Research Administrative Management System (RAMS) Integration

Requirements Specification Document



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Version 1.5

Department of Veterans Affairs

Revision History

Note: The revision history cycle begins once changes or enhancements are requested after the Requirements Specification Document has been baselined.

| Date | Version | Description | Author |
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| 1/3/2016 | 1.5 | Review for 2001 submission |  |
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Artifact Rationale

The Requirements Specification Document (RSD) records the results of the specification gathering processes carried out during the Requirements phase. The RSD is generally written by the functional analyst(s) and should provide the bulk of the information used to create the test plan and test scripts. It should be updated for each increment.

The level of detail contained in this RSD should be consistent with the size and scope of the project. It is not necessary to fill out any sections of this document that do not apply to the project. The resources necessary to create and maintain this document during the life cycle of a large project should be acknowledged and clearly reflected in project schedules. Do not duplicate data that is already defined in another document or a section in this document; note in the section where the information can be found.

Instructions

| Activity | New Capability (1) | Feature Enhancement (2) |
| --- | --- | --- |
| **Field Deployment (A)** | No | No |
| **Cloud/Web Deployment (B)** | Yes | Yes |
| **Mobile Application (C)** | No | No |

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# Introduction

The Veterans Health Administration (VHA) Office of Research and Development (ORD) is responsible for the management and administration of the Department of Veterans Affairs (VA) intramural research program. The ORD aims to improve the efficiency and performance of the VA research program by implementing an enterprise-wide Research Administrative Management System (RAMS) accessible to active field research offices and the ORD Central Office.

The current implementation of RAMS supports the major business functions of the Institutional Review Board (IRB) and provides a common database for administrative research program data. This document specifies the requirements for new functionality and integration of RAMS to allow management of research projects and studies by the Research and Development Committee (R&D), the Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Subcommittee on Research Safety (SRS),and local research offices reporting to ORD.

This document provides a narrative description of these three committees: the Research and Development Committee (R&D), the Institutional Animal Care and Use Committee (IACUC), and the Subcommittee on Research Safety (SRS).

**The Research and Development (R&D) Committee**

The Research and Development (R&D) Committee is responsible for ensuring the effective operation of the research program through oversight of the R&D Committee’s subcommittees, and making appropriate recommendations, including space and resource needs, to the medical center Director based on the Committee’s oversight and evaluation of the research program. The R&D Committee assists the medical center Director in fulfilling responsibilities for the facility’s research program, and additional functions may also include review and approval of individual research projects.

Every VA facility conducting research must have, or establish, an R&D Committee of record. A VA facility may also secure the services of an R&D Committee from another VA facility, from the Veterans Integrated Service Network (VISN), a regional VA R&D Committee that serves multiple VA facilities, or other VA entity through the use of a written agreement that describes the roles and responsibilities of all parties. Renewal of the agreement must occur 60 days prior to the review of proposals by R&D subcommittee or it is to be automatically terminated. If terminated, that committee may no longer serve as the R&D Committee of record for the facility.

The R&D Committee is responsible, through the Chief of Staff (COS), to the medical center Director for:

* Advising and assisting the medical center Director to provide oversight, planning, and execution of the local research Program; and
* Assisting the medical center Director to maintain high standards throughout the R&D Program. Those standards include ensuring the:
* Scientific and ethical quality of VA research projects;
* Protection of human subjects in research;
* Safety of personnel engaged in research;
* Welfare of laboratory animals;
* Security of VA data; and
* Security of VHA research laboratories.

The R&D Committee is assisted by the Associate Chief of Staff (ACOS) for R&D and the Administrative Officer (AO) for R&D in carrying out its duties. NOTE: In small research programs, a Research Coordinator may be appointed in lieu of an ACOS for R&D. For purposes of this Handbook, “ACOS for R&D” includes the Research Coordinator. (June 16, 2009 VHA HANDBOOK 1200.01 3)

Research in which the facility is to be engaged may not be undertaken without review and written approval of all appropriate subcommittees of the R&D Committee. The investigator must not initiate a research project until after being notified in writing by the ACOS for R&D that the project has been approved by all relevant committees, subcommittees, or other entities. The Institutional Review Board (IRB), Subcommittee on Research Safety (SRS), Animal Care and Use Committee (IACUC), and other such entities must notify the R&D Committee of project approvals via a written communication signed by a voting committee member for the committee. The R&D Committee must notify the Associate Chief of Staff (ACOS) for R&D of project approvals via a written communication signed by a voting R&D Committee member for the committee. Notifications need not be in the form of minutes, nor is a separate document needed for each approved project. A single memorandum that lists by title, project number, or similar unique identifier all of the protocols receiving final approval at a given meeting is sufficient. Once R&D Committee approval has been given, the research becomes VA-approved research.

The RAMS integration solution shall enable the R&D Committee to:

1. Manage the activities of the R&D Committee, which includes the following:

1. Adding users and setting permissions
2. Adding members to committees and tracking appointment dates
3. Allow the R&D Committee to complete required reports and forms online
4. Allow the R&D Committee to schedule meetings, notify members and collect feedback from other subcommittees
5. Allow the R&D Committee to publish and store meeting minutes
6. Ensure compliance with federal and VA regulations

2. Provide communications portals among the R&D Committee and subcommittee

3. Provide easily accessible reporting capability at the local headquarters levels

4. Enable the ORD Central Office to create reports covering enterprise wide research activities.

**The Institutional Animal Care and Use Committee (IACUC)**

The IACUC (Institutional Animal Care and Use Committee) is the local committee charged with ensuring compliance with animal research regulations and guidelines. In the VA system, the IACUC is organized administratively as a subcommittee of the Research and Development Committee.

The VA IACUC must perform the review and oversight functions required by the Public Health Service (PHS) Policy (see Sec. IV.B., IV.C., and IV.F), the Guide (see Monitoring the Care and Use of Animals), the Animal Welfare Act (AWA) [see 7 U.S.C. 2143(b)(1)], the United States Department of Agriculture (USDA) AWA (see 9 Code of Federal Regulations (CFR) 2.31), VA policy, and any other Federal regulations that impact IACUC function.

The IACUC is responsible for the following:

* Semi-Annual Program and Facility Self-Assessment Reviews
* According to the USDA Animal Welfare Act Regulations and Standards (see 9 CFR §2.31(c)(1)) and PHS Policy, the designated VA IACUC must perform a self-assessment review of the program of animal care and research use, and an inspection of the animal facilities and husbandry practices at least every 6 months. This self-assessment review must be conducted using the standards established in the most current Guide (see “Institutional Animal Care and Use Committees”), PHS Policy (see Sec. IV.B), the Animal Welfare Act [see 7 U.S.C. 2143(b)(3) and (b)(4)], USDA AWA [see 9 CFR §2.31(c)(2)], and this VA policy.
* Research Proposal Reviews
  + The IACUC must review and approve, require modifications in (to secure approval), or withhold approval of all research proposals involving species and activities included within the definition of an “animal”. All research projects involving animals must be approved by the IACUC and then by the R&D Committee prior to commencement. The date of continuing review is based on the date of IACUC approval. The IACUC must review proposed research at convened meetings at which a quorum (a majority of voting members) is present. In order for the research to be approved, it must receive the approval of a majority of those voting members present at the meeting.
* IACUC Semi-Annual Self-Assessment Reviews
  + Semi-annual Self-Assessment Reviews must be prepared by the IACUC. No later than 60 days after the self-assessment review date, a copy of the approved report signed by a majority of IACUC members and the medical facility Director must be forwarded to the Chief Veterinary Medical Officer (CVMO)’s office through the ACOS for R&D and the medical facility Director.
* Annual VA Veterinary Medical Unit (VMU) Report
  + An annual VA VMU Report for the previous fiscal year must be completed using the Web site designed for that purpose by January 15. In contrast to the USDA Annual Report of Research Facility, all animal species used must be included in the Annual VMU Report. Instructions for properly completing this report can be obtained from the CVMO.

IACUC will be incorporated into the RAMS Integration project which will allow for the management of IACUCs research projects and studies.

**The Subcommittee on Research Safety (SRS)**

The Subcommittee on Research Safety (SRS) is responsible for ensuring the safety of personnel engaged in VA research conducted by the Office of Research and Development (ORD). In the VA system, the IACUC is organized administratively as a subcommittee of the Research and Development Committee.

The SRS verifies that safety standards are being met and resolves deficiencies by working with the following roles:

* Facility Directors
* ACOS
* R&D Committee
* Principle Investigator (PI) or PI Designee

The SRS is responsible for the following:

* Reviewing all research activities involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines prior to submission for R&D funding. This includes a review of all research applications for funding that will be conducted at the VA facility or by VA personnel with VA funding located off-site.
* Providing written notification of the results of SRS review to the R&D Committee, the Research Office, and the PI.
* Reviewing annually all active research protocols involving biological, chemical, physical, and radiation hazards, regardless of funding status or source. The date of continuing review will be based on the date of SRS approval. Research protocol changes not included in the original application must be documented on an amended Research Protocol Safety Survey (RPSS) (see Appendix F) and must be submitted to and reviewed by SRS prior to the implementation of the changes.
* Ensuring that a complete list of all products containing chemicals designated or identified by the Occupational Safety & Health Administration (OSHA) or the Environmental Protection Agency (EPA) as “hazardous” (see subpar. 6c (8), subpar. 6e (2), or applicable State requirements) has been submitted to the Safety Officer for review and approval prior to the submission of a protocol for local review.
* Coordinating all safety-related activities in research laboratories including mandatory and non-mandatory training, safety inspections, accident reporting, and liaison activities with all facility safety committees and officials to include:
  + Coordinating follow-up evaluations to ensure that deficiencies cited during inspections are permanently and effectively abated, and
  + Reporting follow-up results to the R&D Committee.
* Reporting operational problems or violations of directives to the Research Office within 30 days of occurrence or detection, unless SRS determines that a report has been previously filed by the PI.
* Identifying the need for health surveillance of personnel involved in individual research projects; and if appropriate, advising the R&D Committee and Employee Health Practitioner on the need for such surveillance.
* Maintaining adequate documentation of all the SRS or equivalent subcommittee activities.
* Forwarding minutes of SRS to the Research Office.
* Ensuring that all laboratory personnel receive annual research specific safety training.
* Holding SRS meetings at least quarterly.
* Ensuring coordination with other regulatory programs, personnel, or committees such as the Radiation Safety Officer or Radiation Safety Committee.
* Ensuring the collection of appropriate personnel samples to make employee exposure determinations whenever the proposed use of laboratory chemicals may potentially exceed OSHA Permissible Exposure Limits or Action Levels.
* Evaluating annually the effectiveness of the laboratory’s Chemical Hygiene Plan and making necessary revisions.
* Ensuring the review of investigation reports of all lost-time injuries and all significant adverse environmental events.
* Ensuring the proper reporting of injury and illness trends to the R&D Committee, as appropriate.
* Requesting, when appropriate, the appointment of an ad hoc committee (consisting of members with appropriate expertise) to investigate and report on occupational injuries, illnesses, and adverse environmental events.
* Ensuring the development of a policy for the preservation of employee medical and OSHA exposure records and environmental records (i.e., hazardous waste, air monitoring).
* Cooperating with appropriate medical center personnel to review the quantity and type of hazardous waste generated by each PI annually.
* Providing technical assistance, where appropriate, in recycling programs and reduction of the quantity of waste.

RAMS Integration will provide a collaborative system for SRS to work with other areas of ORD to manage hazardous materials, safety risks, and laboratory safety data. Additionally, SRS will be able to manage RAMS access and security for SRS users, as well as automate management of safety documents, including the Research Protocol Safety Survey (RPSS).

## Purpose

The purpose of this RSD is to document the requirements of the RAMS Integration solution that will be developed by Information Technology (IT) resources acquired through a contract.

These requirements have been refined through a series of extensive interviews and workshops with VA Users, business sponsors, and other stakeholders. The initial business requirements have been identified in the approved RAMS Integration Business Requirements Document (BRD).

This document is based on the Office of Enterprise Development (OED) ProPath template for requirements. This document’s organization and content reflect VA guidelines with the Project Management Accountability System (PMAS). The intended audience for this RSD is the VA Integrated Project Team (IPT), with access authorized and controlled by the VA Project Manager.

## Scope

The VA research program currently uses a variety of information systems and supplemental database applications to support research activities at the Central Office and local field levels. The existing non-standard architecture has led to inconsistent data management processes across the national program. This has also resulted in delays when responding to Central Office-initiated data calls.

The scope is to include a single front-end, web-based, data management and reporting application framework, and centralized back-end database system. The RAMS Integration is intended to serve as a multipurpose tool for ORD Central Office and VA Medical Center (VAMC) field research offices. The requirements are scoped to provide the capability to create and track administrative data for each project assigned to the local research office; manage research oversight committees and subcommittees; track research personnel assignments, training requirements, and certifications; manage laboratory data, including space allocations and equipment; and support required reporting to ORD.

This system will serve as a communication portal that is accessible to ORD and the research offices. It will require sufficient server space to exchange numerous tools and resources, many of which are graphic-heavy and require large amounts of storage capacity.

The RAMS Integration will serve as a multipurpose tool for the Veterans Affairs Central Office (VACO) ORD and VAMC field research offices. With the RAMS Integration, these offices will be able to:

* create and track administrative data for individual projects that are active or pending at local research sites;
* manage research oversight committees and sub-committees;
* track research personnel assignments, training requirements, and certifications;
* manage laboratory space and equipment inventory, including space allocations and equipment; and
* support required reporting to ORD.

## References

The following documents were referenced in the development of this Requirements Specification Document (RSD):

* RAMS Integration BRD 5-1-15
* RAMS Elaborated Requirements Document 05OCT15
* 1200 VHA Research Program
* VHA Handbook 1200.01 Research and Development Committee
* VHA Handbook 1200.05 Human Subjects
* VHA Handbook 1200.07 Animal Research
* VHA Handbook 1200.08 Safety

Additional references:

* ProPath Website
* Project Management Accountability System (PMAS) Program Management Document Repository
* Section 508 Requirements
* Technical Reference Model (TRM)
* Department of Veterans Affairs Handbook 6500
* VA Directive 6500 – Information Security Program
* Office of Information and Technology (OI&T) Technical Services Project Repository (TSPR) Website
* NARA – National Archives Records Association Policy
* RCS – Records Control Schedule

# Overall Description

The RAMS Integration is intended to improve on the current version of RAMS. The functionality specifications, among other requirements, will address the increased capability to create and track administrative data for each project assigned to the local research office, and manage oversight committees and subcommittees. The RAMS Integration will expand the capability to cover management of other types of research, such as animal studies that are overseen by the Institutional Animal Care and Use Committee (IACUC).

The non-functional requirements are addressed in Appendix A.

## Accessibility Specifications

The RAMS Integration will be compliant with all Section 508 IT accessibility standards governed under 29 U.S.C 794d, as well as any more specific VA policies that may apply. According to VA Handbook 6102, accessibility is ensuring that content can be navigated and read by every User, regardless of location, experience, or the type of computer technology used. VA Web managers must therefore ensure that all Web pages, documents, and files posted to the Web and/or to a collaboration tool must be accessible. This includes .pdf, .xls, and .doc file types. Refer to the VA’s Section 508 Background and Standards page for more details.

Table 1: Accessibility Specifications

| Req. ID | Requirement | Increment  (1, 2, Future) |
| --- | --- | --- |
| ACC-001 | The RAMS Integration shall comply with Section 508 requirements. | 1,2 (VA Directive) |
| ACC-002 | The RAMS Integration system shall comply with Accessibility Guidelines | 1,2  (VA Directive) |

## Business Rules Specification

In addition to the Epics and User Stories documented in Section 2.6 of this document, the following business rules apply to RAMS:

* The Principal Investigator (PI) or PI Designee can submit a study application for review and complete edits based on feedback.
* Unauthorized Users are not permitted to access or edit study data. **(pertains to 2.2.2 Add users and set permissions – IACUC, R&D, Safety, RCO)**
* Entering a term in the search box produces a list of studies that have that term included in the abstract. **(pertains to 2.3 Provide capability to print complete application (all sections in one document)**
* When assigning personnel to a project, the system provides an alert if a person's training has lapsed. **(pertains to 2.4.2 Manage investigators and personnel related to IACUC research projects)**
* The system calculates which forms are required and provides links to complete the form online. **(pertains 2.5 Support auto fill reports and forms required by R&D and subcommittees.)**
* When viewing a study online, an "attach document" button is available to upload and tag documents. **(pertains 2.6 Attach review committee forms, including data security, COI, safety, radiation, and IRB or IACUC forms to project. Tag uploaded forms by type, date and author.)**
* The system accepts a waiver request and notifies Investment Review Board (IRB) Coordinator. The system tracks the status of the request. (for IRB only). **(pertains to 2.7 Submit and track eligibility and off-site waivers.)**
* The Administrative Officer (AO) can select Project Expenditure Report to review expenses per project. **(pertains to 2.8 Track fiscal year expenditures by project. All fields captured in current RDIS Part II should be captured.)**
* The AO can select Funding Status Report and view funding status for each project by sponsor. **(pertains to 2.9 Track sponsorship and funding status for projects.)**
* The PI or the PI Designee is notified 90 days before the Annual Report is due and can complete the report using online forms. **(pertains to 2.10.2 Submit Annual and Final (or as needed) Project Report – IACUC)**
* An option to add, delete, or configure committees is available on the System Administrator (SA) tool page. **(pertains to 3.1 Add or delete committees based on site SOP)**
* The Committee roster tool is available on the Committee Activities page. **(pertains to 3.2.2 Add members to committees and track appointment dates – IACUC, Safety, and R&D)**
* A User can choose to sign electronically when submitting a document that requires signatures. **(pertains to 3.9 Provide a mechanism for the use of secure electronic signatures for the signing of all forms and correspondence)**
* The Assurance and Accreditation Checklist is provided on the AO landing page. **(pertains to 3.16 Track Federal Wide Assurances, IRB and IACUC registrations, Memorandum of Understanding (MOUs), and other accreditations)**
* The Workflow configuration tool is available on the Local System Administrator (LSA) landing page.  **(pertains to 3.17 Allow for site specific committee configurations and workflows)**
* A link is available in the online study application to access and complete Form 10-0398. **(pertains to 3.19 Automate creation of Research Protocol Safety Survey (RPSS) (VA Form 10-0398)**
* A training record is available for research personnel, and notifications are sent to the PI, or the PI Designee, and the User when training is about to expire. **(pertains to 4.2 Automate the tracking of training, scope of practice, and all necessary certifications for PIs and other employees)**
* The report for Without Compensation (WOC) staff and appointment status is available from the AO landing page. **(pertains to 4.4 Notify WOC/IPA/VA employee and sponsor when appointment renewal is required)**
* The report of keys, badges, and equipment assigned to personnel, is available on the AO landing page. **(pertains to 4.5 Track key, PC, and badge assignments/issues)**
* The Lab Space Report is accessible from the AO landing page. **(pertains to 5.1 Track laboratory space allocations)**
* The LASIF form is available online as a component of RAMS. **(pertains to 5.3 Generate and track annual lab safety self-evaluation forms and lab safety)**
* The Data sharing agreements are stored as tagged documents. **(pertains to 5.6 Manage data sharing agreements, data repository approvals and annual reports)**

Additional details and more specific business needs will be further documented in the RAMS Integration System Design Document (SDD). The anticipated completion date of the SDD is February 2016.

