



Privacy Impact Assessment for the VA IT System called:

Spinal Cord Injury Research Study Mobile/Web App

VHA

Discovery, Education, and Affiliate Networks (DEAN)

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?” and will be published online to accompany the PIA link.

The system is the backend system for a research system to collect pressure monitoring data for veterans with spinal cord injuries. The data will be uploaded from an internet connected mobile phone throughout the day. The data will also be viewable to VA staff research clinicians on a web dashboard to assist in therapy and education of the veteran. The research study is to assess the feasibility of this platform. All research participant data is de-identified as they use a research ID to log into the app. No PHI/PII is collected on the system, only the pressure map data being sent.

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. The IT system name and the name of the program office that owns the IT system.

Spinal Cord Injury Research Study Mobile/Web App- Discovery, Education, and Affiliate Networks (DEAN)

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

System is for research for health technology system feasibility

C. Indicate the ownership or control of the IT system or project.

VA

2. Information Collection and Sharing

D. The expected number of individuals whose information is stored in the system and a brief description of the typical client or affected individual.

20 – 25, The data is that of research study participants that are VA spinal cord injury sufferers

E. A general description of the information in the IT system and the purpose for collecting this information.

The information collected is pressure mat data throughout the day associated with the research participant ID number. This is used by the research staff clinicians for education and training.

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

No information sharing, system is stand-alone

G. Whether 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.

Single Site, Minneapolis VA

3. Legal Authority and SORN

H. A citation of the legal authority to operate the IT system.

34VA10/ 86 FR 33015 Veteran, Patient, Employee, and Volunteer Research and Development Project Records VA.

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?

N/A

D. System Changes

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

N/A

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

N/A

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 (II), 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 (<https://vaww.va.gov/vapubs/>). 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.

Please check any information listed below that your system collects, uses, disseminates, creates, or maintains. If additional SPI is collected, used, disseminated, created, or maintained, please list those in the text box below:

- | | | |
|---|---|--|
| <input type="checkbox"/> Name | Number, etc. of a different individual) | <input type="checkbox"/> Race/Ethnicity |
| <input type="checkbox"/> Social Security Number | <input type="checkbox"/> Financial Information | <input type="checkbox"/> Tax Identification Number |
| <input type="checkbox"/> Date of Birth | <input type="checkbox"/> Health Insurance Beneficiary Numbers | <input type="checkbox"/> Medical Record Number |
| <input type="checkbox"/> Mother's Maiden Name | Account numbers | <input type="checkbox"/> Gender |
| <input type="checkbox"/> Personal Mailing Address | <input type="checkbox"/> Certificate/License numbers* | <input type="checkbox"/> Integrated Control Number (ICN) |
| <input type="checkbox"/> Personal Phone Number(s) | <input type="checkbox"/> Vehicle License Plate Number | <input type="checkbox"/> Military History/Service Connection |
| <input type="checkbox"/> Personal Fax Number | <input type="checkbox"/> Internet Protocol (IP) Address Numbers | <input type="checkbox"/> Next of Kin |
| <input type="checkbox"/> Personal Email Address | <input type="checkbox"/> Medications | <input checked="" type="checkbox"/> Other Data Elements (list below) |
| <input type="checkbox"/> Emergency Contact Information (Name, Phone | <input type="checkbox"/> Medical Records | |

Pressure Sensor Data
 App settings data collected from app
 User ID of Research participant
 User ID of Clinician research staff

PII Mapping of Components (Servers/Database)

Spinal Cord Injury Research Study Mobile/Web App consists of **0** key components (servers/databases). Each component has been analyzed to determine if any elements of that component collect PII. The type of PII collected by Spinal Cord Injury Research Study Mobile/Web App 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 the server names in the table. The first table of 3.9 in the PTA should be used to answer this question.

Internal Database Connections

Database Name of the information system collecting/storing PII	Does this system collect PII? (Yes/No)	Does this system store PII? (Yes/No)	Type of PII (SSN, DOB, etc.)	Reason for Collection/ Storage of PII	Safeguards
N/A	No	No	N/A	N/A	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?

Pressure mat data and application settings are collected directly from the study participant.

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.

N/A

1.2c If the system creates information (for example, a score, analysis, or report), list the system as a source of information.

The mobile app will classify pressure mat data according to criteria as a “pressure relief”

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?

Information is collected by the system itself and the individual

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

N/A

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.

Study participant data will be checked at clinician and user discretion.

1.4b If the system checks for accuracy by accessing a commercial aggregator of information, describe this process and the levels of accuracy required by the contract.

