

# **Department of Veterans Affairs**

## **Requirements Specification Document (RSD)**

### ***Research Administrative Management System (RAMS)***



**July 2014**

**Version 3.4**

## Revision History

Note: The revision history cycle begins once changes or enhancements are requested after the Requirements Specification Document has been baselined. *Place latest revisions at top of table.*

Date	Version	Description	Author
07/17/2014	3.4	Revised RSD	██████ Team
01/14/2014	3.3	Baselined RSD for Solicitation Package	VA ORD

## 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.

## Table of Contents

<b>1.</b>	<b>Introduction.....</b>	<b>1</b>
1.1.	Purpose.....	1
1.2.	Scope.....	1
1.3.	Acronyms and Definitions .....	3
1.4.	References .....	5
<b>2.</b>	<b>Overall Specifications .....</b>	<b>6</b>
2.1.	Accessibility Specifications .....	6
2.2.	Business Rules Specifications .....	6
2.3.	Design Constraints Specifications .....	7
2.4.	Disaster Recovery Specifications .....	8
2.5.	Documentation Specifications .....	9
2.6.	Functional Specifications .....	9
2.6.1.	Database Definition .....	9
2.6.2.	Functional Process Requirements .....	11
2.6.2.1.	Personnel Management.....	11
2.6.2.2.	Projects Management.....	16
2.6.2.3.	Committee Management .....	21
2.6.2.4.	Documents Management .....	27
2.6.2.5.	Communications Management.....	30
2.6.3.	Reporting Functionality.....	31
2.6.4.	Role Based Functionality .....	32
2.7.	Graphical User Interface (GUI) General Specifications .....	32
2.7.1.	Data Entry UI .....	33
2.7.2.	Other UI.....	33
2.8.	Multi-Divisional Specifications.....	34
2.9.	Performance Specifications .....	34
2.10.	Quality Attributes Specifications .....	34
2.11.	Reliability Specifications .....	35
2.12.	Scope Integration .....	35
2.13.	Privacy and Security Specifications .....	35
2.13.1.	Privacy Specifications.....	37
2.14.	System Features.....	37
2.15.	Usability Specifications .....	38

<b>3.</b>	<b>Applicable Standards .....</b>	<b>38</b>
<b>4.</b>	<b>Interfaces.....</b>	<b>38</b>
4.1.	Communications Interfaces .....	38
4.2.	Hardware Interfaces .....	39
4.3.	Software Interfaces .....	39
4.4.	User Interfaces .....	39
<b>5.</b>	<b>Legal, Copyright, and Other Notices .....</b>	<b>39</b>
<b>6.</b>	<b>Purchased Components.....</b>	<b>39</b>
<b>7.</b>	<b>User Class Characteristics .....</b>	<b>41</b>
<b>8.</b>	<b>Estimation .....</b>	<b>45</b>
	<b>Appendix A User Stories Specification .....</b>	<b>46</b>
<b>9.</b>	<b>Approval Signatures.....</b>	<b>47</b>

# 1. Introduction

The Veterans Health Administration (VHA) Office of Research and Development (ORD) is responsible for the management and administration of the national Department of Veterans Affairs (VA) intramural research program. ORD aims to improve the efficiency and performance of the national VA research program by implementing an enterprise-wide Research Administrative Management System (RAMS) accessible to active field research offices and ORD Central Office. The implemented tool will support the major business functions of the Institutional Review Board (IRB) and provide a common database for tracking and reporting of administrative research program data throughout the VA. This document specifies the requirements for the RAMS system.

## 1.1. Purpose

The purpose of this Requirements Specification Document (RSD) is to document the requirements of the RAMS solution proposed through an acquisition 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 Business Requirements Document (BRD) [1].

- This document is based on the OED ProPath Template for requirements [2]. This document's organization and content reflect VA guidelines with the Project Management Accountability System (PMAS) [3]. The intended audience for this RSD is the VA Integrated Project Team (IPT) with access authorized and controlled by the VA ORD Project Manager.

## 1.2. 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.

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 their 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.

The availability and efficient management of national research office program data are critical elements of the business process of ORD. A centralized data repository will enable ORD to capture and translate real time data more rapidly in order to provide a higher level of responsiveness to governmental agencies monitoring research compliance issues, Congressional inquiries, and VA executive management. The consolidated IT infrastructure and elimination of redundant information management systems will also translate into cost savings. RAMS will create a framework enabling the VA research community to merge together divergent business processes, increase knowledge sharing and efficiency, and reduce redundancy and cost.

**As stated in the RAMS Performance Work Statement (PWS) for Transformation Twenty-one Total Technology (T4) Task Order #VA118-1008-0049 awarded 5/14/2014, the scope of RAMS Increment 1 is as follows:**

- a. Add/Edit a Project/Protocol
  - i. User log in and verification
  - ii. Add/Update Project Proposal via web form entry
  - iii. Add/Update General and Required Information
    1. Abstract
    2. Categories of human subjects
    3. Funding source
  - iv. Upload documents related to project
  - v. Create Consent and Health Insurance Portability and Accountability Act (HIPAA) letters from templates
  - vi. Manage project data provided by affiliate IRB

The approximate size of the forms to be transformed to a web form entry is listed below:

- IRB forms – 5 pages
- PI Forms – 3 pages
- Project submission forms – 10 pages
- Agenda forms – 3 pages

**The scope of RAMS Increment 2 is as follows:**

- A. Associate personnel to project
  - i. Add project staff and assign role and permission
  - ii. Add/edit user profile
    1. User Name, Contact, and Affiliations
    2. Scope of Practice
    3. User Education, Licenses and Credentials
    4. Add Bio sketch or CV
    5. User Research Appointment
    6. User Employment data
    7. Project Investigator Profile
- B. Preliminary Project Review
  - i. Online communication between admin and PI (Principal Investigator)
  - ii. Add project to selected agenda
  - iii. Assign type of review

### C. Manage Committee Processes

- i. Create and publish agenda
- ii. Role based notification system
- iii. Assign and receive reviews online
- iv. Upload and manage documents with version control
- v. Create and publish minutes
- vi. Track unexpected events and deviations
- vii. Generate revision and rebuttal letters
- viii. Generate renewal notifications
- ix. Monitor calendar and continuing review deadlines for each project
- x. Manage processes unique to Central IRB (cIRB)
  1. Local site applications
  2. Expanded notification structure

### D. Manage Project Status

- i. Track project status
- ii. Develop project status reports and dashboard
- iii. Update the Project status dashboard
- iv. Generate data submission in MS Word format
- v. Export data for local reports

## 1.3. Acronyms and Definitions

Acronym	Meaning
ACORP	Animal Component of Research Protocol
AO	Administrative Officer
ACOS	Associate Chief of Staff
cIRB	Central Institutional Review Board
CO	Contracting Officer
CoPI	Co Principal Investigator
COTR	Contracting Officer's Technical Representative
COTS	Commercial Off-the-Shelf System
CRADO	Chief Research and Development Officer
DMR	Designated Member Review

