greater than LDS repository. If the repository does not have health information, then a data request that includes any data elements listed in the table is PII excluding PHI, unless the data elements requested in the table are health information as explained below.*

 You should only request the minimum amount of data elements necessary to meet the purpose of the repository.

Direct and Indirect Identifiable Data Elements to be Put into Repository	Hard Copy	DHA Information System
1. Names	☐	☐
2. Postal address with *only* town, city, state, and zip code	☐	☐
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	☐	☐
4. Dates including all elements (except year) directly related to an individual, including birthdate, admission date, discharge date, and date of death	☐	☐
5. Ages over 89 and all elements of dates (including year) indicative of such age, unless you will only request a single category of "age 90 or older"	☐	☐
6. Telephone numbers	☐	☐
7. Fax numbers	☐	☐
8. Electronic mail addresses	☐	☐
9. Social Security Number (SSNs)	☐	☐
10. Medical record numbers	☐	☐
11. Health Plan Beneficiary Number *(including DEERS ID, Electronic Data Interchange Personal Identifier (EDIPI) or Number (EDIPN))*	☐	☐
12. Account numbers	☐	☐
13. Certificate/license numbers	☐	☐
14. Vehicle identifiers and serial numbers, including license plate numbers	☐	☐
15. Device identifiers and serial numbers	☐	☐
16. Web Universal Resource Locator (URLs)	☐	☐
17. Internet Protocol (IP) address numbers	☐	☐
18. Biometric identifiers, including finger and voice prints	☐	☐
19. Full-face photographic images and any comparable images	☐	☐
20. Any other unique identifying number, characteristic, or code	☐	☐
21. Free text fields	☐	☐

h. Will you put health information into the repository?

*Note: If you indicate you are not putting health information into the repository, the answer must be consistent with the DHA data elements to be put into the repository. For a non-health information data request, you may **NOT** include data elements received through an extraction or downloaded from an information system to put into the repository that include: 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.*

☐ Yes   ☐ No

i. Who will use the data in the repository *(include titles/roles of people who will use the data in the respository)*?

Click here to enter text.

j. Describe the requirements for disclosing data from the research repository, including the name of any governing documents related to the sharing of data in the repository and the permissible purposes for the use of the data. *Note: When signing the DHA data sharing agreement (DSA), you must agree to adopt and keep updated governance documents on the uses and disclosures of DHA data from the repository.*

Click here to enter text.

4. **Required Assurances**

As PI of the research study indicated on this template, I make the following assurances to DHA (initial each assurance and sign below):

   a. Click here to enter text. **PI Initials**   No DHA data will be placed in a repository if the repository is not identified in Section 3.b above and if the IRB has not approved the data to be put into the repository.

   b. **Click here to enter text. PI Initials**   I understand that these required representations apply to the above-referenced research study and will inure to the benefit and obligation of the PI, his/her successor investigators, or assigns.

5. **Signature of PI**

In accordance with DoD Instruction 8520.02, only PIs with a Common Access Card (CAC) may provide an electronic signature as permitted on this template. PIs who do not have a CAC must print the completed template and provide a handwritten signature.

PI Printed Name Click here to enter text.   **Date** Click or tap to enter a date.

X
_____
PI Signature