## Design Constraints Specification

All software development by developers shall conform to technology standards as defined in the One-VA Technical Reference Model (TRM).

The new functionality requested by the Research Administrative Management System (RAMS) project spans across multiple applications and is used as a communications portal that is accessible to the ORD and research offices. The following discussion summarizes some, but not all, of the design “constraints” that must be considered to integrate and properly build the new functionality. Further explanation is provided in the more-detailed requirements analysis for each of these topics.

Software is developed and maintained using industry-standard technologies. The project adds functionality to software currently in Production at the Philadelphia Information Technology Center (PITC). The software changes contained in this RSD are minimal changes to an existing Structured Query Language (SQL) Server database. The requirement specifications in this document will be made with the intent to serve as a multipurpose tool for the ORD Central Office and the VAMC field research offices.

The following architectural design constraints for the solutions include technical constraints, standards, nonfunctional requirements, and important architectural decisions. Listed below are currently identified design constraints per the “new” requirement, along with “existing” design constraints from the initial development.

**Memory Constraints and Database Requirements**

* Additional data produced by the IACUC, Safety, and R&D committees will require an increased data storage requirement. Changes to the database structure will be minimal because links to the new features were anticipated in the original database design.

**Dependencies and Constraints**

* Successful implementation of this project requires adequate training and education for end Users and support staff.
* All new functionality to the application/system is subject to funds availability.

**Constraints**

* Providing secure access in a real-time mode will be a major constraint. The system must serve Users who are located at VA affiliates and universities.

**Additional Identified Design Constraints**:

* The system shall comply with all VA Enterprise Architecture Standards
* The system shall be designed as a Service Oriented Architecture (SOA), as defined in “Principles of Service Oriented Architecture Version 1.31, Software Engineering – Standards Division, Office of Enterprise Development, Office of Information & Technology, Department of Veterans Affairs.”
* Software interfaces built for new business functions, legacy applications, databases, middleware, and other infrastructure components shall be implemented as services using Simple Object Access Protocol (SOAP)/Hypertext Transfer Protocol (HTTP(S)), Extensible Markup Language (XML)/HTTP(S), SOAP/Java Message Service (JMS), or XML/JMS.
* Services shall be built using standards that promote interoperability.[5]
* Services shall be designed according to a technical service contract and a negotiated Service Level Agreement (SLA), which together comprise the service contract.
* Services implementation shall be loosely coupled to the service interface.
* A service interface is the sole entry point into service logic and resources.
* Services shall be accessed only via the exposed, published interfaces.
* All service interfaces shall be defined using a technical service contract that includes a WSDL (Web Services Description Language) definition, one or more XML schema definitions, and Web Services (WS)-Policy definitions, as required.
* Services shall be designed so they can be monitored to determine whether services become unavailable, have a detectable security fault, and whether factors specified in the SLA portion of the Service Contract are out of the permitted range, including, but not limited to, resource utilization and the fault behaviors and performance metrics.
* No service shall use static (e.g., hard-coded) service addresses.
* Service logic exposed by the service shall handle concurrent access without deadlock or loss of data integrity.
* Services shall be implemented in a manner that does not require consumers to use a specific language (e.g., Java only) to access the service.
* Services, in the event of exceptions, shall provide fault content to the consumer and the audit log, without compromising security, which shall include sufficient information for consumer recovery.
* The System shall use Representational State Transfer (RESTful) Web services for any service that is accessed through the User interface.

The following table lists the technology that will be utilized with the RAMS Integration.

Table 2: List of Technologies

| Technology Name |
| --- |
| Microsoft Structured Query Language (SQL) Server 2012 |
| Microsoft SQL Server Reporting Services 2012 |
| Microsoft SharePoint 2013 SP1 |
| Microsoft Windows Server 2008 R2/2012 |
| Red Hat Enterprise Linux 7.0.57 |
| SQL Server Integration Services 2012 |

The open-source software application that is utilized is:

* Apache Tomcat 7.x (Latest Stable)

The Software Development framework and platform utilized is:

* Java Enterprise Edition 7

In addition, the list comprises the following applications the VA uses in support of performing project development processes:

* Rational Tool Set
* Microsoft (MS) Visual Studio 2010

The standards that apply to this design document, at a minimum, include:

* VA Handbook 6500.3 Certification & Accreditation
* VA Handbook 6102 Internet/Intranet Services

## Disaster Recovery Specification

RAMS is an operational environment hosted at the PITC, therefore the RAMS application’s systems (sub-systems, components, and databases) will inherit the PITC’s Disaster Recovery Plan (DRP), a related Contingency Plan (CP), and an Incident Response Plan (IRP). In the event that there is an outage and the RAMS application system goes offline, the following is required:

* The system should be fully restored within seventy-two (72) hours of an outage.
* After an outage, 99% of the data will need to be restored.

Fail-over capabilities will be obtained by establishing a similar environment at an alternate data center and synchronizing the transactions as they occur, with the exact method that was determined in the PITC’s DRP.

## Documentation Specifications

Requirements for documentation, including training, User documentation, help systems, help about notices, installation guide, security guide, implementation guide, and any other forms of documentation are provided below. The RAMS Integration will include all of the required components necessary to conform to the documentation requirements mandated by PMAS and ProPath.

Documentation will potentially include, but is not limited to, the following:

* Standard Operating Procedures
* Change Management Process
* User manual for software:
  + Updates shall be made, as necessary, to applicable User manuals and other training tools and shall be delivered to all levels of Users. If no User documentation exists, it shall be produced.
* Technical documentation
* Maintenance agreements/documentation:
  + IT will provide the level of documentation required to support the system and maintain operations and continuity. Documentation shall represent minimal programmatic and lifecycle operations support documentation artifacts, as defined by VA standards in ProPath and as required by the VA Enterprise System Engineering Lifecycle and Release Management Office for sustained operations, maintenance, and support prior to approval by any VA change control board and release into production.
* Implementation Guide
* A technical training curriculum shall be developed and delivered to all levels of staff Users:
  + The training curriculum shall state the expected training time for primary Users and secondary Users to become productive at using system.
  + All training curricula, User manuals, and other training tools shall be updated by proper authorities and delivered to all levels of Users in advance of deployment. The curricula shall include all aspects of the application(s) and all changes to processes and procedures.
  + The training curriculum shall state the expected task completion time for primary and secondary Users.
* Technical Help Desk support for the application shall be provided to Users.

## Functional Specifications

The Epics and User Stories documented in this section represent the analysis conducted to date. It is intended to be exhaustive and reflect all desired requirements for the RAMS Integration.

The format of these User Stories is a standard one, with the “As a…” column on the left, indicating who the actor(s) is/are; the “I want…” column indicating what action they wish to take; and the “So that…” column, indicating the resulting outcome and/or benefits. The final column, “Acceptance Criteria/User Story Notes” provides more specifics about what will take place in a given User story, along with any business rules that must be adhered to, or general notes that must be considered. This column also includes questions for VA personnel to address at some point in the future.

The table below lists the Epic and detailed User Narratives (Business Requirements) for Business Need (BN)1/Elaboration Business Requirement 4.

Table 3: Epic BN1

| Epic BN1: Utilize nationally standardized terminology in all fields in the RAMS system from authoritative sources where available. | | | | | |
| --- | --- | --- | --- | --- | --- |
| ID | Priority | As a… | I want… | So that… | Acceptance Criteria/User Story Notes |
| BN1 | High | RAMS User | To be able to query the database using standardized terminology (for data elements). | I have the ability to successfully query the database using standardized technology. | To be able to query the database using standardized technology. |

The table below lists the Epic and detailed User Narratives (Business Requirements) for BN2/Elaboration Business Requirement 5.

Table 4: Epic BN2

| Epic BN2: Enhance the RAMS application to allow sites to track and manage research projects and studies. | | | | | |
| --- | --- | --- | --- | --- | --- |
| ID | Priority | As a… | I want… | So that… | Acceptance Criteria/User Story Notes |
| BN2.1.2 | High | Principal Investigator (PI) or PI Designee | To enter, edit, and attach documents to IACUC projects in database. | I have the ability to initiate an IACUC application for a new study. This includes entering all data (pertinent and impertinent) in the RAMS database.  I have the ability to initiate review of a new study in order to receive feedback prior to IACUC submission. | To be able to enter, edit, and attach documents to IACUC projects in database.  NOTE: PI or PI Designee can submit study application for review and complete edits based on feedback. |
| BN2.2.2 | High | Local System Administrator (LSA) and Administrative Officer (AO) | To add Users and set permissions for IACUC, R&D, Safety, and Research Compliance Officer (RCO).  And  Add Users and set permissions for IACUC, R&D, Safety, and RCO | I have the ability to add IACUC Users to the system.  I have the ability to assign IACUC Users access permissions.  I have the ability to add R&D Users to the system.  I have the ability to add R&D Users access permissions.  I have the ability to add Safety Users to the system.  I have the ability to assign Safety Users access permissions.  I have the ability to add RCO Users to the system.  I have the ability to assign RCO Users access permissions.  I have the ability to ensure that access to studies is restricted to authorized Users.  I have the ability to ensure that access to IACUC data is restricted to authorized Users. | To be able to add Users and set permissions for IACUC, R&D, Safety, and RCO.  NOTE: Unauthorized Users are not permitted to access or edit study data.  This epics will need to be built to accommodate additional committees in the future. |
| 2.3 | High | RAMS User and Administrative Officer | To print complete application with all sections in one document R&D, Safety, and IACUC committees. | I have the ability to search for key words in the R&D committee.  I have the ability to search in order to identify studies pertaining to specific topics in the R&D committee.  I have the ability to search for key words in the Safety committee.  I have the ability to search in order to identify studies pertaining to specific topics in the Safety committee.  I have the ability to search for key words in the IACUC committee.  I have the ability to search in order to identify studies pertaining to specific topics in the IACUC committee. | To be able to print complete application with all sections in one document.  Note: Entering a term in the search box produces a list of studies that have that term included in abstract.  This epics will need to be built to accommodate additional committees in the future. |
| 2.4 | High | Administrative Officer  and Principal Investigator or PI Designee | To manage investigators and personnel related to research projects in the R&D, Safety, and IACUC committees. | I have the ability to manage investigators and personnel related to research projects in the R&D committee.  I have the ability to manage investigators and personnel related to research projects in the Safety committee.  I have the ability to manage investigators and personnel related to research projects in the IACUC committee. | To be able to manage investigators and personnel related to research projects.  This epics will need to be built to accommodate additional committees in the future. |
| 2.4.2 | High | Administrative Officer  and Principal Investigator or PI Designee | To manage investigators and personnel related to R&D, Safety, and IACUC research projects. | I have the ability to track which personnel are assigned to specific studies in the R&D committees.  I have the ability to ensure that personnel assigned to research studies are qualified per regulations in the R&D committees.  I have the ability to track which personnel are assigned to specific studies in the Safety committees.  I have the ability to ensure that personnel assigned to research studies are qualified per regulations in the Safety committees .  I have the ability to track which personnel are assigned to specific studies in the IACUC committees.  I have the ability to ensure that personnel assigned to research studies are qualified per regulations in the IACUC committees.. | To be able to manage investigators and personnel related to IACUC research projects.  This epics will need to be built to accommodate additional committees in the future. |
| 2.5 | High | Principal Investigator or PI Designee | To support auto fill reports and forms required by R&D, Safety, IACUC and subcommittees. | I have the ability to complete various forms required for an IRB application.  I have the ability to be prompted when a form is required to complete the form online in the IRB committee application.  I have the ability to complete various forms required for an R&D application.  I have the ability to be prompted when a form is required to complete the form online in the R&D committee application.  I have the ability to complete various forms required for an Safety application.  I have the ability to be prompted when a form is required to complete the form online in the Safety committee application.  I have the ability to complete various forms required for an IACUC application.  I have the ability to be prompted when a form is required to complete the form online in the IACUC committee application. | Support autofill reports and forms required by R&D and subcommittees.  Note: System calculates which forms are required and provides links to complete form online.  This epics will need to be built to accommodate additional committees in the future. |
| 2.6 | High | Principal Investigator or PI Designee | To attach review committee forms, including data security, Conflict of Interest (COI), safety, radiation and IRB, R&D, Safety, or IACUC forms to project. Tag uploaded forms by type, date, and author. | I have the ability to digitally attach review committee forms to an IRB study application.  I have the ability to tag uploaded IRB review committee forms by type.  I have the ability to upload review IRB committee forms by date.  I have the ability to upload review IRB committee forms by author.  I have the ability to digitally attach review committee forms to a R&D study application.  I have the ability to tag uploaded R&D review committee forms by type.  I have the ability to upload review R&D committee forms by date.  I have the ability to upload review R&D committee forms by author.  I have the ability to digitally attach review committee forms to a Safety study application. | Attach review committee forms, including data security, Conflict of Interest (COI), safety, radiation and IRB, R&D, Safety or IACUC forms to project. Tag uploaded forms by type, date, and author.  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | I have the ability to tag uploaded review Safety committee forms by type.  I have the ability to upload  review Safety committee forms by date.  I have the ability to upload review Safety committee forms by author.  I have the ability to  digitally attach review  committee forms to an IACUC study application.  I have the ability to tag uploaded review IACUC  committee forms by type.  I have the ability to upload  review IACUC committee forms by date.  I have the ability to upload review IACUC committee formsby author. |  |
| 2.7 | Medium | Principal Investigator or PI Designee | To submit and track eligibility and off-site waivers in the IRB, R&D, Safety, and IACUC committees. | I have the ability to submit a request for an off-site waiver in the IRB committee application.  I have the ability to understand the rules for an off-site waiver in the IRB committee application.  I have the ability to receive a ruling after a request has been made for the waiver in the IRB committee application.  I have the ability to submit a request for an off-site waiver in the R&D application. committee  I have the ability to understand the rules for an off-site waiver in the R&D committee application.  I have the ability to receive a ruling after a request has been made for the waiver in the R&D committee application.  I have the ability to submit a request for an off-site waiver in the Safety committee application.  . | To be able to submit and track eligibility and off-site waivers.  NOTE: System accepts waiver request and notifies IRB Coordinator. System tracks status of the request. (for IRB only)  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | I have the ability to understand the rules  for an off-site waiver in the Safety committee application.  I have the ability to  receive a ruling after a  request has been made  for the waiver in the Safety committee application.  I have the ability to submit a request for an off-site  waiver in the IACUC committee application.  I have the ability to u for an off-site waiver in the IACUC committee application. .  I have the ability to understand the rules  receive a ruling after a request has been made for the waiver in the IACUC committee application. |  |
| 2.9 | High | Administrative Officer and Associate Chief of Staff for Research | To track sponsorship and funding status for projects in the R&D, Safety, and IACUC committees. | I have the ability to track the sponsorship for each project in the R&D committees. I have the ability to track current funding status for each project in the R&D committees.  I have the ability to know the current funding status for each project in order to alert PIs when expenditures exceed obligated funds in the R&D committees.  I have the ability to track the sponsorship for each project in the Safety committees.  I have the ability to track current funding status for each project in the Safety committees.  I have the ability to know the current funding status for each project in order to alert PIs when expenditures exceed obligated funds in the Safety committees.  I have the ability to track the sponsorship for each | To be able to track sponsorship and funding status for projects.  Note: AO can select Funding Status Report and view funding status for each project by sponsor.  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | project in the IACUC committees.  I have the ability to track current funding status for each project in the IACUC committees.  I have the ability to know the current funding status for each project in order to alert PIs when expenditures exceed obligated funds in the IACUC committees. |  |
| 2.10.2 | High | Principal Investigator or PI Designee | To submit all R&D, Safety, and IACUC progress reports and reviews. | I have the ability to submit an annual report electronically for R&D committees.  When needed, I have the ability to submit a tri-annual review for R&D committees.  When needed, I have the ability to submit an ad-hoc review for R&D committees.  I have the ability to be notified when an annual report is due for R&D committees.  I have the ability to be notified when an annual report has the capability to file the report online for R&D committees.  I have the ability to submit an annual report electronically for Safety committees.  When needed, I have the ability to submit a tri-annual review for Safety committees. | To be able to submit Annual or Final (or as needed) R&D, Safety, and IACUC Project Reports.  NOTE: PI or PI Designee is notified 90 days before Annual Report is due and can complete the report using online forms.  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | When needed, I have the ability to submit an ad-hoc review for the Safety committees.  I have the ability to be notified when an annual report is due for the Safety committees.  I have the ability to be notified when an annual report has the capability to file the report online for the Safety committees.  I have the ability to submit an annual report electronically for the IACUC committees.  When needed, I have the ability to submit a tri-annual review for the IACUC committees.  When needed, I have the ability to submit an ad-hoc review for the IACUC committees.  I have the ability to be notified when an annual report is due for the IACUC committees.  I have the ability to be notified when an annual report has the capability to file the report online for the IACUC committees. |  |
| 2.11 | Low | Principal Investigator or PI Designee | To track publications and awards with project data within the R&D, Safety, and IACUC applications. | I have the ability to add publications to the Biosketch.  I have the ability to add awards to the Biosketch.  I have the ability to keep the Biosketch up to date.  I have the ability to create tailored versions for particular IRB applications.  I have the ability to add publications to the Biosketch in the R&D committee application..  I have the ability to add awards to the Biosketch in the R&D committee application.  I have the ability to keep the Biosketch up to date in the R&D committee application..  I have the ability to create tailored versions for particular R&D applications.  I have the ability to add publications to the Biosketch in the Safety committee application. | To be able to track publications and awards with project data.  NOTE: PI or PI Designee can review and edit Biosketch online including publications and awards section.  This epics will need to be built to accommodate additional committees in the future.  A change request may be in order to include the IRB at a later date. |

The table below lists the Epic and detailed User Narratives (Business Requirements) for BN3 / Elaboration Business Requirement 6.