FCR	Full Committee Review
FIPS	Federal Information processing Standard
HTTP	Hyper Text Transport Protocol
HTTPS	Hyper Text Transfer Protocol Secure
IACUC	Institutional Animal Care and Use Committee
IFCAP	Integrated Funds Distribution, Control Point Activity, Accounting and Procurement
IO	Institutional Official
IPA	In Person Authentication
IPT	Integrated Project Team
IRB	Institutional Review Board
ISO	Information Security Officers/International Organization for Standardization
ITARS	IT Acquisition Request System
LIP	Licensed Individual Practioner
LOI	Net Operating Income
LSI	Local Site Investigator
MCD	Medical Center Director
NIST	National Institute of Standards and Technology
ORD	Office of Research and Development
PMAS	Program Management Accountability System
PO	Privacy Officer
RAMS	Research Administration and Management System
RCMS	Research Compliance Management System
RCO	Research Compliance Officer
RSD	Requirements Specification Document
SAML	Security Assertion Markup Language
Service Contract	A service contract is comprised of one or more published documents that express meta-information about a service. The service contract consists of the Service Level Agreement (SLA) in addition to the technical service contract which includes WSDL, XML schema, and WS-Policy definitions. [adapted from ██████ Erl, et. al., 2008, Web Service Contract Design and Versioning for SOA, Prentice Hall]
SLA	The Service Level Agreement (SLA) is a human-readable document describing non-functional service features such as Quality of Service (QoS), behaviors, or limitations. Some SLA-related requirements may also be expressed as machine-readable WS-Policy definitions. [adapted from ██████ Erl, et. al., 2008, Web Service Contract Design and Versioning for SOA, Prentice Hall]
SME	Subject Matter Expert



SOAP	Simple Object Access Protocol
SRS	Subcommittee on Research Safety
TRR	Test Readiness Review
VA	Department of Veterans Affairs
VACO	VA Central Office
VAMC	VA Medical Center
VHA	Veterans Health Administration
VistA	Veterans Health Information Systems and Technology Architecture
winRMS	Windows Research Management System
XML	eXtensible Markup Language

## 1.4. References

1. Research Administrative Management System Business Requirements Document v1.11, Work effort unique identifying **01-02-03-02-11-005**, approved June 2011
2. Office of Enterprise Development (OED) *ProPath Process Guide*, Release 17.5. October 2013
3. Project Management Accountability System (PMAS) Guide V4.0, November 07, 2012
4. *Principles of Service Oriented Architecture Version 1.31*, Software Engineering – Standards Division, Office of Enterprise Development, Office of Information & Technology, Department of Veterans Affairs
5. US Department of Veterans Affairs One-VA TRM v13.11, "Technology/Standard List," <http://www.va.gov/trm/ToolListSummaryPage.asp>, accessed January 24, 2014
6. *Corporate Data Center Catalog of Services*
7. NIST Special Publication 800-52 *Guidelines for the Selection and Use of Transport Layer Security (TLS) Implementations*, <http://csrc.nist.gov/publications/nistpubs/800-52/SP800-52.pdf>
8. FEA Consolidated Reference Model Document Version 2.3, October 2007, [http://www.whitehouse.gov/sites/default/files/omb/assets/fea\\_docs/FEA\\_CRM\\_v23\\_Final\\_Oct\\_2007\\_Revised.pdf](http://www.whitehouse.gov/sites/default/files/omb/assets/fea_docs/FEA_CRM_v23_Final_Oct_2007_Revised.pdf)
9. US Department of Veterans Affairs Health Services Research and Development Service, "Policies", [http://www.hsrp.research.va.gov/for\\_researchers/policies.cfm](http://www.hsrp.research.va.gov/for_researchers/policies.cfm), accessed January 24, 2014
10. Usability.gov, "Guidelines", <http://usability.gov/>, accessed October 4, 2011
11. RAMS Increment 1 User Stories (See Appendix A)

## 2. Overall Specifications

### 2.1. Accessibility Specifications

The contractor shall conform to the following standards required for accessibility of RAMS.

Req. ID	Requirement	Increment (1, 2, Future)
ACC-001	The RAMS shall comply with section 508 requirements as covered at <a href="http://www.section508.gov">http://www.section508.gov</a> .	1, 2 (VA Directive)
ACC-002	The RAMS system shall comply with Accessibility guidelines as covered at <a href="http://usability.gov/guidelines/index.html">http://usability.gov/guidelines/index.html</a>	1, 2 (VA Directive)

### 2.2. Business Rules Specifications

The contractor shall provide the following business rule as specified for the RAMS solution.

Req. ID	Business Rule Description	Increment (1, 2, Future)
BRS-001	The RAMS Data Model shall conform to best practices in database design for business intelligence and data mining applications.	1, 2

Business Rules associated with Feature ID [F4.2.1: Edit Name, Contacts, and Affiliation](#).

Req. ID	Business Rule Description	Increment (1, 2, Future)
BRS 4.2.1 -1	Non-US citizens must provide information on type of Visa, expiry date and also provide a copy	2 (5.6.A.ii.1)

Business Rules associated with Feature ID [F4.2.5: Add User Research Appointment](#).

Req. ID	Business Rule Description	Increment (1, 2, Future)
BRS 4.2.5 -1	PI must update their profiles at the start of a new project	2 (5.6.A.ii.7)
BRS 4.2.5 -2	Appointment letter can either be submitted electronically or on paper	2 (5.6.A.ii.5)

Business Rules associated with Feature ID [F4.2.6: User Employment Profile](#).

Req. ID	Business Rule Description	Increment (1, 2, Future)
BRS 4.2.6 -1	Users will have edit rights to their own profile.	2 (5.6.A.ii.6)

Business Rules associated with Feature ID [F3.7: Conduct a Convened Meeting](#).

Business Rules associated with Feature ID [F3.10: Create/Edit/Manage Minutes](#).

Req. ID	Business Rule Description	Increment (1, 2, Future)
BRS 3.10 -1	Meeting minutes with “Final” status cannot be changed	2 (5.6.C.v)
BRS 3.10 -2	Approved meeting minutes (from a previous meeting) must be locked and cannot be changed except through a “Change Request” mechanism	2 (5.6.C.v)

**Business Rules associated with Feature ID [F3.3.1.1: Create/Manage Agenda and Minutes Sections.](#)**

Req. ID	Business Rule Description	Increment (1, 2, Future)
BRS 3.3.1.1 -1	Status of Business Items must be tracked for e.g. “In Loading Queue”, “On the Agenda”, etc.	2
BRS 3.3.1.1 -2	Each Business item must be assigned a unique identifier <sup>1</sup> that traces back to the specific station and specific committee involved	1
BRS 3.3.1.1 -3	Each Business item’s path must able to be reconstructed for quality assurance and audit purposes	1

**Business Rules associated with Feature ID [F3.10.4: Lock Approved Final Minutes.](#)**

Req. ID	Business Rule Description	Increment (1, 2, Future)
BRS 3.10.4 -1	When the minutes are locked, they must not be changed, except through a change request with a justification and approval of the committee Chair.	2 (5.6.C.v)

## 2.3. Design Constraints Specifications

The contractor shall adhere to the following architectural design constraints for the RAMS solution. These include technical constraints, standards, nonfunctional requirements and important architectural decisions. These are the main drivers of the architectural design for RAMS.

Req. ID	Requirement	Priority <sup>1</sup> (P1, P2, P3)	Increment (1, 2, Future)
DCS-001	The RAMS system shall be free of per person or per seat licenses.	P1	1, 2
DCS-002	The RAMS system shall comply with all VA Enterprise Architecture Standards.	P1	1, 2
DCS-003	The RAMS 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.”[4]	P1	1, 2
DCS-004	RAMS software interfaces built for new business functions,	P1	1, 2

---

<sup>1</sup> This unique identifier is created when an item first appears on the agenda, and becomes inactive when that item receives committee approval in the minutes

Req. ID	Requirement	Priority <sup>1</sup> (P1, P2, P3)	Increment (1, 2, Future)
	legacy applications, databases, middleware and other infrastructure components shall be implemented as services using SOAP/HTTP(S), XML/HTTP(S), SOAP/Java Message Service (JMS), or XML/JMS.		
DCS-005	RAMS services shall be built using standards that promote interoperability.[5]	P1	1, 2
DCS-006	RAMS services shall be designed according to a technical service contract and a negotiated Service Level Agreement (SLA) which together comprise the service contract.	P1	1, 2
DCS-007	RAMS services implementation shall be loosely-coupled to the service interface.	P1	1, 2
DCS-008	A RAMS service interface is the sole entry point into service logic and resources. Services shall be accessed only via the exposed, published interfaces.	P1	1, 2
DCS-009	All RAMS 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 WS-Policy definitions as required.	P1	1, 2
DCS-010	RAMS services shall be designed so they can be monitored to determine whether services become unavailable, has 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.	P1	1, 2
DCS-011	No RAMS service shall use static (e.g. hard coded) service addresses.	P1	1, 2
DCS-012	RAMS service logic exposed by the service shall handle concurrent access without deadlock or loss of data integrity.	P1	1, 2
DCS-013	RAMS 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.	P1	1, 2
DCS-014	RAMS 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.	P1	1, 2
DCS-015	RAMS shall use RESTful Web services (Representational State Transfer) for any service that is accessed through the user interface.	P1	1, 2

<sup>1</sup> future priorities will be assigned during development review sessions between the contractor and government.

