

Privacy Impact Assessment - 2009 (Form) / VistA Laboratory IS System Reengineering-2009 (Item)

Part I. Project Identification and Determination of PIA Requirement

1. PROJECT IDENTIFICATION:

1.1) Project Basic Information:

1.1.a) Project or Application Name:

VistA Laboratory IS System Reengineering-2009

1.1.b) OMB Unique Project Identifier:

029-00-01-11-01-1222-00

1.1.c) Project Description

Project description is pre-populated from Exhibit 300 Part I.A.8. You will not be able to edit the description on this form.

The purpose of this project is to enhance the Veterans Health Administration (VHA) Laboratory Service's information system and associated business processes to address current deficiencies and meet future needs. The VHA Laboratory Service (Pathology and Laboratory Medicine Service) is a critical part of offering high quality clinical care to veterans. This Service provides the principal medical diagnostic laboratory testing and transfusion functions in all VA Medical Centers and sets the standards for quality, test methods, and procedures for clinical laboratory testing in the Medical Centers. Almost 80% of clinical decisions are based on the patient's laboratory test results which have had an average increase of 5% annually and approx. 30% since 2001. The Service relies heavily on information technology to support all phases of lab activities, from specimen collection to dissemination of results. The current Laboratory Information Management System (LIMS) was created more than 20 years ago and has now exceeded its useful life. Currently laboratory information is "facility focused" (records maintained locally) and not "patient focused" (portability of information to another facility). Upgrading the current system to meet future requirements (HDR, HealthVet and interoperability between DoD and PHS as per public law 107-287) would be extremely difficult and costly due to current software architecture. As of March 2007, there are 388 enhancement requests and 546 defects that have been logged and still outstanding. Many cannot be addressed due to the nature of the current application design and architecture. Only after the limitations with the current Laboratory Service information technology are removed will improvements in providing clinical diagnostic services be realized. This project includes reengineering the business processes as well as enhancing the system that supports these processes. This project supports the VA strategic goal of providing high-quality, reliable, accessible, timely, and efficient health care that maximizes the health and functional status of enrolled veterans. The project was granted Milestone 0 approval in Q2FY03 and Milestone 1 approval in Q2FY07. Market research and alternatives analysis in FY06 determined that a Commercial Off The Shelf (COTS) LIMS, available through an existing DoD contract, will provide desired functionality. In Q4FY07, acquisition was completed to prototype an integrated COTS LIMS.

1.1.d) Additional Project Information (Optional)

The project description provided above should be a concise, stand-alone description of the project. Use this section to provide any important, supporting details.

1.2) Contact Information:

1.2.a) Person completing this document:	
Title:	Cheryl Latham
Organization:	VA Office of Information - VHA
Telephone Number:	(518) 449-0263
Email Address:	Cheryl.Latham@va.gov
1.2.b) Project Manager:	
Title:	Latham, Cheryl

Organization:	VA Office of Information - VHA
Telephone Number:	518-449-0263
Email Address:	Cheryl.Latham@va.gov
1.2.c) Staff Contact Person:	
Title:	
Organization:	
Telephone Number:	
Email Address:	

ADDITIONAL INFORMATION: If appropriate, provide explanation for limited answers, such as the development stage of project.

2. DETERMINATION OF PIA REQUIREMENTS:

A privacy impact assessment (PIA) is required for all VA projects with IT systems that collect, maintain, and/or disseminate personally identifiable information (PII) of the public, not including information of Federal employees and others performing work for VA (such as contractors, interns, volunteers, etc.), unless it is a PIV project. All PIV projects collecting any PII must complete a PIA. PII is any representation of information that permits the identity of an individual to be reasonably inferred by either direct or indirect means. Direct references include: name, address, social security number, telephone number, email address, financial information, or other identifying number or code. Indirect references are any information by which an agency intends to identify specific individuals in conjunction with other data elements. Examples of indirect references include a combination of gender, race, birth date, geographic indicator and other descriptors.

2.a) Will the project collect and/or maintain personally identifiable information of the public in IT systems?

Yes

2.b) Is this a PIV project collecting PII, including from Federal employees, contractors, and others performing work for VA?

No

If "YES" to either question then a PIA is required for this project. Complete the remaining questions on this form. If "NO" to both questions then no PIA is required for this project. Skip to section 14 and affirm.

ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)

Part II. Privacy Impact Assessment

3. PROJECT DESCRIPTION:

Enter the information requested to describe the project.

3.a) Provide a concise description of why personal information is maintained for this project, such as determining eligibility for benefits or providing patient care.

Information is necessary in order to provide congressionally mandated health care for Veterans.

3.b) What specific legal authorities authorize this project, and the associated collection, use, and/or retention of personal information?

3.c) Identify, by selecting the appropriate range from the list below, the approximate number of individuals that (will) have their personal information stored in project systems.

