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:

Medical Research Information Technology System (MeRITS)

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

03/29/24

MRDC- HQ Enterprise Information Technology Project Management Office (eIT PMO)

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.

The Medical Research Information Technology System (MeRITS) is located at the US Army Medical Research & Development Command (USAMRDC). MeRITS provides the command with a suite of medical research information technology (IT) capabilities that comply with the US Food and Drug Administration (FDA) standards for Electronic Records and Electronic Signatures. MeRITS supports USAMRDC medical research activities in the performance of core mission activities with the FDA. MeRITS IT products are offered by the Enterprise Information Technology Project Management Office (eIT PMO) to facilitate the administration of Information Technology (IT) capabilities from provisioning, through operations, to retirement ensuring the successful Life Cycle Management of required medical IT solutions for USAMRDC, while providing these capabilities per Army, DHA, DOD and FDA Policies and Regulations. The suite of validated systems (end-to-end clinical trial life-cycle process) includes:

1. Electronic Document Management System (EDMS) provides a centralized coordination/collaborative electronic document management capability for FDA regulated and Research Management Enterprise non-regulated activities across USAMRMC for approximately 1500 users worldwide within the medical research community which is fore-casted to increase month-to-month.

2. Serious Adverse Event (SAE) provides electronic storage and automation for serious adverse event management/reporting. SAE usage is localized within the USAMRDC HQ Office of Regulated Activities (ORA) and the Safety Division.

3. Electronic Data Capture-Clinical Research Data Management System (EDC-CRDMS) supports the full life cycle of clinical studies from inception, through data field definition/specification, data entry, data query, data transfer/output into stand-alone statistical tools, and study close-out, and provides the capability to electronically manage clinical trial data supporting medical research activities across USAMRDC.
4. Electronic Common Technical Document (eCTD) Publisher meets the FDA requirement to submit documentation in standard eCTD format. The eCTD interfaces with EDMS to pull documents for conversion to an FDA acceptable format for electronic submissions.

5. Laboratory Information Management System (LIMS) - the only portion that stores PII will be deployed ~ January 2024. The types of PII collected is specific to clinical trials and includes demographic data, employment information, and medical information. The PII may be collected from the following categories of individuals: Military, DoD civilians, and DoD Contractors.

6. FDA Study Data Validator (SDV) - Validate datasets per FDA guidance for submission (deployed to PROD August 2023).

7. Clinical Trial Management System (CTMS) provides the ability to manage the overall clinical trial/study process. CTMS is a web based application that meets the FDA regulations governing clinical trials with multiple groups and individuals completing the clinical trial/study tasks with minimum delays and maximum coordination. No requirement to store PII. (future system - in requirements phase)

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)*

LIMS - PII is collected for identification and authentication purposes to match individuals with their records and to ensure the accuracy of the records when they are integrated in the individuals records, and for administrative and mission-related purposes to support the medical research activities with clinical and medical trials.

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.

MeRITS suite of systems, specifically EDMS and LIMS functional elements are not the initial collection point of PII from the individuals.

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.

MeRITS suite of systems, specifically EDMS and LIMS functional elements are not the initial collection point of PII from the individuals.

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

MeRITS suite of systems, specifically EDMS and LIMS functional elements are not the initial collection point of PII from the individuals.

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.	USAMRDC Labs
☐ Other DoD Components *(i.e. Army, Navy, Air Force)*	Specify.	
☐ Other Federal Agencies *(i.e. Veteran's Affairs, Energy, State)*	Specify.	
☐ 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.	Leidos Inc. and iDox Solutions. Language in contract: The contractor may use or disclose Protected Health information on behalf, or to provide services to, the Government for treatment, payment, or healthcare operations purposes, in accordance with the specific use and disclosure provisions below, if such use or disclosure of Protected Health Information would not violate the HIPAA Privacy and Security Rule, DoD 6025.18-R or DoD 8580.02-R if done by the Government. The contractor may disclose Protected Health Information for the proper management and administration of the Contract, provided that it will remain confidential and used or further disclosed only as required by law for the purpose for which it was disclosed to the person, and the person notifies the Contractor of any instances of which it is aware in which the confidentiality of the information has been breached. The contractor agrees to use administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits in the execution of this Contract.
☐ Other *(e.g., commercial providers, colleges).*	Specify.	

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

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

PII received via paper and email is uploaded and stored in the Electronic Document Management System (EDMS). LIMS obtains information from existing DoD systems.

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 EDHA-07

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. GRS 3.1, item 012 (DAA-GRS-2013-0005-0008)

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

(3) Retention Instructions.

FILE NUMBER: 1601-11
DISPOSITION: Temporary. Cut off and destroy when related master file or database has been deleted.

RM Note: Subordinate systems will follow their disposition schedules

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.

10 USC 3013, Secretary of the Army; 10 USC 1071-1085, Medical and Dental Care; 50 USC Supplement IV, Appendix 454, as amended, Persons liable for training and service; 42 USC Chapter 117, Sections 11131-11152, Reporting of Information; 10 USC 1097a and 1097b TRICARE Prime and TRICARE Program; 10 USC 1079, Contracts for Medical Care for Spouses and Children; 10 USC 1079a, CHAMPUS; 10 USC 1086, Contracts for Health Benefits for Certain Members, Former Members, and Their Dependents; DoD Instruction 6015.23, Delivery of Healthcare at Military Treatment Facilities (MTFs); DoD Directive 6040.37, Confidentiality of Medical Quality Assurance (QA) Records; DoD 6010.8-R, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) and EO 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.

MeRITS suite of systems, specifically EDMS and LIMS functional elements are not the initial collection point of PII from the individuals.