## 2.4. Disaster Recovery Specifications

The VA host system will provide RAMS with at a minimum incremental backups Monday through Friday and full backup processing once a week. Clones or copies of the backups will be sent offsite for safe keeping in a VA approved storage container. The contractor shall support this process as follows:

Req. ID	Requirement	Priority	Increment
---------	-------------	----------	-----------

		(P1, P2, P3)	(1, 2, Future)
DRS-001	RAMS shall be designed to facilitate database backups within a corporate data center environment.	P1	1, 2
DRS-002	RAMS shall be designed to be reloaded from a backup image and placed back into service.	P1	1, 2
DRS-003	RAMS shall be designed to separate the operational site from the disaster recovery site.	P1	2
DRS-004	RAMS shall be able to replicate the RAMS data from the operational site to the disaster recovery site.	P1	2
DRS-005	RAMS shall receive disaster recovery support at a minimum of “Essential Support.” That is, the capability of recovering applications within a 72-hour period with data being restored from the last backup. The vendor will support VA in any Disaster Recovery effort.	P1	2

## 2.5. Documentation Specifications

All documentation created to support the RAMS project shall comply with existing PMAS policies, use ProPath templates, and will be stored within PMAS. The IPT supports the solution provider in compliance and will balance the scope of the ProPath artifacts with what is reasonable and relevant to the project.

To locate documentation created to support the RAMS project:

[http://vawww.oed.wss.va.gov/process/Web\\_Pages/required\\_artifacts.aspx](http://vawww.oed.wss.va.gov/process/Web_Pages/required_artifacts.aspx)

The following new end-user documents shall be created:

- **RAMS Users Guides** –descriptions and instructions of all User accessible functionality by role
- **RAMS System Administrators Guide** –instructions on system installation, configuration, data synchronization, and system maintenance, security, as well as any other functionality that the System Administrator has specialized access to.

In addition, all documentation and models required by the VA Enterprise Architecture Standards for deployment of applications shall be created.

## 2.6. Functional Specifications

The RAMS solution is logically organized into five (5) different functional capabilities. These capabilities are identified below and expanded in the subparagraphs as noted:

1. Database Definition (Section 2.6.1)
2. Functional Process Requirements (Section 2.6.2)
3. Reporting Functionality (Section 2.6.3)
4. Role Based Functionality (Section 2.6.4)
5. Graphical User Interface (Section 2.7)

### 2.6.1. Database Definition

This section identifies and documents the requirements on how to use the RAMS database to support the RAMS functionalities. The overall database design will be established during Increment 1, however certain features will not be implemented until Increment 2 or beyond.

Req. ID	Requirement	Feature ID	Priority (P1, P2, P3)	Increment (1, 2, Future)
DD-000	The overall database design will be established during Increment 1, however certain features will not be implemented until Increment 2 or beyond.	All	P1	1, 2
DD-001	The RAMS Logical Data Model shall be in 3 <sup>rd</sup> Normal Form.	All	P1	1, 2
DD-002	The RAMS Logical Data Model shall include all major entities and relationships to manage all aspects of RAMS.[6]	All	P1	1, 2
DD-003	The RAMS shall confirm the integrity of all received data through the RAMS application data integrity check.	All	P1	1, 2
DD-004	The RAMS shall confirm the integrity of all received data through the RAMS database referential integrity.	All	P1	1, 2
DD-005	The RAMS shall record the data for managing the RAMS Committees information.	3.1.1	P1	2 (5.6.C)
DD-006	The RAMS shall record the data for checking the RAMS Committees status information.	3.2	P1	2 (5.6.C)
DD-007	The RAMS shall record the Committee Reviewer Comment data.	3.10.2	P1	2 (5.6.C.iii)
DD-008	The RAMS shall allow editing the recorded Committee Reviewer Comment data.	3.10.2	P1	2 (5.6.C)
DD-009	The RAMS shall record the correspondence prepared and sent to the Primary Investigator.	3.10.5	P1	2 (5.6.B.i)
DD-015	The RAMS shall record the data entered for Conducting a Convened Meeting.	3.7	P1	2 (5.6.C.iii)
DD-016	The RAMS shall record the data entered for Assigning Reviewers for the protocol review and investigation of potentially reportable matters.	3.8.1	P1	2 (5.6.A.i)
DD-020	The RAMS shall record the data entered for Categorizing Potentially Reportable Matters IRB.	3.13	P1	2 (5.6.C.vi)
DD-021	The RAMS shall record the data entered for Managing Continuing Reviews.	3.16	P1	Future
DD-026	The Committee Coordinator shall record in RAMS the Compliance Data from Non-VA Committees.	3.21	P1	Future
DD-029	The RAMS shall record the data for Managing Criteria for IRB Review.	3.23.2	P1	2 (5.6.B.iii)
DD-033	The RAMS shall record the data for Managing Documents.	3.24	P1	2 (5.6.C.iv)
DD-045	The RAMS shall record the data entered for Adding a New User.	4.1	P1	2 (5.6.A.ii)
DD-046	The RAMS shall record the data entered for Self Registration.	4.1.1	P1	Future
DD-047	The RAMS shall record the data entered for Editing Existing User profile.	4.2	P1	2 (5.6.A.ii)
DD-048	The RAMS shall record the data entered for the person's Name, Contacts and Affiliations.	4.2.1	P1	2 (5.6.A.ii.1)
DD-049	The RAMS shall record the data entered for the person's Scope Practice.	4.2.2	P1	2 (5.6.A.ii.2)
DD-050	The RAMS shall record the data entered for the person's Education, Licenses and Credentials.	4.2.3	P1	2 (5.6.A.ii.3)
DD-051	The RAMS shall record the data entered for Adding/Creating Biosketch or CV.	4.2.4	P1	2 (5.6.A.ii.4)

Req. ID	Requirement	Feature ID	Priority (P1, P2, P3)	Increment (1, 2, Future)
DD-052	The RAMS shall record the data entered for the person's Research Appointment.	4.2.5	P1	2 (5.6.A.ii.5)
DD-053	The RAMS shall record the data entered for the person's Employment Profile.	4.2.6	P1	2 (5.6.A.ii.6)
DD-055	The RAMS shall record the data entered for the Project Investigator Profile.	4.2.8	P1	2 (5.6.A.ii.7)
DD-061	The RAMS shall record the data entered for Managing Projects.	2.1	P1	1, 2
DD-063	The RAMS shall prepare and transform the data stored in the RAMS database into the formats suitable for Reporting and Analysis.	All	P1	1, 2

## 2.6.2. Functional Process Requirements

There are six major functional processes in RAMS:

1. Personnel Management
2. Projects Management
3. Committees Management
4. Logistics Management
5. Document Management
6. Communication Management

### 2.6.2.1. Personnel Management

The RAMS Personnel Management process manages data about personnel engaged in research at VA Medical Facilities (VAMCs). The functional requirement tables presented in this paragraph contain the requirements for these processes. They are grouped by features.