1,000,000 - 9,999,999

3.d) Identify what stage the project/system is in: (1) Design/Planning, (2) Development/Implementation, (3) Operation/Maintenance, (4) Disposal, or (5) Mixed Stages.

(1) Design/Planning

3.e) Identify either the approximate date (MM/YYYY) the project/system will be operational (if in the design or development stage), or the approximate number of years that the project/system has been in operation.

12/2010

ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)

The project is in the design and planning stage. The exact development and implementation schedule has yet to be stabilized. The Project is expecting a phased deployment starting in FY2010 and completing FY2015.

4. SYSTEM OF RECORDS:

The Privacy Act of 1974 (Section 552a of Title 5 of the United States Code) and VA policy provide privacy protections for employee or customer information that VA or its suppliers maintain in a System of Records (SOR). A SOR is a file or application from which personal information is retrieved by an identifier (e.g. name, unique number or symbol). Data maintained in a SOR must be managed in accordance with the requirements of the Privacy Act and the specific provisions of the applicable SOR Notice. Each SOR Notice is to be published in the Federal Register. See VA Handbook 6300.5 "Procedures for Establishing & Managing Privacy Act Systems Of Records", for additional information regarding Systems of Records.

4.a) Will the project or application retrieve personal information on the basis of name, unique number, symbol, or other identifier assigned to the individual?

If "No" then skip to section 5, 'Data Collection'.

Yes

4.b) Are the project and/or system data maintained under one or more approved System(s) of Records?

IF "No" then SKIP to question 4.c.

Yes

4.b.1) For each applicable System of Records, list:

(1) The System of Records identifier (number),

24VA19

(2) The name of the System of Records, and

"Patient Medical Records-VA"

(3) Provide the location where the specific applicable System of Records Notice(s) may be accessed (include the URL).

<http://vawww.vhaco.va.gov/privacy/systemofrecords.htm>

IMPORTANT: For each applicable System of Records Notice that is not accessible via a URL: (1) Provide a concise explanation of why the System of Records Notice is not accessible via a URL in the "Additional Information" field at the end of this section, and (2) Send a copy of the System of Records Notice(s) to the Privacy Service.

4.b.2) Have you read, and will the application comply with, all data management practices in the System of Records Notice(s)?

Yes

4.b.3) Was the System(s) of Records created specifically for this project, or created for another project or system?

Created for another project or system

If created for another project or system, briefly identify the other project or system.

The Patient Medical Records - VA

4.b.4) Does the System of Records Notice require modification?

If "No" then skip to section 5, 'Data Collection'.

Modification of the System of Records is NOT Required.

4.b.5) Describe the required modifications.

4.c) If the project and/or system data are not maintained under one or more approved System(s) of Records, select one of the following and provide a concise explanation.

Explanation:

ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)

PIA SECTION 5

Project Name

Vista Laboratory IS System Reengineering-2009

5. DATA COLLECTION:

5.1 Data Types and Data Uses

Identify the types of personal information collected and the intended use(s) of that data:

a) Select all applicable data types below. If the provided data types do not adequately describe a specific data collection, select the "Other Personal Information" field and provide a description of the information.

b) For each selected data type, concisely describe how that data will be used.

Important Note: Please be specific. If different data types or data groups will be used for different purposes or multiple purposes, specify. For example: "Name and address information will be used to communicate with individuals about their benefits, while Name, Service, and Dependent's information will be used to determine which benefits individuals will be eligible to receive. Email address will be used to inform individuals about new services as they become available."

Yes	Veteran's or Primary Subject's Personal Contact Information (name, address, telephone, etc.)
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Specifically identify the personal information collected, and describe the intended use of the information.

The name and unique number will be used to identify the patient in the application. Once the patient is identified the patient's laboratory data will be stored appropriately.

Yes	Other Personal Information of the Veteran or Primary Subject
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Specifically identify the personal information collected, and describe the intended use of the information.

The primary use of the clinical data collected is to provide healthcare services to our veterans. The information is used to provide improved and easier access to medical knowledge, expertise and care, and improve the quality of life and economic status of veterans. Demographic information will be used to identify the patient, both for clinical purposes and to support billing activities as appropriate for the patient. The identifying information is not used independently of the test results. Statistical information will be derived from this clinical data and used to support research and study initiatives

No	Dependent Information
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Specifically identify the personal information collected, and describe the intended use of the information.

No	Service Information
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Specifically identify the personal information collected, and describe the intended use of the information.

Yes	Medical Information
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Specifically identify the personal information collected, and describe the intended use of the information.

Patient's laboratory test data will be stored.

No	Criminal Record Information
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Specifically identify the personal information collected, and describe the intended use of the information.

No	Guardian Information
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Specifically identify the personal information collected, and describe the intended use of the information.

No	Education Information
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Specifically identify the personal information collected, and describe the intended use of the information.

No	Rehabilitation Information
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Specifically identify the personal information collected, and describe the intended use of the information.