Accuracy of pressure mat data is only validated against user reports and only to assess if a system error occurs

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

Users sign a Consent Form to collect the Non-PII/PHI Data Sets.
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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:

Principle of Purpose Specification: Explain how the collection ties with the purpose of the underlying mission of the organization and its enabling authority. Research for VA Patient Care and Education.

Principle of Minimization: Is the information directly relevant and necessary to accomplish the specific purposes of the program? Yes

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

*Principle of Data Quality and Integrity: Are there policies and procedures for VA to ensure that personally identifiable information is accurate, complete, and current? Yes
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:

Privacy Risk: Pressure mat data related to research could be viewed and shared by non-study staff

Mitigation: Spinal Cord Injury Research Study Mobile/Web App system data is research specific. The VA AZURE Encrypts all Data at rest and in transit. The VA AZURE uses Role Base Access Control (RBAC). Study staff is given necessary permission to access data, and participant data is coded with a random identifier mitigating any leak of personal information connected to the research

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 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.

Pressure Sensor Data: used to analyze seating behavior
App settings data collected from app: used to save users settings
User ID of Research participant: used as research participant identifier
User ID of Clinician research staff: used as clinician research staff identifier

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.

The system collects pressure mat data and using criteria from the patient and clinician the system analyzes the pressure mat and classifies if the user is performing a pressure relief.

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.

The research system collects the pressure mat and pressure relief inferences and stores them to be viewable to research clinicians. This data is to help the clinicians better understand seating behavior. Only research staff clinicians have access to the user data, and the data is de-identified in the system

as it is associated only with a research ID so it is only usable with research staff with the crosswalk to match research ID with PII (this crosswalk is completely separate from this system as is research protocol).

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?

The VA AZURE Encrypts all Data at rest and in transit.

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

N/A

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

Pressure sensor data is protected by not using any personal identifiable information of the research participant. All the data collected is only associated with the research device and any connection to the research participant is secured off of this system.

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:

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

Principle of Use Limitation: 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?

Clinician (defined as research study staff) are given access to a web-based portal to view sensor data. The access protected with username (generated by research staff) and a password. Authentication uses JWT on the server.

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

VA AZURE uses Role Base Access Control (RBAC).

2.4c Does access require manager approval?

Yes, Through VA OI&T Electronic Permission Access System (ePas).

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

Study use is tracked via logs in Azure

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

Research staff is responsible for monitoring use and protecting as study data.

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*

Pressure data and app settings are retained

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.

7 years per National Achieve Records Administration (NARA) Requirement. (“Request for Records Disposition Authority” Records Schedule DAA-0015-2015-0004 (13 July 2015)

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?

Yes

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

Federal rules set by the National Archives and Records Administration (NARA) mandate that a copy of all research investigator records be maintained for six fiscal years post study closure. The NARA definition of "investigator records" includes (but is not limited to) any and all files, data, manuscript drafts, logs, notes, protocols, and investigator copies of oversight committee letters that pertain to the approved research study. (“Request for Records Disposition Authority” Records Schedule DAA-0015-2015-0004 (13 July 2015)

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.

Records are removed according to Minneapolis VA Health Care System research service SOP (R&D-016). Electronic data and files of any type, including Protected Health Information (PHI), Sensitive Personal Information (SPI), Human Resources records, and more are destroyed in accordance with VA Directive 6500 VA Cybersecurity Program (February 24, 2021) and VA Handbook 6500.1 Electronic Media Sanitization. When required, this data is deleted from their file location and then permanently deleted from the deleted items or Recycle bin. Magnetic media is

wiped and sent out for destruction. Digital media is shredded or sent out for destruction.
https://www.oprm.va.gov/docs/Directive_6500_24_Feb_2021.pdf.

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.

Data in system is de-identified all access is by research staff controlled by research admins.

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:

Principle of Minimization: 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?

Principle of Data Quality and Integrity: 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: Records could be kept longer than necessary.

Mitigation: To mitigate the risk posed by information retention research staff will carefully dispose of the data by the determined method as described in question 3.4. Research staff are trained in the correct process for collecting, using and retaining this data. The Institution Review Board (IRB) and Information System Security Officer (ISSO) review practices associated with

research data to ensure their respective programs are understood and followed by all to protect sensitive information from the time it is captured by the until it is destroyed.

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

<i>List the Program Office or IT System information is shared/received with</i>	<i>List the purpose of the information being shared /received with the specified program office or IT system</i>	<i>List the specific PII/PHI data elements that are processed (shared/received/transmitted) with the Program Office or IT system</i>	<i>Describe the method of transmittal</i>
NA	NA	NA	NA

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:

Privacy Risk: NA

Mitigation: NA

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

Data Shared with External Organizations

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

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.

