Privacy Impact Assessment for the VA IT System called:

Salesforce: VA/David Lynch Foundation Multi-Site PTSD Study

VA San Diego Healthcare System
Veterans Health Administration

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 VA/David Lynch Foundation Multi-Site PTSD Study Salesforce module will support a nine-site study for determining if transcendental meditation (TM) works better than presence-based therapy (PBT) in treating post-traumatic stress disorder. VA research staff can enter therapy service data including session type, age-at-instruction, location (on site, by phone, or on video), meditation regularity, time of session, whether the patient has completed pre- and post-assessments, whether blood samples have been taken, randomization arm and date, and treatment sessions conducted with subject into the module and automatically aggregate it so that principal investigators (PIs) will know the extent to which the VA research staff is maintaining fidelity to study treatment and follow-up protocols. Please note that it will not record the outcomes of the therapy service. The Data Security Categorization of the module has been determined to be Moderate.

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:

- *The IT system name and the name of the program office that owns the IT system.*
- *The business purpose of the program, IT system, or technology and how it relates to the program office and agency mission.*
- *Indicate the ownership or control of the IT system or project.*
- *The expected number of individuals whose information is stored in the system and a brief description of the typical client or affected individual.*
- *A general description of the information in the IT system and the purpose for collecting this information.*
- *Any information sharing conducted by the IT system. A general description of the modules and subsystems, where relevant, and their functions.*
- *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.*
- *A citation of the legal authority to operate the IT system.*
- *Whether the completion of this PIA will result in circumstances that require changes to business processes*
- *Whether the completion of this PIA could potentially result in technology changes*
- *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 Salesforce VA/David Lynch Multi-Site PTSD study is a system for the Veterans Health Administration that will be utilized to help process the results of the multi-site PTSD study. This system is owned by Salesforce but will be operated by VA and David Lynch Foundation employees. The system will record the results of how different types of meditation can help with PTSD. Employees names and employment info will be in this system. Along with patient's information and their progress throughout the study. This system does not share any of its information with other systems it simply generates reports on the studies progress. There are multiple sites for this study spanning over nine universities in America. The legal authority to operate the system is in the Cloud Service Provider Agreement, this system also falls under the following System of Record's Notice: (https://www.oprm.va.gov/privacy/systems_of_records.aspx). 64VA10RCS - Readjustment Counseling Program (RCS) Vet Center Program-VA *https://www.govinfo.gov/content/pkg/FR-2016-06-07/pdf/2016-13378.pdf*

The completion of this PIA will not result in any technological changes.

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 (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:

☒ Name ☐ Social Security Number ☒ Date of Birth
☐ Mother's Maiden Name

☒ Personal Mailing Address
☒ Personal Phone Number(s)
☐ Personal Fax Number
☒ Personal Email Address
☐ Emergency Contact Information (Name, Phone Number, etc. of a different individual)
☐ Financial Account Information
☐ Health Insurance Beneficiary Numbers Account numbers
☐ Certificate/License numbers
☐ Vehicle License Plate Number
☐ Internet Protocol (IP) Address Numbers
☐ Current Medications
☐ Previous Medical Records
☐ Race/Ethnicity
☐ Tax Identification Number
☐ Medical Record Number
☒ Gender
☐ Integration Control Number (ICN)
☐ Military History/Service Connection
☐ Next of Kin
☒ Other Unique Identifying Information (list below)

• Patient Name • Patient Address • Patient Phone • Patient Email • Patient Date of Birth • Session Type • Age at Instruction • Location (dropdown): In Person, Phone, Video • Meditation Regularity • Time of Session • Whether patient has completed pre and post-assessments • Whether blood samples have been taken • Randomization arm and date • Referral source • Phone screen date and result (eligible, ineligible, not interested, on hold) • Reason denied from study • Payment code (matches payment card; patients receive payments when engaged in services or assessments) • Treatment sessions conducted with subject.

Employee PII: • Name • Role • Email • Phone Number

PII Mapping of Components

Salesforce: VA/David Lynch Multi-Site PTSD Study consists of 0 key components (databases). Each component has been analyzed to determine if any elements of that component collect PII. The type of PII collected by Salesforce: VA/David Lynch Multi-Site PTSD Study and the reasons for the collection of the PII are in the table below.

PII Mapped to Components

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.

