## PRIVACY IMPACT ASSESSMENT (PIA)

PRESCRIBING AUTHORITY: DoD Instruction 5400.16, "DoD Privacy Impact Assessment (PIA) Guidance". Complete this form for Department of Defense (DoD) information systems or electronic collections of information (referred to as an "electronic collection" for the purpose of this form) that collect, maintain, use, and/or disseminate personally identifiable information (PII) about members of the public, Federal employees, contractors, or foreign nationals employed at U.S. military facilities internationally. In the case where no PII is collected, the PIA will serve as a conclusive determination that privacy requirements do not apply to system.

## 1. DOD INFORMATION SYSTEM/ELECTRONIC COLLECTION NAME:

Imagine Dental WKS WIN10 AI

2. DOD COMPONENT NAME:

3. PIA APPROVAL DATE:

Defense Health Agency 03/28/23

CyberLOG

## SECTION 1: PII DESCRIPTION SUMMARY (FOR PUBLIC RELEASE)

a. The PII is: (Check one. Note: Federal contractors, military family members, and foreign nationals are included in general public.)

From members of the general public From Federal employees

x from both members of the general public and Federal employees Not Collected (if checked proceed to Section 4)

b. The PII is in a: (Check one.)

New DoD Information System New Electronic Collection

x Existing DoD Information System Existing Electronic Collection

Significantly Modified DoD Information System

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

The Imagine Dental computer aid design (CAD)/computer aid manufacturing (CAM) Workstation (WKS) is an enterprise medical device designed to create and send models to a 3D printer. The workstation consists of a three-dimensional (3D) scanner and a PC tower connected via universal serial bus (USB). The 3D scan data is utilized by various software systems loaded on the Imagine personal computer (PC) workstation to design the dental prosthetic and prepare for fabrication. Numeric code programs dictate the computer controlled manufacturing process. The workstation pushes completed designs and numeric code instructions to be loaded into fabrication equipment such as 3D printer, through an RJ-45 network connection. The Imagine PC workstation may be built with any combination of the following software: the exocad suite, hyperDENT, ScanApp, PreForm, 3D Sprint, and MODJAW applications. The Imagine Dental CAD/CAM WKS will reside at several Defense Health Agency (DHA) clinic locations. Clients include military, civilian, and veterans. This is both federal government personnel and the general public.

Personally identifiable information (PII) or protected health information (PHI) present in the system comes from 3rd party Cone-Beam Computed Tomography (CBCT) scanning systems which builds PII into the digital imaging and communication in medicine (DICOM) file that results from a CBCT scan system. Various CBCT scanning systems could be utilized.

Imagine Dental WKS system is owned and operated by the DHA sites which purchase the workstation. Cyberlog is responsible for the risk management framework (RMF) process, and gaining an approval from DHA J6 Risk Management Executive Division (RMED). Local sites are responsible for day to day operations, maintenance, and management of the device. Sites are responsible for ensuring the device is configured to meet CyberLOG and RMED approved configurations.

d. Why is the PII collected and/or what is the intended use of the PII? (e.g., verification, identification, authentication, data matching, mission-related use, administrative use)

PII is collected for verification and identification purposes. The intended use of the PII to verify the correct patient is receiving the intended care.

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

Yes 🗶 No

- (1) If "Yes," describe the method by which individuals can object to the collection of PII.
- (2) If "No," state the reason why individuals cannot object to the collection of PII.

The Imagine\_Dental\_WKS\_WIN10 is not the initial point of collection of PII, therefore, individuals do not have an opportunity to object to the collection of their PII.

f. Do individuals have the opportunity to consent to the specific uses of their PII? Yes  $\mathbf{x}$  N

(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 Imagine\_Dental\_WKS\_WIN10 is not the initial point of collection of PII, therefore, individuals do not have an opportunity to consent to the specific use of their PII.

g. When an individual is asked to provide PII, a Privacy Act Statement (PAS) and/or a Privacy Advisory must be provided. (Check as appropriate and provide the actual wording.)

**Privacy Act Statement** 

Privacy Advisory

x Not Applicable

The Imagine\_Dental\_WKS\_WIN10 does not collect PII directly from individuals. Therefore, no Privacy Act Statement or Privacy Advisory is required.

h. With whom will the PII be shared through data/system exchange, both within your DoD Component and outside your Component? (Check all that apply)

x Within the DoD Component

Specify. DHA Military Treatment Facilities (MTF)

Other DoD Components (i.e. Army, Navy, Air Force)

Specify.