#### Feature ID F4.1: Add New User

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
FRD 4.1 -1	PI, PI Designee, ACOS, AO, Committee Coordinator, or Local RAMS Admin shall have the ability to request new user account.	P1	2 (5.6.A.i)
FRD 4.1 -2	Local RAMS Admin shall add new user name and email address.	P1	2 (5.6.A.i)
FRD 4.1 -3	RAMS system shall display the available roles based on the requester's role.	P1	2 (5.6.A.i)
FRD 4.1 -4	Local RAMS Admin shall have the ability to select user roles.	P1	2 (5.6.A.i)
FRD 4.1 -5	Local RAMS Admin shall have the ability to complete data required for the new user.	P1	2 (5.6.A.i)

<b>Req. ID</b>	<b>Requirement Description</b>	<b>Priority</b> (P1, P2, P3)	<b>Increment</b> (1, 2, Future)
FRD 4.1 -6	Local RAMS Admin shall have the ability to enter data about the new user (Features 4.2.1 – 4.2.6)	P1	2 (5.6.A.ii)
FRD 4.1 -7	RAMS system shall send notification of account creation to new user (Feature 4.1.1)	P1	2 (5.6.C.ii)
FRD 4.1 -8	Local RAMS Admin shall have the ability to verify and submit enrollment and to create a new user account.	P1	2 <b>(5.6.A i)</b>

#### **Feature ID F4.1.1: Self Registration (Ability to Edit Profile)**

<b>Req. ID</b>	<b>Requirement Description</b>	<b>Priority</b> (P1, P2, P3)	<b>Increment</b> (1, 2, Future)
FRD 4.1.1 -1	RAMS User shall have the ability to receive notification to complete self-registration.	P1	2
FRD 4.1.1 -2	RAMS user shall select option for 5/8 <sup>th</sup> employment at VA.	P1	2
FRD 4.1.1 -3	RAMS System shall notify Local RAMS Admin of WOC employment status (see feature 4.2.5 for details).	P1	2
FRD 4.1.1 -4	RAMS User shall enter data (details are in features 4.2.1-4.2.6) questions/criteria if applicable to role.	P1	2
FRD 4.1.1 -5	RAMS System shall populate sections/questions to complete by the user (if applicable to role).	P1	2
FRD 4.1.1 -6	RAMS User shall have the ability to submit self-registration data.	P1	2
FRD 4.1.1 -9	RAMS System shall notify Local RAMS Admin when a user self registers	P1	2
FRD 4.1.1 -10	Local RAMS Admin/Coordinator shall review package and verify whether the registration package is complete or not.	P1	2
FRD 4.1.1 -11	RAMS System shall notify user to complete the registration package if it is incomplete.	P1	2
FRD 4.1.1 -12	RAMS System shall check off and set status as 'complete' and is ready to upload.	P1	2

#### **Feature ID F4.2: Edit an Existing User Profile**

<b>Req. ID</b>	<b>Requirement Description</b>	<b>Priority</b> (P1, P2, P3)	<b>Increment</b> (1, 2, Future)
FRD 4.2 -1	PI shall have the ability to access the user profile module by logging in.	P1	2 (5.6.A.ii)
FRD 4.2 -2.1	Local RAMS Admin shall have the ability to search on the user's name.	P1	2 (5.6.A.ii)
FRD 4.2 -2.2	Local RAMS Admin may update profile data on behalf of user.	P1	2 (5.6.A.ii)
FRD 4.2 -3	PI shall have the ability to open user profile status.	P1	2 (5.6.A.ii)



<b>Req. ID</b>	<b>Requirement Description</b>	<b>Priority</b> (P1, P2, P3)	<b>Increment</b> (1, 2, Future)
FRD 4.2 -4	RAMS system shall display status of elements with data entry options. Each section of the User profile (Feature 4.1-4.4) has an entry point and a status (not complete, complete, updated, in progress).	P1	2 (5.6.A.ii)
FRD 4.2 -5	PI shall have the ability to update profile information.	P1	2 (5.6.A.ii)
FRD 4.2 -6	PI shall have the ability to submit data when finished each section.	P1	2 (5.6.A.ii)
FRD 4.2 -7	RAMS System shall notify Local RAMS Admin when PI makes changes.	P1	2 (5.6.A.ii)
FRD 4.2 -8	Local RAMS Admin shall have the ability to search users to update.	P1	2 (5.6.A.ii)
FRD 4.2 -9	Local RAMS Admin shall have the ability to enter employment status data.	P1	2 (5.6.A.ii)
FRD 4.2 -10	Local RAMS Admin shall have the ability to view updated information.	P1	2 (5.6.A.ii)
FRD 4.2 -11	Local RAMS Admin shall have the ability to request user to make changes.	P1	Future
FRD 4.2 -12	RAMS system shall verify data as complete.	P1	2 (5.6.A.ii)
FRD 4.2 -13	RAMS system shall save changes.	P1	2 (5.6.A.ii)
FRD 4.2 -14	RAMS system shall set status as updated or complete (w/ timestamp).	P1	2 (5.6.A.ii)

#### **Feature ID F4.2.1: Name, Contacts and Affiliations**

<b>Req. ID</b>	<b>Requirement Description</b>	<b>Priority</b> (P1, P2, P3)	<b>Increment</b> (1, 2, Future)
FRD 4.2.1-1	RAMS System shall display the data entry screen based on user role.	P1	2 (5.6.A.ii.1)
FRD 4.2.1-2	RAMS User shall have the ability to add identification data (i.e. name).	P1	2 (5.6.A.ii.1)
FRD 4.2.1-3	RAMS User shall add contact information.	P1	2 (5.6.A.ii.1)
FRD 4.2.1-4	RAMS User shall answer whether he/she is a US Citizen or not.	P1	2 (5.6.A.ii.1)
FRD 4.2.1-5	RAMS system shall have the ability to notify/warn user to verify citizenship documents with Local RAMS Admin.	P1	2 (5.6.A.ii.1)
FRD 4.2.1-6	Local RAMS Admin shall have the ability to verify and notify user to complete registration.	P1	Future
FRD 4.2.1-7	RAMS User shall answer whether he/she will need keys.	P1	Future
FRD 4.2.1-8	RAMS System shall notify Local RAMS Admin to contact building/facility maintenance.	P1	Future
FRD 4.2.1-9	Local RAMS Admin shall issue keys and record key number/code in database.	P1	Future
FRD 4.2.1-10	RAMS System shall save Building, Room, and Keys.	P1	2 (5.6.A.ii.1)

FRD 4.2.1-11	RAMS User shall have the ability to add affiliations.	P1	2 (5.6.A.ii.1)
FRD 4.2.1-12	RAMS User shall have the ability to submit name, contacts, and affiliations data.	P1	2 (5.6.A.ii.1)
FRD 4.2.1-13	RAMS System shall save changes.	P1	2 (5.6.A.ii.1)