PII Mapped to Components

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	N/A	N/A	N/A	N/A	N/A

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

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?

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 1.3 indicate why the system is using this source of data.

If the system creates information (for example, a score, analysis, or report), list the system as a source of information.
This question is related to privacy controls DI-1, Data Quality, and IP-1, Consent.

The sources of information for this system are the results of the Multi-Site PTSD Study and the databases that include patients and employee's information.

1.3 How is the information collected?

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 technology used in the storage or transmission of information in identifiable form?

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.
This question is related to privacy controls DI-1, Data Quality, and IP-1, Consent.

Information is collected through recording of the results of patient's therapy sessions

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

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.

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.
This question is related to privacy controls DI-1, Data Quality, and DI-2, Data Integrity and Integrity Board.

We will have weekly meetings with each site team to review Salesforce dashboards. This will help maintain accuracy of service data. We will also regularly compare which surveys have been completed according to Salesforce with what surveys have actually been done, which will be stored in REDCap.

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

Inherited "Salesforce Development Platform VA Assessing" Authorization to Operate until December 17, 2023

Veterans Affairs Handbook 6500, Risk Management Framework for VA Information Systems VA Information Security Program, February 24, 2021
- Appendix A, 16

Committee on National Security Systems (CNSSI) No. 4009 April 6, 2015

SORN Link:
(https://www.oprm.va.gov/privacy/systems_of_records.aspx). 64VA10RCS - Readjustment Counseling Program (RCS) Vet Center Program-VA https://www.govinfo.gov/content/pkg/FR-2016-06- 07/pdf/2016-13378.pd

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.

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.

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

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

Principle of Data Quality and Integrity: 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:
Privacy Risk: While details of therapy sessions won't be in the system, if someone saw the PII of a study subject in Salesforce, they would know that this person has been diagnosed with PTSD as that is the inclusion criteria for the study.

Mitigation: Data showing patients therapy results and notes on their sessions can be produced by the system. Salesforce is used to sort and record this data. As Salesforce owns this system but the VA and David Lynch Foundation will operate it.

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.

Results are recorded for future reference in the system and to see what methods of meditation are most effective in assisting with PTSD

2.2 What types of tools are used to analyze data and what type of data may be produced?

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.

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.
This question is related to privacy controls DI-1, Data Quality, DI-2, Data Integrity and Integrity Board, and SE-1, Inventory of Personally Identifiable Information

This system will record and provide data on patient therapy results regarding how effective transcendental meditation is in improving post-traumatic stress disorder symptoms.

2.3 How is the information in the system secured?

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

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

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

This question is related to security and privacy controls SC-9, Transmission Confidentiality, and SC-28, Protection of Information at Rest

Answer: Yes, this system utilizes Salesforce Shield Protect which provides a FIPS 140-2 certified encryption.

2.4 <u>PRIVACY IMPACT ASSESSMENT: Use of the information.</u> How is access to the PII determined? Are criteria, procedures, controls, and responsibilities regarding access documented? Does access require manager approval? Is access to the PII being monitored, tracked, or recorded? Who is responsible for assuring safeguards for the PII?

Describe any types of controls that may be in place to ensure that information is handled in accordance with the uses described above. <u>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.</u>

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?

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.

Only people that are researchers within the PTSD study will have access to PII. Supervisors will have access to employees' names, roles,

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

• Patient Name • Patient Address • Patient Phone • Patient Email • Patient Date of Birth • Session Type • Age at Instruction • Location (dropdown): In Person, Phone, Video • Meditation Regularity • Time of Session • Whether patient has completed pre and post-assessments • Whether blood samples have been taken • Randomization arm and date • Referral source • Phone screen date and result (eligible, ineligible, not interested, on hold) • Reason denied from study • Payment code (matches payment card; patients receive payments when engaged in services or assessments) • Treatment sessions conducted with subject

VA Employees • Name • Role • Email • Phone Number

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. If the system is using cloud technology, will it be following the NARA approved retention length and schedule?

The VA records officer should be consulted early in the development process to ensure that appropriate retention and destruction schedules are implemented.
This question is related to privacy control DM-2, Data Retention and Disposal.

