



## PRIVACY IMPACT ASSESSMENT (PIA)

For the

Clinical Trials Management Solution (Merge Site CTMS)

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

### **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

A0070-45 DASG

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., Chapter 55, Medical and Dental Care; Army Regulation 70-25, Use of Volunteers as Subjects of Research; Army Regulation 70-45, Scientific and Technical Information Program; Occupational Safety and Health Administration Act of 1970; and E.O. 9397 (SSN).

**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 Merge Site CTMS is a feature-rich and scalable solution to organize, centralize, and manage clinical research. It is a commercial product utilized to store basic contact information about potential, past and ongoing research trial volunteers as well as manage research visit scheduling, tracking of volunteer payments and other administrative tasks associated with the performance of human clinical trials.

PII collected includes: Name, Race/Ethnicity, Personal Cell Telephone Number, Mailing/Home Address, Birth Date, Home Telephone Number, Medical Information, Social Security Number, Gender, and Personal E-mail address.

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

The privacy risks associated with the PII collection are unauthorized access, inaccurate information in the system, and unauthorized disclosure of PII. 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.

The PII is shared with physician investigators, clinical research coordinators, and recruiters in the Clinical Trials Center, Walter Reed Army Institute of Research.

**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.

Contracting Company: ClinicalRM, Inc.  
PII Requirements Language (11-C-0516)

Sections 5.1.2, 5.1.7, 5.1.9, and 5.1.11 of this Performance Work Statement require the Contractor to provide Technical Support Services, Clinical Laboratory Services, Design and Print Study Forms, and Statistical Support Services to accomplish an agency function subject to the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 U.S.C. 552a). The Contractor shall comply with the Privacy Act and all applicable agency regulations on individual privacy, to include DoD Directive 5400.11, "Department of Defense Privacy Program" and DoD 5400.11-R, Department of Defense Privacy Program.

#### Systems Access

When requested by the Government, the contractor shall provide access to and information regarding the systems that the contractor operates or maintains on behalf of the Government under this contract.

#### Systems Security

The contractor shall encrypt all contractor-owned laptops or other portable media storage devices that process or store PII, in accordance with NIST Federal Information Processing Standard (FIPS) 140-2 (or successor). The contractor shall require FIPS 140-2 (or successor) encryption of any sensitive PII when transmitted electronically across the internet or other public networks.

#### Data Security

The contractor, unless otherwise authorized by the Government, shall limit access to PII to those employees and subcontractors who require the information in order to perform their official duties under this contract. The contractor, contractor employees, and subcontractors shall physically or electronically protect PII when not in use and/or under the control of an authorized individual.

During the course of contract performance, when PII is no longer needed or required to be retained under applicable Government records retention policies, the contractor shall coordinate with the contracting officer to either turn over the PII to the Government, or destroy it through means that will make the PII irretrievable (i.e., permanently unavailable for access by any person).

The contractor shall only use PII obtained under this contract for purposes of the contract, and shall not collect or use such information for any other purpose without the prior written approval of the contracting officer.

At expiration or termination of this contract, the contractor shall coordinate with the contracting officer to either turn over all PII managed under the contract that is in its possession to the Government or successor contractor, or, if the Government so directs, destroy the PII.

**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 Volunteer Intake Form that is completed by every volunteer contains a Privacy Act Statement. Potential trial volunteers can opt to not provide any PII information and therefore would not be eligible to participate in any of the clinical trials.

(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 Volunteer Intake Form that is completed by every volunteer contains a Privacy Act Statement. Potential trial volunteers who do not consent to the specific uses of their PII, are not eligible to participate in any of the clinical trials.

(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.

The following Privacy Act Statement is available on the Volunteer Intake Form:

Privacy Statement: This statement serves to inform you of the purpose for collecting personal information required by this system and how it will be used.

Authority: 45 CFR160, 162, and 164 'HIPAA Privacy Rule'  
DoD 5400.11-R 'DoD Privacy Program', 14 May 2007

Purpose: Purpose of collected information and demonstrate non-bias in human use clinical trials.

Routine Uses: Provide de-identified information to study sponsor, create labels for laboratory specimens, provide information to the company dispensing compensation, to contact you with further studies if desired.

Disclosure: Voluntary, however failure to provide information may result in denial of enrollment into study.

**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.**