

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:

Abbott EP Cardiac Mapping System V1.x_A&I

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

11/28/23

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

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

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.

Abbott EP (electrophysiology) Cardiac Mapping System V1.x_AI consists of the EP Workmate and the next generation Claris Workmate. The Workmate is a fully computerized system for capturing and measuring physiological data in the clinical EP laboratory. It provides digital signal acquisition and display of those electrical signals on high resolution monitors. The WorkMate Recording System is indicated for use during clinical electrophysiology procedures. An Electrophysiology system is used to monitor and analyze surface ECGs and intracardiac signals. Catheters are guided into the heart and intracardiac electrical signals are acquired from the electrodes on the indwelling catheters from various heart locations. The system is also intended for recording electrocardiograms from multiple sites during clinical assessment of electrophysiological interventions. The EP and Claris WorkMate Recording System provides on-line measurements of intrachannel intervals, and presents these measurements on the display monitor.

Abbott EP Cardiac Mapping System V1.x_AI Personally Identifiable Information (PII) collected are personnel identifiers and medical information to include Protected Health Information (PHI), names, and date of birth. The categories of individuals in which PII is collected includes Department of Defense (DoD) Health Care Beneficiaries such as Military Members of the Armed Forces, Military Retirees, and their family members; DoD Civilian Employees; Foreign Nationals; Members of the United States Coast Guard; and other categories of individuals who receive medical treatment at DoD Treatment Facilities/Activities. PII is collected from both members of the general public and Federal employees and/or Federal contractors.

CyberLog is responsible for the Risk Management Framework (RMF) process and gaining an approval from Defense Health Agency's (DHA's) Joint 6 Risk Management Executive Division (DHA J6 RMED). Local sites are responsible for day-to-day operations, maintenance, and management of EP Cardiac Mapping. Sites are responsible for ensuring the device is configured to meet CyberLOG and RMED approved configurations. EP Cardiac Mapping is owned by DHA's CyberLOG and operated by various MTFs as needed.

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)

PII is collected to match an individual with his/her medical diagnostic cardiac studies and to ensure accuracy of these studies are integrated in the medical records for that individual. The intended use for the collection of PII will be used for mission-related purposes to support the enhancement of the delivery of healthcare services.

e. Do individuals have the opportunity to object to the collection of their PII? 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.

Individuals have the opportunity to object to the collection of their PII verbally before treatment is administered.

f. Do individuals have the opportunity to consent to the specific uses of their PII? 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.

Individuals have the opportunity to consent to the specific uses of their PII.

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

PRIVACY ACT STATEMENT: This statement serves to inform you of the purpose for collecting personal information as required by the Privacy Act of 1974, as amended, and how that information will be stored and used.

AUTHORITY: Public Law 104-191, Health Insurance Portability and Accountability Act of 1996; 10 U.S.C., Chapter 55, Medical and Dental Care; 32 CFR 199.17, TRICARE Program; DoD Manual (DoDM) 6025.18, "Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DOD Health Care Programs;" and E.O. 9397 (SSN), as amended.

PURPOSE:

Collecting information from beneficiaries of the Military Health System to determine eligibility for coverage under TRICARE.

ROUTINE USES:

In addition to those disclosures generally permitted under 5 U.S.C. § 552a(b) of the Privacy Act of 1974, as amended, these records may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. § 552a(b)(3) as follows: to contractors and others performing or working for the Federal Government when necessary to accomplish an agency function related to this System of Records; and to the Department of Veteran's Affairs (VA) for the purpose of providing medical care, to determine the eligibility for benefits, to coordinate cost sharing activities, and to facilitate collaborative research activities between the DOD and VA. For a complete listing of the Routine Uses for this system, refer to the below hyperlinked SORN.

Any protected health information (PHI) in your records may be used and disclosed generally as permitted by the HIPAA Rules, as implemented within DOD. Permitted uses and disclosures of PHI include, but are not limited to, treatment, payment, and healthcare operations.

