



PRIVACY IMPACT ASSESSMENT (PIA)

For the

Pharmacovigilance Defense Application System (PVDAS)

US Army Medical Command - Defense Health Program (DHP) Funded Application

SECTION 1: IS A PIA REQUIRED?

a. Will this Department of Defense (DoD) information system or electronic collection of information (referred to as an "electronic collection" for the purpose of this form) collect, maintain, use, and/or disseminate PII about members of the public, Federal personnel, contractors or foreign nationals employed at U.S. military facilities internationally? Choose one option from the choices below. (Choose (3) for foreign nationals).

- (1) Yes, from members of the general public.
- (2) Yes, from Federal personnel* and/or Federal contractors.
- (3) Yes, from both members of the general public and Federal personnel and/or Federal contractors.
- (4) No

* "Federal personnel" are referred to in the DoD IT Portfolio Repository (DITPR) as "Federal employees."

b. If "No," ensure that DITPR or the authoritative database that updates DITPR is annotated for the reason(s) why a PIA is not required. If the DoD information system or electronic collection is not in DITPR, ensure that the reason(s) are recorded in appropriate documentation.

c. If "Yes," then a PIA is required. Proceed to Section 2.

SECTION 2: PIA SUMMARY INFORMATION

a. Why is this PIA being created or updated? Choose one:

- New DoD Information System
- Existing DoD Information System
- Significantly Modified DoD Information System
- New Electronic Collection
- Existing Electronic Collection

b. Is this DoD information system registered in the DITPR or the DoD Secret Internet Protocol Router Network (SIPRNET) IT Registry?

- Yes, DITPR** Enter DITPR System Identification Number
- Yes, SIPRNET** Enter SIPRNET Identification Number
- No**

c. Does this DoD information system have an IT investment Unique Project Identifier (UPI), required by section 53 of Office of Management and Budget (OMB) Circular A-11?

- Yes**
- No**

If "Yes," enter UPI

If unsure, consult the Component IT Budget Point of Contact to obtain the UPI.

d. 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 should be consistent.

- Yes**
- No**

If "Yes," enter Privacy Act SORN Identifier

DoD Component-assigned designator, not the Federal Register number.
Consult the Component Privacy Office for additional information or
access DoD Privacy Act SORNs at: <http://www.defenselink.mil/privacy/notices/>

or

Date of submission for approval to Defense Privacy Office

Consult the Component Privacy Office for this date.

e. Does this DoD information system or electronic collection have an 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

Enter OMB Control Number

Enter Expiration Date

No

f. Authority to collect information. A Federal law, Executive Order of the President (EO), or DoD requirement must authorize the collection and maintenance of a system of records.

(1) If this system has a Privacy Act SORN, the authorities in this PIA and the existing Privacy Act SORN should be the same.

(2) 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) Whenever possible, cite the specific provisions of the statute and/or EO that authorizes the operation of the system and the collection of PII.

(b) If a specific statute or EO does not exist, determine if an indirect statutory authority can be cited. An indirect 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) 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 should be identified.

10 U.S.C. 3013, Secretary of the Army; 10 U.S.C. 1071-1085, Medical and Dental Care; 50 U.S.C. Supplement IV, Appendix 454, as amended, Persons liable for training and service; 42 U.S.C. Chapter 117, Sections 11131-11152, Reporting of Information; 10 U.S.C. 1097a and 1097b TRICARE Prime and TRICARE Program; 10 U.S.C. 1079, Contracts for Medical Care for Spouses and Children; 10 U.S.C. 1079a, CHAMPUS; 10 U.S.C. 1086, Contracts for Health Benefits for Certain Members, Former Members, and Their Dependents; E.O. 9397 (SSN); 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); Army Regulation 40-66, Medical Record Administration and Health Care Documentation.

g. Summary of DoD information system or electronic collection. Answers to these questions should be consistent with security guidelines for release of information to the public.

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

The Pharmacovigilance Defense Application System (PVDAS) is a web-based analysis tool used for generating descriptive and analytical statistics for drug-related events. This system contains a limited data set. The patient names have been removed and the from the records and the social security number(SSN) and Electronic Data Interchange Person Numbers (EDIPN) have been scrambled so that the data do not identify, link, or describe a specified individual. If there is need to identify specific patients for medical treatment purposes, this data can be linked back to those individuals through the use of an algorithm. However, the system users do not have access to this algorithm and can only view limited data set. This limited data set will be used for drug-related research analyses and studies, compilation of statistical reports, risk mitigation strategies and policies, and development of drug formularies. The types of PII collected in this system include SSN (scrambled),EDIPN (scrambled), gender, race, marital status, date of birth, medical encounter dates, and medical information.

(2) Briefly describe the privacy risks associated with the PII collected and how these risks are addressed to safeguard privacy.

Because the names are removed and SSNs and EDIPNs scrambled from the PII elements, the database records contain a limited data set. The PII data for specific patients is only at risk on the occasion when there is a request to temporarily identify a record for quality improvement/quality management purposes. These risks would include inappropriate access or disclosure of PII during this limited time. The Director of the PVDAS Center is the only person who can approve these requests for PII and there are security measures in place to mitigate these risks.

h. With whom will the PII be shared through data exchange, both within your DoD Component and outside your Component (e.g., other DoD Components, Federal Agencies)? Indicate all that apply.

Within the DoD Component.

Specify. PII will be shared with authorized personnel within the PVDAS Program Office. PVDAS users only have access to limited data set (essentially de-identified) records.

Other DoD Components.

Specify.

Other Federal Agencies.

Specify.

State and Local Agencies.

Specify.

Contractor (Enter name and describe the language in the contract that safeguards PII.)

Specify. Name: Commonwealth Informatics, Lualaba, KYOS. There are clauses in the contract requiring compliance with the Privacy Act and Health Insurance Portability and Accountability Act (HIPAA) requirements to maintain the confidentiality of

personal information. The contractors also sign a Defense Health Agency (DHA) Data Sharing Agreement

Other (e.g., commercial providers, colleges).

Specify.

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

Yes

No

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

(2) If "No," state the reason why individuals cannot object.

PVDAS does not collect PII directly from the individuals. PII is extracted from existing DoD military healthcare databases.

j. 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.

PVDAS does not collect PII directly from the individuals. PII is extracted from existing DoD military healthcare databases.

k. What information is provided to an individual when asked to provide PII data? Indicate all that apply.

- | | |
|---|--|
| <input type="checkbox"/> Privacy Act Statement | <input type="checkbox"/> Privacy Advisory |
| <input type="checkbox"/> Other | <input checked="" type="checkbox"/> None |

Describe each applicable format.

PVDAS does not collect PII directly from the individuals. PII is extracted from existing DoD military healthcare databases.

NOTE:

Sections 1 and 2 above are to be posted to the Component's Web site. Posting of these Sections indicates that the PIA has been reviewed to ensure that appropriate safeguards are in place to protect privacy.

A Component may restrict the publication of Sections 1 and/or 2 if they contain information that would reveal sensitive information or raise security concerns.