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:

Privacy Risk: NA

Mitigation: NA

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.

Research participant signs consent to take part in research study. 34VA10/ 86 FR 33015
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6.1b If notice was not provided, explain why. If it was provided, attach a copy of the current notice.

NA

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.

Research participant signs consent to take part in research study.

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.

Yes, they can withdraw from the study at any time

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.

This is covered in research data consent form

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:

Principle of Transparency: Has sufficient notice been provided to the individual?

Principle of Use Limitation: 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: There is a risk that study participant will not know that the research study is collection pressure mat data.

Mitigation: All study participant a required to go through a consenting process where they are informed of all of the data collected in the study.

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 <http://www.foia.va.gov/> to obtain information about FOIA points of contact and information about agency FOIA processes.***

Research participants have access to their collected data when participating in the research study. Upon completion their access to data is removed. Data is then stored on secured study drive to research analysis.

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).

N/A

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.

Research participants complete a consent form that details data information and individual access.

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.

Research staff can be informed of incorrect data collect by research participants, data can be flagged as erroneous and logged, but all data is still collected and stored.

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.

Research staff will monitor the data and logs and will alert research study participants if research devices are malfunctioning. Study staff will act quickly to mitigate any incorrect data capture.

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.

Data is research data; redress is not possibly from the participant

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:

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

Principle of Individual Participation: 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?

Principle of Individual Participation: 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:

Privacy Risk: The research participants device would collect data with errors and the research participant would not know to inform study staff to correct it.

Mitigation: Research study participants are regularly contacted by study staff and to access to accuracy of system data. They are informed of study staff contact information and told to reach out if any issues arise.

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.

A research participant has access to their data using their assigned random research ID and password. This is accessible to them using the mobile application. They must sign on to the mobile application to access their data. Study staff clinicians are able to view research records through an dashboard with sign with an id (assigned at the beginning of research) and password.

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?

Research clinicians can see research participant data through a web portal

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.

Participants are able to write to only their research ID data and can only read their research data. Research clinicians are able to read study participant data.

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.

VA contractors will not have access to data

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.

Research study staff receive annual Privacy and Health Insurance Portability and Accountability (HIPAA) Training (VA TMS ID: 10203).

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

8.4a *If Yes, provide:*

1. *The Security Plan Status:* Please provide response here
2. *The System Security Plan Status Date:* Please provide response here
3. *The Authorization Status:* Please provide response here
4. *The Authorization Date:* Please provide response here
5. *The Authorization Termination Date:* Please provide response here
6. *The Risk Review Completion Date:* Please provide response here
7. *The FIPS 199 classification of the system (LOW/MODERATE/HIGH):* Please provide response here

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.***

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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)

VA Enterprise Cloud (VAEC) Azure: GS-35F-0884P VA118-17-F-1888

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

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the PTA) This question is related to privacy control AR-3, Privacy Requirements for Contractors and Service Providers.

VA Enterprise Cloud (VAEC) Azure: GS-35F-0884P VA118-17-F-1888

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.

No ancillary data collected.

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.

Research study participants are informed of data accountability, security, and privacy in the research consent document they sign to agree to be a research study participant.

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).

N/A

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
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

ID	Privacy Controls
UL-1	Internal Use
UL-2	Information Sharing with Third Parties

Signature of Responsible Officials

The individuals below attest that the information they provided in this Privacy Impact Assessment is true and accurate.

Privacy Officer, Kimberly Murphy

Information System Security Officer, Robert D. Rude

Information System Owner, Timothy Truty

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).

Research Consent:

<https://www.research.va.gov/programs/orppe/policy/draft/forms/Informed-Consent-Template-HIPAA-Authorization-Elements.docx>

HELPFUL LINKS:

Record Control Schedules:

<https://www.va.gov/vhapublications/rcs10/rcs10-1.pdf>

General Records Schedule 1.1: Financial Management and Reporting Records (FSC):

<https://www.archives.gov/files/records-mgmt/grs/grs01-1.pdf>

National Archives (Federal Records Management):

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

VHA Publications:

<https://www.va.gov/vhapublications/publications.cfm?Pub=2>

VA Privacy Service Privacy Hub:

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

Notice of Privacy Practice (NOPP):

[VHA Notice of Privacy Practices](#)

[VHA Handbook 1605.04: Notice of Privacy Practices](#)