



Privacy Impact Assessment for the VA IT System called:

IRBNet on GovCloud - Enterprise VHA Veteran's Health Administration Office of Research and Development (ORD)

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.

IRBNet on GovCloud – Enterprise (IRBNet-e) is used to facilitate the management of local research and development (R&D) operations related to the R&D committee, and all associated sub-committees, and the execution of their oversight responsibilities associated with research projects at multiple VA medical center research departments. This oversight includes initial approvals, continuing reviews, expirations, amendments, adverse events, personnel changes, training, and compliance documentation.

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.*
IRBNet, Office of Research and Development (ORD) IRBNet, Office of Research and Development (ORD)

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

- C. Indicate the ownership or control of the IT system or project.*
Office of Research and Development (ORD)

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.*
35,000 Registered users. VA employees, Veteran research volunteers
35,000 Registered users. VA employees, Veteran research volunteers

- E. A general description of the information in the IT system and the purpose for collecting this information.*
IRBNET-e is a research compliance solution, which offers secure online access to comprehensive research oversight tools allowing for real-time collection in errors and non-compliance, and improved audit trails and record keeping, between investigators and institutions anywhere in the world.

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

N/A

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.*

N/A

3. *Legal Authority and SORN*

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

Title 38, United States Code, Section 7301. System of Records Veteran, Patient, Employee, and Volunteer Research and Development Project Records—VA (34VA10).

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?*

34VA10 system of records is in the process of modification. 34VA10 does not require amendment or revisions. This SORN includes cover cloud usage and storage.

D. *System Changes*

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

No

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

No

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:

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

<<Adverse event reporting: date of adverse even, subject ID number, subject's date of consent, details of adverse event, protocol title)>>

*Specify type of Certificate or License Number (e.g., Occupational, Education, Medical)

National Provider Identifier (NPI) is collected for clinicians.

PII Mapping of Components (Servers/Database)

IRBNet-e consists of One key component (servers/databases). Each component has been analyzed to determine if any elements of that component collect PII. The type of PII collected by IRBNet-e 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
IRBNet	Yes	Yes	Employee Name, Phone Number, NPI, Email address Subject ID number, Subject date of consent	Identify employees and provide contact information	

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?

VA employees

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.

N/A

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 directly from an 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.

VA employee is responsible for ensuring information is accurate.

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.

N/A

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
Title 38, United States Code, Section 7301

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.

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: Adverse event reporting details

Mitigation: Minimal PII for subjects is collected. Subject ID is collected to protect subject's identity.

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.

Information collected in this system is used to support regulatory review of research projects.

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.

N/A

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.

N/A

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?

AWS KMS keys are used to encrypt the data at rest. Elastic Block Store (EBS) volumes are encrypted within AWS GovCloud to safeguard the data using AES-256 encryption. For long-term backup Research Dataware employs AWS KMS and AWS S3 Server Side Encryption (SSE) within the AWS GovCloud FedRAMP authorization boundary to safeguard the data using AES-256 encryption.

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?

IRBNet-e is hosted in the FedRAMP High/Moderate rated AWS GovCloud. IRBNet (SaaS provider) maintains a FedRAMP ATO and a VA F-package within eMASS that outlines all OMB Memorandum M-06-15 safeguards and security mechanisms. IRBNet-e is hosted in the FedRAMP High/Moderate rated

AWS GovCloud. IRBNet (SaaS provider) maintains a FedRAMP ATO and a VA F-package within eMASS that outlines all OMB Memorandum M-06-15 safeguards and security mechanisms.

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?

Access to PII is determined by job role.

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

IRBNet-e information system account types are limited to VA researchers and IRB participants. IRBNet-e users required VA activated PIV card and results in the ability to view the data that belongs to the individual researcher. All access criteria, procedures, controls, and responsibilities are documented within the IRBNet-e A&A (assessment and authorization) eMASS package.