Table 5: Epic BN3

| Epic BN3: Enhance the RAMS application to automate the management of committees to ensure compliance. | | | | | |
| --- | --- | --- | --- | --- | --- |
| ID | Priority | As a… | I want… | So that… | Acceptance Criteria/User Story Notes |
|  |  |  |  | I have the ability to add awards to the Biosketch  in the Safety committee application.  I have the ability to keep the Biosketch up to date in the Safety committee application.  I have the ability to create tailored versions for particular Safety applications.  I have the ability to add publications to the Biosketch in the IACUC committee application.  I have the ability to add awards to the Biosketch  in the IACUC committee application.  I have the ability to keep the Biosketch up to date in the IACUC committee application.  I have the ability to create tailored versions for particular IACUC applications. |  |
| 3.1/6.1 | High | Site System Administrator (SSA) | To add or delete R&D, Safety, and IACUC committees based on site Standard Operating Procedure (SOP).  NOTE: An option to add, delete, or configure committees is available on the System Administrator (SA) tool page. | I have the ability to configure RAMS to match the R&D committee roster at my site. I have the ability to add R&D committees that are not RAMS’s defaults. I have the ability to hide R&D committees that are not used at my site.  I have the ability to configure RAMS to match the Safety committee roster at my site.  I have the ability to add Safety committees that are not RAMS’s defaults.  I have the ability to hide Safety committees that are not used at my site.  I have the ability to configure RAMS to match the IACUC committee roster at my site.  I have the ability to add IACUC committees that are not RAMS’s defaults.  I have the ability to hide IACUC committees that are not used at my site.  NOTE: An option to add, delete or configure committees is available on the SA tool page. | The SSA is able to add or delete committees based on the site SOP.  NOTES:  An option to add, delete or configure committees is available on the SA tool page.  Currently there is no RAMS default committee. The goal is to have somewhat of a default committee but also have the ability to customize each site.  RAMS is an enterprise like project, but neither one on the RAMS projects are configuring any special committee.  This epics will need to be built to accommodate additional committees in the future. |
| 3.2/6.2 | High | Committee Coordinator | To add members to R&D, Safety, and IACUC committees, track meeting attendance, and track appointment dates. | I have the ability to add members to R&D committees.  I have the ability to track R&D committee meeting attendance.  I have the ability to track R&D committee appointment dates.  I have the ability to add members to Safety committees.  I have the ability to track Safety committee meeting attendance.  I have the ability to track Safety committee appointment dates.  I have the ability to add members to IACUC committees.  I have the ability to track IACUC committee meeting attendance.  I have the ability to track IACUC committee appointment dates. | Add members to committees and track appointment dates.  This epics will need to be built to accommodate additional committees in the future. |
| 3.2.2/6.2.1 | High | Committee Coordinator | To add members to committees, track meeting attendance, and track appointment dates – IACUC, Safety, and R&D | * I have the ability to manage the IACUC committee roster. * I have the ability to manage my Safety committee roster. * I have the ability to manage the R&D committee roster. * I have the ability to monitor IACUC committee member availability in order to ensure that a quorum is available at each meeting. * I have the ability to track IACUC committee member’s appointment dates in order to ensure that a quorum is available at each meeting. * I have the ability to obtain IACUC committee member’s qualifications in order to ensure that a quorum is available at each meeting. * I have the ability to monitor Safety committee members in order to ensure that a quorum is available at each meeting. * I have the ability to track Safety committee member availability in order to ensure that a quorum is available at each meeting. * I have the ability to track Safety committee member’s appointment dates in order to ensure that a quorum is available at each meeting. * I have the ability to obtain Safety committee member’s qualifications in order to ensure that a quorum is available at each meeting. * I have the ability to monitor R&D committee member availability in order to ensure that a quorum is available at each meeting. * I am able to track R&D committee members in order to ensure that a quorum is available at each meeting. * I have the ability to track R&D committee member’s appointment dates in order to ensure that a quorum is available at each meeting. | The Committee Coordinator is able to add members to committees and track appointment dates – IACUC, Safety, and R&D.  NOTES:  The committee roster tool is used to identify the Chair Person and the members of the committee, as well as designated alternates.  The number of quorum members and the makeup of the qualifications of the quorum members are governed and locally managed and the committee actions are locally defined.  See VHA Handbook 1200, VHA Handbook 1200.05 and VHA Handbook 1200.1 for more details.  Committee Management entails:   * Defining members. * Creating agendas. * Scheduling meetings. * Creating minutes. * Posting meetings. * Creating tasks. * Assigning tasks. * Tracking tasks until completion. * Keeping a library of important committee documents, communications announcements, lists, committee knowledge base and URL links.   This epics will need to be built to accommodate additional committees in the future. |
| 3.3/6.3 | High | Committee Coordinator | Add projects, amendments, and other business to R&D, Safety, and IACUC committee agenda. | I have the ability to add projects R&D committee agenda.  I have the ability to add amendments R&D committee agenda.  I have the ability to add other business to R&D committee agenda.  I have the ability to add projects Safety committee agenda.  I have the ability to add amendments Safety committee agenda.  I have the ability to add other business to Safety committee agenda.  I have the ability to add projects IACUC committee agenda.  I have the ability to add amendments IACUC committee agenda.  I have the ability to add other business to IACUC committee agenda. | Add projects, amendments, and other business to committee agenda.  This epics will need to be built to accommodate additional committees in the future. |
| 3.3.2/6.3.1 | High | Committee Coordinator | To add and control the versions of projects, amendments, and other business to committee agenda – IACUC, Safety, and R&D. | I have the ability to create the agenda for each R&D committee meeting. I have the ability to set the meeting schedule for each R&D committee meeting. I have the ability to maintain the agenda for each R&D committee meeting. I have the ability to maintain an electronic version of the R&D committee meeting agenda in order to allow members to review agenda items.  I have the ability to create the agenda for each Safety committee meeting.  I have the ability to set the meeting schedule for each Safety committee meeting.  I have the ability to maintain the agenda for each Safety committee meeting.  I have the ability to maintain an electronic version of the Safety committee meeting agenda in order to allow members to review agenda items. | The Committee Coordinator is able to add projects, amendments, and other business to committee agenda – IACUC, Safety, and R&D.  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | I have the ability to create the agenda for each IACUC committee meeting.  I have the ability to set the meeting schedule for each IACUC committee meeting.  I have the ability to maintain the agenda for each IACUC committee meeting.  I have the ability to maintain an electronic version of the IACUC committee meeting agenda in order to allow members to review agenda items. |  |
| 3.3.3/6.3.2 | Medium | Committee Coordinator | To revise agenda template for R&D, Safety, and IACUC. | I have the ability to revise the agenda template for R&D committees. I have the ability to update the template for R&D committees.  I have the ability to revise the agenda template for Safety committees.  I have the ability to update the template for Safety committees.  I have the ability to revise the agenda template for IACUC committees.  I have the ability to update the template for IACUC committees. | The Committee Coordinator is able to revise the agenda template. Permissions should be limited to not allow new fields to the agenda template. Potential revisions should be limited to drop down lists to maintain consistency.  This epics will need to be built to accommodate additional committees in the future. |
| 3.4/6.4 | High | Site System Administrator | To provide portal/tools for local form creation and form-based collection of safety information for the R&D, Safety, and IACUC. | I have the ability to create a local version of a safety information form for R&D committee.  I have the ability to incorporate the form into the RAMS workflow for the R&D committee.  I have the ability to add custom forms to the RAMS R&D application. The form should be printable to enable upload and attachment to a study. | SSA is able to access a portal / tools for local form creation and form-based collection of safety information.  NOTE: The custom forms will be added to the application electronically.  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | I have the ability to create a local version of a safety information form for Safety committee.  I have the ability to incorporate the form into the RAMS workflow for the Safety committee.  I have the ability to add custom forms to the RAMS Safety application. The form should be printable to enable upload and attachment to a study.  I have the ability to create a local version of a safety information form for IACUC committee.  I have the ability to incorporate the form into the RAMS workflow for the IACUC committee.  I have the ability to add custom forms to the RAMS IACUC application. The form should be printable to enable upload and attachment to a study. |  |
| 3.5/6.5 | High | Principal Investigator or PI Designee | To automate creation of Animal Component of Research Protocol (ACORP) and other compliance forms. | I have the ability to create a new ACORP as a component of a study involving animals.  I have the ability to complete the ACORP online in order to expedite the submission of this form to the IACUC. | The PI or PI Designee is able to automate the creation of ACORP and other compliance forms. |
| 3.7/6.6 | High | Committee Coordinators | Schedule meetings and notify membersin the R&D, Safety, and the IACUC committees. | I have the ability to schedule meetings in R&D committees.  I have the ability to notify members in the R&D committees.  I have the ability to schedule meetings in Safety committees.  I have the ability to notify members in the Safety committees.  I have the ability to schedule meetings in IACUC committees.  I have the ability to notify members in the IACUC  committees. | Schedule meetings and notify members.  This epics will need to be built to accommodate additional committees in the future. |
| 3.8/6.7 | High | IRB Administrator, Safety Committee Administrator, R&D Administrator, IACUC Administrator | Collect reviewer feedbackfor R&D, Safety, and IACUC committees. | I have the ability to collect reviewer feedback for R&D committees.  I have the ability to collect reviewer feedback for Safety committees.  I have the ability to collect reviewer feedback for IACUC committees. | Collect reviewer feedback.  This epics will need to be built to accommodate additional committees in the future. |
| 3.8.2/6.7.1 | High | IRB Administrator | To collect committee feedback – R&D, Safety, and IACUC. | I have the ability to monitor R&D committee correspondence. I have the ability to attach the R&D correspondence to the appropriate study application.  I have the ability to monitor Safety committee correspondence.  I have the ability to attach the Safety correspondence to the appropriate study application.  I have the ability to monitor IACUC committee correspondence.  I have the ability to attach the IACUC correspondence to the appropriate study application. | Reviewer comments should be part of the approval letter.  This epics will need to be built to accommodate additional committees in the future. |
| 3.8.2/6.7.1 | High | Safety Committee Administrator | To collect reviewer feedback – IACUC, Safety, and R&D. | I have the ability to attach the Safety reviewer comments to the appropriate study application.  I have the ability to monitor Safety reviewer comments in order to forward requests for changes or clarification to the PI or PI Designee. | The Safety Committee Administrator is able to collect reviewer feedback –Safety.  This epics will need to be built to accommodate additional committees in the future. |
| 3.8.2/6.7.1 | High | R&D Administrator | To collect reviewer feedback – IACUC, Safety, and R&D. | I have the ability to monitor R&D reviewer comments.  I have the ability to attach the R&D reviewer comments to the appropriate study application.  I have the ability to monitor R&D reviewer comments in order to forward requests for changes or clarification to the PI or PI Designee. | The R&D Administrator is able to collect reviewer feedback – R&D.  This epics will need to be built to accommodate additional committees in the future. |
| 3.8.2/6.7.1 | High | IACUC Administrator | To collect reviewer feedback – IACUC, Safety, R&D. | I have the ability to monitor IACUC reviewer comments in order to forward requests for changes or clarification to the PI or PI Designee. | The IACUC is able to collect reviewer feedback – IACUC.  This epics will need to be built to accommodate additional committees in the future. |
| 3.8.3/6.7.2 | High | IRB Administrator | To collect feedback from other subcommittees – IRB, IACUC, Safety, and R&D. | I have the ability to monitor correspondence from other subcommittees | The IRB Administrator is able to collect reviewer feedback from other subcommittees IRB, IACUC, Safety, and R&D.  This epics will need to be built to accommodate additional committees in the future. |
| 3.8.3/6.7.2 | High | IACUC Administrator | To collect feedback from other subcommittees – IRB, IACUC, Safety, and R&D. | I have the ability to monitor correspondence from other subcommittees. | The IACUC Administrator is able to collect feedback from other subcommittees – IRB, Safety, and R&D.  This epics will need to be built to accommodate additional committees in the future. |
| 3.8.3/6.7.2 | High | Safety Committee Administrator | To collect feedback from other subcommittees – IRB, IACUC, Safety, and R&D. | I have the ability to monitor correspondence from other subcommittees. | The Safety Committee Administrator is able to collect feedback from other subcommittees – IRB, IACUC, and R&D.  This epics will need to be built to accommodate additional committees in the future. |
| 3.8.3/6.7.2 | High | R&D Committee Administrator | To collect feedback from other subcommittees – IRB, IACUC, Safety, and R&D. | I have the ability to monitor correspondence from other subcommittees. | The R&D Committee Administrator is able to collect feedback from other subcommittees –IRB, IACUC, and Safety.  This epics will need to be built to accommodate additional committees in the future. |
| 3.9/6.8 | High | RAMS User | To provide a mechanism for the use of secure electronic signatures for the signing of all forms and correspondence for R&D, Safety, and IACUC committees. | I have the ability to sign documents electronically as part of the study application.  I have the ability to sign documents electronically as part of the approval process.  I have the ability to sign documents electronically to avoid printing of paper documents.  I have the ability to sign documents electronically to avoid distribution of paper documents.  I have the ability to sign documents electronically to avoid storage of paper documents.  NOTE: User can choose to sign electronically when submitting a document that requires signature. | Provide the RAMS User with a mechanism for the use of secure electronic signatures for the signing of all forms and correspondence.   NOTE:  The goal is to get the signatures electronically mandated but not sure if that will happen.  This epics will need to be built to accommodate additional committees in the future. |
| 3.10/6.9 | High | Committee Coordinator | To publish, store, and upload draft and final versions of meeting minutes for the R&D, Safety, and IACUC committees. | I have the ability to publish meeting minutes for R&D committees.  I have the ability to  store minutes of meetings for R&D committees. | Publish and store minutes of meetings  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | I have the ability to upload draft versions of meeting minutes for the R&D committees.  I have the ability to upload final versions of meeting minutes for the R&D committees.  I have the ability to publish meeting minutes for Safety committees.  I have the ability to  store minutes of meetings for Safety committees.  I have the ability to upload draft versions of meeting minutes for the Safety committees.  I have the ability to upload final versions of meeting minutes for the Safety committees.  I have the ability to publish meeting minutes for IACUC committees.  I have the ability to  store minutes of meetings for IACUC committees..  I have the ability to upload draft versions of meeting minutes for the IACUC committees.  I have the ability to upload final versions of meeting minutes for the IACUC committees. |  |
| 3.10.2/6.9.1 | High | Committee Coordinator | To publish, store, and upload draft and final versions of meeting minutes – IACUC, Safety, and R&D | * I have the ability to create IACUC minutes of meetings. * I have the ability to edit IACUC minutes of meetings. * I have the ability to archive IACUC minutes of meetings. * I have the ability to create Safety minutes of meetings. * I have the ability to edit Safety minutes of meetings. * I have the ability to archive Safety minutes of meetings. * I have the ability to create R&D minutes of meetings. * I have the ability to edit R&D minutes of meetings. * I have the ability to archive R&D minutes of meetings * I have the ability to ensure that IACUC meeting minutes are available online to Users who have appropriate permissions. * I have the ability to ensure that IACUC meeting minutes are accessible to Users who have appropriate permissions. * I have the ability to ensure that Safety meeting minutes are available online to Users who have appropriate permissions. * I have the ability to ensure that Safety meeting minutes are accessible to Users who have appropriate permissions. * I have the ability to ensure that R&D meeting minutes are available online to Users who have appropriate permissions. * I have the ability to ensure that R&D meeting minutes are accessible to Users who have appropriate permissions. | The Committee Coordinator is able to publish and store minutes of meetings – IACUC, Safety, and R&D.  This epics will need to be built to accommodate additional committees in the future. |
| 3.10.3/6.9.2 | Medium | IACUC Committee Coordinator | To edit minutes format | I have the ability to revise the format of IACUC meeting minutes. | The IACUC Committee Coordinator is able to revise the format of IACUC minutes format. |
| 3.10.3/6.9.2 | Medium | Safety Committee Coordinator | To edit minutes format | I have the ability to revise the format of Safety meeting minutes. | The Safety Committee Coordinator is able to revise the format of Safety minutes format. |
| 3.10.3/6.9.2 | Medium | R&D Committee Coordinator | To edit minutes format | I have the ability to revise the format of R&D meeting minutes. | The R&D Committee Coordinator is able to revise the format of R&D minutes format. |
| 3.12/6.10 | High | IACUC Administrator, Safety Committee Administrator and R&D Committee Administrator | Provide IACUC, Safety and R&D management Capability | I have the ability to comply with Federal and VA regulations for R&D committees.  I have the ability to comply with Federal and VA regulations for Safety committees.  I have the ability to comply with Federal and VA regulations for IACUC committees. | To adequately satisfy all Federal and VA regulations governing the management of the R&D, Safety, and IACUC committees to include computer usage, storage, and security.  This epics will need to be built to accommodate additional committees in the future. |
| 3.12/6.10.1 | High | IACUC Administrator | To be able to manage all aspects of his/her IACUC committee to ensure compliance with Federal and VA regulations. This includes schedules, meetings, notifications, minutes, and documents. | I have the ability to comply with Federal and VA regulations in the IACUC committees. | Provide management capability - This includes schedules, meetings, notifications, minutes, and documents . |
| 3.12/6.10.1 | High | Safety Committee Administrator | To be able to manage all aspects of his/her Safety committee to ensure compliance with federal and VA regulations. This includes schedules, meetings, notifications, minutes, and documents. | I have the ability to comply with Federal and VA regulations in the Safety committees. | Provide management capability - This includes schedules, meetings, notifications, minutes, and documents . |
| 3.12/6.10.1 | High | R&D Committee Administrator | To be able to manage all aspects of his/her R&D committee to ensure compliance with federal and VA regulations. This includes schedules, meetings, notifications, minutes, and documents. | I have the ability to comply with Federal and VA regulations in the R&D committees. | Provide management capability - This includes schedules, meetings, notifications, minutes, and documents. |
| 3.13/6.11 | High | Committee Coordinator | To track reporting of adverse events, protocol deviations, and protocol exceptions in the R&D, Safety, and IACUC committees. | I have the ability to comply with Federal review events submitted from the PI or PI Designee regarding adverse events, protocol deviations, and VA regulations in the R&D committees.  I have the ability to comply with Federal review events submitted from the PI or PI Designee regarding adverse events, protocol deviations, and VA regulations in the Safety committees. | Track reporting of adverse events, protocol deviations, and protocol exceptions.  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | I have the ability to comply with Federal review events submitted from the PI or PI Designee regarding adverse events, protocol deviations, and VA regulations in the IACUC committees. |  |
| 3.13.2/6.11.1 | High | Committee Coordinator | To track reporting of adverse events, protocol deviations, and protocol exceptions – IACUC,IRB, SRS, and R&D. | I have the ability to track notification regarding adverse events and protocol deviations in IRB committees. I have the ability to coordinate notification regarding adverse events and protocol deviations in IRB committees. I have the ability to maintain records of adverse event documents for filing of required reportsin IRB committees. I have the ability to maintain records of notifications for filing of required reports in IRB committees.  I have the ability to track notification regarding adverse events and protocol deviations in IACUC committees.  I have the ability to coordinate notification regarding adverse events and protocol deviations in IACUC committees..  I have the ability to maintain records of adverse event documents for filing of required reports in IACUC committees..  I have the ability to maintain records of notifications for filing of required reports. | The Committee Coordinator is able to track reporting of adverse events, protocol deviations, and protocol exceptions – IACUC, IRB, and SRS.  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | I have the ability to maintain records of notifications for filing of required reports in IACUC committees.  I have the ability to track notification regarding adverse events and protocol deviations in R&D committees.  I have the ability to coordinate notification regarding adverse events and protocol deviations in R&D committees..  I have the ability to maintain records of adverse event documents for filing of required reports in R&D committees..  I have the ability to maintain records of notifications for filing of required reports in R&D committees.  I have the ability to track notification regarding adverse events and protocol deviations in Safety committees.  I have the ability to coordinate notification regarding adverse  I have the ability to maintain records of adverse event documents for filing of required reports.  I have the ability to maintain records of notifications for filing of required reports. |  |
|  |  |  |  | events and protocol deviations in Safety committees.  I have the ability to maintain records of adverse event documents for filing of required reports in Safety committees.  I have the ability to maintain records of notifications for filing of required reports in Safety committees. |  |
| 3.15/6.12 | Medium | PI or PI Designee | To generate investigational drug information record (Form 10-9012) for the R&D, Safety and IACUC committees. | I have the ability to complete Form 10-9012 in the R&D committees. I have the ability to attach Form 10-9012 to a study application in the R&D committees. I am prompted when an Investigational Drug form is required in the R&D committees. I am prompted when an Investigational Drug form is provided with a link to a fillable version of the form in the R&D committees.  I have the ability to complete Form 10-9012 in the Safety committees.  I have the ability to attach Form 10-9012 to a study application in the Safety committees.  I am prompted when an Investigational Drug form is required in the Safety committees.  I am prompted when an Investigational Drug form is provided with a link to a fillable version of the form in the Safety committees. | PI or PI Designee is able to generate investigational drug information record (Form 10-9012)  After the form is generated, a signature is required by the R&D and IRB chairs.  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | I have the ability to complete Form 10-9012 in the IACUC committees.  I have the ability to attach Form 10-9012 to a study application in the IACUC committees.  I am prompted when an Investigational Drug form is required in the IACUC committees.  I am prompted when an Investigational Drug form is provided with a link to a fillable version of the form in the IACUC committees.  NOTE: If study is of type "Investigational Drug Study", User is prompted to complete Form 10-9012 and link provided. |  |
| 3.16/6.13 | High | Committee Coordinator | To notify investigator when continuing renewals of subcommittee reviews are due in R&D, Safety, and IACUC committees. | I have the ability to notify the PI or PI Designee 60 days before a study expires that a continuing review/annual report is due in R&D committees.  I have the ability to notify the PI or PI Designee 60 days before a study expires that a continuing review/annual report is due in Safety committees.  I have the ability to notify the PI or PI Designee 60 days before a study expires that a continuing review/annual report is due in IACUC committees. | The PI or PI Designee is notified when annual renewals of subcommittee reviews are due.  This epics will need to be built to accommodate additional committees in the future. |
| 3.16.2/6.13.1 | High | PI or PI Designee | To be notified when annual renewals of subcommittee reviews are done – IACUC and IRB | I am notified when an annual review is due in order to complete the annual review of a study and submit in IACUC.  I am notified 90 days before a study expires to submit Annual Report in IACUC. | PI or PI Designee is notified when annual renewals of subcommittee reviews are done – IACUC |
| 3.17/6.14 | Medium | AO and Committee Coordinators | To track Federal-wide Assurances, IRB, R&D, Safety, and IACUC registrations, Memorandums of Understanding (MOUs), and other accreditations in R&D, Safety, and IACUC committees. | I have the ability to track Assurances in the R&D committees. I have the ability to track MOUs in the R&D committees.. I have the ability to track other accreditations in the R&D committees. I have the ability to monitor assurances in order to ensure compliance with Federal and VA regulations in the R&D committees. I have the ability to monitor MOUs in order to ensure compliance with Federal and VA regulations in the R&D committees. I have the ability to monitor accreditations in order to ensure compliance with Federal and VA regulations in the R&D committees.  I have the ability to track Assurances in the Safety committees.  I have the ability to track MOUs in the Safety committees.  I have the ability to track other accreditations in the Safety committees.  I have the ability to monitor assurances in order to ensure compliance with Federal and VA regulations.  I have the ability to monitor MOUs in order to ensure compliance with Federal  .  NOTE: Assurance and Accreditation Checklist is provided on AO landing page. | The AO is able to track Federal Wide Assurances, IRB and IACUC registrations, MOUs, and other accreditations.  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | and VA regulations in the Safety committees.  I have the ability to monitor  accreditations in order to  ensure compliance with  Federal and VA  Regulations in the Safety committees.  I have the ability to track Assurances in the IACUC committees.  I have the ability to track MOUs in the IACUC committees.  I have the ability to track other accreditations in the IACUC committees.  I have the ability to monitor assurances in order to ensure compliance with Federal and VA regulations in the IACUC committees.  I have the ability to monitor MOUs in order to ensure compliance with Federal and VA regulations in the IACUC committees.  I have the ability to monitor accreditations in order to ensure compliance with Federal and VA regulations in the IACUC committees. |  |
| 3.18/6.15 | High | LA (Local System Administrator) | To allow for site specific committee configurations and workflows in the R&D, Safety, and IACUC committees. | I have the ability to configure the workflow for each R&D committee.  I have the ability to configure the workflow for each Safety committee.  I have the ability to configure the workflow for each IACUC committee. | The LA is able to implement site specific committee configurations and workflows.  This epics will need to be built to accommodate additional committees in the future. |
| 3.18/6.15 | High | SA | To allow for site specific committee configurations and workflows R&D, Safety, and IACUC committees. | I have the ability to configure the workflows within and among R&D committees in order to comply with local situation and SOPs.  I have the ability to configure the workflows within and among Safety committees in order to comply with local situation and SOPs.  I have the ability to configure the workflows within and among IACUC committees in order to comply with local situation and SOPs.  NOTE: Workflow configuration tool is available on the LSA landing page. | The SA is able to implement site-specific committee configurations and workflows  This epics will need to be built to accommodate additional committees in the future. |
| 3.19/6.16 | Medium | RCO | Provide compliance checklist for RCO and the Safety committees. | The RCO should be able to have a version of the ORO checklist online.  The RCO should be able to have an online version of the checklist available in order to complete compliance reports.  The Safety committee should be able to have a version of the ORO checklist online.  The Safety committee should be able to have an online version of the checklist available in order to complete compliance reports.  NOTE: Checklist is available on RCO landing page. | The RCO is able to obtain the compliance checklist online. |
| 3.2/6.17 | High | PI or PI Designee | Automate creation of Research Protocol Safety Survey (RPSS) (VA Form 10-0398) | The PI or PI Designee must be able to submit Form 10-0398 as a component of a study application.  The PI or PI Designee must be able to complete the Safety Survey in order to determine which types of safety reviews may be required.  NOTE: A link is available in the online study application to access and complete Form 10-0398 (for IRB only) | The PI or PI Designee is able to access, fill out and submit an automated Research Protocol Safety Survey (RPSS) (VA Form 10-0398) online. |
| 3.21/6.18 | High | Associate Chief of Staff (ACOS) | To be provided with a landing page for ACOS and AOin the R&D, Safety, and IACUC committees. | The ACOS will be provided with a landing page in the R&D committees.  The ACOS will be provided with a landing page in the Safety committees.  The ACOS will be provided with a landing page in the IACUC committees. | The ACOS will be provided with a landing page.  This epics will need to be built to accommodate additional committees in the future. |
| 3.21/6.18 | High | AO | To be provided with a landing page for ACOS and AO in the R&D, Safety, and the IACUC committees.  AO – Administrative Officer  ACOS - Assistant Chief of Staff | The AO will be provided with a landing page in the R&D committees.  The AO will be provided with a landing page in the Safety committees.  The AO will be provided with a landing page in the IACUC committees. | The AO will be provided with a landing page.  This epics will need to be built to accommodate additional committees in the future. |