Yes	Other Personal Information (specify):
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The "Other Personal Information" field is intended to allow identification of collected personal information that does not fit the provided categories. If personal information is collected that does not fit one of the provided categories, specifically identify this information and describe the intended use of the information.

The primary use of the clinical data collected is to provide healthcare services to our veterans. The information is used to provide improved and easier access to medical knowledge, expertise and care, and improve the quality of life and economic status of veterans. Demographic information will be used to identify the patient, both for clinical purposes and to support billing activities as appropriate for the patient. The identifying information is not used independently of the test results. Statistical information will be derived from this clinical data and used to support research and study initiatives

ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)

5.2 Data Sources

Identify the source(s) of the collected information.

a) Select all applicable data source categories provided below.

b) For each category selected:

i) Specifically identify the source(s) - identify each specific organization, agency or other entity that is a source of personal information. ii) Provide a concise description of why information is collected from that source(s). iii) Provide any required additional clarifying information.

Your responses should clearly identify each source of personal information, and explain why information is obtained from each identified source. (Important Note: This section addresses sources of personal information; Section 6.1, "User Access and Data Sharing" addresses sharing of collected personal information.)

Note: PIV projects should use the "Other Source(s)" data source.

Yes

Veteran Source

Provide a concise description of why information is collected from Veterans. Provide any required additional, clarifying information.

The veteran will provide information to uniquely identify themselves to the laboratory.

No

Public Source(s)

i) Specifically identify the Public Source(s) - identify the specific organization(s) or other entity(ies) that supply personal information. ii) Provide a concise description of why information is collected from each identified source. iii) Provide any required additional, clarifying information.

Yes

VA Files and Databases

i) Specifically identify each VA File and/or Database that is a source of personal information. ii) Provide a concise description of why information is collected from each identified source. iii) Provide any required additional, clarifying information.

The laboratory information system will receive data from the laboratory automated instruments through electronic interface.

Yes	Other Federal Agency Source(s)
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i) Specifically identify each Federal Agency that is a source of personal information. ii) Provide a concise description of why information is collected from each identified source. iii) Provide any required additional, clarifying information.

The laboratory information system will store data received from Federal Agency Source such as the DoD hospitals for veterans whose care is shared with VHA.

No	State Agency Source(s)
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i) Specifically identify each State Agency that is a source of personal information. ii) Provide a concise description of why information is collected from each identified source. iii) Provide any required additional, clarifying information.

No	Local Agency Source(s)
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i) Specifically identify each Local Agency (Government agency other than a Federal or State agency) that is a source of personal information. ii) Provide a concise description of why information is collected from each identified source. iii) Provide any required additional, clarifying information.

No	Other Source(s)
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i) If the provided Data Source categories do not adequately describe a source of personal information, specifically identify and describe each additional source of personal information. ii) For each identified data source, provide a concise description of why information is collected from that source. iii) Provide any required additional, clarifying information.

ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)

5.3 Collection Methods

Identify and describe how personal information is collected:

a) Select all applicable collection methods below. If the provided collection methods do not adequately describe a specific data collection, select the "Other Collection Method" field and provide a description of the collection method. b) For each collection method selected, briefly describe the collection method, and provide additional information as indicated.

No	Web Forms:	Information collected on Web Forms and sent electronically over the Internet to project systems.
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Identify the URL(s) of each Web site(s) from which information will be submitted, and the URL(s) of the associated privacy statement. (Note: This question only applies to Web forms that are submitted online. Forms that are accessed online, printed and then mailed or faxed are considered "Paper Forms.")

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Yes	Paper Forms:	Information collected on Paper Forms and submitted personally, submitted via Postal Mail and/or submitted via Fax Machine.
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Identify and/or describe the paper forms by which data is collected. If applicable, identify standard VA forms by form number.

The Paper Forms by which data is collected include surgical pathology and anatomic pathology forms such as the SF515.

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No	Electronic File Transfer:	Information stored on one computer/system (not entered via a Web Form) and transferred electronically to project IT systems.
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Describe the Electronic File Transfers used to collect information into project systems. (Note: This section addresses only data collection – how information stored in project systems is acquired. Sharing of information stored in project systems and data backups are addressed in subsequent sections.)

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No	Computer Transfer Device:	Information that is entered and/or stored on one computer/ system and then transferred to project IT systems via an object
		or device that is used to store data, such as a CD-ROM, floppy disk or tape.

Describe the type of computer transfer device, and the process used to collect information.

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Yes	Telephone Contact:	Information is collected via telephone.
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Describe the process through which information is collected via telephone contacts.

Telephone contact may utilize information such as patient name and demographic information used to retrieve data from the laboratory information system.

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Yes	Other Collection Method:	Information is collected through a method other than those listed above.
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If the provided collection method categories do not adequately describe a specific data collection, select the "Other Collection Method" field and specifically identify and describe the process used to collect information.

Laboratory re-engineering may utilize bar codes for collecting information such as patient ID, demographic information and blood groups.

ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)

5.4 Notice

The Privacy Act of 1974 and VA policy requires that certain disclosures be made to data subjects when information in identifiable form is collected from them. The following questions are directed at notice to the individual of the scope of information collected, the right to consent to uses of said information, and the right to decline to provide information.

5.4.a) Is personally identifiable information collected directly from individual members of the public and maintained in the project's IT systems?

Yes

Note: If you have selected NO above, then SKIP to Section 5.5, 'Consent'.

5.4.b) Is the data collection mandatory or voluntary?

Mandatory

5.4.c) How are the individuals involved in the information collection notified of the Privacy Policy and whether provision of the information is mandatory or voluntary?

The VA consent form (VA Form 1010EZ) is signed by the patient upon request for care. The text on the consent form includes notice of Privacy Act Information. Patients are provided VA Notice of Privacy Practices.

5.4.d) Is the data collection new or ongoing?

Ongoing

5.4.e.1) If personally identifiable information is collected online, is a privacy notice provided that includes the following elements? (Select all applicable boxes.)

Yes	Not applicable
	Privacy notice is provided on each page of the application.
	A link to the VA Website Privacy Policy is provided.
	Proximity and Timing: the notice is provided at the time and point of data collection.
	Purpose: notice describes the principal purpose(s) for which the information will be used.
	Authority: notice specifies the legal authority that allows the information to be collected.
	Conditions: notice specifies if providing information is voluntary, and effects, if any, of not providing it.
	Disclosures: notice specifies routine use(s) that may be made of the information.

5.4.e.2) If necessary, provide an explanation on privacy notices for your project:

5.4.f) For each type of collection method used (identified in Section 5.3, "Collection Method"), explain:

a) What the subjects will be told about the information collection. b) How this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). c) How a privacy notice is provided.

Note: if PII is transferred from other projects, explain any agreements or understandings regarding notification of subjects.

No	Web Forms:
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Explain:

a) What the subjects will be told about the information collection. b) How this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). c) How a privacy notice is provided.

Yes	Paper Forms:
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Explain:

a) What the subjects will be told about the information collection. b) How this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). c) How a privacy notice is provided.

Patient's are told about the information collection and the message is conveyed by the VA Form 1010EZ.

No	Electronic File Transfer:
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For electronic transfers of information, where this system is receiving the information from another system and is not collected from the primary information source, please explain what agreements are in place that govern the responsibilities of the system collecting information from the primary information source to notify subjects regarding:

a) What they will be told about the information collection? b) How the message will be conveyed (e.g. written notice, electronic notice if web-based collection, etc.)? c)How a privacy notice is provided?

No	Computer Transfer Device:
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For electronic transfers of information, where this system is receiving the information from another system and is not collected from the primary information source, please explain what agreements are in place that govern the responsibilities of the system collecting information from the primary information source to notify subjects regarding:

a) What they will be told about the information collection? b) How the message will be conveyed (e.g. written notice, electronic notice if web-based collection, etc.)? c)How a privacy notice is provided?

Yes	Telephone:
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Explain:

a) What the subjects will be told about the information collection. b) How this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). c) How a privacy notice is provided.

Patient's are told about the information collection and the message is conveyed by the VA Form 1010EZ.

Yes	Other Method:
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Explain:

a) What the subjects will be told about the information collection. b) How this message will be conveyed to them (e.g., written notice, electronic notice if a web-based collection, etc.). c) How a privacy notice is provided.

Patient's are told about the information collection and the message is conveyed by the VA Form 1010EZ.

ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)

5.5 Consent For Secondary Use of PII:

The Privacy Act and VA policy require that personally identifiable information only be used for the purpose(s) for which it was collected, unless consent (opt-in) is granted. Individuals must be provided an opportunity to provide consent for any secondary use of information, such as use of collected information for marketing.

5.5.a) Will personally identifiable information be used for any secondary purpose?

Note: If you have selected No above, then SKIP to question 5.6, "Data Quality."

No

5.5.b) Describe and justify any secondary uses of personal information.

5.5.c) For each collection method identified in question 5.3, "Collection Method," describe:

1) The opportunities individuals have to decline to provide information, for instances where providing information is voluntary. 2) The opportunities individuals have to grant consent for particular uses of the information. 3) How individuals may grant consent.

Some examples of consent methods are: (1) Approved OMB consent forms and (2) VA Consent Form (VA Form 1010EZ). Provide justification if no method of consent is provided.

	Web Forms:
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Describe:

1) The opportunities individuals have to decline to provide information, for instances where providing information is voluntary. 2) The opportunities individuals have to grant consent for particular uses of the information. 3) How individuals may grant consent.

	Paper Forms:
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Describe:

1) The opportunities individuals have to decline to provide information, for instances where providing information is voluntary. 2) The opportunities individuals have to grant consent for particular uses of the information. 3) How individuals may grant consent.

