



PRIVACY IMPACT ASSESSMENT (PIA)

For the

Integrated Operating Room (IOR) System (Multiple Devices)

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 11131-152, Reporting of Information; 10U.S.C. 10997a 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 Integrated Operating Room (IOR) System is a medical device that allows virtually any video, still image or required data from an imaging device, camera, navigation system or computer display to be centrally controlled and displayed on any monitor or display console within the Operating Room (OR) Suite or dedicated remote device. The system does not require direct connectivity to the Picture Archiving and Communication System (PACS), medical system, or medical treatment facility (MTF) network to conduct in-room integration. Any interaction with medical records, PACS, etc. will be through an approved system. The current IOR systems include Karl Storz OR1 NEO IOR; Stryker IOR; and Steris Harmony iQ IOR. The system only routes PACS images or laboratory data that needs to be displayed in the OR by utilizing the images/data being displayed by another system. Any PII used must be manually entered if required to identify captured video/data that is temporarily stored on the system. Captured data can include audio and video surgical footage that would be temporarily stored in the system to be used during procedures. No PII is permanently stored by the IOR. The system does have the capability to transfer the files to another system or to DVD. These capabilities are currently disabled, but may be enabled if required for future workflow or patient care.

The patient information that could possibly be displayed includes patient demographic data and medical information.

This PIA updates the IOR System PIA approved in 2012.

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

Risks for this system as similar to any other system which requires human data entry. These can include inaccurate information entry, unauthorized access, and inadvertent data viewing. The specific security safeguards are addressed in Section 3 below.

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. The PII will be shared with health care providers and identified super users within the US Army Medical Command (MEDCOM) medical treatment facilities (MTF) using this system.

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.

The Manufacturer servicing the device may have access to some data. Contracts for Manufacturers supporting this device include a standard Military Health System (MHS) HIPAA Business Associate Agreement; DoD Privacy Act and HIPAA guidelines: and MEDCOM Information Assurance (IA) guidelines.

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

Specify.

The data may be shared with commercial providers under contract with DoD to provide specific health care related patient support. There are clauses in their contracts to protect PII IAW Privacy Act and HIPAA standards.

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.

The IOR does not directly collect PII from the individual. PII is incidental to the data from existing systems which are used/displayed by the IOR.

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.

The IOR does not directly collect PII from the individual. PII is incidental to the data from existing systems which are used/displayed by the IOR.

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.

The IOR does not directly collect PII from the individual. PII is incidental to the data from existing systems which are used/displayed by the IOR.

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.