

Privacy Impact Assessment for the VA IT System called:

### Ceribell EEG -E (CEEG -E)

### Veterans Health Administration

# National Tele-EEG and Epilepsy Program (NTEEG-EP)

**eMASS ID #2445** 

Date PIA submitted for review:

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#### **System Contacts:**

#### System Contacts

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#### **Abstract**

The abstract provides the simplest explanation for "what does the system do?".

Non-convulsive seizures are a potentially life-threatening condition that can only be diagnosed by examining a patient's brain activity with an electroencephalogram (EEG). Traditional EEG is often difficult or impossible to obtain in critical care and emergency department settings, and most VA hospitals cannot obtain EEGs within the time frames required by established medical society guidelines. The Ceribell EEG system provides a point-of-care EEG capability that enables VHA caregivers to obtain EEG within 5 minutes, resulting in faster and easier access to EEG in critical care environments. With the Ceribell EEG, a bedside point-of-care EEG recorder transmits patient EEG data to a cloud-hosted web portal. VHA neurologists are able to review the data in real-time; and simultaneously, a Ceribell AI algorithm continuously monitors the EEG to identify potential seizure activity, ensuring that life-threatening seizures are recognized and treated immediately.

#### **Overview**

The overview is the most important section of the PIA. A thorough and clear overview gives the reader the appropriate context to understand the responses in the PIA. The overview should contain the following elements:

- 1 General Description
  - A. What is the IT system name and the name of the program office that owns the IT system?

The name of this IT system is Ceribell EEG. Ceribell EEG is under the Discovery, Education, and Affiliate Networks (DEAN-14); Healthcare Innovation and Learning (HIL14); SimLEARN National SimVET Center (14HIL2) program office.

B. What is the business purpose of the program, IT system, or technology and how it relates to the program office and agency mission?

The purpose of the DEAN program office and the VHA SimLEARN National SimVET Center is to advance the use of Clinical Training and Simulation to improve quality, safety, and modernization of medical facilities. VHA SimLEARN National SimVET Center seeks to modernize seizure care by utilizing web-enabled electroencephalogram (EEG) to improve POC seizure triage throughout VA. Ceribell relates to the DEAN program goals by allowing practitioners to administer EEG's more often with the ease of portability and without needing a specially trained EEG technologist.

C. Who is the owner or control of the IT system or project?

VA Controlled / non-VA Owned and Operated

- 2. Information Collection and Sharing
  - D. What is the expected number of individuals whose information is stored in the system and a brief description of the typical client or affected individual?

The number of expected internal users is expected to be between 10-20 VA employees, Clinical Trainees, VA Contractors and about 120 Veteran patients per year at each VA Hospital that adopts the Ceribell system. In the event all VA hospitals were to adopt the Ceribell system, there would be a total of about 3,400 internal users and an estimate of 20,400 patients per year impacted.

E. What is a general description of the information in the IT system and the purpose for collecting this information?

The Ceribell System uses the minimum amount of PII & PHI to accurately document EEG recordings and results data to the correct patients. The information within the IT system is made accessible to the approved clinicians in order to provide the benefit of rapid point-of-care recognition of seizures. Due to Ceribell's web-based, clinicians can remotely review the EEG data in real-time. Other information types used within the system are in relationship to VHA clinicians login access to the system. For these individuals, this only includes the clinician's name and e-mail address.

F. What information sharing conducted by the IT system? A general description of the modules and subsystems, where relevant, and their functions.

Ceribell EEG portal is not connected to any internal VA systems. Ceribell EEG portal receives the information via Wifi connection from the Ceribell Recording devices. This information is encrypted in transit and at rest via FIPS 140-2 validated cryptographic modules.

G. Is the system is operated in more than one site, and if so, a description of how use of the system and PII is maintained consistently in all sites and if the same controls are used across sites?

To approximately leverage the Ceribell system there are two major components. The first is the physical headgear component that is placed on patients to conduct EEG recordings. The second component is the web-based portal that directly receives the data and results from the headgear. Currently the connection to the cloud-based EEG portal has been disabled but the Ceribell system has been procured at 10 VAMCs and will be in operation once granted a FedRAMP authority to operate.

Because Ceribell EEG is a SaaS application, it can be used at any VHA facility that has procured the product and services. The cloud service provider is AWS East/West Government Cloud.

#### 3. Legal Authority and SORN

H. What is the citation of the legal authority to operate the IT system?

Privacy Act System of Record Notice 24VA10A7, "Patient Medical Records-VA: <a href="https://www.govinfo.gov/content/pkg/FR-2020-10-02/pdf/2020-21426.pdf">https://www.govinfo.gov/content/pkg/FR-2020-10-02/pdf/2020-21426.pdf</a>. Authority for maintenance of the system: Title 38, United States Code, Sections 501(b) and 304.

I. If the system is in the process of being modified and a SORN exists, will the SORN require amendment or revision and approval? If the system is using cloud technology, does the SORN for the system cover cloud usage or storage?

The system is using cloud technology, and the SORN for the system (24VA10A7/85\_FR\_62406 Patient Medical Records-VA) does cover cloud usage and storage.

#### 4. System Changes

J. Will the completion of this PIA will result in circumstances that require changes to business processes?

Yes

K. Will the completion of this PIA could potentially result in technology changes?

Yes. Ceribell EEG will make technological changes deemed appropriate or needed in response to the completion of this document.

#### Section 1. Characterization of the Information

The following questions are intended to define the scope of the information requested and collected as well as the reasons for its collection as part of the program, IT system, or technology being developed.

1.1 What information is collected, used, disseminated, created, or maintained in the system?

Identify and list all Sensitive Personal Information (SPI) that is collected and stored in the system, including Individually Identifiable Information (III), Individually Identifiable Health Information (IIHI), Protected Health Information (PHI), and Privacy- Protected Information. For additional information on these information types and definitions, please see VA Directives and Handbooks in the 6500 series (<a href="https://vaww.va.gov/vapubs/">https://vaww.va.gov/vapubs/</a>). If the system creates information (for example, a score, analysis, or report), list the information the system is responsible for creating.

If a requesting system receives information from another system, such as a response to a background check, describe what information is returned to the requesting system.

This question is related to privacy control AP-1, Authority To Collect, and AP-2, Purpose Specification.

