PRIVACY IMPACT ASSESSMENT (PIA)

PRESCRIBING AUTHORITY: DoD Instruction 5400.16, "DoD Privacy Impact Assessment (PIA) Guidance". Complete this form for Department of Defense (DoD) information systems or electronic collections of information (referred to as an "electronic collection" for the purpose of this form) that collect, maintain, use, and/or disseminate personally identifiable information (PII) about members of the public, Federal employees, contractors, or foreign nationals employed at U.S. military facilities internationally. In the case where no PII is collected, the PIA will serve as a conclusive determination that privacy requirements do not apply to system.

1. DOD INFORMATION SYSTEM/ELECTRONIC COLLECTION NAME:

Military Traumatic Brain Injury Initiative (MTBI2)

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

08/28/24

Uniformed Services University of the Health Sciences (USUHS)

SECTION 1: PII DESCRIPTION SUMMARY (FOR PUBLIC RELEASE)

a. The PII is: *(Check one. Note: Federal contractors, military family members, and foreign nationals are included in general public.)*

- [ ] From members of the general public
- [ ] From Federal employees
- [x] from both members of the general public and Federal employees
- [ ] Not Collected *(if checked proceed to Section 4)*

b. The PII is in a: *(Check one.)*

- [ ] New DoD Information System
- [ ] New Electronic Collection
- [x] Existing DoD Information System
- [ ] Existing Electronic Collection
- [ ] Significantly Modified DoD Information System

c. Describe the purpose of this DoD information system or electronic collection and describe the types of personal information about individuals collected in the system.

Military Traumatic Brain Injury Initiative (MTBI2) is a collaborative research program consisting of the Uniformed Services University of the Health Sciences (USUHS), the National Institutes of Health (NIH), and Walter Reed National Military Medical Center (WRNMMC). MTBI2 consists of 2 major informatics systems; The Collection, Access, Sharing and Analytics (CASA) platform, and the MTBI2 Data Repository. The CASA platform is an instance of the Biomedical Research Informatics Computing System (BRICS), a joint NIH – DoD/ DHA system. This system is used for the electronic data collection and storage of research data from service members and dependents to include personal identifiable information (PII), protected health information (PHI), rank, service information, injury history and any relevant study data (MRI, CT, EEG, blood draws, etc.). The CASA system is used for patient management, randomization for clinical trial treatment options, collection of medical histories, medications and regulatory compliance for the various clinical research studies to include clinical trials. The CASA system can perform remote data collection via transmission of secure encrypted links to the research patients to complete applicable web forms. Patients will not have login permissions to MTBI2 or view system data post data collection. Access for approved users to MTBI2 is accomplished using CAC, PIV,NEATS Alternate Token or ECA Certificate. The Data Repository is used to house de-identified data from all funded studies.

d. Why is the PII collected and/or what is the intended use of the PII? *(e.g., verification, identification, authentication, data matching, mission-related use, administrative use)*

To generate subject profiles, to reach out to subjects for follow up visits, electronic consent, remote data collection and to generate global unique identifiers for data deidentification.

e. Do individuals have the opportunity to object to the collection of their PII? [x] Yes [ ] No

(1) If "Yes," describe the method by which individuals can object to the collection of PII.

(2) If "No," state the reason why individuals cannot object to the collection of PII.

PII will be collected in the study specific consent form when the subject provides signed informed consent to participate in the study.

f. Do individuals have the opportunity to consent to the specific uses of their PII? [x] Yes [ ] No

(1) If "Yes," describe the method by which individuals can give or withhold their consent.

(2) If "No," state the reason why individuals cannot give or withhold their consent.

All subjects are required to sign an informed consent form. Individuals can inform in writing the study specific PI that they do not wish to continue participating in the study or that they would like to stop their data from being used, upon which their data and information will be removed from the system.

g. When an individual is asked to provide PII, a Privacy Act Statement (PAS) and/or a Privacy Advisory must be provided. *(Check as appropriate and provide the actual wording.)*

☒ Privacy Act Statement ☐ Privacy Advisory ☐ Not Applicable

Authority: Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at: https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf,
The research team will keep your research records. These records may be looked at by staff from the Military Traumatic Brain Injury Initiative (MTBI2) or the Institutional Review Board (IRB) at the Uniformed Service University (USUHS) or Walter Reed National Military Medical Center (WRNMMC) as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Purpose: Procedures to protect the confidentiality of the data in this study include but are not limited to: Your research records will not be disclosed outside of WRNMMC or USU. Data will be stored in a secure database which is maintained by the Military Traumatic Brain Injury Initiative (MTBI2) but your data will only be identified only by a unique code number, not your name, social security number or any other personal identifier that could be associated with you. A link between the code will be kept in a protected file in a secure location, with access strictly limited to authorized research study personnel. Data collected during this study will be shared with MTBI2 and organizations associated with MTBI2, the Uniformed Services University, US Department of Defense. Your name and personally identifying information will be removed before the data is shared so that the shared data will not contain any information that could identify you. You will not be personally identified; all information will be presented as anonymous data. Your name or other ways to identify you personally will not appear in any published paper or presentation related to this study. Your research records may be shared with research collaborators at other sites, but in this case will only be identified by a unique code number, not with any personal identifying information.

Routine uses. Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This web site will not include information that can identify you. At most, the Web site will include a summary of results. You can search this Web site at any time.

