## **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:				
ICAD Powerlook Pro (IPP)				
2. DOD COMPONENT NAME:			3. PIA APPROVAL DATE:	
Defense Health Agency			09/25/24	
Fort Belvoir Community Hospital				
SECTION 1: PII DESCRIPTION S	SUMMA	RY (FOR PUBLIC RELEASE)		
a. The PII is: (Check one. Note: Federal contractors, military family members	rs, and fo	reign 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.  ICAD Powerlook Pro (iPP) application is based on the Microsoft Windows Server platform (64-bit architecture), Operating on Windows 10. iPP is a host-based system with four major functionalities to include the Powerlook, Profound AI, SecondLook and Density Assessment.  PowerLook serves as the host platform for iCAD's Breast Health algorithm solution. The system consists of hardware and software and manages all DICOM connectivity for receiving images for processing from acquisition systems and sending results and display and storage systems such as mammography workstations, PACS, and DICOM archives.  ProFound AI detects malignant soft-tissue densities and calcifications in digital breast tomosynthesis (DBT) images. ProFound AI has the same performance with the DBT systems cleared for use with ProFound AI; furthermore, it provides support for additional DBT systems. The ProFound AI Software allows a radiologist to quickly identify suspicious soft tissue densities (masses, architectural distortions and asymmetries) and calcifications by marking the detected areas in the tomosynthesis images.				
The SecondLook computer-aided detection system for 2D mammography is intended to identify and mark regions of interest on standard 2D mammographic views to bring them to the attention of the radiologist after the initial reading has been completed. Thus, the system assists the radiologist in 0minimizing observational oversights by identifying areas on the original mammogram that may warrant a second review.				
The PowerLook Density Assessment Software analyzes digital breast tomosynthesis 2D synthetic images to calculate the dense tissue area of each breast. The iPP has no requirement for a monitor, keyboard, or mouse.				
ICAD Powerlook Pro (iPP) collects, processes, and distributes Personally Identifiable Information (PII), including Protected Health Information (PHI), demographic and personal descriptors, Identification (ID) numbers, health information, personal contact information, and employment contact information. These categories of PII are collected from DoD, VA, and USCG beneficiaries and their dependents for the delivery of health care services, the determination and processing of patient benefit information, as well as for Defense Health Agency (DHA) authorized clinical trials, medical research, and oncology registries.				
d. Why is the PII collected and/or what is the intended use of the PII? (e administrative use)	(e.g., ver	ification, identification, authentication, o	data matching, mission-related use,	
The PII/PHI information is collected for the purposes of patient iden	entificat	ion, tracking, and delivery of time	ly and effective patient care.	
e. Do individuals have the opportunity to object to the collection of their PII?				
(1) If "Yes," describe the method by which individuals can object to the colle	lection of	PII.		

	If "No," state the reason why individuals cannot object to the collection of					
The opportunity for individuals to object to the collection of PII is provided to patients at FBCH reception areas. The MHS Notice of Privacy						
	tices explains the MHS practices and responsibilities regarding P					
to in	spect/amend records, and to request restrictions to or an accounti	ng of disc	losures.			
f. Do	individuals have the opportunity to consent to the specific uses of	their PII?	X Yes No			
(1)	If "Yes," describe the method by which individuals can give or withhold the	eir consent				
	If "No," state the reason why individuals cannot give or withhold their cons					
	ridual are provided the opportunity to consent to specific uses or	sharing of	FII by submitting DD Form 2870 and request restrictions on			
the u	se of the PHI by submitting DD Form 2871.					
a. W	hen an individual is asked to provide PII, a Privacy Act Statement (P.	AS) and/or	a Privacy Advisory must be provided. (Check as appropriate and			
	ovide the actual wording.)	,	,			
X	Privacy Act Statement Privacy Advisory		Not Applicable			
AUT	HORITY: 10 USC 8111, Sharing of Department of VA and Do	D Healtho	are Resources: 10 USC 1104 Sharing of Healthcare			
	surces with the Department of Veterans Affairs; 38 USC 8111, Sl					
	th Care Resources; National Defense Authorization Act (NDAA)					
	nse for Personnel and Readiness; 10 USC Chapter 55, Medical a					
and I	Medical Care; 32 CFR Part 199, Civilian Health and Medical Pro	gram of t	ne Uniformed Services (CHAMPUS); DoD Instruction			
6025	.18, Privacy of Individually Identifiable Health Information in D	oD Healt	n Care Programs; DoD Regulation 6025.18-R, DoD Health			
	rmation Privacy Regulation; DoD Instruction 6040.45, DoD Heal		•			
Milit	ary Personnel Care and Uniform Business Offices in Military Tr	eatment F	acilities (MTFs).			
DIID	POSE T. II (' C. d'		. 1 . 14			
	POSE: To collect information required to provide and document lements; adjudicate claims; determine third party responsibility for					
	ver that cost; evaluate your fitness for duty and medical concerns		• • • • • • • • • • • • • • • • • • • •			
	rd; evaluate the MHS and its programs; and perform administration					
maza	ru, evaluate the 191115 and its programs, and perform administrati	ve tasks i	crated to WIIIS operations and personner readmess.			
ROU	TTINE USES: Information in your records may be disclosed to: I	rivate ph	vsicians and Federal agencies, including the Department of			
	rans Affairs, Health and Human Services, and Homeland Securit					
your	medical care; Government agencies to determine your eligibility	for benef	its and entitlements; Government and non-government third			
parti	es to recover the cost of MHS provided care; Public health autho	rities to d	ocument and review occupational and environmental			
	sure data; and Government and non-government organizations to					
	for other lawful reasons which may include teaching, compiling					
your	records outside of DoD may also occur in accordance with 5 US	C 552a(b)	of the Privacy Act of 1974, as amended.			
A	must sated be self- information (DIII) in years making may be used	and disals	and composally as manufitted by the LUDAA Drivery Dule (45			
	protected health information (PHI) in your records may be used Parts 160 and 164), as implemented within DoD by DoD 6025.1					
	eatment, payment, and healthcare operations.	. 0-IX. I CII	inted uses and disclosures of 1111 metade, but are not immed			
,	eatment, payment, and neatment operations.					
DISC	CLOSURE: Voluntary. Failure to provide the requested informat	ion, comp	rehensive health care services may not be possible, you may			
expe	rience administrative delays, and you may be rejected for service	or an ass	ignment. However, care will not be denied.			
	ith whom will the PII be shared through data/system exchange, both heck all that apply)	within you	r DoD Component and outside your Component?			
X	Within the DoD Component	Specify.	Authorized FBCH Medical Staff members			
_	Other De D. Ouron and the first Armed March Air Formal	0	Medical Staff at other MTFs for collaboration, diagnosis,			
X	Other DoD Components (i.e. Army, Navy, Air Force)	Specify.	and treatment of patients with similar medical conditions.			
	Other Federal Agencies (i.e. Veteran's Affairs, Energy, State)	Specify.				
	State and Local Agencies	Specify.				
			The Manufacturer servicing the device may have access to			
X	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.	some data. Contractor oncologists providing support will			
			need direct access to patient studies. Contracts for			
			manufacturers accessing this device include a standard			
			Military Health System (MHS), Health Insurance Portability			
			and Accountability Act (HIPAA) Business Associate Agreement, and Information Assurance (IA) guidelines.			
			Agreement, and information Assurance (IA) guidennes.			