The table below lists the Epic and detailed User Narratives (Business Requirements) for BN4/Elaboration Business Requirement 7.

Table 6: Epic BN4

| Epic BN4: Manage data about personnel engaged in research at VAMC facilities. | | | | | |
| --- | --- | --- | --- | --- | --- |
| ID | Priority | As a… | I want… | So that… | Acceptance Criteria/User Story Notes |
| 4.2 | High – automate connections between Collaborative Institutional Training (CITI), Talent Management System (TMS) and RAMS | Principal Investigator or PI Designee and Committee Coordinators | To automate the tracking of training, scope of practice, and all necessary certifications for PIs and other employees in the R&D, Safety, and IACUC committees. | I have the ability to track the training status of personnel attached to a study in the R&D committee. I have the ability to certify that personnel attached to a study have the prerequisite and requisite training in order to meet Federal and VA guidelines, rules, and regulations in the R&D committee. I have the ability to certify that personnel attached to a study have the certifications in order to meet Federal and VA guidelines, rules, and regulations in the R&D committee.  I have the ability to track the training status of personnel attached to a study in the Safety committee.  I have the ability to certify that personnel attached to a study have the prerequisite and requisite training in order to meet Federal and VA guidelines, rules, and regulations in the Safety committee.  I have the ability to certify that personnel attached to a study have the certifications in order to meet Federal and VA guidelines, rules, and regulations in the Safety committee.  I have the ability to track the training status of personnel attached to a study in the IACUC committee.  I have the ability to certify that personnel attached to a study have the prerequisite and requisite training in order to meet Federal and VA guidelines, rules, and regulations in the IACUC committee.  I have the ability to certify that personnel attached to a study have the certifications in order to meet Federal and VA guidelines, rules, and regulations in the IACUC committee. | To be able to automate the tracking of training, scope of practice, and all necessary certifications for PIs and other employees.  NOTE: A training record is available for research personnel and notifications are sent to the PI or PI Designee and User when training is about to expire.  This epics will need to be built to accommodate additional committees in the future. |
| 4.3 | Medium | Principal Investigator or PI Designee and RAMS User | To notify PI or PI Designee and employee when training is required including annual/biannual re-training in the R&D, Safety, and IACUC committees. | I have the ability to have a link to reference what training is required for every assigned research task in the R&D committee. I have the ability to be notified if a team member’s training is about to expire in order to maintain a qualified staff in the R&D committee. I have the ability to have a link to know what training is required for my assigned research tasks in the R&D committee.  I have the ability to have a link to reference what training is required for every assigned research task in the Safety committee.  I have the ability to be notified if a team member’s training is about to expire in order to maintain a qualified staff in the Safety committee.  I have the ability to have a link to know what training is required for my assigned research tasks in the Safety committee. | To be able to notify PI or PI Designee and employee when training is required including annual/biannual re-training.  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | I have the ability to have a  link to reference what  training is required for every assigned research  task in the IACUC committee.  I have the ability to be  notified if a team member’s training is  about to expire in order to maintain a qualified staff in the IACUC committee.  I have the ability to have a  link to know what training is required for my assigned research tasks in the IACUC committee. |  |
| 4.4 | Medium | Administrative Officer | To notify Without Compensation (WOC)/In-Person Authentication (IPA)/VA employee and sponsor when appointment renewal is required in the R&D, Safety, and IACUC committees. | I have the ability to be informed when WOC employee appointments are about to expire in the R&D committee. I have the ability to monitor WOC appointments to ensure all research staff is qualified in the R&D committee.  I have the ability to be informed when WOC employee appointments are about to expire in the Safety committee.  I have the ability to monitor WOC appointments to ensure all research staff is qualified in the Safety committee.    I have the ability to be informed when WOC employee appointments are about to expire in the IACUC committee.  I have the ability to monitor WOC appointments to ensure all research staff is qualified in the IACUC committee. | To be able to notify WOC/IPA/VA employee and sponsor when appointment renewal is required.  NOTE: Report of WOC staff and appointment status is available from AO landing page.  This epics will need to be built to accommodate additional committees in the future. |
| 4.5 | Low | Administrative Officer | To track key, personal computer (PC), and badge assignments/issues in the R&D, Safety, and the IACUC committees. | I have the ability to access data that links personnel to badges in the R&D committee. I have the ability to access data that links personnel to keys in the R&D committee. I have the ability to access data that links personnel to equipment in the R&D committee.  I have the ability to ensure that badges are assigned to the appropriate personnel in order to maintain physical security in the R&D committee. I have the ability to ensure that keys are assigned to the appropriate personnel in order to maintain physical security in the R&D committee.  I have the ability to access data that links personnel to badges in the Safety committee.  I have the ability to access data that links personnel to keys in the Safety committee. | To be able to track key, PC, and badge assignments/issues.  NOTE: Report of key, badges, and equipment assigned to personnel is available on the AO landing page.  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | I have the ability to access data that links personnel to equipment in the Safety committee.  I have the ability to ensure that badges are assigned to the  appropriate personnel in order to maintain physical  security in the Safety committee.  I have the ability to ensure that keys are  assigned to the appropriate personnel in  order to maintain physical security in the Safety committee.  I have the ability to access data that links personnel to badges in the IACUC committee.  I have the ability to access data that links personnel to keys in the IACUC committee.  I have the ability to access data that links personnel to equipment in the IACUC committee.  I have the ability to ensure that badges are assigned to the appropriate personnel in order to maintain physical security in the IACUC committee.  I have the ability to ensure that keys are assigned to the appropriate personnel in order to maintain physical security in the IACUC committee. |  |
| 4.6 | Low | Administrative Officer | To track and certify effort on projects in the R&D, Safety, and the IACUC committees. | I have the ability to monitor labor charged to research projects at a station for the R&D committee. I have the ability to monitor effort on projects to avoid cost overruns for the R&D committee.  I have the ability to monitor labor charged to research projects at a station for the Safety committee.  I have the ability to monitor effort on projects to avoid cost overruns for the Safety committee.  I have the ability to monitor labor charged to research projects at a station for the IACUC committee.  I have the ability to monitor effort on projects to avoid cost overruns for the IACUC committee. | To be able to track and certify effort on projects.  This epics will need to be built to accommodate additional committees in the future. |
| 4.7 | Medium | Committee Coordinator | To track COI Disclosures in the R&D, Safety, and IACUC committees. | I have the ability to track COI disclosures for submitted study application and renewals in the R&D committees.  I have the ability to track COI disclosures for submitted study application and renewals in the Safety committees.  I have the ability to track COI disclosures for submitted study application and renewals in the IACUC committees. | To be able to track COI Disclosures.  This epics will need to be built to accommodate additional committees in the future. |
| 4.8 | High | Principal Investigator or PI Designee | To add personnel to study team; set roles and notificationsin the R&D, Safety, and IACUC committees. | I have the ability to add personnel to the study team in the R&D committees. I have the ability to set roles for each study in the R&D committees.  I have the ability to add personnel to the study team in the Safety committees.  I have the ability to set roles for each study in the Safety committees..  I have the ability to add personnel to the study team in the IACUC committees.  I have the ability to set roles for each study in the IACUC committees. | To be able to add personnel to study team; set roles and notifications.  This epics will need to be built to accommodate additional committees in the future. |
| 4.9 | High | Committee Coordinator | To receive a notification when changes or additions are made to the study team in the R&D, Safety, and IACUC committees. | I can be aware of additions of changes made by the PI or PI Designee in the R&D committees.  I can be aware of additions of changes made by the PI or PI Designee in the Safety committees.  I can be aware of additions of changes made by the PI or PI Designee in the IACUC committees. | To receive notifications when personnel are added/removed from the study team.  This epics will need to be built to accommodate additional committees in the future. |

The table below lists the Epic and detailed User Narratives (Business Requirements) for BN5/Elaboration Business Requirement 8.

Table 7: Epic BN5

| Epic BN5: Manage data about laboratory space and safety. | | | | | |
| --- | --- | --- | --- | --- | --- |
| ID | Priority | As a… | I want… | So that… | Acceptance Criteria/User Story Notes |
| 5.1 | Medium | Administrative Officer | To track laboratory space allocations R&D, Safety, and IACUC committees. | I have the ability to have data about how lab space is allocated and who is responsible for each lab in the R&D committee. I have the ability to track usage of lab space to ensure that facilities for VA research are available in the R&D committee.  I have the ability to have data about how lab space is allocated and who is responsible for each lab in the Safety committee..  I have the ability to track usage of lab space to ensure that facilities for VA research are available in the Safety committee.  I have the ability to have data about how lab space is allocated and who is responsible for each lab in the IACUC committee.  I have the ability to track usage of lab space to ensure that facilities for VA research are available in the IACUC committee. | To be able to track laboratory space allocations.  NOTE: Lab Space Report is accessible from the AO landing page.  This epics will need to be built to accommodate additional committees in the future. |
| 5.2 | Medium | Principal Investigator or PI Designee | To add data to laboratory inspection form in the Safety committees. | I have the ability to track lab inspections in the Safety committees.  I have the ability to record lab inspections in the Safety committees.  I have the ability to ensure that lab inspections are up to date in order to avoid shutdowns in the Safety committees. | To be able to add data to laboratory inspection form.  NOTE: Atlanta VAMC LASIF form available online as a component of RAMS. |
| 5.3 | Medium | Administrative Officer and Principal Investigator or PI Designee | To generate and track annual lab safety self-evaluation forms and lab safety in the Safety committees. | I have the ability to track various lab safety reports in the Safety committees.  I have the ability to ensure that lab inspections are up to date in order to avoid shutdowns in the Safety committees. | To be able to generate and track annual lab safety self-evaluation forms and lab safety.  NOTE: LASIF form available online as a component of RAMS. |
| 5.4 | Medium | Principal Investigator or PI Designee | To maintain inventory of chemicals, select agents, and biohazards of the Safety commitee. | I have the ability to monitory inventory of chemicals in the Safety committees.  I have the ability to monitor inventory of biohazards in the Safety committees.  I have the ability to access data detailing stored chemicals in order to comply with Federal regulations in the Safety committees.  I have the ability to access data detailing stored miscellaneous agents in order to comply with Federal regulations in the Safety committees.  I have the ability to specify if materials are lab specific in the Safety committees. | To be able to maintain inventory of chemicals, select agents, and biohazards. |
| 5.5 | Medium | Administrative Officer | To manage tissue bank location data in the R&D, Safety and IACUC committees. | I have the ability to monitor information about a tissue bank in the R&D committees.  I have the ability to monitor information about a tissue bank in the Safety committees.  I have the ability to monitor information about a tissue bank in the IACUC committees. | To be able to manage tissue-banking data.  This epics will need to be built to accommodate additional committees in the future. |
| 5.6 | Medium | Administrative Officer | To manage data sharing agreements, data repository approvals, and annual reports in the R&D, Safety, and IACUC committees. | I have the ability to manage electronic versions of data sharing agreements in the R&D committees. I have the ability to manage electronic versions of data repository agreements in the R&D committees. I have the ability to have legal prepared reviews that require MOU agreements in the R&D committees. I have the ability to have regulatory reviews that require MOU agreements in the R&D committees. I have the ability to have regulatory reviews that require data sharing agreements in the R&D committees.  I have the ability to manage electronic versions of data sharing agreements in the Safety committees.  I have the ability to manage electronic versions of data repository agreements in the Safety committees. | To be able to manage data sharing agreements, data repository approvals, and annual reports.  NOTE: Data sharing agreements are stored as tagged documents.  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | I have the ability to have legal prepared reviews that require MOU agreements in the Safety committees.  I have the ability to have  regulatory reviews that require MOU agreements in the Safety committees.  I have the ability to have regulatory reviews that require data sharing  Agreements in the Safety committees.  I have the ability to manage electronic versions of data sharing agreements in the Safety committees.  I have the ability to manage electronic versions of data repository agreements in the Safety committees.  I have the ability to have legal prepared reviews that require MOU agreements in the Safety committees. |  |
|  |  |  |  | I have the ability to have regulatory reviews that require MOU agreements in the Safety committees.  I have the ability to have regulatory reviews that require data sharing agreements in the Safety committees. |  |
| 5.7 | Medium | Animal Facility Manager (AFM) | To manage animal census in the IACUC and Safety committee. | I have the ability to maintain a census of animals stored in our Veterinary Medical Unit (VMU) in the IACUC committees.  I have the ability to maintain an up-to-date animal census to ensure that animals are available for studies in the Safety committees.  I have the ability to ensure the AFM is a role in RAMS and in the Safety committees.. | To be able to manage animal census. |

The table below lists the Epic and detailed User Narratives (Business Requirements) for BN6/Elaboration Business Requirement 9.

