



## PRIVACY IMPACT ASSESSMENT (PIA)

For the

Risk Evaluation and Management Strategy (Thalomid® REMS™)
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 purpose of the Thalomid® Risk Evaluation and Management Strategy (REMS) is to inform patients, prescribers, and pharmacists of the serious risks and safe-use conditions for Thalomid medication.. Thalomid (thalidomide) is only available under this restricted distribution program to ensure the avoidance of embryo-fetal exposure. The Celgene Corporation, a global biopharmaceutical company, produces Thalomid and is responsible for administering its REMS program. Only certified prescribers can prescribe Thalomid and only certified pharmacies can dispense Thalomid. In order to receive Thalomid, patients must be enrolled in Thalomid REMS program and agree to comply with the requirements of the program. Both the patients and providers must complete an agreement form to participate in the Thalomid REMS program. This agreement form is generated by and maintained by the Celgene Corporation.

The types of PII collected includes patient demographics and medical information.

This PIA updates the PIA approved on 15 October 2013.

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

Risks include unauthorized access to PII and unauthorized disclosure of PII. These privacy risks have been mitigated using a variety of technical, physical, and administrative security safeguards as indicated 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.

**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.

Celegene will protect and secure personal information.  
- Some individuals in the medical treatment facility are employed on a contractual basis. There are clauses in their contracts requiring compliance with the Privacy Act and Health Insurance Portability and Accountability Act (HIPAA) provisions to protect the confidentiality of personal information.

**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.

The Department of Defense (DD) Form 2005, Privacy Act Statement – Health Care Records, is provided to the patient for review and signature. This form is placed in the patient's medical record. If the individual objects to the collection of PII, care will not be denied.

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

**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.

The Department of Defense (DD) Form 2005, Privacy Act Statement – Health Care Records, is provided to the patient for review and signature. This form is placed in the patient's medical record. If the individual does not consent to the specific uses of their PII, care will not be denied.

(2) If "No," state the reason why individuals cannot give or withhold their consent.



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

- Privacy Act Statement**                       **Privacy Advisory**
- Other**     **None**

Describe each applicable format.

DD FORM 2005, June 2016, PRIVACY ACT STATEMENT - HEALTH CARE RECORDS

1. **AUTHORITY FOR COLLECTION OF INFORMATION INCLUDING SOCIAL SECURITY NUMBER (SSN):**  
 10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness; 10 U.S.C. Chapter 55, Medical and Dental Care; 42 U.S.C. Chapter 32, Third Party Liability for Hospital and Medical Care; 32 CFR Part 199, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); DoDI 6055.05, Occupational and Environmental Health (OEH); and E.O. 9397 (SSN), as amended.

2. **PRINCIPAL PURPOSES FOR WHICH INFORMATION IS INTENDED TO BE USED:**  
 Information may be collected from you to provide and document your medical care; determine your eligibility for benefits and entitlements; adjudicate claims; determine whether a third party is responsible for the cost of Military Health System (MHS) provided healthcare and recover that cost; evaluate your fitness for duty and medical concerns which may have resulted from an occupational or environmental hazard; evaluate the MHS and its programs; and perform administrative tasks related to MHS operations and personnel readiness.

3. **ROUTINE USES:**  
 Information in your records may be disclosed to:

- Private physicians and Federal agencies, including the Department of Veterans Affairs, Health and Human Services, and Homeland Security (with regard to members of the Coast Guard), in connection with your medical care;
- Government agencies to determine your eligibility for benefits and entitlements;
- Government and nongovernment third parties to recover the cost of MHS provided care;
- Public health authorities to document and review occupational and environmental exposure data;

and

- Government and nongovernment organizations to perform DoD-approved research.

Information in your records may be used for other lawful reasons which may include teaching, compiling statistical data, and evaluating the care rendered. Use and disclosure of your records outside of DoD may also occur in accordance with 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, which incorporates the DoD Blanket Routine Uses published at:  
<http://dpclid.defense.gov/privacy/SORNsIndex/BlanketRoutineUses.aspx>.

Any protected health information (PHI) in your records may be used and disclosed generally as permitted by the HIPAA Privacy Rule (45 CFR Parts 160 and 164), as implemented within DoD by DoD 6025.18-R. Permitted uses and disclosures of PHI include, but are not limited to, treatment, payment, and healthcare operations.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:**

Voluntary. If you choose not to provide the requested information, comprehensive health care services may not be possible, you may experience administrative delays, and you may be rejected for

service or an assignment. However, care will not be denied.

This all inclusive Privacy Act Statement will apply to all requests for personal information made by MHS health care treatment personnel or for medical/dental treatment purposes and is intended to become a permanent part of your health care record.

Your signature merely acknowledges that you have been advised of the foregoing. If requested, a copy of this form will be furnished to you.

**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.**