The information selected below must match the information provided in question 2.1 as well as the data elements columns in 4.1 and 5.1. It must also match the information provided in question 3.4 of the PTA.

below that your system collects, uses, disted, used, disseminated, created, or main	
☐ Date of Birth ☐ Mother's Maiden Name	Personal Mailing
	ted, used, disseminated, created, or main  Date of Birth  Mother's Maiden Name

Personal Phone	☐ Certificate/License	☐ Integrated Control
Number(s)	numbers <sup>1</sup>	Number (ICN)
Personal Fax Number	☐ Vehicle License Plate	Military
Personal Email	Number	History/Service
Address	☐ Internet Protocol (IP)	Connection
☐ Emergency Contact	Address Numbers	☐ Next of Kin
Information (Name, Phone	Medications	Other Data Elements
Number, etc. of a different		(list below)
individual)	☐ Race/Ethnicity	,
☐ Financial Information	☐ Tax Identification	
☐ Health Insurance	Number	
Beneficiary Numbers	Medical Record	
Account numbers	Number	
	☐ Gender	
Other PII/PHI data elements:		
EEG Recordings		
EEG Descriptive Data (Date, Tin	me and Location of recording)	
EEG provider notes	ne, and Location of recording)	
Patient Unique identifier		
VA organization name		
EEG review status		
	guaga (SAMI) Cradentials	
Security Assertion Mark-up Lan EEG Waveform	guage (SAML) Credentials	

#### PII Mapping of Components (Servers/Database)

Ceribell consists of 1 key components (servers/databases/instances/applications/software/application programming interfaces (API). Each component has been analyzed to determine if any elements of that component collect PII. The type of PII collected by Ceribell and the reasons for the collection of the PII are in the table below.

**Note**: Due to the PIA being a public facing document, please do not include server names in the table. The first table of 3.9 in the PTA should be used to answer this question.

Internal Components Table

<b>Component Name</b>	Does this system	Does	Type of	Reason for	Safeguards
(Database, Instances,	collect PII?	this	PII (SSN,	Collection/	
Application,	(Yes/No)	system	DOB,	Storage of PII	
Software,		store	etc.)		
Application Program		РП?			
<b>Interface (API) etc.)</b>		(Yes/No)			
that contains					
PII/PHI					

<sup>&</sup>lt;sup>1</sup>\*Specify type of Certificate or License Number (e.g., Occupational, Education, Medical)

ClarityPro	No	No	EEG Waveform	Captures EEG waves, transfers the information to Ceribell cloud, and VA MDs access the information through the cloud	N/A

#### 1.2 What are the sources of the information in the system?

These questions are related to privacy controls DI-1, Data Quality, and IP-1, Consent.

1.2a List the individual, entity, or entities providing the specific information identified above. For example, is the information collected directly from the individual as part of an application for a benefit, or is it collected from other sources such as commercial data aggregators?

The identifying information for the Veteran patient is manually entered into the Ceribell EEG system by the bedside VA clinician; the patient's EEG data is recorded by the system directly from the patient and displayed within the web portal.

1.2b Describe why information from sources other than the individual is required? For example, if a program's system is using data from a commercial aggregator of information or data taken from public Web sites, state the fact that this is where the information is coming from and then in question indicate why the system is using this source of data.

The PII & PHI for the Veteran patient must be entered into the Ceribell EEG system by the bedside VA clinician because the system has restricted access for approved VA staff only. The reason the system is storing the above referenced data is because the Ceribell EEG Portal displays a list of available EEG recordings when an authorized neurologist logs in to review EEG files. The VA neurologist use the patient name to identify that they are looking at the correct EEG file.

1.2c Does the system create information (for example, a score, analysis, or report), list the system as a source of information?

Ceribell EEG does not act as a source of information, it only displays the Veteran patient EEG data recorded from ClarityPro.

#### 1.3 How is the information collected?

These questions are related to privacy controls DI-1, Data Quality, and IP-1, Consent.

1.3a This question is directed at the means of collection from the sources listed in question 1.2. Information may be collected directly from an individual, received via electronic transmission from another system, or created by the system itself. Specifically, is information collected through technologies or other technologies used in the storage or transmission of information in identifiable form?

The personal identifiable information of the Veteran is collected manually by the VA clinician. The patient's personal health information such as the EEG recordings and raw data is collected through electronic transmission between the Ceribell EEG device and the Ceribell SaaS Web Portal.

1.3b If the information is collected on a form and is subject to the Paperwork Reduction Act, what is the form's OMB control number and the agency form number?

N/A - There are no forms associated with the system. Data recorded by the system is strictly digital.

#### 1.4 How will the information be checked for accuracy? How often will it be checked?

These questions are related to privacy controls DI-1, Data Quality, and DI-2, Data Integrity and Integrity Board.

1.4a Discuss whether and how often information stored in the system is checked for accuracy. Is information in the system checked against any other source of information (within or outside your organization) before the information is used to make decisions about an individual? For example, is there a computer matching agreement in place with another government agency? For systems that receive data from internal data sources or VA IT systems, describe the system checks to ensure that data corruption has not occurred during transmission.

EEG waveforms data is collected directly from the individual patient- it is their brain waves so accuracy is verified by the original source and data validation is checked at the time of ingest into the Ceribell EEG portal. There are no connections to other VA IT systems or other internal data sources. Other data elements used within the system such as name, DOB, etc are manually entered by a VA clinician. A manual mis-entry can later be corrected on the EEG web portal.

1.4b Does the system check for accuracy by accessing a commercial aggregator of information, describe this process and the levels of accuracy required by the contract?

Not applicable – Ceribell does not use a commercial aggregator.

### 1.5 What specific legal authorities, arrangements, and agreements defined the collection of information?

List the full legal authority for operating the system, specifically the authority to collect the information listed in question 1.1. Provide the authorities in a manner understandable to any potential reader, i.e., do not simply provide a legal citation; use statute names or regulations in addition to citations. Legal authorities include Federal laws, regulations, statutes, and Executive Orders. This question is related to privacy control AP-1, Authority to Collect

Privacy Act System of Record Notice 24VA10A7, "Patient Medical Records-VA: <a href="https://www.govinfo.gov/content/pkg/FR-2020-10-02/pdf/2020-21426.pdf">https://www.govinfo.gov/content/pkg/FR-2020-10-02/pdf/2020-21426.pdf</a>. Authority for maintenance of the system: Title 38, United States Code, Sections 501(b) and 304.

#### 1.6 PRIVACY IMPACT ASSESSMENT: Characterization of the information

Consider the specific data elements collected and discuss the potential privacy risks and what steps, if any are currently being taken to mitigate those identified risks. (Work with your System ISSO to complete this section)

Consider the following Fair Information Practice Principles (FIPPs) when assessing the risk to individual privacy:

<u>Principle of Purpose Specification:</u> Explain how the collection ties with the purpose of the underlying mission of the organization and its enabling authority.

<u>Principle of Minimization:</u> Is the information directly relevant and necessary to accomplish the specific purposes of the program?

<u>Principle of Individual Participation:</u> Does the program, to the extent possible and practical, collect information directly from the individual?

<u>Principle of Data Quality and Integrity:</u> Are there policies and procedures for VA to ensure that personally identifiable information is accurate, complete, and current? This question is related to privacy control AR-1, Governance and Privacy Program, and AR-2, Privacy Impact and Risk Assessment.