Table 8: Epic BN6

| Epic BN6: Central Office reporting requirements. | | | | | |
| --- | --- | --- | --- | --- | --- |
| ID | Priority | As a… | I want… | So that… | Acceptance Criteria/User Story Notes |
| 6.1 | Medium | Administrative Officer | To create real-time expenditure reports R&D, Safety, and IACUC committees. | I have the ability to complete reports that detail expenditures by Fiscal Year (FY) in the R&D committees. I have the ability to allocate expenditures to research projects in order to ensure each is within budget in the R&D committees..  I have the ability to complete reports that detail expenditures by Fiscal Year (FY) in the Safety committees.  I have the ability to allocate expenditures to research projects in order to ensure each is within budget in the Safety committees.  I have the ability to complete reports that detail expenditures by Fiscal Year (FY) in the IACUC committees.  I have the ability to allocate expenditures to research projects in order to ensure each is within budget in the IACUC committees. | To be able to create real-time expenditure reports.  This epics will need to be built to accommodate additional committees in the future. |
| 6.2 | High | Administrative Officer | To provide query and reporting tools for administrative research data in the R&D, Safety and IACUC. | I have the ability to respond to data requests from Central Office in the R&D committees. I have the ability to respond to status requests from Central Office in the R&D committees.  I have the ability to respond to data requests from Central Office in the Safety committees.  I have the ability to respond to status requests from Central Office in the Safety committees.  I have the ability to respond to data requests from Central Office in the IACUC committees.  I have the ability to respond to status requests from Central Office in the IACUC committees. | To be able to provide query and reporting tools for administrative research data.  This epics will need to be built to accommodate additional committees in the future. |
| 6.12 | High | RAMS User | To export raw data in XML that can be analyzed with third-party business intelligence analysis and visualization tools in the R&D, Safety, and IACUC committees. | I have the ability to export data for use in Microsoft (MS) Excel and other analysis packages in the R&D committees. I have the ability to export data for use in other analysis packages in the R&D committees. I have the ability to export data to MS PowerPoint in order to make presentation graphs in the R&D committees.  I have the ability to export data for use in Microsoft (MS) Excel and other analysis packages in the Safety committees.  I have the ability to export data for use in other analysis packages in the Safety committees.  I have the ability to export data to MS PowerPoint in order to make presentation graphs in the Safety committees.  I have the ability to export data for use in Microsoft (MS) Excel and other analysis packages in the IACUC committees. | To be able to export raw data in XML that can be analyzed with third-party business intelligence analysis and visualization tools.  This epics will need to be built to accommodate additional committees in the future. |

Table 9: Epic BN7

| Epic BN7: System will interface with VA systems | | | | | |
| --- | --- | --- | --- | --- | --- |
| ID | Priority | As a… | I want… | So that… | Acceptance Criteria/User Story Notes |
|  |  |  |  | I have the ability to export data for use in other analysis packages in the IACUC committees.  I have the ability to export data to MS PowerPoint in order to make presentation graphs in the IACUC committees. |  |
| 7.2/10.2 | Medium | Administrative Officer | to support automated data import from Collaborative Institutional Training (CITI). | the CITI system must interface with RAMS and the CITI training data will available to RAMS users. | The AO is able to access data in CITI using RAMS. |
| 7.5/10.5 | Medium | Administrative Officer | to support automated data import from Talent Management System (TMS). | the TMS must interface with RAMS in order to access the RAMS training records. | The AO is able to access data in TMS using RAMS. |

The table below lists the Epic and detailed User Narratives (Business Requirements) for BN8. This Business Requirement was not in the initial Business Requirements Document (BRD). Updates will be made to the BRD. The table below was not included in the initial Research Office, all committeesElaboration Business Requirements document.

Table 10: Epic BN8

| Epic BN8: The system will create a Document Management Process. | | | | | |
| --- | --- | --- | --- | --- | --- |
| ID | Priority | As a… | I want… | So that… | Acceptance Criteria\User Story Notes |
| 8.1 | High | * Administrative Officer * Associate Chief of Staff for Research * Committee Coordinator/ * Committee Administrator * Principle Investigator or PI Designee * Co-Principle Investigator * IRB Administrator * IRB Chair * IRB Member * IRB Staff * Local Site * Investigator (CIRB Role Only) * Local RAMS Administrator * Study Coordinator * ORD Administrator | The system to allow editing, printing, and storage of IRB, IACUC, R&D and Safety documents. | The system must allow editing of IRB documents.  The system must allow printing of IRB documents.  The system must allow storage of IRB documents.  The system must allow editing of IACUC documents.  The system must allow printing of IACUC documents.  The system must allow storage of IACUC documents.  The system must allow editing of R&D documents.  The system must allow printing of R&D documents.  The system must allow storage of R&D documents.  The system must allow editing of Safety documents.  The system must allow printing of Safety documents.  The system must allow storage of Safety documents. | The system will successfully edit, print, and store documents for each committee.  This epics will need to be built to accommodate additional committees in the future. |

The table below lists the Epic and detailed User Narratives (Business Requirements) for BN8. This Business Requirement was not in the initial Business Requirements Document (BRD). Updates will be made to the BRD. The table below was not included in the initial Elaboration Business Requirements document.

Table 11: Epic BN9

| Epic BN9: Develop a Reporting Management Module | | | | | |
| --- | --- | --- | --- | --- | --- |
| ID | Priority | As a… | I want… | So that… | Acceptance Criteria/User Story Notes |
| 9.1 | High | Committee Coordinator/Committee Administrator, IRB Administrator, IRB Staff | To integrate a complete reporting capability for User defined and pre-defined generated reports in the R&D, Safety, and IACUC committees. | I have tracking capabilities for necessary R&D committee activity.  I have tracking capabilities for necessary Safety committee activity.  I have tracking capabilities for necessary IACUC committee activity. | I have tracking capabilities for necessary committee activity.  This epics will need to be built to accommodate additional committees in the future. |
| 9.2 | High | Administrative Officer,  Associate Chief of Staff for Research, Committee Coordinator/ Committee Administrator, IRB Administrator, IRB Staff | To see a study listing by Local Site in the R&D, Safety, and IACUC committees. | Reports can be printed out by site listing all of the studies open at those sites to include IRB Number, funding agency, study title, the LSI/Co-LSIs, approval date, and continuing review expiration date in the IRB committees.  Reports can be printed out by site listing all of the studies open at those sites to include R&D Number, funding agency, study title, the LSI/Co-LSIs, approval date, and continuing review expiration date in the R&D committees.  Reports can be printed out by site listing all of the studies open at those sites to include Safety Number, funding agency, study title, the LSI/Co-LSIs, approval date, and continuing review expiration date in the Safety committees.  Reports can be printed out by site listing all of the studies open at those sites to include IACUC Number, funding agency, study title, the LSI/Co-LSIs, approval date, and continuing review expiration date in the IACUC committees. | Reports can be printed out by site listing all of the studies open at those sites to include IRB Number, funding agency, study title, the LSI/Co-LSIs, approval date, and continuing review expiration date.  This epics will need to be built to accommodate additional committees in the future. |
| 9.3 | High | Committee Coordinator/ Committee Administrator, IRB Administrator, IRB Staff | To retrieve an Active study listing in the R&D, Safety, and IACUC committees. | A listing of all active studies can be retrieved by IRB number, funding source, whether study is FDA-regulated, study title, number of sites, PI/Co-PIs, Primary Reviewer, Assigned VA Central IRB Manger, Risk Level, Approval Date, Continuing Review, and Approval Expiration Date. (I am assuming that we will be able to sort this particular report to run a report, for example, only FDA-regulated studies or only studies funded by CSP in the R&D committees.  A listing of all active studies can be retrieved by IRB number, funding source, whether study is FDA-regulated, study title, number of sites, PI/Co-PIs, Primary Reviewer, Assigned VA Central IRB Manger, Risk Level, Approval Date, Continuing Review, and Approval Expiration Date. (I am assuming that we will be able to sort this. | To retrieve an Active study listing.  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | particular report to run a report, for example, only FDA- regulated studies or only studies funded by CSP in the Safety committees.  A listing of all active studies can be retrieved by IRB number, funding source, whether study is FDA-regulated, study title, number of sites, PI/Co-PIs, Primary Reviewer, Assigned VA Central IRB Manger, Risk Level, Approval Date, Continuing Review, and Approval Expiration Date. (I am assuming that we will be able to sort this particular report to run a report, for example, only FDA-regulated studies or only studies funded by CSP in the IACUC committees. |  |
| 9.4 | High | Committee Coordinator/ Committee Administrator, R&D Administrator, R&D Staff, Safety Administrator, Safety Staff, IACUC Administrator, IACUC Staff | To retrieve an Expedited Listing in the R&D, Safety, and IACUC committees. | A report can be run for a specified period of time to report all study action approved under expedited procedures for the next Board meeting in the R&D committees. This includes approval of new studies, local sites, continuing reviews of both PI and LSI Applications, and PI and LSI Amendments, as well as review and action taken on UAP, SAE, Protocol Deviation, Site Closure, and Study Closure Reports for the R&D committee.  A report can be run for a specified period of time to report all study action approved under expedited procedures for the next Board meeting for the Safety committee. This includes approval of new studies, local sites, continuing reviews of both PI and LSI Applications, and PI and LSI Amendments, as well as review and action taken on UAP, SAE, Protocol Deviation, Site Closure, and Study | To retrieve an Expedited Listing  This epics will need to be built to accommodate additional committees in the future. |
|  |  |  |  | Closure Reports in the Safety committees.  A report can be run for a specified period of time to report all study action approved under expedited procedures for the next Board meeting the IACUC committee. This includes approval of new studies, local sites, continuing reviews of both PI and LSI Applications, and PI and LSI Amendments, as well as review and action taken on UAP, SAE, Protocol Deviation, Site Closure, and Study Closure Reports in the IACUC committees. |  |
| 9.5 | High | Administrative Officer,  Associate Chief of Staff for Research, Committee Coordinator/ Committee Administrator,R&D Administrator, R&D Staff, Safety Administrator, Safety Staff, IACUC Administrator, IACUC Staff | To retrieve a Listing of studies due continuing review run for specified periods in the R&D, Safety, and IACUC committees. | A listing of studies due continuing review can be run for specified periods showing R&D number, study title, date due, date report received, date CR approved, and date CR reported to Board for expedited review, if applicable. Also includes sub headings of sites for each study listing: site, LSI, date report received, date approved, and date expedited review reported to R&D if applicable in the R&D committees.  A listing of studies due continuing review can be run for specified periods showing Safety number, study title, date due, date report received, date CR approved, and date CR reported to Board for expedited review, if applicable. Also includes sub headings of sites for each study listing: site, LSI, date report received, date approved, and date expedited review reported to Safety if applicable in the Safety committees.  A listing of studies due continuing review can be run for specified periods showing IACUC number, study title, date due, date report received, date CR approved, and date CR reported to Board for expedited review, if applicable. Also includes sub headings of sites for each study listing: site, LSI, date report received, date approved, and date expedited review reported to IACUC if applicable in the IACUC committees. | To retrieve a Listing of studies due continuing review run for specified periods.  This epics will need to be built to accommodate additional committees in the future. |
| 9.6 | High | Committee Coordinator/ Committee Administrator, R&D Administrator, R&D Staff, Safety Administrator, Safety Staff, IACUC Administrator, IACUC Staff | To retrieve a Listing of closed projects and sites in the R&D, Safety, and IACUC committees. | I can differentiate between site study closure and main study closure in the R&D application.  I can differentiate between site study closure and main study closure in the Safety application.  I can differentiate between site study closure and main study closure in the IACUC application. | I can differentiate between site study closure and main study closure.  This epics will need to be built to accommodate additional committees in the future. |
| 9.7 | High | Committee Coordinator/ Committee Administrator, R&D Administrator, R&D Staff, Safety Administrator, Safety Staff, IACUC Administrator, IACUC Staff | To retrieve study Action Reports in the R&D, Safety and IACUC committee application. | A listing of all pending open actions that can also be broken down and run by specific action such as pre-reviews, new studies, PI and LSI amendments, Local Site Applications, Updates, SAE/UAPs, Protocol Deviations, Updates in Progress, and Review of Audit and Closure Reports R&D committee application.  A listing of all pending open actions that can also be broken down and run by specific action such as pre-reviews, new studies, PI and LSI amendments, Local Site Applications, Updates, SAE/UAPs, Protocol Deviations, Updates in Progress, and Review of Audit and Closure Reports Safety committee application.  A listing of all pending open actions that can also be broken down and run by specific action such as pre-reviews, new studies, PI and LSI amendments, Local Site Applications, Updates, SAE/UAPs, Protocol Deviations, Updates in Progress, and Review of Audit and Closure Reports IACUC committee application. | To retrieve study Action Reports.  This epics will need to be built to accommodate additional committees in the future. |
| 9.8 | High | Administrative Officer,  Associate Chief of Staff for Research, Committee Coordinator/ Committee Administrator | Review the Action Reports in the R&D, Safety, and IACUC committee application. | A listing of all open actions by assigned VA Central IRB Manager or Reviewer will include study status notes R&D committee application.  A listing of all open actions by assigned VA Central IRB Manager or Reviewer will include study status notes Safety committee application.  A listing of all open actions by assigned VA Central IRB Manager or Reviewer will include study status notes IACUC committee application. | A listing of all open actions by assigned VA Central IRB Manager or Reviewer will include study status notes.  This epics will need to be built to accommodate additional committees in the future. |
| 9.9 | High | Administrative Officer,  Associate Chief of Staff for Research, Committee Coordinator/ Committee Administrator | To receive an annual report from each committee member to the RDC (that includes –   * Committee Review Statistics * Committee Review Statistics- Committee Members * Committee Review Statistics – Events * Committee Review Statistics – Initial Approvals   Committee Review Statistics – Reviewers for the R&D, safety, and IACUC committees. | I can review ongoing activities of the R&D committee.  I can review ongoing activities of the Safety committee.  I can review ongoing activities of the IACUC committee. | I can review ongoing activities of the committee.  This epics will need to be built to accommodate additional committees in the future. |
| 9.10 | High | Administrative Officer,  Associate Chief of Staff for Research, Committee Coordinator/ Committee Administrator, R&D Administrator, R&D Staff, Safety Administrator, Safety Staff, IACUC Administrator, IACUC Staff | Receive an annual report  For Director’s Certification including the following details:   * Protocols searches * Summary – Protocol Counts by Type/Status * Summary – Active Protocols * Protocol Details by PI * By Type (Animal, Animal/Human, Human, Science-Safety, Science- only, ACORP) * By Status (Active, Pending, Closed, Expired, etc.) * By Event Type, Item Type   in the R&D, Safety, and IACUC committees. | I can review ongoing activities of the R&D committee.  I can review ongoing activities of the Safety committee.  I can review ongoing activities of the IACUC committee. | I can review ongoing activities of the committee.  This epics will need to be built to accommodate additional committees in the future. |
| 9.11 | High | Administrative Officer,  Associate Chief of Staff for Research | To receive a report from each of the committees with the following information: (Committee Rosters, training and appointment expiration dates   * Initial approval dates * Continuing Reviews   o Approvals – Expiration Unknown [No CR Mths]  o Approvals – Expired  o Approvals – Unexpired [No CR Event]  in the R&D, Safety, and IACUC committees. | I can review ongoing activities of the R&D committee.  I can review ongoing activities of the Safety committee.  I can review ongoing activities of the IACUC committee. | I can review ongoing activities of the committee.  This epics will need to be built to accommodate additional committees in the future. |
| 9.12 | High | Administrative Officer,  Associate Chief of Staff for Research, Committee Coordinator/ Committee Administrator, R&D Administrator, Safety Administrator, IACUC Administrator | To research financial conflict of interest in the R&D, Safety, and IACUC committees. | Financial conflict of interest can be managed in the R&D committees.  Financial conflict of interest can be managed in the Safety committees.  Financial conflict of interest can be managed in the IACUC committees. | Financial conflict of interest can be managed.  This epics will need to be built to accommodate additional committees in the future. |

## Graphical User Interface (GUI) Specifications

No new GUI Specifications have been defined at this time. The RAMS Integration development team will add additional graphics, coordinated with the sustainment team, as necessary.

## Multi-Divisional Specifications

From the perspective of the end User, there are no functional differences between User location and the functionalities provided by the RAMS Integration.

## Performance Specifications

The requirements listed in this section are the same as existing RAMS requirements.

The solution performance specifications solution will execute performance, capacity, and independent testing of its product, and as part of Software Quality Assurance (SQA) analysis and testing.

The ORD aims to improve the efficiency and performance of the national VA research program by implementing an enterprise-wide research administrative management system accessible to:

* ORD Central Office.
* Active field research offices

The implemented tool will support the major business functions of the:

* Local Research Office
* Management of the Research and Development (R& D) Committee and its subcommittees (Institutional Review Board (IRB)
* Institutional Animal Care and Use Committee (IACUC)
* Subcommittee on Research Safety (SRS)
* Local research office reporting to ORD

This new functionality will provide a common database for tracking and reporting of administrative research program data throughout the VA.

The following table provides the capacity and performance information for the RAMS Integration.

Table 12: Capacity and Performance

| SLR Question | SLR Criteria |
| --- | --- |
| How many Users will be on the system hourly? | 101-1000 estimated |
| How many transactions will each average User perform each hour? | >10 estimated |
| What are the anticipated peak User times during the day? | Business day (highest peak User times Mon. through Fri. during administrative hours) |
| What is the anticipated peak transaction load (when do you think that there will be the most transactions being performed on the system) during the day? | Business day (highest peak User times Mon. through Fri. during administrative hours) |
| How many new Users will be added in one year? | 101-1000 estimated |
| How many more (if any) transactions will be added in one year? | >10 estimated |
| What kind of information will be stored? (Specify average of each kind per month) | Small documents (example pdf or Word file)  Forms & Documents that are formatted (example forms or documents with images |
| What kind of search capacity is required? | Medium (11-1000 per hour)  estimated |
| What type of system(s) is/are required? | Web based and managed from central service and database  Intranet (All VA) |
| Is there a need for heavy application reporting? If yes, when? | End of day, End of month, End of quarter |

**Existing Performance Specification Requirements**

* RAMS service consumers shall consume services offered by a service provider in accordance with the service contract.
* The RAMS Service Level Agreement (SLA) component of the service contract shall be negotiated with the service provider.
* The RAMS SLA shall not be unique to the service consumer, and it is preferable that it not be unique.
* RAMS shall support Users at peak usage levels, where peak usage is defined in the Users’ Service Level Agreement.
* RAMS hardware and software resources shall be sufficiently scalable to support increased workloads by adding equivalent resources.
* RAMS shall process and use Coordinated Universal Time (UTC) for internal and external time synchronization.
* RAMS shall support 1000 concurrent Users at peak usage levels, where peak usage is defined in the Users’ Service Level Agreement.
* The data in the RAMS datamart shall be refreshed from the operational database once a day.
* RAMS Users shall have consistent response times when accessing RAMS capabilities during normal operation.
* RAMS Users may experience degraded performance when accessing RAMS capabilities from the disaster recovery site when in failure or recovery mode.

Recurring discussions with the Systems Engineering and Design Review (SEDR) workgroup will articulate requirements for performance and capacity transactions.

## Quality Attributes Specification

The requirements listed in this section are the same as existing RAMS requirements.