	Electronic File Transfer:
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For electronic transfers of information, where this system is receiving the information from another system and is not collected from the primary information source, please explain what agreements are in place that govern the responsibilities of the system collecting information from the primary information source to provide the following:

a) The opportunities individuals have to decline to provide information, for instances where providing information is voluntary. b) The opportunities individuals have to grant consent for particular uses of the information. c) How individuals may grant consent.

	Computer Transfer Device:
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For electronic transfers of information, where this system is receiving the information from another system and is not collected from the primary information source, please explain what agreements are in place that govern the responsibilities of the system collecting information from the primary information source to provide the following:

a) The opportunities individuals have to decline to provide information, for instances where providing information is voluntary. b) The opportunities individuals have to grant consent for particular uses of the information. c) How individuals may grant consent.

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	Telephone Contact Media:
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Describe:

1) The opportunities individuals have to decline to provide information, for instances where providing information is voluntary. 2) The opportunities individuals have to grant consent for particular uses of the information. 3) How individuals may grant consent.

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	Other Media
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Describe:

1) The opportunities individuals have to decline to provide information, for instances where providing information is voluntary. 2) The opportunities individuals have to grant consent for particular uses of the information. 3) How individuals may grant consent.

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ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)

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5.6 Data Quality

5.6.a) Explain how collected data are limited to required elements:

The laboratory information system will be defined by specific files and fields that store data used or produced by the laboratory information system. The system architecture and database environment will be defined during the development life cycle that has not started.

5.6.b) How is data checked for completeness?

The laboratory information system will contain specific field definitions and algorithms that check for completeness of data. The database standards will be defined during the development lifecycle that has not started.

5.6.c) What steps or procedures are taken to ensure the data are current and not out of date?

The laboratory information system will be integrated with VHA HealtheVet-Vista applications that will ensure complete and accurate availability of data and will store data within the laboratory system that is date and time stamped. Laboratory information system will be designed to meet Privacy Act, HIPAA legislation and NIST standards as well as project specific architecture and database standards.

5.6.d) How is new data verified for relevance, authenticity and accuracy?

New data will be verified by passing specific file and field definition algorithms that are part of the laboratory information system. The database standards will be defined during the development lifecycle that has not started.

ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)

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Project Name

VistA Laboratory IS System Reengineering-2009

6. Use and Disclosure

6.1 User Access and Data Sharing

Identify the individuals and organizations that have access to system data.

--> Individuals - Access granted to individuals should be limited to the data needed to perform their assigned duties. Individuals with access to personal information stored in project system must be identified, and documented assurance must be provided that appropriate policies and procedures are in place to prevent as well as detect unauthorized access and browsing.

--> Other Agencies – Any Federal, State or local agencies that have authorized access to collected personal information must be identified, and documented assurance must be provided that appropriate policies and procedures are in place to protect personal information.

--> Other Systems – Information systems of other programs or projects that interface with the information system(s) of this project must be identified and the transferred data must be defined. Also, the controls that are in place to ensure that only the defined data are transmitted must be defined.

6.1.a) Identify all individuals and organizations that will have access to collected information. Select all applicable items below.

Yes	System Users
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No	System Owner, Project Manager
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Yes	System Administrator
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Yes	Contractor
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If contractors to VA have access to the system, describe their role and the extent of access that is granted to them. Also, identify the contract(s) that they operate under.

Contracts include Cerner (contract # GS03T05DS0003) and the VA set of VA Contractor Services (VCS) contracts with EDS, Perot Systems, SAIC, and Merlin (contract #'s TBD). Cerner is the developer of the COTS-based product and the VCS contracts provide professional services to assist in integration, configuration, and testing of the integrated solution. In developing, integrating, field testing, and maintaining the system, contractors will require access to private information to verify performance and trouble shoot issues. Contract terms & conditions require contractor to adhere to VA privacy and security policy and procedures.

No	Internal Sharing: Veteran Organization
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If information is shared internally, with other VA organizations identify the organization(s). For each organization, identify the information that is shared and for what purpose.

No	Other Veteran Organization
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If information is shared with a Veteran organization other than VA, identify the organization(s). For each organization, identify the information that is shared and for what purpose.

Yes	Other Federal Government Agency
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If information is shared with another Federal government agency(ies), identify the agency(ies). For each organization, identify the information that is shared and for what purpose.

The DoD and the VA are required to interchange patient medical records for continuity of care. To support this need, the developed Laboratory Information Management System (LIMS) is required to interchange Laboratory Orders and Laboratory Test Results with the DoD LIMS. Lab Orders and Lab Test Results include personally identifiable information to enable patient safety policies and procedures.

No	State Government Agency
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If information is shared with a State government agency(ies), identify the agency(ies). For each organization, identify the information that is shared and for what purpose.

No	Local Government Agency
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If information is shared with a local government agency(ies), identify the agency(ies). For each organization, identify the information that is shared and for what purpose.