Follow the format below when entering your risk assessment:

<u>Privacy Risk:</u> There is a privacy risk that data within the Ceribell system may be inconsistent due human entry errors into the source data systems.

<u>Mitigation:</u> The Ceribell system will employ a variety of security measures to ensure that the information is not incomplete when entered or shared. These measures include application peer review, spell check, drop down options, etc. Ceribell employs all security controls in the respective to high impact security control baseline unless specific exceptions have been allowed based on the tailoring guidance provided in National Institute of Standards and Technology (NIST) Special Publication 800 - 37 and specific VA Directives. Any incorrectly entered data can be corrected through the Ceribell EEG Portal.

#### Section 2. Uses of the Information

The following questions are intended to clearly delineate the use of information and the accuracy of the data being used.

### 2.1 Describe how the information in the system that will be used in support of the program's business purpose.

Identify and list each use (both internal and external to VA) of the information collected or maintained. This question is related to privacy control AP-2, Purpose Specification.

PII/PHI Data Element	Internal Use	External Use

Name	The name, Date of Birth, and	Not used
Tame	Medical Record Number are	Tiot used
	Part of the medical assessment	
	are needed so that the VA	
	neurologist who logs on to the	
	EEG web portal can be assured	
	that they are reviewing the	
	correct EEG recording. Part of	
	the medical assessment.	
Date of Birth	The name, Date of Birth, and	N/A
	Medical Record Number are	
	Part of the medical assessment	
	are needed so that the VA	
	neurologist who logs on to the	
	EEG web portal can be assured	
	that they are reviewing the	
	correct EEG recording. Part of	
	the medical assessment.	
Medical Record	The name Date of Digith and	N/A
Medical Record	The name, Date of Birth, and Medical Record Number are	N/A
	Part of the medical assessment	
	are needed so that the VA	
	neurologist who logs on to the	
	EEG web portal can be assured	
	that they are reviewing the	
	correct EEG recording. Part of	
	the medical assessment.	
Phone Numbers	The name, Date of Birth, and	N/A
	Medical Record Number are	
	Part of the medical assessment	
	are needed so that the VA	
	neurologist who logs on to the	
	EEG web portal can be assured	
	that they are reviewing the	
	correct EEG recording. Part of	
	the medical assessment.	N/A
Personal Email Address	This data is collected to assist	N/A
	VA providers in acquiring	
	access to the VA specific	
	instance of Ceribell EEG	
	portal. This information will	
	allow access to the system for	
	training purposes	
VA Organization Name	This data is collected to assist	N/A
organization runne	VA providers in acquiring	- ··
	vis providers in acquiring	

	access to the VA specific instance of Ceribell EEG portal. This information will allow access to the system for training purposes	
SAML Credentials	This data is collected to assist VA providers in acquiring access to the VA specific instance of Ceribell EEG portal. This information will allow access to the system for training purposes	N/A
EEG Recordings	The EEG recording data and associated data such as the EEG descriptive data, provider notes, and review status are needed to provide the clinical benefit of the system. A neurologist logs into the EEG waveform data and forms a diagnostic recommendation for the patient.	N/A
EEG Descriptive Data (Date, Time, and Location of recording)	The EEG recording data and associated data such as the EEG descriptive data, provider notes, and review status are needed to provide the clinical benefit of the system. A neurologist logs into the EEG waveform data and forms a diagnostic recommendation for the patient.	N/A
EEG provider notes	The EEG recording data and associated data such as the EEG descriptive data, provider notes, and review status are needed to provide the clinical benefit of the system. A neurologist logs into the EEG	N/A

	waveform data and forms a diagnostic recommendation for the patient.	
EEG review status	The EEG recording data and associated data such as the EEG descriptive data, provider notes, and review status are needed to provide the clinical benefit of the system. A neurologist logs into the EEG waveform data and forms a diagnostic recommendation for the patient.	N/A
Medical Records	The EEG recording data and associated data such as the EEG descriptive data, provider notes, and review status are needed to provide the clinical benefit of the system. A neurologist logs into the EEG waveform data and forms a diagnostic recommendation for the patient.	N/A

## **2.2** What types of tools are used to analyze data and what type of data may be produced? These questions are related to privacy controls DI-1, Data Quality, DI-2, Data Integrity and Integrity Board, and SE-1, Inventory of Personally Identifiable Information.

2.2a Many systems sift through large amounts of information in response to a user inquiry or programmed functions. Systems may help identify areas that were previously not obvious and need additional research by agents, analysts, or other employees. Some systems perform complex analytical tasks resulting in, among other types of data, matching, relational analysis, scoring, reporting, or pattern analysis. Describe any type of analysis the system conducts and the data that is created from the analysis?

Not applicable – no additional analytics is conducted by Ceribell

2.2b If the system creates or makes available new or previously unutilized information about an individual, explain what will be done with the newly derived information. Will it be placed in the individual's existing record? Will a new record be created? Will any action be taken against or for the individual identified because of the newly derived data? If a new record is created, will the newly created information be accessible to Government employees who make determinations about the

individual? If so, explain fully under which circumstances and by whom that information will be used.

Not applicable – no additional analytics is conducted by Ceribell

#### 2.3 How is the information in the system secured?

These questions are related to security and privacy controls SC-9, Transmission Confidentiality, and SC-28, Protection of Information at Rest.

2.3a What measures are in place to protect data in transit and at rest?

Data is encrypted in transit and at rest utilizing FIPS 140-2 validated cryptographic modules throughout the boundary. Ceribell EEG will be assessed on this through control family SC of the SSP.

2.3b If the system is collecting, processing, or retaining Social Security Numbers, are there additional protections in place to protect SSNs?

System does not contain SSNs.

2.3c How is PII/PHI safeguarded in accordance with OMB Memorandum M-06-15?

Ceribell employs all security controls in the respective to high impact security control baseline unless specific exceptions have been allowed based on the tailoring guidance provided in National Institute of Standards and Technology (NIST) Special Publication 800 - 37 and specific VA Directives which protect the Confidentiality, Integrity and Availability of Federal data.

#### **2.4 PRIVACY IMPACT ASSESSMENT: Use of the information.**

Describe any types of controls that may be in place to ensure that information is handled in accordance with the uses described above. Example: Describe if training for users of the project covers how to appropriately use information. Describe the disciplinary programs or system controls (i.e. denial of access) that are in place if an individual is inappropriately using the information.

Consider the following FIPPs below to assist in providing a response:

<u>Principle of Transparency:</u> Is the PIA and SORN, if applicable, clear about the uses of the information?

<u>Principle of Use Limitation:</u> Is the use of information contained in the system relevant to the mission of the project?

This question is related to privacy control AR-4, Privacy Monitoring and Auditing, AR-5, Privacy Awareness and Training, and SE-2, Privacy Incident response.

2.4a How is access to the PII determined?