#### Feature ID F4.2.3: Add User Education/Credentials

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
FRD 4.2.3-2	RAMS User shall have the ability to request to add or edit education data.	P1	2 (5.6.A.ii.3)
FRD 4.2.3-3	RAMS System shall display data entry options for education/credentials.	P1	2 (5.6.A.ii.3)
FRD 4.2.3-4	RAMS User shall have the ability to answer whether he/she has degree or not.	P1	2 (5.6.A.ii.3)
FRD 4.2.3-5	RAMS User shall have the ability to add education information including degree, year, and registrar address.	P1	2 (5.6.A.ii.3)
FRD 4.2.3-6	RAMS User shall have the ability to answer whether he/she is a LIP or not.	P1	2 (5.6.A.ii.3)
FRD 4.2.3-7	RAMS User shall have the ability to add LIP information.	P1	2 (5.6.A.ii.3)
FRD 4.2.3-8	RAMS User shall have the ability to answer whether he/she has a license or not.	P1	2 (5.6.A.ii.3)
FRD 4.2.3-9	RAMS User shall have the ability to add license information.	P1	2 (5.6.A.ii.3)
FRD 4.2.3-10	RAMS User shall have the ability to submit education, license, and credentials data.	P1	2 (5.6.A.ii.3)
FRD 4.2.3-11	RAMS System shall notify Local RAMS Admin to verify education, license, and credentials data.	P1	2 (5.6.A.ii.3)
FRD 4.2.3-12	Local RAMS Admin shall have the ability to verify data and decide whether it is accurate or not.	P1	2 (5.6.A.ii.3)
FRD 4.2.3-13	RAMS System shall notify user to resubmit in case the data is not accurate.	P1	2 (5.6.A.ii.3)
FRD 4.2.3-14	RAMS System shall add education, license, and credentials data to user profile.	P1	2 (5.6.A.ii.3)

#### Feature ID F4.2.4: Edit Biosketch.

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
FRD 4.2.4-1	RAMS User shall have the ability to upload Biosketch/CV.	P1	2 (5.6.A.ii.4)

#### Feature ID F4.2.5: Add User Research Appointment.

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
---------	-------------------------	--------------------------	-----------------------------

FRD 4.2.5-1	RAMS System shall retrieve applicable user information (Appt data includes apt dates and citizenship if applicable).	P1	2 (5.6.A.ii.5)
FRD 4.2.5-2	RAMS System shall notify Local RAMS Admin that a WOC appointment letter is required.	P1	2 (5.6.A.ii.5)
FRD 4.2.5-3	Local RAMS Admin shall have the ability to navigate to Research Appointment Section.	P1	2 (5.6.A.ii.5)
FRD 4.2.5-4	Local RAMS Admin shall select WOC by name.	P1	2 (5.6.A.ii.5)
FRD 4.2.5-5	Local RAMS Admin shall verify non US-citizenship documents	P1	2 (5.6.A.ii.5)
FRD 4.2.5-6	RAMS System shall pre-populate user data into downloaded form/letter.	P1	2 (5.6.A.ii.5)
FRD 4.2.5-7	RAMS System shall generate formal letter.	P1	2 (5.6.A.ii.5)
FRD 4.2.5-8	RAMS System shall display draft letter in edit format.	P1	2 (5.6.A.ii.5)
FRD 4.2.5-9	Local RAMS Admin shall review and make edits to the draft letter.	P1	2 (5.6.A.ii.5)
FRD 4.2.5-10	Local RAMS Admin shall have the ability to finalize the letter.	P1	2 (5.6.A.ii.5)
FRD 4.2.5-11	Local RAMS Admin shall have the ability to sign off with electronic signature.	P1	2 (5.6.A.ii.5)
FRD 4.2.5-12	RAMS System shall notify PI to sign off.	P1	2 (5.6.A.ii.5)
FRD 4.2.5-13	PI shall have the ability to sign off with electronic signature.	P1	2 (5.6.A.ii.5)
FRD 4.2.5-14	RAMS System shall save approval with timestamp.	P1	2 (5.6.A.ii.5)

#### Feature ID F4.2.6: User Employment Profile.

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
FRD 4.2.6-1	Research Office (Local RAMS Admin) shall have the ability to select user employment profile.	P1	2 5.6.A.ii.6
FRD 4.2.6-2	Research Office (Local RAMS Admin) shall have the ability to search and select Employee.	P1	2 5.6.A.ii.6
FRD 4.2.6-3	Research Office (Local RAMS Admin) shall have the ability to navigate to employment profile section.	P1	2 5.6.A.ii.6
FRD 4.2.6-4	Research Office (Local RAMS Admin) shall have the ability to verify job title and description section.	P1	2 5.6.A.ii.6
FRD 4.2.6-10	Research Office (Local RAMS Admin) shall have the ability to submit.	P1	2 5.6.A.ii.6
FRD 4.2.6-11	RAMS System shall save changes to database.	P1	2 5.6.A.ii.6

## 2.6.2.2. Projects Management

RAMS Projects processes allow individual sites to track and manage research projects and studies. The functional requirements tables contain the requirements for these processes. They are grouped by features.

### Feature ID F2.1: Add or Edit Project

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
FRD 2.1-0	User with write permissions shall have the ability to add projects.	P1	1 (5.5.a)
FRD 2.1-1	User with write permissions shall have the ability to edit projects that currently are not in administrative review or approved.	P1	1 (5.5.a)
FRD 2.1-2	RAMS system shall allow User with write permissions to either add or edit project option for projects that currently are not in administrative review or approved.	P1	1 (5.5.a)
FRD 2.1-3	RAMS system shall display the list of User's projects when User with write permissions chooses to update a project that currently is not in administrative review or approved.	P1	1 (5.5.a)
FRD 2.1-4	RAMS system shall retrieve User's project data in case User with write permissions wishes to edit an existing project that currently is not in administrative review or approved.	P1	1 (5.5.a)

### Feature ID F2.1.1a: Add Project Description

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
FRD 2.1.1a-1.1	Users with write permissions shall have the ability to edit the Project Description for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.iii)
FRD 2.1.1a-1.2	Users with write permissions shall have the ability to add the Project Description for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.iii)
FRD 2.1.1a-2	Users with write permissions shall have the ability to edit Project Abstract/Summary for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.iii.1)
FRD 2.1.1a-3	Users with write permissions shall have the ability to add Project Abstract/Summary for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.iii.1)
FRD 2.1.1a-4	Users with write permissions shall have the ability to upload file of abstract/summary for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.iv)

<b>Req. ID</b>	<b>Requirement Description</b>	<b>Priority</b> (P1, P2, P3)	<b>Increment</b> (1, 2, Future)
FRD 2.1.1a-5	RAMS System shall display current text of abstract/summary of uploaded file, and a list of the features of the project that may require oversight.	P1	Future
FRD 2.1.1a-6	RAMS System shall prompt the User to answer questions needed to determine supporting documentation required for the project.	P1	1 (5.5.a.ii); (5.5.a.iv)
FRD 2.1.1a-7	Users with write permissions shall have the ability to add project relevance for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.iii)
FRD 2.1.1a-8	Users with write permissions shall have the ability to upload the project proposal for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.iv)
FRD 2.1.1a-9	Users with write permissions shall have the ability to add project funding information (1. Describe who is sponsoring/funding project; 2. List the amount approved; 3. Enter funding duration (start & end dates)) for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.iii.3)
FRD 2.1.1a-10	Users with write permissions shall have the ability to upload Letter of Intent (LOI)/Grant Application for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.iv)
FRD 2.1.1a-11	Users with write permissions shall have the ability to enter location and duration of project for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.iii)
FRD 2.1.1a-12	Users with write permissions shall have the ability to verify scope of practice for that User's project(s) currently not in administrative review or approved.	P1	TBD
FRD 2.1.1a-13	Users with write permissions shall have the ability to select Project Uses Information for that User's project(s) currently not in administrative review or approved.	P1	TBD

#### **Feature ID F2.1.1b: Add Project Description - Uses Buttons**

<b>Req. ID</b>	<b>Requirement Description</b>	<b>Priority</b> (P1, P2, P3)	<b>Increment</b> (1, 2, Future)
FRD 2.1.1b-1	Users with write permissions shall have the ability to state if human subjects are involved for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.iii.2)
FRD 2.1.1b-4	RAMS system shall add IRB required forms.	P1	1 (5.5.a.vi)
FRD 2.1.1b-5	Users with write permissions shall have the ability to state if there is any individually identifiable data for that User's project(s) currently not in administrative review or approved.	P1	TBD
FRD 2.1.1b-6	RAMS system shall add PII required forms.	P1	1 (5.5.a.v)