Yes	Other Project/ System
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If information is shared with other projects or systems:

1) Identify the other projects and/or systems, and briefly describe the data sharing. 2) For each project and/or system with which information will be shared, identify the information that will be shared with that project or system. 3) For each project and/or system with which information will be shared, describe why information is shared. 4) For each project and/or system with which information will be shared, describe who will be responsible for protecting the privacy rights of the individuals whose data will be shared across this interface.

The Laboratory System is a critical clinical care component of the VHA HealthVet Vista system of systems. Personally identifiable information is required to be transferred with other VHA HealthVet Vista systems to enable patient safety policies and procedures, Personally identifiable information is required in Patient Admit, Discharge, Transfer events, laboratory orders, and laboratory test results. These VHA internal interfaces are electronic and subject to the privacy and security policies and procedures established by VHA and will be verified by the LSRP project office and the Office of Cyber and Information Security (OCIS).

No	Other User(s)
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If information is shared with persons or organization(s) that are not described by the categories provided, use this field to identify and describe what other persons or organization(s) have access to personal information stored on project systems. Also, briefly describe the data sharing.

6.1.a.1) Describe here who has access to personal information maintained in project's IT systems:
The project is in the planning and initial concept development phase. At this time the project's IT system is not in place.
6.1.b) How is access to the data determined?
Access to data is governed by the "Patient Medical Records - VA" system of records.
6.1.c) Are criteria, procedures, controls, and responsibilities regarding access documented? If so, identify the documents.
Yes. The VA currently maintains resource sharing agreements with the Department of Defense (DoD), and Indian Health Service (IHS). Healthcare information is currently shared with these organizations, and the scope of this sharing will be expanded with the new laboratory application. Clinical information will be shared with the Health Data Repository within VHA to support the composite health record as required by HealtheVetVista. The project has not identified the Contractor, State and Local agencies at this point in the project. System will meet Privacy Act, HIPAA legislation and NIST standards.
6.1.d) Will users have access to all data on the project systems or will user access be restricted? Explain.
Yes. Access will be restricted according to agency security and patient privacy requirements and rights as mandated by HIPAA regulations. The project will meet OMB guidance consistent with the Federal Information Security Management Act once the system is identified.
6.1.e) What controls are in place to prevent the misuse (e.g. unauthorized browsing) of data by those having access? (Please list processes and training materials that specifically relate to unauthorized browsing)
The System will meet Privacy Act, HIPAA legislation and NIST standards.
6.1.f) Is personal information shared (is access provided to anyone other than the system users, system owner, Project Manager, System Administrator)? (Yes/No)
Yes
Note: If you have selected No above, then SKIP to question 6.2, "Access to Records and Requests for Corrections".
6.1.g) Identify the measures taken to protect the privacy rights of the individuals whose data will be shared.
The system of records will provide privacy rights protection.
6.1.h) Identify who is responsible, once personal information leaves your project's IT system(s), for ensuring that the information is protected.
VHA will be responsible for protecting the privacy rights.
6.1.i) Describe how personal information that is shared is transmitted or disclosed.
The project is in the planning stage and this process has not been developed yet. The project will meet requirements as required by privacy act, HIPAA legislation and NIST standards.
6.1.j) Is a Memorandum of Understanding (MOU), contract, or any other agreement in place with all external organizations with whom information is shared, and does the agreement reflect the scope of the information currently shared? If an MOU is not in place, is the sharing covered by a routine use in the System of Records Notice? If not, explain the steps being taken to address this omission.
No MOU is in place. The sharing will be covered by a routine use in the system of records notice.
6.1.k) How is the shared information secured by the recipient?
The project is in the planning stage and this process has not been developed yet. The project will meet all requirements as required by privacy act, HIPAA legislation and NIST standards.
6.1.l) What type of training is required for users from agencies outside VA prior to receiving access to the information?
The project will meet training requirements as required by privacy act, HIPAA legislation and NIST standards.
ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)

6.2 Access to Records and Requests for Corrections

The Privacy Act and VA policy provide certain rights and mechanisms by which individuals may request access to and amendment of information relating to them that is retained in a System of Records.

6.2.a) How can individuals view instructions for accessing or amending data related to them that is maintained by VA? (Select all applicable options below.)

--

No	The application will provide a link that leads to their information.
No	The application will provide, via link or where data is collected, written instructions on how to access/amend their information.
No	The application will provide a phone number of a VA representative who will provide instructions.
Yes	The application will use other method (explain below).
No	The application is exempt from needing to provide access.

6.2.b) What are the procedures that allow individuals to gain access to their own information?

Individuals will access their information at their VAMC. They will contact the Privacy Officer at the site.

6.2.c) What are the procedures for correcting erroneous information?

The same procedure as above.

6.2.d) If no redress is provided, are alternatives available?

Alternatives are available via handbook 1605.1 Privacy and Release of Information

6.2.e) Provide here any additional explanation; if exempt, explain why the application is exempt from providing access and amendment.

ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)

7 Retention and Disposal

By completing this section, you provide documented assurance that proper data retention and disposal practices are in place.

The "Retention and disposal" section of the applicable System of Records Notice(s) often provides appropriate and sufficiently detailed documented data retention and disposal practices specific to your project.

VA HBK 6300.1 Records Management Procedures explains the Records Control Schedule procedures.

System of Records Notices may be accessed via:

<http://vaww.vhaco.va.gov/privacy/SystemofRecords.htm>

or

http://vaww.va.gov/foia/err/enhanced/privacy_act/privacy_act.html

For VHA projects, VHA Handbook 1907.1 (Section 6j) and VHA Records Control Schedule 10-1 provide more general guidance.

VHA Handbook 1907.1 may be accessed at:

http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=434

For VBA projects, Records Control Schedule (RCS) VB-1 provides more general guidance. VBA Records Control Schedule (RCS) VB-1 may be accessed via the URL listed below.

Start by looking at the <http://www.warms.vba.va.gov/20rcs.html>

7.a) What is the data retention period? Given the purpose of retaining the information, explain why the information is needed for the indicated period.

The system architecture and database environment will be defined during the development life cycle beginning in FY2008. The retention requirement for the system of records 24VA19 is 75 years.

7.b) What are the procedures for eliminating data at the end of the retention period?

This information is not known at this time however will be addressed as the development life cycle matures.

7.c) Where are procedures documented?

This information is not known at this time however will be addressed as the development life cycle matures.

7.d) How are data retention procedures enforced?

This information is not known at this time however will be addressed as the development life cycle matures.

7.e) If applicable, has the retention schedule been approved by the National Archives and Records Administration (NARA)?

ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)

8 SECURITY

OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002, (OMB M-03-22) specifies that privacy impact assessments must address how collected information will be secured.

8.1 General Security Measures

8.1.a) Per OMB guidance, citing requirements of the Federal Information Security Management Act, address the following items (select all applicable boxes.):

Yes	The project is following IT security requirements and procedures required by federal law and policy to ensure that information is appropriately secured.
Yes	The project has conducted a risk assessment, identified appropriate security controls to protect against that risk, and implemented those controls.
Yes	Security monitoring, testing, and evaluating are conducted on a regular basis to ensure that controls continue to work properly, safeguarding the information.

8.1.b) Describe the security monitoring, testing, and evaluating that is conducted on a regular basis:

This process will be in place once this project has identified a laboratory information system. The project will follow the C&A process

8.1.c) Is adequate physical security in place to protect against unauthorized access?

Yes

8.2 Project-Specific Security Measures

8.2.a) Provide a specific description of how collected information will be secured.

• A concise description of how data will be protected against unauthorized access, unauthorized modification, and how the availability of the system will be protected.

• A concise description of the administrative controls (Security Plans, Rules of Behavior, Procedures for establishing user accounts, etc.).

• A concise description of the technical controls (Access Controls, Intrusion Detection, etc.) that will be in place to safeguard the information.

• Describe any types of controls that may be in place to ensure that information is used in accordance with the above described uses. For example, are audit logs regularly reviewed to ensure appropriate use of information? Are strict disciplinary programs in place if an individual is found to be inappropriately using the information?

Note: Administrative and technical safeguards must be specific to the system covered by the PIA, rather than an overall description of how the VA's network is secured. Does the project/system have its own security controls, independent of the VA network? If so, describe these controls.

Information will be secured by implementing the standards and utilizing the security systems set forth by the HealthVet-Vista specification. This includes interfacing with the enterprise-wide Authentication, Authorization and Access to be implemented by OCIS in CY 2005, and compliance with all patient privacy requirements and rights as mandated by HIPAA regulations. The project will meet OMB guidance consistent with the Federal Information Security Management Act once the system is identified.

8.2.b) Explain how the project meets IT security requirements and procedures required by federal law.

All VHA HealthVet applications, including Lab Reengineering, will migrate to a service-oriented architecture-based security model that leverages the existing integration investment in assets such as single sign-on, identity and access management, and LDAP. The security infrastructure includes Authentication Services (PKI, Password/ID, Tokens), Authorization Services (central access control), Identity and Access Management Services (grant, revoke, suspend), and Audit Services (security transaction logging, security event notification, and reporting). A security plan update was completed in April 2006 and delineates the requisite controls for incorporation into the prototype system, and subsequent testing. The project will advance the C&A process as the development phase of the project takes place in FY2008. Project funds for security were included in FY07, FY08 and FY09 requests.

9. CHANGE RECORD

OMB Memorandum M-03-22, OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002, mandates that PIAs address any project/ system changes that potentially create new privacy risks. By completing this section, you provide documented assurance that significant project/ system modifications have been appropriately evaluated for privacy-related impacts.