Decided by the VA and dependent on the roles and responsibilities of the VA user.

2.4b Are criteria, procedures, controls, and responsibilities regarding access documented? Yes

2.4c Does access require manager approval?

Ceribell is able to put VA specific controls in place which could require manager approval prior to granting access to the Ceribell EEG portal.

2.4d Is access to the PII being monitored, tracked, or recorded?

Yes. These include but is not limited to monitoring, and logging of activities. For all activities Ceribell employs security controls in the respective to high impact security control baseline.

2.4e Who is responsible for assuring safeguards for the PII?

Ceribell is responsible for ensuring safeguards are in place for all PII once the data has entered the Ceribell EEG portal.

#### Section 3. Retention of Information

The following questions are intended to outline how long information will be retained after the initial collection.

#### 3.1 What information is retained?

Identify and list all information collected from question 1.1 that is **retained** by the system. This question is related to privacy controls DM-1, Minimization of Personally Identifiable Information, and DM-2, Data Retention and Disposal

All data items collected by the system will be retained, these include Name, DOB, Medical Record Number, Medical Records, Personal Email Address, EEG Recordings, EEG Descriptive Data (Date, Time, and Location of recording), EEG provider notes, Patient Unique identifier, VA organization name, EEG review status, SAML Credentials.

#### 3.2 How long is information retained?

In some cases, VA may choose to retain files in active status and archive them after a certain period of time. State active file retention periods, as well as archived records, in number of years, for the information and record types. For example, financial data held within your system may have a different retention period than medical records or education records held within your system, please be sure to list each of these retention periods. The VA records officer should be consulted early in the development process to ensure that appropriate retention and destruction schedules are implemented. If the system is using cloud technology, will it be following the NARA approved retention length and schedule? This question is related to privacy control DM-2, Data Retention and Disposal.

Per SORN 24VA10A7, POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS: In accordance with the records disposition authority approved by the Archivist of the United States, paper records and information stored on electronic storage media are maintained for seventy-five (75) years after the last episode of patient care and then destroyed/or deleted. VHA Records Control Schedule (RCS 10–1), Chapter 6, 6000.1d (N1–15–91–6, Item 1d) and 6000.2b (N1–15–02–3, Item 3).

### 3.3 Has the retention schedule been approved by the VA records office and the National Archives and Records Administration (NARA)?

An approved records schedule must be obtained for any IT system that allows the retrieval of a record via a personal identifier. The VA records officer will assist in providing a proposed schedule. The schedule must be formally offered to NARA for official approval. Once NARA approves the proposed schedule, the VA records officer will notify the system owner. Please work with the system Privacy Officer and VA Records Officer to answer these questions. This question is related to privacy control DM-2, Data Retention and Disposal.

3.3a Are all records stored within the system of record indicated on an approved disposition authority?

As outlined in SORN 24VA10A7 records are stored in accordance with VHA Records Control Schedule (RCS 10–1), Chapter 6, 6000.1d (N1–15–91–6, Item 1d) and 6000.2b (N1–15–02–3, Item 3). RCS 10-1: <a href="https://www.va.gov/vhapublications/rcs10/rcs10-1.pdf">https://www.va.gov/vhapublications/rcs10/rcs10-1.pdf</a>.

3.3b Please indicate each records retention schedule, series, and disposition authority?

VHA Records Control Schedule (RCS 10–1), Chapter 6, 6000.1d (N1–15–91–6, Item 1d) and 6000.2b (N1–15–02–3, Item 3). RCS 10-1: <a href="https://www.va.gov/vhapublications/rcs10/rcs10-1.pdf">https://www.va.gov/vhapublications/rcs10/rcs10-1.pdf</a>.

#### 3.4 What are the procedures for the elimination or transfer of SPI?

Explain how records are destroyed, eliminated or transferred to NARA at the end of their mandatory retention period. Please give the details of the process. For example, are paper records shredded on site, or by a shredding company and accompanied by a certificate of destruction, etc.? This question is related to privacy control DM-2, Data Retention and Disposal.

At the end of contract, Ceribell will securely transfer all VA EEG records stored on the Ceribell system to the VA. The data will then be securely deleted from the Ceribell system and a certificate of data destruction will be provided by Ceribell. Transfer of Ceribell records to the VA will be done using a secure file transfer mechanism designated by the VA (e.g. SFTP). There are no paper records associated with use of the Ceribell system.

3.5 Does the system, where feasible, use techniques to minimize the risk to privacy by using PII for research, testing, or training?

Organizations often use PII for testing new applications or information systems prior to deployment. Organizations also use PII for research purposes and for training. These uses of PII increase the risks associated with the unauthorized disclosure or misuse of the information. Please explain what controls have been implemented to protect PII used for testing, training and research. This question is related to privacy control DM-3, Minimization of PII Used in Testing, Training and Research.

No PII/PHI from Ceribell is used for research, testing, or training.

#### **3.6 PRIVACY IMPACT ASSESSMENT: Retention of information**

Discuss the risks associated with the length of time data is retained and what steps, if any, are currently being taken to mitigate those identified risks. (Work with your System ISSO to complete all Privacy Risk questions inside the document this section).

While we understand that establishing retention periods for records is a formal process, there are policy considerations behind how long a project keeps information. The longer a project retains information, the longer it needs to secure the information and assure its accuracy and integrity. The proposed schedule should match the requirements of the Privacy Act to keep the minimum amount of PII for the minimum amount of time, while meeting the Federal Records Act. The schedule should align with the stated purpose and mission of the system.

Consider the following FIPPs below to assist in providing a response:

<u>Principle of Minimization:</u> Does the project retain only the information necessary for its purpose? Is the PII retained only for as long as necessary and relevant to fulfill the specified purposes?

<u>Principle of Data Quality and Integrity:</u> Has the PIA described policies and procedures for how PII that is no longer relevant and necessary is purged?

This question is related to privacy controls DM-1, Minimization of Personally Identifiable Information, and DM-2, Data Retention and Disposal.

Follow the format below:

**Privacy Risk:** There is a privacy risk that data within the Ceribell system may be held longer than needed which places it at risk of impermissible access or loss.

<u>Mitigation:</u> The Ceribell system will employ a variety of security measures to ensure that the information is only kept for as long as it is needed. These measures include monitoring and alerting of automated jobs and periodic testing of configurations. Ceribell employs all security controls in the respective to high impact security control baseline unless specific exceptions have been allowed based on the tailoring guidance provided in National Institute of Standards and Technology (NIST) Special Publication 800 - 37 and specific VA Directives.

#### Section 4. Internal Sharing/Receiving/Transmitting and Disclosure

The following questions are intended to define the scope of information sharing/receiving/transmitting within VA.

## 4.1 With which internal organizations is information shared/received/transmitted? What information is shared/received/transmitted, and for what purpose? How is the information transmitted?