Results are recorded for future reference in the system and to see what methods of meditation are most effective in assisting with PTSD. Salesforce will not be used to record any outcome data (that is REDCap) so data in Salesforce can't be used to tell whether any treatment is effective. In addition, the Retention and Disposal section is being amended to remove the counseling folder.

Department of Veterans Affairs Record Control Schedule 10-1" this is the standard VA control schedule.

3.3 Has the retention schedule been approved by the VA records office and the National Archives and Records Administration (NARA)? If so please indicate the name of the records retention schedule.

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.
This question is related to privacy control DM-2, Data Retention and Disposal.

8300.6	**Research Investigator Files.** Research records maintained by the investigator that span the entire lifecycle of the project and the records required by regulations such as the investigator's regulatory file. Records include but are not limited to: research protocol and all amended versions of the protocol; grant application; review committee correspondence (e.g., Institutional Review Board, Institutional Animal Care and Use Committee, Research & Development Committee) including documents approved by the review committees; correspondence with ORD, regulatory entities, sponsor and/or funding source, correspondence; case report forms and supporting data (including, but not limited to, signed and dated informed consent forms and HIPAA authorization forms); documentation on each subject including informed consent, interactions with subjects by telephone or in person, observations, interventions, and other data relevant to the research study; data collected during the research including photos, video recordings, and voice recording, all derivative data, and derivative databases; lists of all subjects entered in the study and the crosswalk connecting the subjects name with the code used for each subject; subject compensation records; reports of adverse events, complaints and deviations from IRB-approved protocol; data analyses; codes and keys used to de-identify and re-identify subjects' PHI; reports (including, but not limited to, abstracts and other publications);

	research study correspondence not involving ORD, Office of Research Oversight (ORO), sponsor, or funding source; correspondence and written agreements with the funding source or sponsor, ORD and applicable oversight entities such as IRB, Research and Development (R&D) Committee, VA Office of Research and Oversight (ORO), VA Office of Human Research Protections (OHRP) and FDA; research study correspondence not involving ORD, Office of Research Oversight (ORO), sponsor, or funding source; signed and dated forms submitted to regulatory agencies; investigator's brochure; records related to the investigational drugs such as drug accountability records; monitoring and audit reports such as Data Safety Monitoring Board Reports and audits by oversight entities; documents related to budget and funding; other forms required by policy and regulation **NOTE:** If the investigator leaves VA, all research records are retained by the VA facility where the research was conducted. If the grant is ongoing and the investigator leaves one VA facility to go to another VA facility, the investigator must obtain approval for a copy of relevant materials to be provided to the new VA facility's research office. The investigator is not the grantee, nor does the investigator own the data.

3.4 What are the procedures for the elimination of SPI?

Explain how records are destroyed or eliminated at the end of the 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

All electronic files will be deleted six years after the Multi-Site PTSD Study ends. Staying in accordance with the NARA records retention schedule 8300.6 Research Investigator files.

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. Have policies and procedures been developed to minimize the use of PII for testing, training, and research?
This question is related to privacy control DM-3, Minimization of PII Used in Testing, Training and Research

Yes, this system utilizes Salesforce Shield to help protect the systems data. In addition, data is all stored in electronic records and will be deleted at the end of the retention cycle fifty years after the project concludes.

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.

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: Patients personal information and transcendental meditation study results are in this system.

Mitigation: This system uses a Salesforce Shield FIPS 140-2 connection in addition, the Retention and Disposal section is being amended to remove the counseling folder and to add that all information maintained in the Client Record of obsolete Vet Center paper client records are being archived through VA Records Management and will be retained at one or more of the authorized Department of Veterans Affairs Records Center Vaults for 50 years after the date of last activity. Section (b) will state the Client Record will be maintained electronically for the duration of the program.

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

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

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

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

Follow the format below:
Privacy Risk: N/A

Mitigation: N/A

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

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 than one)***	***List the method of transmission and the measures in place to secure data***
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.

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: N/A

Mitigation: N/A

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 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?

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. If notice was provided in the Federal Register, provide the citation.

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

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. This question is 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.

Yes, all patients have agreed to the collection of information through undergoing the PTSD study. Under the following Statement of records notice. (https://www.oprm.va.gov/privacy/systems_of_records.aspx). 64VA10RCS - Readjustment Counseling Program (RCS) Vet Center Program-VA https://www.govinfo.gov/content/pkg/FR-2016-06- 07/pdf/2016-13378.pd

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

In order for an individual to take part in this study they must be a veteran who was diagnosed by a doctor to have PTSD and have agreed to take part in the study because their medical records are already known it is difficult to not provide information.