Processes for artifact delivery will follow ProPath guidelines, including quality gate reviews for requirements, design, code, test plans/cases/executions, and other document deliverables.

The RAMS Integration services will comply with the quality specifications set forth by the VA PMAS Quality specifications.

The following types of testing will be performed to assess the quality of the solution:

* Unit testing
* Integration / functional testing
* User Acceptance Testing (UAT)
* Section 508 testing
* Performance testing

The RAMS Integration services will also consist of the following quality specifications:

* The system comprises tools, applications, and software that conform to the VA’s standard server and database operating systems. The VA Technical Reference Model (TRM) provides more information.
* The system is designed to operate in VA’s standard, virtualized, operating system environment according to the VA TRM.

Additionally, as previously defined, the following quality specifications will be adhered to:

* The RAMS Integration services shall apply open data standards where possible, such as W3C/IETF, REST, SOAP, and OASIS.
* Services shall apply open schemas and not create custom schema definitions where possible. This is to include service interface standards as well.

## Reliability Specifications

The requirements listed in this section are the same as existing RAMS requirements.

The first step in the reliability engineering process is to specify the required reliability that the equipment/system must be designed to achieve. The essential elements of a reliability specification are:

* A quantitative statement of the reliability requirement;
* A full description of the environment in which the equipment/system will be stored, transported, operated and maintained;
* The time measure or mission profile;
* A clear definition of what constitutes failure; and
* A description of the test procedure, with accept/reject criteria that will be used to demonstrate the specified reliability

The RAMS solution must be available 24 hours per day and 7 days a week The entire application is monitored at multiple tiers, from application performance/tuning, hardware and infrastructure (CPU, memory, I/O), to network performance monitoring and control. Reliability Specification requirements ensure the uptimes of the systems are met, ensure monitoring services, and proactively respond to projected system demands.

Monitoring also provides capacity trending, allowing proactive system modifications or planning for upgrades.

The system must be reliable and enable User trust. The following summarizes requirements for the new functionality from RAMS Integration reliability specifications by providing the following:

* Stable and reliable performance
* Availability – The system shall be available 24 hours per day and 7 days a week
* Accurate data – The system shall return entries exactly as they were passed with no modification.
* Defect repair – It is expected that all defects related to the implementation get resolved during initial development and subsequent UAT testing.
* Display of all data that is available in native or interfaced systems and intended to be available in the application
* Accessible information related to the source of data
* When the system goes live in Production, the development team will address defects of a critical nature that are deemed “show stoppers.” Enhancement requests made after ‘go-live’ will be logged for consideration in a future, coordinated release.

The following table lists the availability of the RAMS Integration system.

Table 13: Availability

| SLR Question | SLR Criteria | Description |
| --- | --- | --- |
| How much time should the system be available (and how much down time is acceptable due to incident [unexpected] outage)? | 99.9% (8.76 hours down time) | Intentionally left blank. |
| When should the system be available (what will be the core operating hours of the system)? | 8 a.m. to 8 p.m., EST, Mon. through Fri. | The system shall require no more than 24 hours of maintenance per month. Servicing and maintenance is expected to occur during nights and weekends. |
| What are the core operating hours of the RAMS Help Desk? | 9 a.m. to 6 p.m., EST, Mon. through Fri. | The response time of a trouble ticket is dependent upon the severity of the ticket. |
| How soon should the system fully recover from an outage? (Includes Mean Time to Restore [MTRS]) | Disaster Recovery within 72 hours | Intentionally left blank. |
| How much data will be restored when outage is recovered? | 100% (continuous back-up) | Intentionally left blank. |
| What time period should be considered for maintenance periods? | After hours (these would be off peak hours approved by the Office of Research and Development) | Intentionally left blank. |
| In what standard time zone will the system operate? | All time zones | Intentionally left blank. |

## Scope Integration

Since the primary purpose of the RAMS Integration is the successful and efficient management of a research site, there should be equal importance placed on the ability for the system to integrate and share data with other internal and external systems, as well as the ability to act autonomously from outside systems, if needed. For example, Master Veteran Index (MVI) integration for Veteran demographic verification may be important, but the ability to capture and store such data, in the event that interface is not operational, is equally important.

In general, these interfaces should be fully automated, but as stated, there should be a level of independence in the event of site connectivity issues. All interfaces, therefore, are expected to be RESTful and have built-in fault tolerance for data exchanges. Security Specifications

The Federal Information Processing Standard 199 (FIPS 199), *Standards for Security Categorization of Federal Information and Information Systems*, defines the security categories, security objectives, and impact levels to which National Institute of Standards and Technology (NIST) Special Publication (SP) 800-60 Volume 1 Revision 1, maps information types. A FIPS 199 analysis was completed for the proposed RAMS application, and it has been determined that the security categorization is ***MODERATE*** in accordance with FIPS 199. The tables below (for management controls, operational controls, technical controls, and privacy controls, respectively) include the relevant references, publications, and directives based on this categorization**:**

Table 14: Security Specifications – Moderate Impact Controls

| Control Number | Control Name | Moderate Impact | VA Guidance |
| --- | --- | --- | --- |
| AC-1 | ACCESS CONTROL POLICY AND PROCEDURES | AC-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-2 | ACCOUNT MANAGEMENT | AC-2 (1) (2) (3) (4) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-3 | ACCESS ENFORCEMENT | AC-3 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-4 | INFORMATION FLOW ENFORCEMENT | AC-4 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-5 | SEPARATION OF DUTIES | AC-5 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-6 | LEAST PRIVILEGE | AC-6 (1) (2) (5) (9) (10) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-7 | UNSUCCESSFUL LOGON ATTEMPTS | AC-7 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-8 | SYSTEM USE NOTIFICATION | AC-8 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-11 | SESSION LOCK | AC-11 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-12 | SESSION TERMINATION | AC-12 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-14 | PERMITTED ACTIONS WITHOUT IDENTIFICATION OR AUTHENTICATION | AC-14 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-17 | REMOTE ACCESS | AC-17 (1) (2) (3) (4) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-18 | WIRELESS ACCESS | AC-18 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-19 | ACCESS CONTROL FOR MOBILE DEVICES | AC-19 (5) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-20 | USE OF EXTERNAL INFORMATION SYSTEMS | AC-20 (1) (2) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-21 | INFORMATION SHARING | AC-21 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AC-22 | PUBLICLY ACCESSIBLE CONTENT | AC-22 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AT-1 | SECURITY AWARENESS AND TRAINING POLICY AND PROCEDURES | AT-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AT-2 | SECURITY AWARENESS TRAINING | AT-2 (2) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AT-3 | ROLE-BASED SECURITY TRAINING | AT-3 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AT-4 | SECURITY TRAINING RECORDS | AT-4 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AU-1 | AUDIT AND ACCOUNTABILITY POLICY AND PROCEDURES | AU-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AU-2 | AUDIT EVENTS | AU-2 (3) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AU-3 | CONTENT OF AUDIT RECORDS | AU-3 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AU-4 | AUDIT STORAGE CAPACITY | AU-4 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AU-5 | RESPONSE TO AUDIT PROCESSING FAILURES | AU-5 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AU-6 | AUDIT REVIEW, ANALYSIS, AND REPORTING | AU-6 (1) (3) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AU-7 | AUDIT REDUCTION AND REPORT GENERATION | AU-7 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AU-8 | TIME STAMPS | AU-8 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AU-9 | PROTECTION OF AUDIT INFORMATION | AU-9 (4) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AU-11 | AUDIT RECORD RETENTION | AU-11 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AU-12 | AUDIT GENERATION | AU-12 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CA-1 | SECURITY ASSESSMENT AND AUTHORIZATION POLICY AND PROCEDURES | CA-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CA-2 | SECURITY ASSESSMENTS | CA-2 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CA-3 | SYSTEM INTERCONNECTIONS | CA-3 (5) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CA-5 | PLAN OF ACTION AND MILESTONES | CA-5 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CA-6 | SECURITY AUTHORIZATION | CA-6 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CA-7 | CONTINUOUS MONITORING | CA-7 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CA-9 | INTERNAL SYSTEM CONNECTIONS | CA-9 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CM-1 | CONFIGURATION MANAGEMENT POLICY AND PROCEDURES | CM-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CM-2 | BASELINE CONFIGURATION | CM-2 (1) (3) (7) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CM-3 | CONFIGURATION CHANGE CONTROL | CM-3 (2) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CM-4 | SECURITY IMPACT ANALYSIS | CM-4 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CM-5 | ACCESS RESTRICTIONS FOR CHANGE | CM-5 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CM-6 | CONFIGURATION SETTINGS | CM-6 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CM-7 | LEAST FUNCTIONALITY | CM-7 (1) (2) (4) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CM-8 | INFORMATION SYSTEM COMPONENT INVENTORY | CM-8 (1) (3) (5) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CM-9 | CONFIGURATION MANAGEMENT PLAN | CM-9 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CM-10 | SOFTWARE USAGE RESTRICTIONS | CM-10 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CM-11 | USER-INSTALLED SOFTWARE | CM-11 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CP-1 | CONTINGENCY PLANNING POLICY AND PROCEDURES | CP-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CP-2 | CONTINGENCY PLAN | CP-2 (1) (3) (8) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CP-3 | CONTINGENCY TRAINING | CP-3 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CP-4 | CONTINGENCY PLAN TESTING | CP-4 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CP-6 | ALTERNATE STORAGE SITE | CP-6 (1) (3) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CP-7 | ALTERNATE PROCESSING SITE | CP-7 (1) (2) (3) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CP-8 | TELECOMMUNICATIONS SERVICES | CP-8 (1) (2) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CP-9 | INFORMATION SYSTEM BACKUP | CP-9 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| CP-10 | INFORMATION SYSTEM RECOVERY AND RECONSTITUTION | CP-10 (2) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IA-1 | IDENTIFICATION AND AUTHENTICATION POLICY AND PROCEDURES | IA-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IA-2 | IDENTIFICATION AND AUTHENTICATION (ORGANIZATIONAL USERS) | IA-2 (1) (2) (3) (8) (11) (12) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IA-3 | DEVICE IDENTIFICATION AND AUTHENTICATION | IA-3 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IA-4 | IDENTIFIER MANAGEMENT | IA-4 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IA-5 | AUTHENTICATOR MANAGEMENT | IA-5 (1) (2) (3) (11) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IA-6 | AUTHENTICATOR FEEDBACK | IA-6 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IA-7 | CRYPTOGRAPHIC MODULE AUTHENTICATION | IA-7 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IA-8 | IDENTIFICATION AND AUTHENTICATION (NON-ORGANIZATIONAL USERS) | IA-8 (1) (2) (3) (4) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IR-1 | INCIDENT RESPONSE POLICY AND PROCEDURES | IR-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IR-2 | INCIDENT RESPONSE TRAINING | IR-2 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IR-3 | INCIDENT RESPONSE TESTING | IR-3 (2) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IR-4 | INCIDENT HANDLING | IR-4 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IR-5 | INCIDENT MONITORING | IR-5 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IR-6 | INCIDENT REPORTING | IR-6 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IR-7 | INCIDENT RESPONSE ASSISTANCE | IR-7 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IR-8 | INCIDENT RESPONSE PLAN | IR-8 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| MA-1 | SYSTEM MAINTENANCE POLICY AND PROCEDURES | MA-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| MA-2 | CONTROLLED MAINTENANCE | MA-2 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| MA-3 | MAINTENANCE TOOLS | MA-3 (1) (2) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| MA-4 | NONLOCAL MAINTENANCE | MA-4 (2) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| MA-5 | MAINTENANCE PERSONNEL | MA-5 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| MA-6 | TIMELY MAINTENANCE | MA-6 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| MP-1 | MEDIA PROTECTION POLICY AND PROCEDURES | MP-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| MP-2 | MEDIA ACCESS | MP-2 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| MP-3 | MEDIA MARKING | MP-3 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| MP-4 | MEDIA STORAGE | MP-4 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| MP-5 | MEDIA TRANSPORT | MP-5 (4) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| MP-6 | MEDIA SANITIZATION | MP-6 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| MP-7 | MEDIA USE | MP-7 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-1 | PHYSICAL AND ENVIRONMENTAL PROTECTION POLICY AND PROCEDURES | PE-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-2 | PHYSICAL ACCESS AUTHORIZATIONS | PE-2 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-3 | PHYSICAL ACCESS CONTROL | PE-3 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-4 | ACCESS CONTROL FOR TRANSMISSION MEDIUM | PE-4 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-5 | ACCESS CONTROL FOR OUTPUT DEVICES | PE-5 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-6 | MONITORING PHYSICAL ACCESS | PE-6 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-8 | VISITOR ACCESS RECORDS | PE-8 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-9 | POWER EQUIPMENT AND CABLING | PE-9 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-10 | EMERGENCY SHUTOFF | PE-10 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-11 | EMERGENCY POWER | PE-11 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-12 | EMERGENCY LIGHTING | PE-12 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-13 | FIRE PROTECTION | PE-13 (3) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-14 | TEMPERATURE AND HUMIDITY CONTROLS | PE-14 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-15 | WATER DAMAGE PROTECTION | PE-15 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-16 | DELIVERY AND REMOVAL | PE-16 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PE-17 | ALTERNATE WORK SITE | PE-17 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PL-1 | SECURITY PLANNING POLICY AND PROCEDURES | PL-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PL-2 | SYSTEM SECURITY PLAN | PL-2 (3) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PL-4 | RULES OF BEHAVIOR | PL-4 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PL-8 | INFORMATION SECURITY ARCHITECTURE | PL-8 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PS-1 | PERSONNEL SECURITY POLICY AND PROCEDURES | PS-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PS-2 | POSITION RISK DESIGNATION | PS-2 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PS-3 | PERSONNEL SCREENING | PS-3 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PS-4 | PERSONNEL TERMINATION | PS-4 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PS-5 | PERSONNEL TRANSFER | PS-5 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PS-6 | ACCESS AGREEMENTS | PS-6 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PS-7 | THIRD-PARTY PERSONNEL SECURITY | PS-7 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| PS-8 | PERSONNEL SANCTIONS | PS-8 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| RA-1 | RISK ASSESSMENT POLICY AND PROCEDURES | RA-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| RA-2 | SECURITY CATEGORIZATION | RA-2 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| RA-3 | RISK ASSESSMENT | RA-3 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| RA-5 | VULNERABILITY SCANNING | RA-5 (1) (2) (5) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SA-1 | SYSTEM AND SERVICES ACQUISITION POLICY AND PROCEDURES | SA-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SA-2 | ALLOCATION OF RESOURCES | SA-2 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SA-3 | SYSTEM DEVELOPMENT LIFE CYCLE | SA-3 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SA-4 | ACQUISITION PROCESS | SA-4 (1) (2) (9) (10) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SA-5 | INFORMATION SYSTEM DOCUMENTATION | SA-5 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SA-8 | SECURITY ENGINEERING PRINCIPLES | SA-8 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SA-9 | EXTERNAL INFORMATION SYSTEM SERVICES | SA-9 (2) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SA-10 | DEVELOPER CONFIGURATION MANAGEMENT | SA-10 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SA-11 | DEVELOPER SECURITY TESTING AND EVALUATION | SA-11 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-1 | SYSTEM AND COMMUNICATIONS PROTECTION POLICY AND PROCEDURES | SC-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-2 | APPLICATION PARTITIONING | SC-2 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-4 | INFORMATION IN SHARED RESOURCES | SC-4 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-5 | DENIAL OF SERVICE PROTECTION | SC-5 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-7 | BOUNDARY PROTECTION | SC-7 (3) (4) (5) (7) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-8 | TRANSMISSION CONFIDENTIALITY AND INTEGRITY | SC-8 (1) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-10 | NETWORK DISCONNECT | SC-10 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-12 | CRYPTOGRAPHIC KEY ESTABLISHMENT AND MANAGEMENT | SC-12 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-13 | CRYPTOGRAPHIC PROTECTION | SC-13 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-15 | COLLABORATIVE COMPUTING DEVICES | SC-15 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-17 | PUBLIC KEY INFRASTRUCTURE CERTIFICATES | SC-17 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-18 | MOBILE CODE | SC-18 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-19 | VOICE OVER INTERNET PROTOCOL | SC-19 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-20 | SECURE NAME / ADDRESS RESOLUTION SERVICE (AUTHORITATIVE SOURCE) | SC-20 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-21 | SECURE NAME / ADDRESS RESOLUTION SERVICE (RECURSIVE OR CACHING RESOLVER) | SC-21 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-22 | ARCHITECTURE AND PROVISIONING FOR NAME / ADDRESS RESOLUTION SERVICE | SC-22 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-23 | SESSION AUTHENTICITY | SC-23 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-28 | PROTECTION OF INFORMATION AT REST | SC-28 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SC-39 | PROCESS ISOLATION | SC-39 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SI-1 | SYSTEM AND INFORMATION INTEGRITY POLICY AND PROCEDURES | SI-1 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SI-2 | FLAW REMEDIATION | SI-2 (2) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SI-3 | MALICIOUS CODE PROTECTION | SI-3 (1) (2) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SI-4 | INFORMATION SYSTEM MONITORING | SI-4 (2) (4) (5) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SI-5 | SECURITY ALERTS, ADVISORIES, AND DIRECTIVES | SI-5 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SI-7 | SOFTWARE, FIRMWARE, AND INFORMATION INTEGRITY | SI-7 (1) (7) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SI-8 | SPAM PROTECTION | SI-8 (1) (2) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SI-10 | INFORMATION INPUT VALIDATION | SI-10 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SI-11 | ERROR HANDLING | SI-11 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SI-12 | INFORMATION HANDLING AND RETENTION | SI-12 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SI-16 | MEMORY PROTECTION | SI-16 | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |

Table 15: Security Specifications - Privacy Controls

| Control  ID | Privacy Control Name | VA Guidance |
| --- | --- | --- |
| AP | Authority and Purpose | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AP-1 | Authority to Collect | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AP-2 | Purpose Specification | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AR | Accountability, Audit, and Risk Management | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AR-1 | Governance and Privacy Program | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AR-2 | Privacy Impact and Risk Assessment | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AR-3 | Privacy Requirements for Contractors and Service Providers | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AR-4 | Privacy Monitoring and Auditing | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AR-5 | Privacy Awareness and Training | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AR-6 | Privacy Reporting | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AR-7 | Privacy-Enhanced System Design and Development | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| AR-8 | Accounting of Disclosures | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| DI | Data Quality and Integrity | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| DI-1 | Data Quality | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| DI-2 | Data Integrity and Data Integrity Board | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| DM | Data Minimization and Retention | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| DM-1 | Minimization of Personal Identification Information (PII) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| DM-2 | Data Retention and Disposal | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| DM-3 | Minimization of PII used in Testing, Training, and Research | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IP | Individual Participation and Redress | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IP-1 | Consent | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IP-2 | Individual Access | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IP-3 | Redress | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| IP-4 | Complaint Management | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SE | Security | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SE-1 | Inventory of Personal Identification Information (PII) | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| SE-2 | Privacy Incident Response | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| TR | Transparency | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| TR-1 | Privacy Notice | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| TR-2 | System of Records Notices and Privacy Act Statements | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| TR-3 | Dissemination of Privacy Program Information | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| UL | Use Limitation | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| UL-1 | Internal Use | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |
| UL-2 | Information Sharing with Third Parties | VA Directive 6500, VA Handbook 6500, March 2015, Appendix C: (References), Appendix E: (VA System Privacy Controls), Appendix F: (VA System Security Controls). |

## System Features

There are several feature sets that the RAMS application will encompass; these consist of the following: Research Project Management, Document Management, Personnel and Facility Management, Committee and Communications Management, and Logistics Management. Each feature set can be further defined into more-detailed subsets and ultimately transformed into the end state Web GUI.