2.4c Does access require manager approval?

Access to system is determined by local VA research office.

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

N/A

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

VA employee

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*

Employee's Name, Phone Number, NPI, Email address

Subject ID number and date of consent

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.*

Information is retained according to Records Control Schedule 10-1

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.

Records Control Schedule 10-1

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.

IRBNet-e does not transfer SPI. Records are archived according to the Records Control Schedule.

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 is retained according to the Records Control Schedule as defined by the agency before being purged from the system. All testing and training are conducted in the sandbox environment where no PII exists.

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: If IRBNet-e systems' maintaining data within the IRBNet-e longer than retention times require increases the risk that information can be compromised or breached. IRBNet-e manages and retains data and information indefinitely and will only be removed from the system with authorization from the system owner. The breach or accidental release of IRBNet-e data to inappropriate parties or the public will have Low impact on VA organizational operations, organizational assets, or individuals.

Mitigation: To mitigate the risk posed by information retention, any remaining data is pushed onto the S3 bucket in an automated process until the next round of data is pushed to the bucket at which point the deprecated data is removed.

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.

<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>
N/A			

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: The risk might include researchers who do not log out of the IRBNet-e tool when away from their computers or mobile devices. There is a risk that information may be shared with unauthorized VA personnel.

Mitigation: The tool will have a “time-out” setting which will automatically log the user out after a period of inactivity. Safeguards are implemented to ensure data is not sent to unauthorized VA employees, including employee security and privacy training, and required reporting of suspicious activity. Use of secure passwords, access for need-to-know basis, Personal Identification Verification (PIV) Cards, Personal Identification Numbers (PIN), encryption, and access authorization are all measures that are utilized for the system.

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>
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: Data maintained outside of the Department and there is a risk that information may be accessed by an external organization or agency that does not have a need or legal authority to access VA data.

Mitigation: VA has contracted IRBNet-e to deliver services that include maintaining VA data. A contract is in place that clearly articulates IRBNet-e roles and responsibilities. Authorized personnel access user level data to provision and provide the IRBNet-e service. Access is controlled by authentication and is restricted to authorized individuals. Security policies address the required security controls that must be followed in order to protect PII. The Interconnection Security Agreement (ISA) documentation is reviewed and updated annually to confirm that all security requirements are still being met and that no changes to the connections have occurred. The annual review can be done as part of the annual internal security assessment and third-party assessment. eMASS and other security documents must also be reviewed to ensure they accurately reflect the status of each interconnection. IRBNet-e utilizes VA onboarding processes to protect against unauthorized access to information within the system. All users must have an active PIV card and authenticate through IAM single-sign-on mechanisms.

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.

Yes. Veteran subjects are provided an Informed Consent and must agree before participating in research project.

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

N/A.

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.

N/A.

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, without any penalty or denial of service.

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. Veteran subjects are provided an Informed Consent and must agree before participating in research project.

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 members of the general public may not know that the IRBNet-e system exists within the Department of Veterans Affairs. This poses a low risk to the enterprise

Mitigation: Upon login to IRBNet-e web application and management console, all users will be presented with a system notification banner which explicitly states that the user is entering a federal information system. This banner will inform the users that their actions are being monitored, recorded, and actively audited in accordance with a system which is classified as FIPS 199 Moderate. Lastly, the banner will inform the user that only acceptable use, in accordance with the rules of behavior, is permitted. This banner shall be unconditionally displayed.

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.***

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).

Not exempt from the access provisions

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.

This is a Privacy Act system

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.

IRBNet-e does allow changes to research approval submissions once submission is completed by using the “Unlock” feature. An individual may request to permanently opt-out of participating in research at any time by administratively closing the research project.

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.

The local research administration will contact the study team via email or using the “Project Mail” feature within IRBNet.

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

IRBNet-e does allow changes to research approval submissions once submission is completed by using the “Unlock” feature. An individual may request to permanently opt-out of participating in research at any time by administratively closing the research project.

