

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:

Electronic Institutional Review Board (EIRB)

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

02/21/25

Program Executive Office (PEO) Medical Systems (J-6)

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.

The purpose of Electronic Institutional Review Board (EIRB) is to track research protocols from inception throughout the entire life cycle of the project to ensure processes are streamlined and regulatory compliance requirements are met.

The EIRB is a world-wide, 24/7 accessible, web-based business platform that allows horizontal and vertical multi-level transparency to foster collaboration, submission, management, tracking, oversight, auditing, and reporting of clinical and graduate medical education research and related projects throughout their life cycle. EIRB is not a mobile application. Access to the EIRB system requires an active Department of Defense Common Access Card (CAC), External Certificate Authority (ECA), or a Personal Identity Verification (PIV) authentication credentials from the Department of Veterans Affairs (VA), Department of Homeland Security (DHS), Department of Health and Human Services (HHS), which includes the National Institutes of Health (NIH), Department of Justice (DOJ), Department of State (DOS), or Department of Transportation (DOT).

Types of personally identifiable information (PII) that may be collected include personal descriptors, contact information, and education background. Information will be collected from any category of individuals, including members of the general public, federal employees, and federal contractors that use this system to submit a research proposal and/or review the proposal.

EIRB is owned and managed by the Clinical Support Program Management Office (CSPMO)/Solution Delivery Division (SDD)/Program Executive Office (PEO) Medical Systems (J-6)/Defense Health Agency (DHA).

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)

EIRB collects PII for identification and oversight of researchers at each stage of a study's life cycle. The intended use of the PII is for identification of researchers and reviewers that are using the EIRB system and for inclusion into EIRB User Profiles.

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; however, if an individual chooses to object to the collection of their PII, they will not be authorized to conduct or review research using EIRB at any Department of Defense (DoD) member institution.

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; however, if an individual chooses to withhold consent, they will not be authorized to conduct or review research using EIRB at any Department of Defense (DoD) member institution.

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

This statement serves to inform you of the purpose for collecting personal information as required by the Electronic Institutional Review Board (EIRB) and how that information will be stored and used.

AUTHORITY: 10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness; 32 CFR 219, Protection of Human Subjects; DoD Directive 5136.01, Assistant Secretary of Defense for Health Affairs (ASD(HA)); DoDI 3216.01, Use of Animals in DoD Programs; and DoDI 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research.

PURPOSE: The purpose of Electronic Institutional Review Board (EIRB) is to track research protocols from inception throughout the entire life cycle of the project to ensure processes are streamlined, and regulatory compliance requirements are met. EIRB is a world-wide, 24/7 accessible, web-based business platform that allows horizontal and vertical multi-level transparency to foster collaboration, submission, management, tracking, oversight, auditing, and reporting of clinical and graduate medical education research and related projects throughout their life cycle. Access to the EIRB system requires an active Department of Defense Common Access Card (CAC), External Certificate Authority (ECA), or a Personal Identity Verification (PIV) authentication credentials from the Department of Veterans Affairs (VA), Department of Homeland Security (DHS), Department of Health and Human Services (HHS), which includes the National Institutes of Health (NIH), Department of Justice (DOJ), Department of State (DOS), or Department of Transportation (DOT).

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 Department of Defense (DoD) as a routine use pursuant to 5 U.S.C. § 552a(b)(3) as follows: to Federal, State, local, or foreign government agencies for identification, tracking, and oversight of authorized research procedures and tracking of individual researchers and reviewers involved in the process; to private business entities for matters relating to eligibility, quality assurance, peer review and program integrity; and the DoD Blanket Routine Uses may apply to this system of records.

APPLICABLE SORN: EDHA 18, Research Regulatory Oversight Records (July 15, 2014, 79 FR 41265) <https://dpcl.d.defense.gov/Privacy/SORNsIndex/DOD-wide-SORN-Article-View/Article/570681/edha-18/>

DISCLOSURE: Voluntary. If you choose not to provide your information, no penalty may be imposed, but absence of the requested information may result in administrative delays.

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 Health Agency (DHA) |
| <input checked="" type="checkbox"/> Other DoD Components (i.e. Army, Navy, Air Force) | Specify. | Under Secretary of Defense for Personnel and Readiness (USD(P&R)); Under Secretary of Defense for Research and Engineering (USD(R&E)); Under Secretary of Defense for Acquisition and Sustainment (USD(A&S)); Departments of the Army, Navy, and Air Force |
| <input type="checkbox"/> Other Federal Agencies (i.e. Veteran's Affairs, Energy, State) | Specify. | |
| <input type="checkbox"/> State and Local Agencies | Specify. | |
| <input type="checkbox"/> 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. | |
| <input type="checkbox"/> 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)

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

Individuals: EIRB end users provide PII directly in the account profile section of the EIRB Application: <https://eirb.csd.disa.mil>

Existing DoD Information Systems: Identity Authentication Services (iAS)

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

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

Website/E-Form: EIRB end users provide PII directly in the account profile section of the EIRB Application: <https://eirb.csd.disa.mil>

Information Sharing - System to System: iAS

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://dpcl.d.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.

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

(3) Retention Instructions.

FILE NUMBER: 1805-42
DISPOSITION: Temporary. Cut off upon completion or termination of the research protocol (which coincides with the term of the research).
Destroy 10 years cutoff.

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.

32 CFR 219, Protection of Human Subjects; DoD Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research; and DoD Instruction 3216.01, Use of Animals in DoD Programs.

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.

EIRB does not require an OMB Control Number in accordance with DoDM 8910.01, Volume 2, Enclosure 3, subsection b(10): "Comparable items to those described above as designated by OMB." OMB has determined that EIRB constitutes a "nominal information collection," which does not require an OMB Control Number.