## Usability Specifications

The requirements listed in this section are the same as existing RAMS requirements.

Usability specification requirements are as outlined below:

Table 16: Usability Specification Requirements

| Req. ID | Requirement | Priority (P1, P2, P3) | Increment (1, 2, Future) |
| --- | --- | --- | --- |
| USA-001 | RAMS shall follow the Government Usability process as specified in the usability.gov website http://usability.gov/methods/process.html | TBD | 1, 2 |
| USA-002 | RAMS shall follow the usability testing as specified in the usability.gov website http://usability.gov/pdfs/chapter18.pdf | TBD | 1, 2 |
| USA-003 | RAMS shall follow a User-centered design (UCD) | TBD | 1, 2 |

User Experience encompasses direct and indirect interactions between the User and the system. Improving usability over the prior version is a key requirement for this application. The International Organization for Standardization (ISO) defines usability as “the extent to which a product can be used by specified Users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use” (1998).

For an optimal User experience, the system must meet the requirements outlined in this section, which involve attributes of the application and the process required to achieve them.

In order to improve usability of VA-developed or purchased applications, the following actions are required:

• In accordance with the Office of the National Coordinator for Health Information Technology’s Meaningful Use Stage 2 final ruling, employ an industry recognized User-Centered Design (UCD) process. The methods for UCD are well defined in documents and requirements, such as ISO 9241–11, ISO 13407, ISO 16982, National Institute of Standards and Technology Interagency Report 7741, ISO/International Electrochemical Commission 62366, and ISO 9241-210. Developers will choose their UCD approach; one or more specific UCD processes will not be prescribed.

• Adhere to an industry-recognized User Interface (UI) Best Practices Guideline or Style Guide. For example, first follow UI guidelines for the development platform. In instances where platform guidelines are not available, adhere to the VA Best Practices Guidelines/Style Guide.

• Inform requirements and designs with detailed human factors work products that have been/will be completed for the specific project. Examples of specific human factors activities might include heuristic evaluations, site visits, interviews, application-specific design guides, and usability testing on existing systems or prototypes.

A sound UCD and development process based on human factors should include the following activities:

• Understanding of the Users, the Users’ tasks, and the Users’ environments

• Review of similar or competitive systems to inform requirements and design

• Heuristic evaluation of prior versions, prototypes, or baseline applications, if applicable

• Iterative design and formative usability testing (formative usability testing is used to discover usability problems during the design and development process)

• User risk analysis

• Summative validation usability testing (summative usability testing is used to quantify and validate usability of a product with measures of effectiveness, efficiency, User perceptions, etc.)

To demonstrate high usability, the application should be:

* Intuitive and easy to learn, with minimal training;
* Effective by allowing Users to successfully complete tasks;
* Efficient by allowing Users to complete their work in a manner consistent with clinical practice and workflow;
* Perceived to have high usability, as demonstrated by appropriate survey measures; and
* Designed to aid Users in meeting task goals without being an additional burden.

The system must be reliable and enable User trust by providing:

• Stable and reliable performance;

• Accurate data;

• Display of all data that is available in native or interfaced systems and intended to be available in the application; and

• Accessible information related to the source of data.

The application should include a modern GUI that allows the User to view data from multiple sources and includes:

• Integrated display of structured and unstructured data;

• Rich data visualization and graphical display of data;

• Ability to switch between tabular and graphical data views;

• Ability to interact with displayed data to obtain additional details related to the data and source of the data; and

• User customizable components and settings.

The application must provide for advanced and up-to-date searching, to include:

• Fast search functionality with auto-complete and real-time display of matched results during typing; and

• Search history.

The application must provide for advanced filtering capabilities, to include:

• Filtering of data tables, lists, and grids; and

• Filtering of search results.

The application design should be modified to:

• Address the specific findings from a human factor heuristic evaluation conducted on the prior version of the application;

• Address the specific findings reported from field use of the prior version; and

• Address the specific findings reported from usability testing of the prior version or relevant prototypes.

The following table outlines the usability/User interface requirements for the RAMS Integration.

Table 17: Usability/User Interface Requirements

| Identifier | Usability/User Interface Requirements |
| --- | --- |
| No identifier provided in BRD. | Left align content in table cells to facilitate quick visual scan. |
| No identifier provided in BRD. | Left align text for column headers to facilitate visual scan and make columns and content appear more organized. |
| No identifier provided in BRD. | Use mixed case instead of all caps whenever possible (e.g., dropdown list items, table data, table headers, hyperlinks, tab names). Limit the use of “all caps” throughout the application. |
| No identifier provided in BRD. | Simplify button labels. Re-label buttons to reflect standard terminology that is common in web interfaces and other applications (e.g., “Cancel”). Emphasize the action being performed in the most succinct way possible. Minimize redundancy in text/terminology that is used to convey the same action. |
| No identifier provided in BRD. | Left align page/section titles to anchor titles in consistent locations regardless of window sizing. |
| No identifier provided in BRD. | Labels for fields should be left aligned to facilitate quick visual scan and make forms and field groupings appear more organized. |
| No identifier provided in BRD. | Avoid using acronyms or abbreviations unless (a) they are widely understood/well known or (b) there is very limited space to display the full meaning. This supports naïve User understanding. If limited space results in using a non-common acronym/abbreviation, ensure it is specified within “Help” and/or as a tooltip. |
| No identifier provided in BRD. | Use colors such as red and green only for status driven content. Avoid using red for text/content, links, button labels, etc. This will reduce risk for User error, improve link discoverability, and facilitate understanding of differences in navigation/actions/content. It will also help Users to isolate important status information (using red, green, etc.) from other less important information when viewing and processing information provided to them on a page. |
| No identifier provided in BRD. | Provide visual separation between the navigation space and the main content area. |
| No identifier provided in BRD. | Add field level validation and notification of missing information on the same page without launching a new window or navigating to another page. |
| No identifier provided in BRD. | Make all text hyperlinks appear consistent in style. |
| No identifier provided in BRD. | Make drop-down selection box widths appropriate for content and visual appeal. |
| No identifier provided in BRD. | Use standard and always visible radio buttons for “Yes/No” options instead of requiring the User to click in a drop down box and then click to select the “Yes” or “No” option. |
| No identifier provided in BRD. | Use standard date and time selection widgets. Where date and time are selected/picked from a standard widget, also provide direct data entry to support keyboard navigation. Enable field level validation immediately upon entry. Include instructional format text within the field entry box. |
| No identifier provided in BRD. | Provide standard sort behavior and visual indications on columns in all tables. |
| No identifier provided in BRD. | Define and adhere to a standard model for use and design of controls, buttons, hyperlinks, and navigation elements. |
| No identifier provided in BRD. | Ensure that text is sized to be readable (for example, by using the 007 Rule to assure text size is readable for Users with 20/40 vision. The formula: Text height = .007 \* distance between eyes and screen). |
| No identifier provided in BRD. | Place common navigation elements in consistent locations. |
| No identifier provided in BRD. | Place critical information “above the fold” (i.e., in the top portion of the screen that is immediately viewable). |
| No identifier provided in BRD. | Use consistent screen flow models, elements, and terms to support similar workflows. |
| No identifier provided in BRD. | Use consistently named buttons when actions are the same (e.g., Add, vs. Save, vs. Submit). |
| No identifier provided in BRD. | Enable Users to print views from where they are in the interface. Avoid requiring the User to “run a report” in order to print something that is viewable on the screen. |
| No identifier provided in BRD. | Provide field entry tool tips at the field location. Ensure consistency across the application in field labels, formats, location of tool tips, and tool tip text. |
| No identifier provided in BRD. | Provide visual indication of required fields. |
| No identifier provided in BRD. | Display field labels in close proximity to entry elements. |
| No identifier provided in BRD. | Use consistent elements to filter data. |
| No identifier provided in BRD. | Use consistent elements to sort data. |
| No identifier provided in BRD. | Use a consistent model for display, layout, and grouping of data entry fields. |
| No identifier provided in BRD. | Provide alternate row shading in lengthy tables of data, form elements, etc. |
| No identifier provided in BRD. | Ensure that icons are recognized by Users. |
| No identifier provided in BRD. | Provide some “white space” between status icons in report views, white board views, etc. |
| No identifier provided in BRD. | Auto-populate default values in entry/selection fields when possible and appropriate. |
| No identifier provided in BRD. | Visually differentiate status icons from clickable icons, when appropriate. |
| No identifier provided in BRD. | Define and support the appropriate User tab sequence through fields in forms in order to support keyboard navigation when entering data in forms. |
| No identifier provided in BRD. | Define and adhere to standard action button placement on screens, forms, etc. |
| No identifier provided in BRD. | Visually distinguish the primary action button on a page. |
| No identifier provided in BRD. | Consistently use screen elements, action elements, workflow sequences within/across screens, language, etc. |
| No identifier provided in BRD. | Provide error messages in User-centric language with specific instructions on the meaning of the error and how to recover from it. Use error messages and method of display consistently across the interface. |
| No identifier provided in BRD. | Provide context-specific Help. |
| No identifier provided in BRD. | Do not use the term “sex” or any like abbreviations to represent gender. |

# Purchased Components

No components have been purchased specifically for RAMS. RAMS uses enterprise licenses for all software components.

# Estimation

Information for the estimation is not available at this time. The RAMS Integration Milestone 1 (MS1) Review will not be until July 2016. To receive function point analysis results, the following details will have to be submitted to EMAIL REDACTED

* The name of the project as it appears in the Project Management Accountability System (PMAS)
* The increment Number and Type (delivery, IOC, deployment, visibility, and monitoring)
* The correct Enterprise Project Structure (EPS) number
* The date of MS1 review
* Link to the functional specifications that list and describe all of the functional User requirements for that increment (BRD, RSD, SDD, User Stories, Use Cases, etc.)

Project Software Functional Size and Size-Based Effort and Duration Estimate

Application

| Item | A | B | C | D | E | Total |
| --- | --- | --- | --- | --- | --- | --- |
| **Counted Function Points** |  |  |  |  |  |  |
| **Estimated Scope Growth** |  |  |  |  |  |  |
| **Estimated Size at Release** |  |  |  |  |  |  |

| Size-Based Effort Estimates | Labor Hours | Probability |
| --- | --- | --- |
| **Low-Effort Estimate – With indicated probability, project will consume no more than:** |  |  |
| **High-Effort Estimate – With indicated probability, project will consume no more than:** |  |  |

| Size-Based Duration Estimates | Work Days | Probability |
| --- | --- | --- |
| **Low-Duration Estimate – With indicated probability, project will consume no more than:** |  |  |
| **High-Duration Estimate -- With indicated probability, project will consume no more than:** |  |  |

Figure 1: Cumulative Probability (“S-curve”) Chart

[Insert Cumulative Probability (“S-curve”) Charts here]

# Approval Signatures

REVIEW DATE: February 5, 2016

SCRIBE: Paul Bockewitz

Signed:

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Glenda Miller, Integrated Project Team (IPT) Chair Date

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James Breeling, M.D., Business Sponsor Date

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Glenda Miller, Project Manager Date

Appendix A: Non-Functional Requirements

The following non-functional requirements should be reviewed and accessed while developing the requirements for the project.

System Performance Reporting Requirements

The existing non-standard architecture has led to inconsistent data management processes across the national program. This has also resulted in delays when responding to Central Office initiated data calls.

Each field research office must be in compliance with Federal and industry regulations. In the absence of an enterprise solution the field offices expend excessive local resources to track critical data for ongoing projects to ensure that they are meeting all of the requirements of the law. In the absence of a uniform, standardized software solution, both ORD and our field research offices will continue to experience limited ability to efficiently respond to Congressional and Secretary level inquiries, review progress of research portfolios to address current and future VA research needs and meet VA and industry mandated compliance reporting requirements.

In order to operate effectively, each field research office must be in compliance with the Common Rule, United States Department of Agriculture Animal Welfare Act Regulations, Occupational Safety and Health Administration guidelines, Environmental Protection Agency guidelines, and all pertinent VA regulations, including pharmacy, bio-safety, occupational health, and human resource management. These offices use a variety of subject matter expert (SME) committees. In the absence of an enterprise solution, the field offices expend excessive resources to track the status of each ongoing project and all of the personnel involved in each project to ensure that they are meeting all of the requirements of the law.

We rely on our investigators in the field to provide twenty-first century, transformational research, in which VA takes great pride. In the absence of a system-wide research office management and reporting tool, ORD and our field research offices will continue to experience limited ability to efficiently respond to Congressional- and Secretary-level inquiries, review progress of research portfolios to address current and future VA research needs, and meet VA and industry-mandated compliance reporting requirements.

Listed below is Business Need 6, The Central Office Reporting Requirements:

Table 18: Reporting Requirements

| BN6 | Central Office Reporting Requirements | Priority |
| --- | --- | --- |
| 6.1 | Create real-time expenditure reports. | Medium priority |
| 6.2 | Provide query and reporting tools for  administrative research data. | High priority |
| 6.3 | Define portfolio reporting categories of funded research projects, with tools for administrate research data. | Completed in an alternative project |
| 6.4 | Support 200+ pre-defined categories from the  NIH. | Completed in an alternative  project |
| 6.5 | Support VA-specific portfolio categories. | Completed in an alternative  project |
| 6.6 | Ability to individually re-weight concepts in any category to meet expectations | Completed in an alternative  project |
| 6.7 | Screen incoming proposals against similar applications in existing portfolios of VA, NIH, and other funding institutions. | Completed in an alternative project |
| 6.8 | Generate internal and external reviewer profiles based on published research data | Completed in an alternative  project |
| 6.9 | Ability to categorize internal and external reviewer profiles based on known concepts. | Completed in an alternative  project |
| 6.10 | Automatic detection of conflicts of interest between incoming proposal and reviewer profiles. | Completed in an alternative  project |
| 6.11 | Ability to compare incoming proposals to internal and external reviewer profiles. | Completed in an alternative project |
| 6.12 | Export raw data in XML which can be analyzed with third-party business intelligence, analysis and visualization tools. | High priority |

**Operational Environment Requirements**

1. System response times and page load times shall be consistent with PITC Enterprisestandards.
2. Maintenance, including maintenance of externally developed software incorporated into the RAMS application, shall be scheduled during off peak hours or in conjunction with relevant maintenance schedules. The business owner should provide specific requirements for establishing system maintenance windows when planned service disruptions can occur in support of periodic maintenance.
3. Information about response time degradation resulting from unscheduled system outages and other events that degrade system functionality and/or performance shall be disseminated to the User community within 30 minutes of the occurrence. The notification shall include the information described in the current Automated Notification Reporting (ANR) template maintained by the VA Service Desk. The specific business impact must be noted in order for OIT to provide accurate data in the service impact notice of the ANR.
4. Provide a real-time monitoring solution to report agreed/identified critical system performance parameters.
5. Critical business performance parameters shall be identified, e.g., transaction speed, response time for screen display/refresh, data retrieval, etc., in a manner that data capture can occur to support metric reporting and support the OI&T performance dashboard display. If no such performance metrics are required or provided, there will be no program specific Service Level Agreements (SLA) created, nor shall there be any active/real time monitoring through OI&T Performance Dashboard to provide the business owners any performance metrics.
6. Notification of scheduled maintenance periods that require the service to be offline or that may degrade system performance shall be disseminated to the business User community a minimum of 48 hours prior to the scheduled event.

**Documentation Requirements**

1. The training curriculum shall state the expected training time for primary Users and secondary Users to become proficient at using the RAMS application.
2. All training curricula, User manuals, and other training tools shall be developed/updated by ORD or Collaborative Institutional Training Initiativeand delivered to all levels of Users. The curricula shall include all aspects of the new functionality of the RAMS application and all changes to processes and procedures.
3. The training curriculum developed by the Program Office shall state the expected task completion time for primary and secondary Users.
4. User manuals and training tools shall be developed. If they already exist, updates shall be made to them, as necessary, and they shall be delivered to all levels of Users.
5. IT will provide the level of documentation required to support the system and maintain operations and continuity. Documentation shall represent minimal programmatic and lifecycle operations support documentation artifacts as defined by VA standards in ProPath and as required by the VA Enterprise System Engineering Lifecycle and Release Management office for sustained operations, maintenance, and support prior to approval by any VA change control board and release into production.

**Implementation Requirements**

As part of the system implementation process, a detailed RACI (R – Responsible, A- Accountable, C – Consulted, I – Informed) Matrix will be created to identify all areas addressed in the OM Plan and show specific roles and responsibilities by environment. Once developed, this detailed matrix will be added as an attachment to this OM Plan.

The following is a list of Implementation Requirements

* There is a need to train the targeted staff groups on the new functionality.
* Early identification of subject matter experts and test sites required to successfully define the master test strategy, the deployment plan, and the implementation plan.
* Close coordination with OIT is required in order to ensure business requirements are met and deployment plans are aligned.

**Data Protection/Back-up/Archive Requirements**

1. The system shall ensure a back-up and data recovery process is available for when the system is brought off-line for maintenance or technical issues/problems.
2. The system shall ensure data protection measures, such as back-up intervals and redundancy shall be consistent with systems categorized as routine (30 day restoration), mission essential (72 hour restoration), or mission critical (12 hour restoration).

Business owners are required to state the mission criticality of the IT services required in order to assist the planners and developers in determining best strategies for engineering an IT solution to meet their business objectives/needs. The business owner needs to state the criticality of the data and the impact to the business during a service disruption so appropriate technologies can be considered.

**Levels for Disaster Recovery**

Classification Recovery Time Objective Recovery Point

Objective Routine 30 day restoration TBD

Mission Essential 72 hour restoration 24 hours

Mission Critical 12 hour restoration 2 hours

Recovery Time Objective (RTO) – RTO defines the maximum amount of time that a system resource can remain unavailable before there is an unacceptable impact on other system resources, supported mission/business processes, and the MTD.

Maximum Tolerable Downtime (MTD) - The MTD represents the total amount of time the system owner/authorizing official is willing to accept for a mission/business process outage or disruption and includes all impact considerations.

Recovery Point Objective (RPO) - The RPO represents the point in time, prior to a disruption or system outage, to which mission/business process data can be recovered (given the most recent backup copy of the data) after an outage.

Table 19: Data Protection Requirements

| **SLR Question** | **SLR Criteria** |
| --- | --- |
| 1. How much time should the system be available (and how much down time is acceptable due to incident [unexpected] outage)? | 99.9% (8.76 hours down time) |
| 1. When should the system be available (what will be the core operating hours of the system)? | 8 a.m. to 8 p.m., EST, Mon. through  Fri. |
| 1. How soon should the system fully recover from an outage? (Includes Mean Time to Restore [MTRS]) | Disaster Recovery within 72 hours |
| 1. How much data will be restored when outage is recovered? | 100% (continuous back-up) |
| 1. What time period should be considered for maintenance periods? | After hours (these would be off peak hours approved by the Office of Research and Development) |
| 1. What standard time zone will the system operate in? | All time zones |

**Data Quality/Assurance Requirements**

A monitoring process shall be provided to ensure that data is accurate and up-to-date and provides accurate alerts for malfunctions while minimizing false alarms.