NOTE: Question 3.9 (second table) on Privacy Threshold Analysis should be used to answer this question.

Identify and list the names of any program offices, contractor-supported IT systems, and any other organization or IT system within VA with which information is shared.

State the purpose for the internal sharing. If you have specific authority to share the information, provide a citation to the authority.

For each interface with a system outside your program office, state what specific data elements (PII/PHI) are shared with the specific program office, contractor-supported IT system, and any other organization or IT system within VA.

Describe how the information is transmitted. For example, is the information transmitted electronically, by paper, or by some other means? Is the information shared in bulk, on a case-by-case basis, or does the sharing partner have direct access to the information? This question is related to privacy controls AP-2, Purpose Specification, AR-3, Privacy Requirements for Contractors and Service Providers, AR-8, Accounting of Disclosures, TR-1, Privacy Notice, and UL-1, Internal Use.

#### Data Shared with Internal Organizations

Office or IT System information is shared/received with	information being shared /received with the specified program office or IT system	data elements that are processed (shared/received/transmitted) with the Program Office or IT system	method of transmittal
ClarityPro	ClarityPro is a machine learning algorithm that interprets EEG signals and provides alerts when continuous seizures indicating status epilepticus are detected	EEG Waveform	Captures EEG waves, transfers the information through WiFi to the Ceribell cloud, and VA MDs access the information through the cloud.

#### 4.2 PRIVACY IMPACT ASSESSMENT: Internal sharing and disclosure

Discuss the privacy risks associated with the sharing of information within the Department and what steps, if any, are currently being taken to mitigate those identified risks. (Work with your System ISSO to complete all Privacy Risk questions inside the document this section).

This question is related to privacy control UL-1, Internal Use.

Follow the format below:

<u>Privacy Risk:</u> N/A, Ceribell does not share receive/Transmit/and/or disclosure data with internal VA systems or databases.

<u>Mitigation:</u> N/A, Ceribell does not share receive/Transmit/and/or disclosure data with internal VA systems or databases.

#### Section 5. External Sharing/Receiving and Disclosure

The following questions are intended to define the content, scope, and authority for information sharing external to VA, which includes Federal, State, and local governments, and the private sector.

5.1 With which external organizations (outside VA) is information shared/received? What information is shared/received, and for what purpose? How is the information transmitted and what measures are taken to ensure it is secure?

Is the sharing of information outside the agency compatible with the original collection? If so, is it covered by an appropriate routine use in a SORN? If not, please describe under what legal mechanism the IT system is allowed to share the information in identifiable form or personally identifiable information outside of VA.

NOTE: Question 3.10 on Privacy Threshold Analysis should be used to answer this question.

Identify and list the names of any Federal, State, or local government agency or private sector organization with which information is shared.

For each interface with a system outside VA, state what specific data elements (PII/PHI) are shared with each specific partner.

What legal mechanisms, authoritative agreements, documentation, or policies are in place detailing the extent of the sharing and the duties of each party? For example, is the sharing of data compatible with your SORN? Then list the SORN and the applicable routine use from the SORN. Is there a Memorandum of Understanding (MOU), Computer Matching Agreement (CMA), or law that mandates the sharing of this information?

Describe how the information is transmitted to entities external to VA and what security measures have been taken to protect it during transmission.

This question is related to privacy control UL-2, Information Sharing with Third Parties

List External Program Office or IT System information is shared/received with	List the purpose of information being shared / received / transmitted with the specified program office or IT system	List the specific PII/PHI data elements that are processed (shared/received/transmitted) with the Program or IT system	List the legal authority, binding agreement, SORN routine use, etc. that permit external sharing (can be more	List the method of transmission and the measures in place to secure data
			than one)	
N/A	N/A	N/A	N/A	N/A

#### 5.2 PRIVACY IMPACT ASSESSMENT: External sharing and disclosure

Discuss the privacy risks associated with the sharing of information outside the Department and what steps, if any, are currently being taken to mitigate those identified risks.

If no External Sharing listed on the table above, (State there is no external sharing in both the risk and mitigation fields).

Discuss whether access controls have been implemented and whether audit logs are regularly reviewed to ensure appropriate sharing outside of the Department. For example, is there a Memorandum of Understanding (MOU), contract, or agreement in place with outside agencies or foreign governments.

Discuss how the sharing of information outside of the Department is compatible with the stated purpose and use of the original collection.

This question is related to privacy control AR-2, Privacy Impact and Risk Assessment, AR-3, Privacy Requirements for Contractors and Service Providers, and AR-4, Privacy Monitoring and Auditing

Follow the format below:

<u>Privacy Risk:</u> N/A, Ceribell does not share receive/Transmit/and/or disclosure data with any systems or databases external to VA.

<u>Mitigation:</u> N/A, Ceribell does not share receive/Transmit/and/or disclosure data with any systems or databases external to VA.

#### Section 6. Notice

The following questions are directed at providing notice to the individual of the scope of information collected, the right to consent to uses of the information, and the right to decline to provide information.

6.1 Was notice provided to the individual before collection of the information? If yes, please provide a copy of the notice as an Appendix-A 6.1 on the last page of the document. Also provide notice given to individuals by the source system (A notice may include a posted privacy policy, a Privacy Act notice on forms, or a system of records notice published in the Federal Register.) If notice was not provided, why not?

These questions are related to privacy control TR-1, Privacy Notice, and TR-2, System of Records Notices and Privacy Act Statements, and TR-3, Dissemination of Privacy Program Information.

6.1a This question is directed at the notice provided before collection of the information. This refers to whether the person is aware that his or her information is going to be collected. A notice may include a posted privacy policy, a Privacy Act statement on forms, or a SORN published in the Federal Register, Notice of Privacy Practice provided to individuals for VHA systems. If notice was provided in the Federal Register, provide the citation.

For VA end-users of the Ceribell system, a banner notification is provided upon user sign-in stating that the Ceribell EEG system is a Federal System and user actions are monitored. This notification must be accepted prior to proceeding further in the Ceribell EEG system.

#### The VHA Notice of Privacy Practice (NOPP)

https://www.va.gov/vhapublications/ViewPublication.asp?pub\_ID=9946 explains the collection and use of protected health information to individuals receiving health care from VA. The NOPP is mailed every three years or when there is a major change to all enrolled Veterans. Non Veterans receiving care are provided the notice at the time of their encounter.

Privacy Act System of Record Notice 24VA10A7, "Patient Medical Records-VA: https://www.govinfo.gov/content/pkg/FR-2020-10-02/pdf/2020-21426.pdf.

This Privacy Impact Assessment (PIA) also serves as notice As required by the eGovernment Act of 2002, Pub.L. 107–347 §208(b)(1)(B)(iii), the Department of Veterans Affairs "after completion of the [PIA] under clause (ii), make the privacy impact assessment publicly available through the website of the agency, publication in the Federal Register, or other means."