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
FRD 2.1.1b-7	Users with write permissions shall have the ability to state if the project involves minors or vulnerable for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.iii.2)
FRD 2.1.1b-8	RAMS system shall notify PI, ACOS and AO that CRADO approval is required.	P1	2
FRD 2.1.1b-9	RAMS system shall track CRADO approval status.	P1	2
FRD 2.1.1b-15	Users with write permissions shall have the ability to state if the project involves clinical drugs for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.iii)
FRD 2.1.1b-16	RAMS system shall add drug information to required forms.	P1	1
FRD 2.1.1b-19	Users with write permissions shall have the ability to state if the pharmacy support is required for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.iii)
FRD 2.1.1b-21	Users with write permissions shall have the ability to upload Letter of Intent and add "not funded" for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.iv) (5.5.a.iii.3)

#### Feature ID F2.1.1c: Add Project Description - Uses Buttons

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
FRD 2.1.1c-1	Users with write permissions shall have the ability to state if the research will be conducted in a VA clinic for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.ii)
FRD 2.1.1c-3	Users with write permissions shall have the ability to state if the project requires pathology services for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.ii)
FRD 2.1.1c-5	Users with write permissions shall have the ability to state if the project involves safety hazards for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.ii)
FRD 2.1.1c-12	Users with write permissions shall have the ability to state if the project will require cIRB review for that User's project(s) currently not in administrative review or approved.	P1	1 (5.5.a.ii)
FRD 2.1.1c-13	RAMS system shall notify cIRB administrator or coordinating center.	P1	TBD

#### Feature ID F2.3: Add Project Personnel

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
---------	-------------------------	--------------------------	-----------------------------

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
FRD 2.3-1	Users with write permissions shall have the ability to choose project personnel for that User's project(s) currently not in administrative review or approved.	P1	2 (5.6.A)
FRD 2.3-2	Users with write permissions shall have the ability to identify CoPI to add for that User's project(s) currently not in administrative review or approved.	P1	2 (5.6.A.i)
FRD 2.3-3	RAMS system shall verify whether the selected CoPI is in the system.	P1	2 (5.6.A.i)
FRD 2.3-4	Users with write permissions shall have the ability to initiate a request to add a new user.	P1	2 (5.6.A.i)
FRD 2.3-5	Users with write permissions shall have the ability to select CoPI and assign role for that User's project(s) currently not in administrative review or approved.	P1	2 (5.6.A.i)
FRD 2.3-7	RAMS system shall retrieve station staff list.	P1	2 (5.6.A.i)
FRD 2.3-8	RAMS system shall display staff checkbox.	P1	2 (5.6.A.i)
FRD 2.3-9	Users with write permissions shall have the ability to assign roles.	P1	2 (5.6.A.i)

### Feature ID 3.5: Manage Project/Study Application/Protocol Review

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
<b>Feature ID F3.5.2: Complete and Submit Study Application for Review</b>			
FRD 3.5.2 -3	PI shall have the ability to submit the study application for review.	P1	1
<b>Feature ID F3.5.2.2: Complete Pre-Submission Requirements – IRB</b>			
FRD 3.5.2.2 -1	PI or PI Representative shall have the ability to notify IRB RAMS Administrator of relevant documents required with application.	P1	2 (5.6.B)
FRD 3.5.2.2 -2	RAMS System shall set the status of IRB application "In Draft".	P1	1
FRD 3.5.2.2 -4	IRB RAMS Administrator shall have the ability to enter list of required relevant documents.	P1	1
FRD 3.5.2.2 -24	Users with write permissions shall have the ability to complete Electronic Form(s)/Smart Forms for that User's project(s) currently not in administrative review or approved.	P1	1
FRD 3.5.2.2 -27	Users with write permissions shall have the ability to manage and upload required documents for that User's project(s) currently not in administrative review or approved.	P1	1
FRD 3.5.2.2 -29	RAMS System shall set status of pre-submission requirements = Complete.	P1	1
<b>Feature ID F3.5.3: Overall Process for Review of Study Application</b>			
FRD 3.5.3 -2	PI or PI Representative shall have the ability to identify and select the study application.	P1	2
FRD 3.5.3 -3	RAMS System shall list the latest version of each study application that may be the study application of interest, while maintaining prior versions for future reference.	P1	1

FRD 3.5.3 -9	RAMS System shall query type of submission (Continuing Review, Amendment, Closure).	P1	2 (5.6.B.iii)
FRD 3.5.3 -10	PI or PI Representative shall have the ability to enter type of submission.	P1	2 (5.6.B.iii)

### Feature ID 3.25: Overall Project Management

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
<b>Feature ID F3.25.1: Project Management – Closure/Withdrawal.</b>			
FRD 3.25.1 -1	PI shall have the ability to decide that the project is closed, no further oversight applies.	P1	2 (5.6.D)
FRD 3.25.1 -2	Research Coordinator shall have the ability to decide that the project is to be withdrawn from consideration for approval.	P1	2 (5.6.D)
FRD 3.25.1 -3	Local Administrators shall have the ability to decide that the project is to be withdrawn from consideration for approval.	P1	2 (5.6.D)
FRD 3.25.1 -6	RAMS system shall be able to set the approval and progress status of study applications as required	P1	2 (5.6.D)



### 2.6.2.3. Committee Management

RAMS Committees processes automate the management of committees to ensure compliance. The major functions of the IRB are:

- Manage Committee Membership
- Manage Committee Meetings
- Manage Committee Processes

The functional requirements tables in this section contain the requirements, grouped by features, for the **IRB committee (only)**. .

The Committee Membership functions consists of:

1. Update Committee Composition (Feature ID F3.1.1)
2. Check Committee Status (Feature ID F3.2)

#### Feature ID F3.1.1: Update Committee Composition

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
FRD 3.1.1 -3	RAMS system shall have the ability to store the following information for each member in the committee roster: name, role(s), status, begin/end dates of appointment.	P1	2 (5.6.A.i)
FRD 3.1.1 -8	Committee Administrator shall have the ability to add/inactivate/update the following information for any member: name, role(s), begin/end dates of appointment, ID code.	P1	2 (5.6.A.i)
FRD 3.1.1 -14	Committee Administrator shall have the ability to upload completed and signed qualifications form(s).	P1	2 (5.6.C.iv)
FRD 3.1.1 -23	Committee Administrator shall have the ability to confirm and enter official appointment.	P1	2 (5.6.A.i)
FRD 3.1.1 -24	Research Office shall have the ability to upload signed letter of appointment to RAMS.	P1	2 (5.6.C.iv)
FRD 3.1.1 -29	RAMS system shall notify Member, Committee Coordinator, or IO of any appointment confirmation.	P1	2 (5.6.A.i)

#### Feature ID F3.3: Manage Agenda & Minutes

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
<b>Feature ID F3.3.1.1: Create/Manage Agenda and Minutes Sections</b>			
<b>Feature ID F3.3.1.1.1: Add New Agenda/Minutes Section</b>			
FRD 3.3.1.1.1 -2	IRB Administrator shall have the ability to choose the committee template.	P1	2 (5.6.C.i)
<b>Feature ID F3.3.1.2.2: Manually Add New Agenda Item</b>			
FRD 3.3.1.2.2 -1	Research Office or Committee Coordinator shall have the ability to manually add new agenda item(s).	P1	2 (5.6.C.i)

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
<b>Feature ID F3.3.1.5: Create draft pre-meeting Agenda (Pre-Release Quality Control Review)</b>			
FRD 3.3.1.5 -1	Committee Coordinator shall have the ability to view draft agenda.	P1	2 (5.6.C.i)
FRD 3.3.1.5 -2	RAMS system shall notify Committee Coordinator that no changes possible if agenda is locked.	P1	2 (5.6.C.i)