**User Access/Security Requirements**

Ensure the proposed solution meets all Veterans Health Administration (VHA) Security, Privacy, and Identity Management requirements, including VA Handbook 6500 (see the Enterprise Requirements section of the RTM).

Table 20: User Access/Security Requirements

| User Level | Role | Responsibilities | RAMS Access Level |
| --- | --- | --- | --- |
| Administrative Officer | Senior ORD official at each research station | Administrative functions of the research program -  All committees | Read/Write |
| Associate Chief of Staff for Research | Chief Operational Officer for the research station | Oversees committees and subcommittees and responsible for coordination with audit agencies, as well as day to day management of the research program at facilities with large active programs - All committees | Read/Write |
| Committee Coordinator/ Committee Administrator | Manages all activities of the committee | Communication with Principle Investigators, assignment of projects to agendas, minutes, coordinator of reviewer comments, scheduling meetings, tracking committee members, and quorums - All committees | TBD |
| Principal Investigator | Directs research project or program | Oversees scientific, technical, and day-to-day management of the research and is leader of research team - All committees | Read/Write |
| Principal Investigator Designee | Assists in preparation of project/protocol | Completes entry of components associated with the protocol, submits to IRB - All committees | TBD |
| Co-Principal Investigator | Similar to Principal Investigator | Ensures project is conducted in compliance with applicable laws and regulations and institutional policy - All committees | Read/Write |
| IRB Administrator | Conducts review process for considerations | Reviews for issues, such as conflicts of interest, initial review of disclosure forms, determines whether referrals are needed to specific committees - All committees | TBD |
| IRB Chair | Determines if an application is complete | Determines if application lacks any disqualifying features and forwards all application materials to members of IRB Committee - All committees | TBD |
| IRB Member | A member of IRB | Member of an elected board or other group formally designated by an institution to review, approve, require modification in, disapprove, and conduct continuing oversight of human research in accordance with laws and regulations - All committees | TBD |
| IRB Staff | Assists the Administrative Officer, IRB Chair in administrative functions | Performs administrative functions. - All committees | TBD |
| Local Site Investigator (CIRB Role Only) | Investigator at site participating in a multi-site research study | Oversees scientific, technical, and day-to-day management of the research at a local site | TBD |
| Local RAMS Administrator | User with special privileges to establish and maintain local User accounts | Administrative functions - All committees | Read/Write |
| Study Coordinator | Specialized research coordinator working under direction of the Principle Investigator | Facilitates the daily trial activities and conduct of the study, reports with administrative, scientific proposal preparation and review, budget, award acceptance, etc. - All committees | TBD |
| ORD Administrator | Determines whether or not a given project is a candidate for review by the VA Central IRB | Administrative VA Central IRB support. | TBD |

**Usability/User Interface Requirements**

Adhere to good User Interface/User Centered Design (UI/UCD) principles as outlined in the Usability Appendix of the BRD. Additional information is available in Section 2.15 of this document.

**Conceptual Integrity**

The system shall provide standards-based messaging and middleware infrastructure needed to support RAMS deployment.

**Availability**

1. Maintenance window, including maintenance of externally developed software incorporated into the RAMS application, will be by mutual agreement between OI&T and the VHA Point of Contact (POC) for the affected facility(ies). VHA will provide POCs for each facility.
2. The RAMS application unavailability, due to an unplanned outage or planned outages that exceed the defined maintenance window, will not exceed 8.76 hours per year and will not exceed 43.8 minutes per month (99.9% availability).
3. The application shall be available 24 hours a day, seven days a week, with an uptime of 99.9%.
4. All system updates and scheduled maintenance should occur between the hours of 1800 and 0600 (per local time zone), when clinical usage would be lightest.

Table 21: Availability

|  |  |
| --- | --- |
| **SLR Question** | **SLR Criteria** |
| 1. How much time should the system be available (and how much down time is acceptable due to incident [unexpected] outage)? | 99.9% (8.76 hours down time) |
| 1. When should the system be available (what will be the core operating hours of the system)? | 8 a.m. to 8 p.m., EST, Mon. through  Fri. |
| 1. How soon should the system fully recover from an outage? (Includes Mean Time to Restore [MTRS]) | Disaster Recovery within 72 hours |
| 1. How much data will be restored when outage is recovered? | 100% (continuous back-up) |
| 1. What time period should be considered for maintenance periods? | After hours (these would be off-peak hours approved by the Office of Research and Development) |
| 1. In what standard time zone will the system operate? | All time zones |

Table 22: Goal/Objective

|  |  |  |  |
| --- | --- | --- | --- |
| Goal/Objective | Desired Outcome | Measurement | Impact |
| Provide a centralized enterprise-level repository of national VA research office program data. | All VHA national research program administrative data is stored in a central database and accessible by a common tool set, at appropriate levels, to all research program stakeholders. | The centralized data repository is available by web connection to all VA research offices and stakeholders located at Central Office. | The centralized data repository supports the internal exchange of information within the VA research environment and communication of data with stakeholders in the research community. |

**Interoperability**

The RAMS solution utilizes Java as the primary platform for User interaction in the View and Controller components of the Java Model View Controller (MVC) design framework in Struts2. The tradeoff of choosing Java development vs. SharePoint development includes more ease of customization of the User front-end, graphics, functionality, and easier interoperability between backend systems.

1. The system shall support all recognized health system standards

2. Systems must be heterogeneous and agnostic for operating systems and code bases.

3. Provide the ability to securely transfer large files (of 4-8 gigabytes) from an external source to VA systems.

4. Provide access to the system over a remote access solution.

**Manageability**

1. Provide Service Desk/Incident and Problem Management tracking related to maintenance events of patient care systems with priority over non-patient care systems.
2. Provide data-related to maintenance events, both routine and exceptional, including key metadata:

* Predicted routine work
* Occurrences where maintenance is completed, including restart from down time
* Identity of the organization performing maintenance
* User performing maintenance (if available)
* Identity of the system
* Date/time, physical location
* Systems impacted
* Whether it affects patient care
* Non-urgent or emergent

1. Provide audit capabilities for system access and usage with settings that are configurable to support internal and external audits based on Federal and VHA mandates.
2. The system must comply with VA Directive 6300 Records and Information Management and with VHA Records Control Schedule (RCS) 10-1, in general and specifically with Electronic Final Version of Health Record: Destroy/Delete 75 years after last episode of patient care, or longer (if specified).

**Performance**

The performance specifications solution will execute performance, capacity, and independent testing of its product, and as part of Software Quality Assurance (SQA) analysis and testing.

The ORD aims to improve the efficiency and performance of the national VA research program by implementing an enterprise-wide research administrative management system accessible to:

* ORD Central Office.
* Active field research offices

The implemented tool will support the major business functions of the:

* Local research office
* Management of the Research and Development (R& D) Committee and its subcommittees (Institutional Review Board [IRB])
* Institutional Animal Care and Use Committee (IACUC)
* Subcommittee on Research Safety (SRS),
* local research office reporting to ORD

The tool will also provide a common database for tracking and reporting of administrative research program data throughout the VA.

Table 23: Performance

| SLR Question | SLR Criteria |
| --- | --- |
| How many Users will be on the system hourly? | 101-1000 estimated |
| How many transactions will each average User perform each hour? | >10 estimated |
| What are the anticipated peak User times during the day? | Business day (highest peak User times Mon. through Fri. during administrative hours) |
| What is the anticipated peak transaction load (when do you think that there will be the most transactions being performed on the system) during the day? | Business day (highest peak User times Mon through Fri during administrative hours) |
| How many new Users will be added in one year? | 101-1000 estimated |
| How many more (if any) transactions will be added in one year? | >10 estimated |
| What kind of information will be stored? (Specify average of each kind per month) | Small documents (example PDF or Word file)  Forms & Documents that are formatted (example forms or documents with images) |
| What kind of search capacity is required? | Medium (11-1000 per hour)  estimated |
| What type of system(s) is/are required? | Web-based and managed from central service and database  Intranet (All VA) |
| Is there a need for heavy application reporting? If yes, when? | End of day, End of month, End of quarter |

**Reliability**

The system must be reliable and enable User trust. The following summarizes requirements for the RAMS new functionality reliability specifications by providing:

* Stable and reliable performance
* Availability – the system shall be available 8 a.m. to 8 p.m., EST, Mon. through Fri.
* Accurate data - The system shall return entries exactly as they were passed, with no modification
* Defect repair – It is expected that all defects related to the implementation get resolved during initial development and subsequent UAT testing
* Display of all data that is available in native or interfaced systems, and intended to be available in the application
* Accessible information related to the source of data
* When the system goes live in Production, the development team will address defects of a critical nature that are deemed “show stoppers.” Enhancement requests made after ‘go-live’ will be logged for consideration in a future, coordinated release.

Table 24: Reliability

| SLR Question | SLR Criteria | Description |
| --- | --- | --- |
| 1. How much time should the system be available (and how much down time is acceptable due to incident [unexpected] outage)? | 99.9% (8.76 hours down time) | Intentionally left blank. |
| 1. When should the system be available (what will be the core operating hours of the system)? | 8 a.m. to 8 p.m., EST, Mon. through  Fri. | The system shall require no more than 24 hours of maintenance per month. Servicing and maintenance is expected to occur during nights and weekends. |
| 1. How soon should the system fully recover from an outage? (Includes Mean Time to Restore [MTRS]) | Disaster Recovery within 72 hours | Intentionally left blank. |
| 1. How much data will be restored when outage is recovered? | 100% (continuous back-up) | Intentionally left blank. |
| 1. What time period should be considered for maintenance periods? | After hours (these would be off peak hours approved by the Office of Research and Development) | Intentionally left blank. |
| 1. In what standard time zone will the system operate? | All time zones | Intentionally left blank. |

**Security**

The RAMS system shall remain behind the VA firewall and subject to VA security initiatives and protocols. RAMS will exchange PII or other data that would be deemed sensitive; therefore, there is a need for encryption of the data that is exchanged between RAMS and external data bases. RAMS Sign-on shall be in compliance with VA security and privacy standards.

**Supportability**

The following table lists the priority levels of the systems that will interface with the VA systems.

Table 25: System Supportability

|  |  |  |  |
| --- | --- | --- | --- |
| BN 7 | System will interface with VA systems |  | Priority Level |
| 7.2 | RAMS interfacing with CITI | | Medium priority |
| ~~7.3~~ | ~~RAMS incorporating the functionality of WinRMS~~ | | ~~Medium priority~~ |
| ~~7.4~~ | ~~RAMS incorporating the functionality of eJIT~~ | | ~~Medium priority~~ |
| 7.5 | RAMS interfacing with TMS | | Medium priority |
| ~~7.6~~ | ~~RAMS incorporating the functionality of RAFT~~ | | ~~Medium priority~~ |

1. Provide alerts (that extend beyond system messages to external systems, like mobile devices) for malfunctions, while preventing false alarms for local, regional, and national evaluations in real time.
2. Provide reports on performance metrics, as specified in the RAMS Effectiveness and Value / Benefits Framework, on a bi-weekly basis.
3. Provide national, regional, and local reports on performance metrics, as specified in the RAMS Effectiveness and Value / Benefits Framework.
4. Provide performance metrics (from request for information to receipt of information on the screen) monitored by the system and system administrators so they know what the User experience is like without Users having to call them and tell them the system is running very slow.
5. Provide the ability for VHA and IT staff to create standard and ad-hoc reports of usage, bandwidth, response time, login time, and other variables with a verification process for measuring the capabilities of the system.
6. Provide end-User training on how to generate the various system performance reports (e.g., in standard file formats, such as Comma Separated Values [CSV], Portable Document Format [PDF], or Excel) depending on the User's needs.
7. Provide the ability to view system statistics (e.g., information on the specific network environment) and identify areas that are having issues, or are beyond capacity, in near-real-time (to be quantified at a later time).
8. Technical Help Desk support for the application via instant message, on-line, phone, and remote desktop access support, shall be provided for Users to obtain assistance 24/7.
9. The IT solution shall be designed to comply with the applicable approved Enterprise SLAs.
10. Data protection measures, such as back-up intervals and redundancy, shall be consistent with systems categorized as mission critical (1hr restoration, 2hrs backup recovery). Impact of system failure must be monitored on a near-real-time basis.
11. Provide the ability to set thresholds and notification type (e.g., email or text alerts) when alerting the User about response time degradation and unscheduled outages.
12. Disaster Recovery Plans (DRP) and Continuity of Operations Plan (COOP) will be updated and tested semi-annually to address the RAMS application (see National Security and Homeland Security Presidential Directive: National Continuity Policy. NSPD-51/HSPD-20, May 9, 2007)

**Usability**

User Experience encompasses direct and indirect interactions between the User and the system. Improving usability over the prior version is a key requirement for this application. The International Organization for Standardization (ISO) defines usability as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use” (1998).

For an optimal User experience, the system must meet the requirements outlined in this section, which involve attributes of the application and the process required to achieve them.

In order to improve usability of VA-developed or purchased applications, the following actions are required:

* In accordance with the Office of the National Coordinator for Health Information Technology’s Meaningful Use Stage 2 final ruling, employ an industry-recognized User-Centered Design (UCD) process. The methods for UCD are well defined in documents and requirements, such as ISO 9241–11, ISO 13407, ISO 16982, National Institute of Standards and Technology Interagency Report 7741, ISO/International Electrochemical Commission 62366, and ISO 9241-210. Developers will choose their UCD approach; one or more specific UCD processes will not be prescribed.
* Adhere to an industry-recognized User Interface (UI) Best Practices Guideline or Style Guide. For example, first follow UI guidelines for the development platform. In instances where platform guidelines are not available, adhere to the VA Best Practices Guidelines/Style Guide.
* Inform requirements and designs with detailed human factors work products that have been/will be completed for the specific project. Examples of specific human factors activities might include heuristic evaluations, site visits, interviews, application-specific design guides, and usability testing on existing systems or prototypes.

A sound UCD and development process based on human factors should include the following activities:

* Understanding of the Users, the Users’ tasks, and the Users’ environments
* Review of similar or competitive systems to inform requirements and design
* Heuristic evaluation of prior versions, prototypes, or baseline applications, if applicable
* Iterative design and formative usability testing (formative usability testing is used to discover usability problems during the design and development process)
* User risk analysis
* Summative validation usability testing (summative usability testing is used to quantify and validate usability of a product with measures of effectiveness, efficiency, User perceptions, etc.)

To demonstrate high usability, the application should be:

* Intuitive and easy to learn, with minimal training;
* Effective by allowing Users to successfully complete tasks;
* Efficient by allowing Users to complete their work in a manner consistent with clinical practice and workflow;
* Perceived to have high usability, as demonstrated by appropriate survey measures; and
* Designed to aid Users in meeting task goals without being an additional burden.

The system must be reliable and enable User trust by providing:

* Stable and reliable performance;
* Accurate data;
* Display of all data that is available in native or interfaced systems and intended to be available in the application; and
* Accessible information related to the source of data.

The application should include a modern Graphical User Interface that allows the User to view data from multiple sources and includes:

* Integrated display of structured and unstructured data;
* Rich data visualization and graphical display of data;
* Ability to switch between tabular and graphical data views;
* Ability to interact with displayed data to obtain additional details related to the data and source of the data; and
* User customizable components and settings.

The application must provide for advanced and up-to-date searching, to include:

* Fast search functionality with auto-complete and real-time display of matched results during typing; and
* Search history.

The application must provide for advanced filtering capabilities, to include:

* Filtering of data tables, lists, and grids; and
* Filtering of search results.

The application design should be modified to:

* Address the specific findings from a human factor heuristic evaluation conducted on the prior version of the application;
* Address the specific findings reported from field use of the prior version; and
* Address the specific findings reported from usability testing of the prior version or relevant prototypes.

**Documentation**

The following references BN4 on the documentation criteria of the RAMS training curriculum:

* Manage data about personnel engaged in research at VAMC facilities
* Automate the tracking of training, scope of practice, and all necessary certifications for PIs and other employees
* Notify PI or PI Designee and employee when training is required including annual/biannual re-training

Appendix B: Acronyms

The following is a list of acronym definitions:

Table 26: Acronyms

| Term | Definition |
| --- | --- |
| ACORP | Animal Component of Research Protocol |
| ACOS | Associate Chief of Staff |
| AFM | Animal Facility Manager |
| AO | Administrative Officer |
| BN | Business Need |
| BRD | Business Requirements Document |
| CITI | Collaborative Institutional Training Talent Management System (TMS) |
| COI | Conflict of Interest |
| CR | Continuing Review |
| CSP | Cooperative Studies Program |
| FY | Fiscal Year |
| IACUC | Institutional Animal Care and Use Committee |
| IPA | In-Person Authentication (IPA) |
| IRB | Institutional Review Board |
| LASIF | Large Scale Seismic Inversion Framework |
| LSA | Local System Administrator |
| LSI | Local Site Investigator |
| MOU | Memorandum of Understanding |
| MS | Microsoft |
| NDO | Normalized Data Object |
| NSR | New Service Request |
| ORO | Office of Research Oversight |
| PI | Principal Investigator |
| R&D | Research and Development |
| RAMS | Research Administrative Management System |
| RCO | Research Compliance Officer |
| RDIS | Research and Development Information System |
| RDM | Requirements Development and Management |
| RED | Requirements Elaboration Document |
| RPSS | Research Protocol Safety Survey |
| RSD | Requirements Specification Document |
| SAE | Serious Adverse Event |
| SDD | Software Design Document |
| SOP | Standard Operating Procedure |
| SRS | Subcommittee on Research Safety |
| SSA | System Site Administrator |
| TMS | Talent Management System |
| UAP | Unanticipated Problem Report |
| VA | Department of Veterans Affairs |
| VAMC | Department of Veterans Affairs Medical Center |
| VMU | Veterinary Medical Unit |
| WOC | Without Compensation |
| XML | Extensible Markup Language |

In addition to the above referenced acronym table, please refer to the RAMS Library for additional VA acronym information.

Template Revision History

| **Date** | **Version** | **Description** | **Author** |
| --- | --- | --- | --- |
| September 2015 | 1.7 | Updated Headings and spacing to conform with latest OIT Documentation Standards guidelines | Process Management |
| June 2015 | 1.6 | Updated to conform with latest Section 508 guidelines and remediated with Common Look Office tool | Process Management |
| May 2015 | 1.5 | Revised by the PMAS Process Improvement Lockdown Team | PMAS Process Improvement Lockdown Team |
| December 2014 | 1.4 | Updated to conform with latest Section 508 guidelines and remediated with Common Look Office tool | Process Management |
| May 2014 | 1.3 | Reordered cover page to enhance search capabilities | Process Management |
| May 2013 | 1.2 | Add Appendix for acronyms and glossary | Process Management |
| March 2013 | 1.1 | Formatted to current ProPath documentation standards and edited to conform with latest Alternative Text (Section 508) guidelines | Process Management |
| January 2013 | 1.0 | Initial Version | PMAS Business Office |