6.1b If notice was not provided, explain why. If it was provided, attach a copy of the current notice.

Individuals are notified of how information about them may be used as explained in question 6.1a above.

6.1c Describe how the notice provided for the collection of information is adequate to inform those affected by the system that their information has been collected and is being used appropriately. Provide information on any notice provided on forms or on Web sites associated with the collection.

The VHA Notice of Privacy Practice (NOPP) is a document which explains the collection and use of protected health information to individuals receiving health care from VA. The NOPP is

mailed every three years or when there is a major change to all enrolled Veterans. Non Veterans receiving care are provided the notice at the time of their encounter.

This Privacy Impact Assessment (PIA) also serves as notice As required by the eGovernment Act of 2002, Pub.L. 107–347 §208(b)(1)(B)(iii), the Department of Veterans Affairs "after completion of the [PIA] under clause (ii), make the privacy impact assessment publicly available through the website of the agency, publication in the Federal Register, or other means."

A Privacy Act Statement is provided on all forms that collect information that will be maintained in a privacy act system of records. The statement provides the purpose, authority and the conditions under which the information can be disclosed.

### 6.2 Do individuals have the opportunity and right to decline to provide information? If so, is a penalty or denial of service attached?

This question is directed at whether the person from or about whom information is collected can decline to provide the information and if so, whether a penalty or denial of service is attached. This question is related to privacy control IP-1, Consent, IP-2, Individual Access, and IP-3, Redress.

Information is requested when it is necessary to administer benefits to veterans and other potential beneficiaries. While an individual may choose not to provide information, this may prevent them from obtaining the benefits necessary to them. The individual shall not be denied any right, benefit, or privilege provided by law because of refusal to disclose to VHA an SSN (see 38 CFR 1.575(a)).

### 6.3 Do individuals have the right to consent to particular uses of the information? If so, how does the individual exercise the right?

This question is directed at whether an individual may provide consent for specific uses, or the consent is given to cover all uses (current or potential) of his or her information. If specific consent is required, how would the individual consent to each use? This question is related to privacy control IP-1. Consent.

Individuals are provided with a copy of the Notice of Privacy Practices that indicates when information will be used without their consent and when they will be asked to provide consent. Information is used, accessed and disclosed in accordance with the Privacy Act, 5 USC 552a, Title 38 USC 5701, Confidential Nature of Claims, Title USC 7332 and the HIPAA Privacy Rule 45 CFR.

Individuals or their legal representative may consent to the use or disclosure of information via a written request submitted to their facility Privacy Officer. Individuals also have the right to request a restriction to the use of their information. The written request must state what information and/or to whom the information is restricted and must include their signature and date of the request. The request is then forwarded to facility Privacy Officer for review and processing.

#### **6.4 PRIVACY IMPACT ASSESSMENT: Notice**

Describe the potential risks associated with potentially insufficient notice and what steps, if any, are currently being taken to mitigate those identified risks. (Work with your System ISSO to complete all Privacy Risk questions inside the document this section).

Consider the following FIPPs below to assist in providing a response:

<u>Principle of Transparency:</u> Has sufficient notice been provided to the individual?

<u>Principle of Use Limitation:</u> Is the information used only for the purpose for which notice was provided either directly to the individual or through a public notice? What procedures are in place to ensure that information is used only for the purpose articulated in the notice? This question is related to privacy control TR-1, Privacy Notice, AR-2, Privacy Impact and Risk Assessment, and UL-1, Internal Use. Follow the format below:

**Privacy Risk:** A Potential Risk could be that an individual is not aware of how their information is going to be collected, shared, and maintained.

Mitigation: This risk is mitigated by the common practice of providing the NOPP when Veterans apply for benefits. Additionally, new NOPPs are mailed to beneficiaries at least every 3 years and periodic monitoring is performed to check that all employees are aware of the requirement to provide guidance to Veterans and that the signed acknowledgment form, when applicable, is scanned into electronic records. The NOPP is also available at all VHA medical centers from the facility Privacy Officer.

The System of Record Notices (SORNs) and Privacy Impact Assessment (PIA) are also available for review online, as discussed in question 6.1.

#### Section 7. Access, Redress, and Correction

The following questions are directed at an individual's ability to ensure the accuracy of the information collected about him or her.

#### 7.1 What are the procedures that allow individuals to gain access to their information?

These questions are related to privacy control IP-2, Individual Access, and AR-8, Accounting of Disclosures.

7.1a Cite any procedures or regulations your program has in place that allow access to information. These procedures, at a minimum, should include the agency's FOIA/Privacy Act practices, but may also include additional access provisions. For example, if your program has a customer satisfaction unit, that information, along with phone and email contact information, should be listed in this section in addition to the agency's procedures. See 5 CFR 294 and the VA FOIA Web

page at <a href="https://department.va.gov/foia/">https://department.va.gov/foia/</a> to obtain information about FOIA points of contact and information about agency FOIA processes.

There are several ways a veteran or other beneficiary may access information about them. The Department of Veterans' Affairs has created the MyHealthEVet program to allow online access to their medical records. More information on this program and how to sign up to participate can be found online at https://www.myhealth.va.gov/index.html. Veterans and other individuals may also request copies of their medical records and other records containing personal data from the medical facility's Release of Information (ROI) office.

VHA Directive 1605.01, Privacy and Release of Information, Paragraph 7 outlines policy and procedures for VHA and its staff to provide individuals with access to and copies of their PII in compliance with the Privacy Act and HIPAA Privacy Rule requirements. VHA also created VA form 10-5345a for use by individuals in requesting copies of their health information under right of access. VA Form 10-5345a is voluntary but does provide an easy way for individual to request their records.

7.1b If the system is exempt from the access provisions of the Privacy Act, please explain the basis for the exemption or cite the source where this explanation may be found, for example, a Final Rule published in the Code of Federal Regulations (CFR)?

The information stored in this system is not exempt from the Privacy Act.

7.1c If the system is not a Privacy Act system, please explain what procedures and regulations are in place that covers an individual gaining access to his or her information?

Information in this system is protected under Privacy Act SORN 24VA10A7.

#### 7.2 What are the procedures for correcting inaccurate or erroneous information?

Describe the procedures and provide contact information for the appropriate person to whom such issues should be addressed? If the correction procedures are the same as those given in question 7.1, state as much. This question is related to privacy control IP-3, Redress, and IP-4, Complaint Management.

Individuals are required to provide a written request to amend or correct their records to the appropriate Privacy Officer or System Manager as outlined in the Privacy Act SOR. Every Privacy Act SOR contains information on Contesting Record Procedure which informs the individual who to contact for redress. Further information regarding access and correction procedures can be found in the notices listed in Appendix A. The VHA Notice of Privacy Practices also informs individuals how to file an amendment request with VHA.