#### Feature ID F3.10: Create/Edit/Manage Minutes

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
<b>Feature ID F3.10.1: Add New Business Items Introduced in the Meeting.</b>			
FRD 3.10.1 -2	Multiple: <ul style="list-style-type: none"> <li>RAMS system shall allow coordinator to assign reviewers</li> <li>RAMS system shall add review to assigned reviewer's task list</li> <li>RAMS system shall notify committee of items to be reviewed at the meeting</li> </ul>	P1	2 (5.6.C.i)
FRD 3.10.1 -4	Research Office or Committee Coordinator shall have the ability to insert revised reviewer comments.	P1	2 (5.6.C.i)
<b>Feature ID F3.10.3: Complete (Create) Draft Minutes of Meeting</b>			
FRD 3.10.3 -1	RAMS Committee Coordinator shall have the ability to prepare draft minutes.	P1	2 (5.6.C.v)
FRD 3.10.3 -2	RAMS System shall record attendance at the meeting (manually input by Coordinator).	P1	2 (5.6.C.v)
FRD 3.10.3 -6	RAMS Coordinator shall have the ability to edit multiple agenda items.	P1	2 (5.6.C.v)
FRD 3.10.3 -7	RAMS Coordinator shall have the ability to state whether the minutes are ready to be sent to the agenda queue for the next meeting or not.	P1	2 (5.6.C.v)
FRD 3.10.3 -8	RAMS System shall add to agenda loading queue for next meeting.	P1	2 (5.6.C.v)
<b>Feature ID F3.10.5: Prepare Correspondence to PI</b>			
FRD 3.10.5 -2	RAMS System shall ask user if the agenda item is ready to be sent to PI.	P1	2 (5.6.C.i)
FRD 3.10.5 -3	RAMS System shall save the draft item.	P1	2 (5.6.C.i)
FRD 3.10.5 -4	RAMS System shall save the notification.	P1	2 (5.6.C.i)
FRD 3.10.5 -5	RAMS System shall notify and place notification on PI's notification list.	P1	2 (5.6.C.i)

Manage committee processes has the following functions:

1. Determine Compliant Method of Review (Feature ID: 3.8)
2. Manage Continuing Review (Feature ID: 3.16)

**Feature ID F3.8: Determine Compliant Method of Review.**

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
<b>Feature ID F3.8: Determine Compliant Method of Review</b>			
FRD 3.8 -1	RAMS System shall list the study applications submitted for review.	P1	2 (5.6.C.i)
FRD 3.8 -2	RAMS System shall notify the Committee Coordinator that study application has been submitted for review.	P1	2 (5.6.C.i)
FRD 3.8 -3	RAMS System shall make submitted study application available to Committee Coordinator.	P1	2 (5.6.C.i)
FRD 3.8 -4	Committee RAMS Administrator or Committee Coordinator shall have the ability to notify PI if information is incomplete and ask them to complete and re-submit.	P1	2 (5.6.C.i)
FRD 3.8 -5	Committee RAMS Administrator or Committee Coordinator shall notify PI if any administrative corrections are needed (include recommendations).	P1	2 (5.6.C.i)
FRD 3.8 -11	Committee RAMS Administrator or Committee Coordinator shall have the ability to identify alternate method of review.	P1	2 (5.6.C.i)
FRD 3.8 -12	RAMS System shall notify PI of selected review method to be used.	P1	2 (5.6.C.i)

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
<b>Feature ID F3.8.1: Assign Reviewers (for protocol review, investigation of potentially reportable matters)</b>			
FRD 3.8.1 -4	Committee Coordinator shall have the ability to assign reviewers.	P1	2 (5.6.A.i)
FRD 3.8.1 -5	Committee Chair shall have the ability to assign reviewers.	P1	2 (5.6.A.i)
FRD 3.8.1 -13	Committee Coordinator shall have the ability to enter names of assigned reviewers.	P1	2 (5.6.A.i)
<b>Feature ID F3.8.1.2: Full Committee Review (FCR).</b>			
FRD 3.8.1.2 -5	Committee members shall have the ability to enter recommendations, by text entry or file upload (optional).	P1	2 (5.6.C.iii)
FRD 3.8.1.2 -6	Assigned reviewers shall have the ability to enter recommendations by text entry or file upload (required).	P1	2 (5.6.C.iii)
FRD 3.8.1.2 -13	Committee RAMS Administrator shall have the ability to enter description of modifications required by committee.	P1	2 (5.6.C.iii)
FRD 3.8.1.2 -18	Committee Rams Administrator shall have the ability to enter summary of committee deliberations and outcome.	P1	2 (5.6.C.iii)

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
FRD 3.8.1.2 -25	RAMS System shall and make PI study application documents available to each site liaison and LSI.	P1	2 (5.6.C.iii)
FRD 3.8.1.2 -30	RAMS System shall make comments available to Central IRB members.	P1	2 (5.6.C.iii)
FRD 3.8.1.2 -32	RAMS System shall notify Central IRB Members to review comments.	P1	2 (5.6.C.iii)
FRD 3.8.1.2 -39	Committee RAMS Administrator shall have the ability to enter summary of committee deliberations and outcome.	P1	2 (5.6.C.iii)

#### Feature ID 3.16: Manage continuing reviews

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
<b>Feature ID F3.16: Manage continuing reviews.</b>			
FRD 3.16 -1	RAMS System shall retrieve interval specified by committee for continuing review.	P1	2 (5.6.C.ix)
FRD 3.16 -2	RAMS System shall calculate due dates for Continuing Review = Continuing Review date + (interval for continuing review)	P1	2 (5.6.C.ix)
FRD 3.16 -3	RAMS System shall monitor calendar.	P1	2 (5.6.C.ix)
FRD 3.16 -4	2 months before continuing review is due, RAMS System shall set Continuing Review status = "Continuing Review Due".	P1	2 (5.6.C.ix)
FRD 3.16 -5	A Reviewer shall complete and submit checklist for continuing review of approved study application.	P1	2 (5.6.C.ix)

The IRB specific functions are grouped as:

1. Manage Criteria for IRB Review (Feature ID: 3.23.2)
2. Feature ID F3.8.3: Determine Eligibility for Review by Alternate Method -- Expedited IRB Review.
3. Track Enrollment of Subjects (Feature ID: 3.22)
4. Categorize Potentially Reportable Matters (Feature ID: 3.13)
5. Manage DSMB Reports (Feature ID: 3.14)

#### Feature ID 3.23.2: Manage Criteria for IRB Review

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
<b>Feature ID F3.23.2: Manage criteria for IRB Review.</b>			
<b>Feature ID F3.23.2.1: Determine Type of Review Required.</b>			
FRD 3.23.2.1 -1	RAMS System shall note that study application has been submitted to be considered by IRB.	P1	2 (5.6.B.iii)

FRD 3.23.2.1 -2	RAMS System shall determine if the funding source is VA ORD.	P1	2 (5.6.B.iii)
FRD 3.23.2.1 -3	RAMS System shall query if more than 1 study site is involved.	P1	2 (5.6.B.iii)
FRD 3.23.2.1 -7	PI shall have the ability to enter info about each additional site: location, name of local PI.	P1	2 (5.6.B.iii)
FRD 3.23.2.1 -8	RAMS System shall add location and name of local Site Investigator for each additional (engaged) site to database.	P1	2 (5.6.B.iii)
FRD 3.23.2.1 -18	IRB Coordinator shall have the ability to enter name of reviewer assigned by Chair.	P1	2 (5.6.B.iii)
FRD 3.23.2.1 -19	RAMS System shall make application available to the Reviewer.	P1	2 (5.6.B.iii)