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: There is a risk that members of the general public may not know that the IRBNet-e system exists within the Department of Veterans Affairs. This poses a low risk to the enterprise. When VA collects personal data from an individual, VA will inform him or her of the intended uses of the data, the disclosures that will be made, the authorities for the data’s collection, and whether the collection is mandatory or voluntary. VA will collect no data subject to the Privacy Act unless a Privacy Act system notice has been published in the Federal Register and posted on the VA Systems of Records website.

Mitigation: VA will collect only those personal data elements required to fulfill an official function or mission grounded in law. Those collections will be conducted by lawful and fair means. IRBNet-e shall follow the VA’s Code of Fair Information Principles. http://www.oprm.va.gov/docs/VA_Code_Of_Privacy_Principles.pdf

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.

VA employees are granted access to the system based on the employee's job role. A request is submitted by local VA research office to vendor. VA employees are granted access to the system based on the employee's job role. A request is submitted by local VA research office to vendor.

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?

N/A

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.

Read-only, Researcher, Committee Member, Committee Administrator

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.

System Administrator from IRBNet and contractor for VA and maintains governing authority over all IRBNet environments, where he maintains users, updates environments with system-level updates and new functionality, governs deployment activity and ensures user operability. The System Administrator is not a primary user of IRBNet-e. VA product owner and COR approve all new or modified incoming or outgoing contracts involving IRBNet-e. The contractors who provide support to the system are required to complete annual VA Privacy and Information Security and Rules of Behavior training via the VA's Talent Management System (TMS).

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.

VA Directive 6500 requires mandatory periodic training in computer security awareness and accepted computer security practices for all VA employees, contractors, and all other users of VA sensitive information and VA information systems. All members of the workforce are required to complete computer security training annually and must complete computer security awareness training before they can be authorized to access any VA computer system. Each site identifies personnel with significant information system security roles and responsibilities (i.e., management, system managers, system administrators, contracting staff, HR staff), documents those roles and responsibilities, and provides appropriate additional information system security training. Security training records will be monitored and maintained. The workforce will receive security awareness training annually as part of the Mandatory Training Program. In addition, the training for the tool will include awareness training regarding the possible existence of PII/PHI information submitted from the Veterans and eligible dependents. Each employee is asked to refresh their understanding of the appropriate way to handle the data.

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

8.4a If Yes, provide:

1. The Security Plan Status: Approved
2. The System Security Plan Status Date: March 11,2022
3. The Authorization Status: Approved
4. The Authorization Date: October 7,2021
5. The Authorization Termination Date: October 6,2024
6. The Risk Review Completion Date: September 30,2021
7. The FIPS 199 classification of the system
(LOW/MODERATE/HIGH):LOW/MODERATE/LOW (OVERRALL: MODERATE)

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.***

N/A

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)

IRBNet is a Software as a Service (SaaS) application powered the (Research Dataware, LLC). IRBNet is a fully FedRAMP authorized system is hosted externally in an AWS GovCloud. IRBNet is a Software as a Service (SaaS) application powered the (VENDOR COMPANY). IRBNet is a fully FedRAMP authorized system is hosted externally in an AWS GovCloud.

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

Yes. IRBNet FedRAMP package (FR2100757165). CSP – Research Dataware LLC – AWS GovCloud.

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.

CSP does not collect any ancillary data

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.

See contract language below: The Contractor/Subcontractor must store, transport, or transmit VA sensitive information in an encrypted form, using VA-approved encryption tools that are, at a minimum, FIPS 140-2 validated. The Contractor/Subcontractor’s firewall and Web services security controls, if applicable, shall meet or exceed VA’s minimum requirements.

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).

System does not use robotics processes

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
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.

Privacy Officer, Kimberly E. Murphy

Information Systems Security Officer, Quintela George

Information System Owner, Aimee Barton

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).

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](#)