#### 7.3 How are individuals notified of the procedures for correcting their information?

How are individuals made aware of the procedures for correcting his or her information? This may be through notice at collection or other similar means. This question is meant to address the risk that even if procedures exist to correct information, if an individual is not made fully aware of the existence of those procedures, then the benefits of the procedures are significantly weakened. This question is related to privacy control IP-3, Redress, and IP-4, Complaint Management.

Veterans are informed of the amendment process by many resources to include the VHA Notice of Privacy Practice (NOPP) which states:

#### **Right to Request Amendment of Health Information.**

You have the right to request an amendment (correction) to your health information in our records if you believe it is incomplete, inaccurate, untimely, or unrelated to your care. You must submit your request in writing, specify the information that you want corrected, and provide a reason to support your request for amendment. All amendment requests should be submitted to the facility Privacy Officer at the VHA health care facility that maintains your information.

If your request for amendment is denied, you will be notified of this decision in writing and provided appeal rights. In response, you may do any of the following:

- File an appeal
- File a "Statement of Disagreement"
- Ask that your initial request for amendment accompany all future disclosures of the disputed health information.

Additional notice is provided through the SORN listed in 6.1 of this PIA and through the Release of Information Office where care is received.

#### 7.4 If no formal redress is provided, what alternatives are available to the individual?

Redress is the process by which an individual gains access to his or her records and seeks corrections or amendments to those records. Redress may be provided through the Privacy Act and Freedom of Information Act (FOIA), and also by other processes specific to a program, system, or group of systems. Example: Some projects allow users to directly access and correct/update their information online. This helps ensures data accuracy.

This question is related to privacy control IP-3, Redress, and IP-4, Complaint Management.

Formal redress via the amendment process is available to all individuals, as stated in questions 7.1-7.3.

#### 7.5 PRIVACY IMPACT ASSESSMENT: Access, redress, and correction

Discuss what risks there currently are related to the Department's access, redress, and correction policies and procedures for this system and what, if any, steps have been taken to mitigate those risks. For example, if a project does not allow individual access, the risk of inaccurate data needs to be discussed in light of the purpose of the project. For example, providing access to ongoing law enforcement activities could negatively impact the program's effectiveness because the individuals involved might change their behavior. (Work with your System ISSO to complete all Privacy Risk questions inside the document this section).

Consider the following FIPPs below to assist in providing a response:

<u>Principle of Individual Participation:</u> Is the individual provided with the ability to find out whether a project maintains a record relating to him?

<u>Principle of Individual Participation:</u> If access and/or correction is denied, then is the individual provided notice as to why the denial was made and how to challenge such a denial?

<u>Principle of Individual Participation:</u> Is there a mechanism by which an individual is able to prevent information about him obtained for one purpose from being used for other purposes without his knowledge?

This question is related to privacy control IP-3, Redress.

Follow the format below:

<u>Privacy Risk:</u> A Potential Risk could be that a patient is not aware of relevant access, redress, and correction policies.

<u>Mitigation</u>: The risk of incorrect information in an individual's records is mitigated by authenticating information when possible. Additionally, staff verifies information in medical records and corrects information identified as incorrect during each patient's medical appointments.

The NOPP discusses the process for requesting an amendment to one's records.

The Release of Information (ROI) office is available to assist Veterans with obtaining access to their health records and other records containing personal information.

The Veterans' Health Administration (VHA) established MyHealtheVet program to provide Veterans remote access to their medical records. The Veteran must enroll and have access to the premium account to obtain access to all the available features. In addition, VHA Directive 1605.01 Privacy and Release of Information establishes procedures for Veterans to have their records amended where appropriate.

#### **Section 8. Technical Access and Security**

The following questions are intended to describe technical safeguards and security measures.

### 8.1 What procedures are in place to determine which users may access the system, and are they documented?

These questions are related to privacy control AR-7, Privacy-Enhanced System Design and Development.

8.1a Describe the process by which an individual receives access to the system? Authorized end-users are VA clinicians involved in the care of patients who receive Ceribell EEG. End-user accounts are created by Ceribell once the VA identifies which providers require access. End-user credentialling/authentication is managed by the VA through the VA's existing single-signon systems.

8.1b Identify users from other agencies who may have access to the system and under what roles these individuals have access to the system. Who establishes the criteria for what PII can be shared?

*NA* – no other agencies will have access to the Ceribell EEG system.

8.1c Describe the different roles in general terms that have been created to provide access to the system? For example, certain users may have "read-only" access while others may be permitted to make certain amendments or changes to the information.

VA clinicians who have access to the Ceribell EEG system are able to view Veteran patient EEG recordings and make notes/annotations. The VA end-users are not able to modify or augment the EEG waveforms themselves.

8.2 Will VA contractors have access to the system and the PII? If yes, what involvement will contractors have with the design and maintenance of the system? Has a contractor confidentiality agreement, Business Associate Agreement (BAA), or a Non-Disclosure Agreement (NDA) been developed for contractors who work on the system?

If so, how frequently are contracts reviewed and by whom? Describe the necessity of the access provided to contractors to the system and whether clearance is required. If Privacy Roles and Responsibilities have been established to restrict certain users to different access levels, please describe the roles and associated access levels. Explain the need for VA contractors to have access to the PII. This question is related to privacy control AR-3, Privacy Requirements for Contractors, and Service Providers.

The only Contractor would be Ceribell EEG. No other 3rd party Applications or Vendors would have access to the system.

### 8.3 Describe what privacy training is provided to users either generally or specifically relevant to the program or system?

VA offers privacy and security training. Each program or system may offer training specific to the program or system that touches on information handling procedures and sensitivity of information. Please describe how individuals who have access to PII are trained to handle it appropriately. This question is related to privacy control AR-5, Privacy Awareness and Training.

Ceribell has a formally documented, reviewed, and approved Training procedure for all Ceribell EEG Federal Information System personnel. This training includes but is not limited to privacy awareness training at the time of hire, job change and on at minimum an annual basis thereafter.

#### 8.4 Has Authorization and Accreditation (A&A) been completed for the system?

No

8.4a If Yes, provide:

- 1. The Security Plan Status: In Progress
- 2. The System Security Plan Status Date: 4/19/2024
- 3. The Authorization Status: In process
- 4. The Authorization Date: TBD

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- 5. The Authorization Termination Date: TBD
- 6. The Risk Review Completion Date: TBD
- 7. The FIPS 199 classification of the system (LOW/MODERATE/HIGH): High

Please note that all systems containing SPI are categorized at a minimum level of "moderate" under Federal Information Processing Standards Publication 199.

8.4b If No or In Process, provide your Initial Operating Capability (IOC) date.

In A&A is in process, IOC date is 6/9/2024

#### **Section 9 - Technology Usage**

The following questions are used to identify the technologies being used by the IT system or project.