Disclosure: Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty. Those who have access to your records as identified above agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law. Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will deidentified.

h. With whom will the PII be shared through data/system exchange, both within your DoD Component and outside your Component? *(Check all that apply)*

☒	Within the DoD Component	Specify.	Uniformed Services University of the Health Sciences (USUHS)
☒	Other DoD Components *(i.e. Army, Navy, Air Force)*	Specify.	Army, Navy, Air Force, Coast Guard
☒	Other Federal Agencies *(i.e. Veteran's Affairs, Energy, State)*	Specify.	VA, Department of State, Department of Health and Human Services
☐	State and Local Agencies	Specify.	
☒	Contractor *(Name of contractor and describe the language in the contract that safeguards PII. Include whether FAR privacy clauses, i.e., 52.224-1, Privacy Act Notification, 52.224-2, Privacy Act, and FAR 39.105 are included in the contract.)*	Specify.	Contracting companies specific to each location
☒	Other *(e.g., commercial providers, colleges).*	Specify.	Allow specific users who need to create subject profiles and have been approved on the specific IRB approved study ex. PI, Co-PI, study data manager. Access is restricted to those who need PII information for supporting the study.

i. Source of the PII collected is: *(Check all that apply and list all information systems if applicable)*

☒ Individuals ☐ Databases

☐ Existing DoD Information Systems ☐ Commercial Systems

☐ Other Federal Information Systems

j. How will the information be collected? *(Check all that apply and list all Official Form Numbers if applicable)*

- [x] E-mail
- [x] In-Person Contact
- [ ] Fax
- [ ] Information Sharing - System to System
- [ ] Other *(If Other, enter the information in the box below)*
- [ ] Official Form (*Enter Form Number(s) in the box below)*
- [x] Paper
- [x] Telephone Interview
- [x] Website/E-Form

k. Does this DoD Information system or electronic collection require a Privacy Act System of Records Notice (SORN)?

A Privacy Act SORN is required if the information system or electronic collection contains information about U.S. citizens or lawful permanent U.S. residents that is retrieved by name or other unique identifier. PIA and Privacy Act SORN information must be consistent.

- [x] Yes
- [ ] No

If "Yes," enter SORN System Identifier EDHA08

SORN Identifier, not the Federal Register (FR) Citation. Consult the DoD Component Privacy Office for additional information or http://dpcld.defense.gov/Privacy/SORNs/

or

If a SORN has not yet been published in the Federal Register, enter date of submission for approval to Defense Privacy, Civil Liberties, and Transparency Division (DPCLTD). Consult the DoD Component Privacy Office for this date

If "No," explain why the SORN is not required in accordance with DoD Regulation 5400.11-R: Department of Defense Privacy Program.

l. What is the National Archives and Records Administration (NARA) approved, pending or general records schedule (GRS) disposition authority for the system or for the records maintained in the system?

(1) NARA Job Number or General Records Schedule Authority. N1-330-91-002, item 914-01a, N1-330-91-002, item 914-01b

(2) If pending, provide the date the SF-115 was submitted to NARA.

(3) Retention Instructions.

As applicable:

FILE NUMBER: 1920-01
DISPOSITION: Permanent. Cut off when project is concluded; transfer to the NARA 20 years after cut off. NOTE: Files created in the course of research undertaken at the request of non-DoD agencies, e.g., the NIH, are not covered by this schedule, must be clearly identified, and must be kept separate from defense-related work.

FILE NUMBER: 1920-02
DISPOSITION: Temporary. Cut off and destroy all other materials when no longer required for research or reference purposes.
NOTE: Those experiments involving human subjects and/or deemed to be of historical significance should be reappraised on an individual basis for permanent retention. Such experiments might deal with a cure of a disease, a major scientific discovery, a major health program, or other event generating great media, public, or historic interest. Notify NARA so that an analysis and appraisal of these experiments can be conducted and appropriate disposition authorized.
Files created in the course of research undertaken at the request of non-DoD agencies, e.g., the NIH, are not covered by this schedule, must be clearly identified, and must be kept separate from defense-related work.

m. What is the authority to collect information? A Federal law or Executive Order must authorize the collection and maintenance of a system of records. For PII not collected or maintained in a system of records, the collection or maintenance of the PII must be necessary to discharge the requirements of a statue or Executive Order.

(1) If this system has a Privacy Act SORN, the authorities in this PIA and the existing Privacy Act SORN should be similar.
(2) If a SORN does not apply, cite the authority for this DoD information system or electronic collection to collect, use, maintain and/or disseminate PII. (If multiple authorities are cited, provide all that apply).

(a) Cite the specific provisions of the statute and/or EO that authorizes the operation of the system and the collection of PII.

(b) If direct statutory authority or an Executive Order does not exist, indirect statutory authority may be cited if the authority requires the operation or administration of a program, the execution of which will require the collection and maintenance of a system of records.

(c) If direct or indirect authority does not exist, DoD Components can use their general statutory grants of authority ("internal housekeeping") as the primary authority. The requirement, directive, or instruction implementing the statute within the DoD Component must be identified.

n. Does this DoD information system or electronic collection have an active and approved Office of Management and Budget (OMB) Control Number?

Contact the Component Information Management Control Officer or DoD Clearance Officer for this information. This number indicates OMB approval to collect data from 10 or more members of the public in a 12-month period regardless of form or format.

☐ Yes ☒ No ☐ Pending

(1) If "Yes," list all applicable OMB Control Numbers, collection titles, and expiration dates.
(2) If "No," explain why OMB approval is not required in accordance with DoD Manual 8910.01, Volume 2, " DoD Information Collections Manual: Procedures for DoD Public Information Collections."
(3) If "Pending," provide the date for the 60 and/or 30 day notice and the Federal Register citation.

The information collected within this system does not collect PHI/PII directly from individuals of the general public; however, the system components, applications, or electronic collections within, in accordance with DoDM 8910.01, Volume 2, Enclosure 3, paragraph 8b(5).