



## PRIVACY IMPACT ASSESSMENT (PIA)

For the

MRI Quantitative Imaging Analysis System (CorTech NeuroQuant®)

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.**



**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 MRI Quantitative Imaging Analysis System is a Commercial Off-the-Shelf (COTS) product consisting of the physical information system and the application software installed on that system. It is commercially marketed as a medical device. The Imaging Analysis System is intended for use in post-acquisition quantitative analysis of MRI brain studies. It performs automatic labeling and volumetric quantification of segmentable brain structures from a set of MR images. Output of the software provides these values as numerical volumes and images that have been annotated with graphical color overlays, with each color representing a specific segmental structure. The output is provided in standard Digital Imaging and Communications in Medicine (DICOM) format as additional series (with appropriate descriptors) and report links so that it can be displayed on most third-party commercial DICOM workstations. CorTech NeuroQuant® is the current product used for this purpose, but other, similar vendor products may be used in the future.

The types of personal information about individuals collected in the system are patient demographics and medical information.

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

Privacy risks associated with the PII collected include inaccurate information entry, unauthorized access, and inadvertent data viewing. There are administrative, technical, and physical security safeguards in place to mitigate these risks. 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 Health Insurance Portability and Accountability Act (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 PII in the MRI Quantitative Imaging Analysis System is obtained from existing systems.

**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 PII in the MRI Quantitative Imaging Analysis System is obtained from existing systems.

**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 PII in the MRI Quantitative Imaging Analysis System is obtained from existing systems.

**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.**