X Other Federal Agencies (i.e. Veteran's Affairs, Energy, State)

Department of Veterans Affairs, Health and Human

Services, Homeland Security, and Private Physicians

State and Local Agencies Specify.

The military treatment facilities (MTF) may utilize contractor services to support this product. DoD policy requires such contracts include language to safeguard PII

Contractor (Name of contractor and describe the language in the contract that safeguards PII. Include whether FAR privacy clauses, i.e., 52.224-1, Privacy Act Notification, 52.224-2, Privacy Act, and FAR 39.105 are included in the contract.)

Specify. including FAR clauses: 52.224-1, Privacy Act Notification; 52.224-2, Privacy Act; and FAR 39.105, Privacy. When the contractor has access to PHI, a HIPAA Business Associate

Agreement is also required

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

Specify.

i. Source of the PII collected is: (Check all that apply and list all information systems if applicable)

Individuals Databases

x Existing DoD Information Systems Commercial Systems

Other Federal Information Systems

The only PII or PHI present in the system comes from 3rd party CBCT scanning systems which builds PII into the DICOM file that results from a CBCT scan system.

j. How will the information be collected? (Check all that apply and list all Official Form Numbers if applicable)

E-mail Official Form (Enter Form Number(s) in the box below)

In-Person Contact Paper

Fax Telephone Interview

x Information Sharing - System to System Website/E-Form

Other (If Other, enter the information in the box below)

## k. 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 <u>retrieved</u> by name or other unique identifier. PIA and Privacy Act SORN information must be consistent.

Yes X No

If "Yes," enter SORN System Identifier

SORN Identifier, not the Federal Register (FR) Citation. Consult the DoD Component Privacy Office for additional information or http://dpcld.defense.gov/Privacy/SORNs/

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If a SORN has not yet been published in the Federal Register, enter date of submission for approval to Defense Privacy, Civil Liberties, and Transparency Division (DPCLTD). Consult the DoD Component Privacy Office for this date

If "No," explain why the SORN is not required in accordance with DoD Regulation 5400.11-R: Department of Defense Privacy Program.

Imagine Dental does not retrieve such information by an individual's name or other personal identifier. Therefore, a system of record notice is not required.

- I. What is the National Archives and Records Administration (NARA) approved, pending or general records schedule (GRS) disposition authority for the system or for the records maintained in the system?
  - (1) NARA Job Number or General Records Schedule Authority. GRS 5.2, item 020 (DAA-GRS-2017-0003-0002)
  - (2) If pending, provide the date the SF-115 was submitted to NARA.
  - (3) Retention Instructions.

FILE NUMBER: 103-14

DISPOSITION: Temporary. Delete no more than 7 years from the date last modified. (See DoD DTM 22-001 on default disposition policies and OSD Records Manager guidance which file number to associate).

- m. What is the authority to collect information? A Federal law or Executive Order must authorize the collection and maintenance of a system of records. For PII not collected or maintained in a system of records, the collection or maintenance of the PII must be necessary to discharge the requirements of a statue or Executive Order.
  - (1) If this system has a Privacy Act SORN, the authorities in this PIA and the existing Privacy Act SORN should be similar.
  - (2) If a SORN does not apply, 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) Cite the specific provisions of the statute and/or EO that authorizes the operation of the system and the collection of PII.
    - (b) If direct statutory authority or an Executive Order does not exist, indirect statutory 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) If direct or indirect authority does not exist, 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 must be identified.

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness; 10 U.S.C., Chapter 55, Medical and Dental Care; 32 CFR Part 199, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); 45 CFR 164, Security and Privacy; Department of Defense (DoD) Instruction 6015.23, Foreign Military Personnel Care and Uniform Business Offices in Military Treatment Facilities (MTFS); DoD Instruction 6025.18, Privacy of Individually Identifiable Health Information in DoD Health Care Programs; DoD Manual 6025.18, Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs; DoD Instruction 6040.45, DoD Health Record Life Cycle Management; and E.O. 9397 (SSN), as amended.

n. Does this DoD information system or electronic collection have an active and approved Office of Management and Budget (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 X No Pending

- (1) If "Yes," list all applicable OMB Control Numbers, collection titles, and expiration dates.
- (2) If "No," explain why OMB approval is not required in accordance with DoD Manual 8910.01, Volume 2, " DoD Information Collections Manual: Procedures for DoD Public Information Collections."
- (3) If "Pending," provide the date for the 60 and/or 30 day notice and the Federal Register citation.

The information collected in this system is for the diagnosis and treatment of medical disorders and is not considered a public information collection in accordance with DoDM 8910.01, V2, Encl 3, paragraph 8b(5).