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

Yes, by agreeing to take part in the transcendental meditation study patients have consented to their information being used in the PTSD study or they're VA or David Lynch Foundation employees/researchers involved in the study. They also fill out a consent form prior to taking part in the study.

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.

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: A patient's information could be obtained if the system was breached.

Mitigation: All Patients fill out a consent form prior to taking part in the study in addition the system utilizes a FIPS 140-2 connection to protect the system.

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?

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.

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).

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.
This question is related to privacy control IP-2, Individual Access, and AR-8, Accounting of Disclosures.

Employees can view their information by looking themselves up in the VA systems as it is just their name and position listed in the system. Supervisors have access to reports generated by researchers. Patients will have access to their results through doctors and researchers letting them know their progress.

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.

Employees meet weekly to discuss results, so errors would be corrected during those conversations/meetings. This process would be the same process stated in 7.1.

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.

Study subjects won't know what data is in the system about them as they do not see the notes recorded so they would not know it's incorrect. In addition employees meet and discuss results and their notes on patients weekly so information would be corrected then.

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

Example: Some projects allow users to directly access and correct/update their information online. This helps ensures data accuracy.

Redress will be provided through a Privacy Act and Freedom of Information Act (FOIA) request.

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.

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: Personal information is in the system to record their meditation results. This system is prone to human error as errors are corrected through notes comparisons and discussions at weekly meetings.

Mitigation: All patients have signed a consent form to participate in the study. In addition the project does not allow individual access for patients and patient data is discussed at weekly meetings in order to be corrected.

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?

Describe the process by which an individual receives access to the system.

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?

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.

This question is related to privacy control AR-7, Privacy-Enhanced System Design and Development.

There is a top-down overview of the system. With supervisors having the most top-down view of action items and reports. Researchers generate the reports and can view their own reports and

other researchers reports. Patients may only be able to view the reports on their own progress if briefed by a supervisor or researcher.

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.

Yes, members of the David Lynch Foundation that help with the multi-site PTSD studies will also have access to the information in the system. In addition, Salesforce is building this system and an NDA is in the Cloud Service Provider agreement.

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.

Standard yearly VA training is provided/required to be completed by all individuals working on this system. People working on Salesforce are required to be up to date on the CITI Human Subjects Research training

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

If Yes, provide:

1. *The Security Plan Status,*
2. *The Security Plan Status Date,*
3. *The Authorization Status,*
4. *The Authorization Date,*
5. *The Authorization Termination Date,*

6. *The Risk Review Completion Date,*
7. *The FIPS 199 classification of the system /MODERATE/HIGH.*

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

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

Salesforce has an approved security plan as 24 Feb 2021 and a full ATO, through October 2024. Salesforce: David Lynch Foundation currently has a Moderate DSC.

The Salesforce Development Platform VA last ATO was issued on 6/5/2019. It is set to expire 12/31/2023.

This system's Initial Operation Capacity is 4/29/2022.

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).

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.

Yes, Salesforce GovCloud has FedRAMP authorization

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)

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

Yes it does, the cloud service provider states that Salesforce has ownership of the data while Salesforce owns the system.

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 will be created by this system.

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 it is it is clear the VA owns the data and that salesforce must protect the data while operating the system.

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).

No RPA is used in this system.

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 provided in this Privacy Impact Assessment is true and accurate.

RITA K GREWAL 114938

Digitally signed by RITA K GREWAL 114938
Date: 2022.01.05 08:41:15 -05'00'

Privacy Officer, Rita Grewal

James C. Boring 149438

Digitally signed by James C. Boring 149438
Date: 2022.01.05 09:16:59 -05'00'

Information Systems Security Officer, James Boring

Michael S. Domanski 326889

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Date: 2022.01.05 10:21:19 -05'00'

Information Systems Owner, Michael Domanski

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).
https://www.oprm.va.gov/privacy/systems_of_records.aspx

64VA10RCS - Readjustment Counseling Program (RCS) Vet Center Program-VA
https://www.govinfo.gov/content/pkg/FR-2016-06- 07/pdf/2016-13378.pd