9.a Since the last PIA submitted, have any significant changes been made to the system that might impact the privacy of people whose information is retained on project systems? (Yes, No, n/a: first PIA)

No

If no, then proceed to Section 10, "Children's Online Privacy Protection Act."

If yes, then please complete the information in the table below. List each significant change on a separate row. 'Significant changes' may include:

Conversions - when converting paper-based records to electronic systems;

Anonymous to Non-Anonymous - when functions applied to an existing information collection change anonymous information into information in identifiable form;

Significant System Management Changes - when new uses of an existing IT system, including application of new technologies, significantly change how information in identifiable form is managed in the system:

• For example, when an agency employs new relational database technologies or web-based processing to access multiple data stores; such additions could create a more open environment and avenues for exposure of data that previously did not exist.

Significant Merging - when agencies adopt or alter business processes so that government databases holding information in identifiable form are merged, centralized, matched with other databases or otherwise significantly manipulated:

• For example, when databases are merged to create one central source of information; such a link may aggregate data in ways that create privacy concerns not previously at issue.

New Public Access - when user-authenticating technology (e.g., password, digital certificate, biometric) is newly applied to an electronic information system accessed by members of the public;

Commercial Sources - when agencies systematically incorporate into existing information systems databases of information in identifiable form purchased or obtained from commercial or public sources. (Merely querying such a source on an ad hoc basis using existing technology does not trigger the PIA requirement);

New Interagency Uses - when agencies work together on shared functions involving significant new uses or exchanges of information in identifiable form, such as the cross-cutting E-Government initiatives; in such cases, the lead agency should prepare the PIA;

Internal Flow or Collection - when alteration of a business process results in significant new uses or disclosures of information or incorporation into the system of additional items of information in identifiable form:

• For example, agencies that participate in E-Gov initiatives could see major changes in how they conduct business internally or collect information, as a result of new business processes or E-Gov requirements. In most cases the focus will be on integration of common processes and supporting data. Any business change that results in substantial new requirements for information in identifiable form could warrant examination of privacy issues.

Alteration in Character of Data - when new information in identifiable form added to a collection raises the risks to personal privacy (for example, the addition of health or financial information);

List All Major Project/System Modification(s)	State Justification for Modification(s)	* Concisely describe:	Modification Approver	Date

* The effect of the modification on the privacy of collected personal information

10. CHILDREN'S ONLINE PRIVACY PROTECTION ACT

10.a) Will information be collected through the Internet from children under age 13?

No

If "No" then SKIP to Section 11, "PIA Considerations".

10.b) How will parental or guardian approval be obtained.

ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)

11. PIA CONSIDERATIONS

11) Identify what choices were made regarding the project/system or collection of information as a result of performing the PIA. Examples of choices made include reconsideration of: collection source, collection methods, controls to mitigate misuse of information, provision of consent and privacy notice, and security controls.

The project is in the planning phase with the system development lifecycle to begin in FY2008. All PIA information will be utilized in the selection of the IT system.

ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)

12. PUBLIC AVAILABILITY

The Electronic Government Act of 2002 requires that VA make this PIA available to the public. This section is intended to provide documented assurance that the PIA is reviewed for any potentially sensitive information that should be removed from the version of the PIA that is made available to the public.

The following guidance is excerpted from M-03-22, "OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002," Section II.C.3, "Review and Publication": iii. Agencies must ensure that the PIA document and, if prepared, summary, are made publicly available (consistent with executive branch policy on the release of information about systems for which funding is proposed).

1. Agencies may determine to not make the PIA document or summary publicly available to the extent that publication would raise security concerns, reveal classified (i.e., national security) information or sensitive information (e.g., potentially damaging to a national interest, law enforcement effort or competitive business interest) contained in an assessment⁹. Such information shall be protected and handled consistent with the Freedom of Information Act (FOIA).

2. Agencies should not include information in identifiable form in their privacy impact assessments, as there is no need for the PIA to include such information. Thus, agencies may not seek to avoid making the PIA publicly available on these grounds.

12.a) Does this PIA contain any sensitive information that could cause harm to the Department of Veterans Affairs or any party if disclosed to the public?

No

12.b) If yes, specify:

ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)

13. ACCEPTANCE OF RESPONSIBILITY AND ACKNOWLEDGEMENT OF ACCOUNTABILITY:

13.1) I have carefully reviewed the responses to each of the questions in this PIA. I am responsible for funding and procuring, developing, and integrating privacy and security controls into the project. I understand that integrating privacy and security considerations into the project may affect the development time and cost of this project and must be planned for accordingly. I will ensure that VA privacy and information security policies, guidelines, and procedures are followed in the development, integration, and, if applicable, the operation and maintenance of this application.

Yes

13.2) Project Manager/Owner Name and Date (mm/dd/yyyy)

Cheryl Latham, Project Manager, Lab System Reengineering Project 05/31/2007

ADDITIONAL INFORMATION: (Provide any necessary clarifying information or additional explanation for this section.)