APPLICABLE SORN:

EDHA 07, Military Health Information System (June 15, 2020; 85 FR 36190) <https://dpcl.d.defense.gov/Portals/49/Documents/Privacy/SORNs/DHA/EDHA-07.pdf>

DISCLOSURE:

Voluntary. If you choose not to provide the requested information, there may be an administrative delay and it could result in a failure to enroll; however, no penalties will be imposed.

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)

- | | | | |
|-------------------------------------|--|----------|---|
| <input checked="" type="checkbox"/> | Within the DoD Component | Specify. | Defense Heath Agency Military Treatment Facilities |
| | Other DoD Components <i>(i.e. Army, Navy, Air Force)</i> | Specify. | |
| | Other Federal Agencies <i>(i.e. Veteran's Affairs, Energy, State)</i> | Specify. | |
| | State and Local Agencies | Specify. | |
| <input checked="" type="checkbox"/> | Contractor <i>(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.)</i> | Specify. | The MTFs may utilize contractor services to support this product. DoD's Policy requires such contracts include language to safeguard PII including FAR clauses: 52.224-1, Privacy Act Notification; 52.224-2, Privacy Act; and FAR 39.105, Privacy. When the contractor has access to PHI, a HIPAA Business Associate Agreement is also required. |
| | Other <i>(e.g., commercial providers, colleges).</i> | Specify. | |

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

- | | |
|---|--------------------|
| <input checked="" type="checkbox"/> Individuals | Databases |
| Existing DoD Information Systems | Commercial Systems |
| Other Federal Information Systems | |

The information is collected from the patient's identification sticker at bedside after verifying Name and Date of Birth (DOB). It is then typed onto the vendor's mapping system.

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

- | | |
|--|---|
| E-mail | Official Form (Enter Form Number(s) in the box below) |
| <input checked="" type="checkbox"/> In-Person Contact | Paper |
| Fax | Telephone Interview |
| Information Sharing - System to System | Website/E-Form |
| Other (If Other, enter the information in the box below) | |

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.

Yes No

If "Yes," enter SORN System Identifier

SORN Identifier, not the Federal Register (FR) Citation. Consult the DoD Component Privacy Office for additional information or <http://dpclid.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. GRS 5.2, item 020 (DAA-GRS-2017-0003-0002)

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

(3) Retention Instructions.

FILE NUMBER: 103-14

DISPOSITION: Temporary. Delete no more than 7 years from the date last modified. (See DoD DTM 22-001 on default disposition policies and OSD Records Manager guidance which file number to associate).

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 statute 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.

Public Law 104-191, Health Insurance Portability and Accountability Act of 1996; 10 U.S.C. Ch. 55, Medical and Dental Care; 10 U.S.C. 1097a, TRICARE Prime: Automatic Enrollments; Payment Options; 10 U.S.C. 1097b, TRICARE Prime and TRICARE Program: Financial Management; 10 U.S.C. 1079, Contracts for Medical Care for Spouses and Children: Plans; 10 U.S.C. 1079a, TRICARE Program: Treatment of Refunds and Other Amounts Collected Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); 10 U.S.C. 1086, Contracts for Health Benefits for Certain Members, Former Members, and Their Dependents; 10 U.S.C. 1095, Health Care Services Incurred on behalf of Covered Beneficiaries: Collection From Third-party Payers; 42 U.S.C. 290dd, Substance Abuse Among Government and Other Employees; 42 U.S.C. 290dd-2, Confidentiality Of Records; 42 U.S.C. Ch. 117, Sections 11131-11152, Reporting of Information; 45 CFR 164, Security and Privacy; Department of Defense (DoD) Instruction 6015.23, Foreign Military Personnel Care and Uniform Business Offices in Military Treatment Facilities (MTFS); DoD Manual 6025.18, Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs; and E.O. 9397 (SSN).

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.

This system does not require clearance since it is not collecting information directly from members of the public and it is for the diagnosis and treatment of medical disorders and is not considered a public information collection in accordance with DoDM 8910.01, V2, Encl 3, paragraph 8b(5).