	Other (e.g., commercial providers, colleges).	Specify	ify.	
i. Sc	ource of the PII collected is: (Check all that apply and list all inform	nation systems	s if applicable)	
X	Individuals		Databases	
X	Existing DoD Information Systems		Commercial Systems	
	Other Federal Information Systems			
MH	S Genesis			
j. Ho	w will the information be collected? (Check all that apply and list	t all Official For	orm Numbers if applicable)	
	E-mail		Official Form (Enter Form Number(s) in the box below)	
X	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)	Ш	Website/E-i offi	
k. [	Ooes this DoD Information system or electronic collection requi	re a Privacy A	Act System of Records Notice (SORN)?	
		_		
	<u>trieved</u> by name or other unique identifier. PIA and Privacy Act SOF		tains information about U.S. citizens or lawful permanent U.S. residents that on must be consistent.	
	Yes X No			
If "Y	es," enter SORN System Identifier			
	RN Identifier, not the Federal Register (FR) Citation.  Consult the Do acy/SORNs/	D Component	nt Privacy Office for additional information or http://dpcld.defense.gov/	
	or			
	SORN has not yet been published in the Federal Register, enter da sion (DPCLTD). Consult the DoD Component Privacy Office for this		sion for approval to Defense Privacy, Civil Liberties, and Transparency	
If "I	No," explain why the SORN is not required in accordance with DoD	Regulation 540	400.11-R: Department of Defense Privacy Program.	
	· ·		re the records is retrieved by the individual's name, number or	
unic	que identifier IAW the Privacy Act of 1974, as amended. (C	napter 33 of	1 Title 10 USC, §10/1 - 1106.)	
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, ite	tem 020 (DAA-GRS-2022-0009-0002)	
(2	) If pending, provide the date the SF-115 was submitted to NARA.			
(;	3) Retention Instructions.			
	E NUMBER: 103-14		117 1 (0 D D D D D D 001 1 1 0 1 1 1 1 1 1 1 1	
	POSITION: Temporary. Delete no more than 7 years from the OSD Records Manager guidance which file number to associate the control of the cont		modified. (See DoD DTM 22-001 on default disposition policies	
	obb iteration in many is a many in the manual to make it			

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.
<ul><li>(1) If this system has a Privacy Act SORN, the authorities in this PIA and the existing Privacy Act SORN should be similar.</li><li>(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).</li></ul>
(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.
10 USC 3013, Secretary of the Army; 10 USC 1071-1085, Medical and Dental Care; 50 USC Supplement IV, Appendix 454, as amended, Persons liable for training and service; 42 USC Chapter 117, Sections 11131-11152, Reporting of Information; 10 USC 1097a and 1097b TRICARE Prime and TRICARE Program; 10 USC 1079, Contracts for Medical Care for Spouses and Children; 10 USC 1079a, CHAMPUS; 10 USC. 1086, Contracts for Health Benefits for Certain Members, Former Members, and Their Dependents; 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)
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
<ul> <li>(1) If "Yes," list all applicable OMB Control Numbers, collection titles, and expiration dates.</li> <li>(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."</li> <li>(3) If "Pending," provide the date for the 60 and/or 30 day notice and the Federal Register citation.</li> </ul>
The information collected in this system is not from members of the public.