9.1 Does the system use cloud technology? If so, what cloud model is being utilized?

If so, Does the system have a FedRAMP provisional or agency authorization? If the system does use cloud technology, but does not have FedRAMP authorization, explain how the Cloud Service Provider (CSP) solution was assessed and what FedRAMP documents and processes were used for the assessment in order to comply with VA Handbook 6517. Types of cloud models include: Software as a Service (SaaS), Infrastructure as a Service (IaaS), Platform as a Service (PaaS), Commercial off the Shelf (COTS), Desktop as a Service (DaaS), Mobile Backend as a Service (MBaaS), Information Technology Management as a Service (ITMaaS). This question is related to privacy control UL-1, Information Sharing with Third Parties.

Note: For systems utilizing the VA Enterprise Cloud (VAEC), no further responses are required after 9.1. (Refer to question 3.3.1 of the PTA)

This Information System uses AWS East/West Government Cloud.

9.2 Does the contract with the Cloud Service Provider, Contractors and VA customers establish who has ownership rights over data including PII? (Provide contract number and supporting information about PII/PHI from the contract). (Refer to question 3.3.2 of the PTA) This question is related to privacy control AR-3, Privacy Requirements for Contractors, and Service Providers.

Yes, is does, please see the current contract language in place regarding PII data ownership: For information systems that are hosted, operated, maintained, or used on behalf of VA at non-VA facilities, Contractors/Subcontractors are fully responsible and accountable for ensuring compliance with all HIPAA, Privacy Act, FISMA, NIST, FIPS, and VA security and privacy directives and handbooks. This includes conducting compliant risk assessments, routine vulnerability scanning, system patching and change management procedures, and the completion of an acceptable contingency plan for each system. The Contractor's security control procedures must be equivalent to those procedures used to secure VA systems. A Privacy Impact Assessment (PIA) must also be provided to the COR and approved by VA Privacy Service prior to operational approval. All external Internet connections to VA network involving VA information must be in accordance with the TIC Reference Architecture and reviewed and approved by VA prior to implementation. For Cloud Services hosting, the Contractor shall also ensure compliance with the Federal Risk and Authorization Management Program (FedRAMP). Adequate security

controls for collecting, processing, transmitting, and storing of Personally Identifiable Information (PII), as determined by the VA Privacy Service, must be in place, tested, and approved by VA prior to hosting, operation, maintenance, or use of the information system, or systems by or on behalf of VA. These security controls are to be assessed and stated within the PIA and if these controls are determined not to be in place, or inadequate, a Plan of Action and Milestones (POA&M) must be submitted and approved prior to the collection of PII.

### 9.3 Will the CSP collect any ancillary data and if so, who has ownership over the ancillary data?

Per NIST 800-144, cloud providers hold significant details about the accounts of cloud consumers that could be compromised and used in subsequent attacks. Ancillary data also involves information the cloud provider collects or produces about customer-related activity in the cloud. It includes data collected to meter and charge for consumption of resources, logs and audit trails, and other such metadata that is generated and accumulated within the cloud environment.

This question is related to privacy control DI-1, Data Quality.

For Veteran patients, no ancillary data is collected; patients do not directly log in to the Ceribell EEG system. For VA clinician end-users, the only ancillary data collected are data mandated by FedRAMP requirements for logging and audit trails, such as IP address and web-browser information. All ancillary data is owned by the VA.

## 9.4 NIST 800-144 states, "Organizations are ultimately accountable for the security and privacy of data held by a cloud provider on their behalf." Is this principle described in contracts with customers? Why or why not?

What are the roles and responsibilities involved between the organization and cloud provider, particularly with respect to managing risks and ensuring organizational requirements are met? This question is related to privacy control AR-3, Privacy Requirements for Contractors and Service Providers.

Yes, 36C10A23P0012

### 9.5 If the system is utilizing Robotics Process Automation (RPA), please describe the role of the bots.

Robotic Process Automation is the use of software scripts to perform tasks as an automated process that executes in parallel with or in place of human input. For example, will the automation move or touch PII/PHI information. RPA may also be referred to as "Bots" or Artificial Intelligence (AI).

NA – no RPA is used to move or touch PII/PHI.

#### **Section 10. References**

### Summary of Privacy Controls by Family

Summary of Privacy Controls by Family

ID	Privacy Controls
AP	Authority and Purpose
AP-1	Authority to Collect
AP-2	Purpose Specification
AR	Accountability, Audit, and Risk Management
AR-1	Governance and Privacy Program
AR-2	Privacy Impact and Risk Assessment
AR-3	Privacy Requirements for Contractors and Service Providers
AR-4	Privacy Monitoring and Auditing
AR-5	Privacy Awareness and Training
AR-7	Privacy-Enhanced System Design and Development
AR-8	Accounting of Disclosures
DI	Data Quality and Integrity
DI-1	Data Quality
DI-2	Data Integrity and Data Integrity Board
DM	Data Minimization and Retention
DM-1	Minimization of Personally Identifiable Information
DM-2	Data Retention and Disposal
DM-3	Minimization of PII Used in Testing, Training, and Research
IP	Individual Participation and Redress
IP-1	Consent
IP-2	Individual Access
IP-3	Redress
IP-4	Complaint Management
SE	Security
SE-1	Inventory of Personally Identifiable Information

ID	Privacy Controls
SE-2	Privacy Incident Response
TR	Transparency
TR-1	Privacy Notice
TR-2	System of Records Notices and Privacy Act Statements
TR-3	Dissemination of Privacy Program Information
UL	Use Limitation
UL-1	Internal Use
UL-2	Information Sharing with Third Parties

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Signature of Responsible Officials
The individuals below attest that the information they provided in this Privacy Impact Assessment is true and accurate.
Privacy Officer, Phillip Cauthers
Information System Security Officer, Scott Miller
Information System Owner, Thomas Adams

#### **APPENDIX A-6.1**

Please provide a link to the notice or verbiage referred to in Section 6 (a notice may include a posted privacy policy; a Privacy Act notice on forms; screen shot of a website collection privacy notice).

The VHA Notice of Privacy Practice (NOPP) https://www.va.gov/vhapublications/ViewPublication.asp?pub\_ID=9946

Privacy Act System of Record Notice 24VA10A7, "Patient Medical Records-VA: https://www.govinfo.gov/content/pkg/FR-2020-10-02/pdf/2020-21426.pdf.

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#### **HELPFUL LINKS:**

#### **General Records Schedule**

https://www.archives.gov/records-mgmt/grs.html

#### **National Archives (Federal Records Management):**

https://www.archives.gov/records-mgmt/grs

#### **VA Publications:**

https://www.va.gov/vapubs/

#### **VA Privacy Service Privacy Hub:**

https://dvagov.sharepoint.com/sites/OITPrivacyHub

#### **Notice of Privacy Practice (NOPP):**

VHA Notice of Privacy Practices

VHA Directive 1605.04: Notice of Privacy Practices

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