### Feature ID 3.13: Categorize Potentially Reportable Matters

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
<b>Feature ID F3.13: Categorize Potentially Reportable Matters IRB.</b>			
FRD 3.13 -1	Members of VA Research Community shall have the ability to indicate awareness of a matter that raises concern about appropriate protection of human subjects, research personnel, or others.	P1	2 (TBD)
<b>Feature ID F3.13.2: Manage potentially reportable matters –IRB.</b>			
FRD 3.13.2 -1	IRB Members shall have the ability to review submitted reports from any VA personnel who become aware of a matter that raises concern about appropriate protection of human subjects, research personnel, or others.	P1	2 (TBD)
FRD 3.13.2 -3	RAMS System shall notify IRB Coordinator of any concern about appropriate protection of humans.	P1	2 (TBD)
FRD 3.13.2 -16	IRB Members shall have the ability to make determination regarding whether matter is reportable.	P1	2 (TBD)
FRD 3.13.2 -54	IRB Chair and/or the convened IRB shall have the ability to suspend for safety reasons Activity Involving Human Subjects. Only the convened IRB shall have the ability to terminate Activity Involving Human Subjects.	P1	2 (TBD)
FRD 3.13.2 -56	IRB Members shall have the ability to enter findings and description of actions.	P1	2 (TBD)
<b>Feature ID F3.13.2a: Manage Potentially Reportable Matters IRB -- Termination/Suspension of Activities Involving Human Subjects.</b>			
FRD 3.13.2a -1	IRB Members shall have the ability to review matter and make a determination about suspension/termination (requires majority vote of a quorum).	P1	2 (TBD)
FRD 3.13.2a -2	IRB Chair shall have the ability to make unilateral determination about suspension only in certain circumstances involving patient safety.	P1	2 (TBD)
FRD 3.13.2a -3	IO shall have the ability to make unilateral determination about suspension/termination.	P1	2 (TBD)
FRD 3.13.2a -4	IRB Members shall have the ability to determine if it is necessary to terminate the work.	P1	2 (TBD)

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
FRD 3.13.2a -5	IRB Members shall have the ability to enter status of work = Terminated.	P1	2 (TBD)
FRD 3.13.2a -6	IRB Members shall have the ability to determine if it is necessary to suspend the activity.	P1	2 (TBD)

### Feature ID 3.27: VA Central IRB Basic Workflow

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
<b>Feature ID F3.27: VA Central IRB Basic Workflow.</b>			
FRD 3.27 -1	Users with write permissions shall have the ability to answer new project setup questions.	P1	1
FRD 3.27 -7	Users with write permissions shall have the ability to determine if it is a multi-site study for that User's project(s) currently not in administrative review or approved.	P1	1
FRD 3.27 -8	Users with write permissions shall have the ability to determine if it meets Central IRB review criteria for that User's project(s) currently not in administrative review or approved. [Eligibility questions will be utilized].	P1	1
FRD 3.27 -20	<p>Multiple:</p> <p>Users with write permissions shall have the ability to add or edit VA Central IRB application for review for that User's project(s) currently not in administrative review or approved.</p> <p>Users with write permissions shall have the ability upload "references" to study documents for that User's project(s) currently not in administrative review or approved.</p> <p>Users with write permissions shall have the ability answers applicable questions including review type, vulnerable populations, and waivers for that User's project(s) currently not in administrative review or approved.</p> <p>PI shall have the ability to approve the application and submit it to the IRB for review.</p>	P1	1
FRD 3.27 -21	The RAMS System shall validate that all Co-PIs (if any) have approved the application prior to PI submission for IRB review.	P1	1
FRD 3.27 -22	Study PI shall submit documents for new application to VA cIRB for review.	P1	2
FRD 3.27 -33	RAMS System shall notify Study PI and all potential sites expected to engage in the research that the study application is approved or approved with minor modification prior to the 15 day comment period.	P1	2
FRD 3.27 -40	Study PI shall review LSI application.	P1	2
FRD 3.27 -41	Study PI shall have the ability to determine if it is approved for submission to cIRB.	P1	2

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
FRD 3.27 -42	PI shall have the ability to submit LSI documents for review by cIRB.	P1	2
FRD 3.27 -46	Study PI and LSI are notified of cIRB approval for the local study application site.	P1	2
FRD 3.27 -49	RAMS System shall issue ACOS letter notifying LSI of local approval [currently req'd by Handbook 1200.01].	P1	TBD
FRD 3.27 -50	cIRB, study PI, and local PI notified; RAMS System shall notify study PI and LSI that local recruitment can begin.	P1	TBD

## 2.6.2.4. Documents Management

**Feature ID 3.24: Manage documents (creation, editing, version-control, storage, access).**

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
<b>Feature ID F3.24.1: Set Up Email/Task Reminders.</b>			
FRD 3.24.1 -1	Committee Coordinator shall have the ability to click to set up notification and/or task reminder related to receiving or sending a document.	P1	2
FRD 3.24.1 -2	Coordinator shall have the ability to describe document that should be received or sent.	P1	TBD
FRD 3.24.1 -3	Coordinator shall have the ability to provide due date, and specify how many reminders how many days in advance of the deadline will be sent, and who will get them.	P1	TBD
FRD 3.24.1 -4	Coordinator shall have the ability to add to task list of designated recipients.	P1	TBD
FRD 3.24.1 -5	Coordinator shall have the ability to confirm notification and/or task reminder settings.	P1	TBD
<b>Feature ID F3.24.2: Upload a Document.</b>			
FRD 3.24.2 -1	Coordinator shall have the ability to upload a document file.	P1	2 (5.6.C.iv)
FRD 3.24.2 -2	Coordinator shall have the ability to allow document retrieval with different search strategies, please provide information about this document file.	P1	2 (5.6.C.iv)
FRD 3.24.2 -3	Coordinator shall have the ability to answer if this file will contain a single document or multiple different documents? (if multiple documents are in the file, ask how many documents are present, and cycle through the process once for each document).	P1	2 (5.6.C.iv)
FRD 3.24.2 -4	RAMS System shall determine if more than one document is in the file.	P1	2 (5.6.C.iv)
FRD 3.24.2 -5	RAMS System shall determine if this document is dated. If so, collect date.	P1	2 (5.6.C.iv)
FRD 3.24.2 -6	Coordinator shall have the ability to indicate the primary author(s) of the document (usually only	P1	2 (5.6.C.iv)

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
	one): <input type="checkbox"/> Your VA station <input type="checkbox"/> An affiliate <input type="checkbox"/> ORD- Office for Research and Development (CRADO, BLRD, CSRD, RRD, HSRD, PRIDE, CVMO, etc.) <input type="checkbox"/> ORO- Office for Research Oversight <input type="checkbox"/> OHRP- Office for Human Research Protections <input type="checkbox"/> FDA- Food and Drug Agency <input type="checkbox"/> AAHRPP- Association for the Accreditation of Human Research Protection programs <input type="checkbox"/> NIH- National Institutes of Health <input type="checkbox"/> OLAW- Office for laboratory Animal Welfare <input type="checkbox"/> USDA- United States Department of Agriculture <input type="checkbox"/> AAALAC- Association for Assessment and Accreditation of Laboratory Animal Care <input type="checkbox"/> OIG- Office of the Inspector General <input type="checkbox"/> CDC- Centers for Disease Control <input type="checkbox"/> Other VA administrative unit <input type="checkbox"/> Other, specify: _____		
FRD 3.24.2 -7	Coordinator shall have the ability to answer how this document is best described. <input type="checkbox"/> Correspondence related to regulatory or issues, including deficiencies and accreditation issues <input type="checkbox"/> Correspondence between committees and researchers regarding committee project/protocol/application reviews <input type="checkbox"/> A standard periodic regulatory form or report submitted to a non-VA agency <input type="checkbox"/> Committee documents- agenda, minutes, project/protocol/application, LASIF, , DSMB report, or other similar documents used for committee review or to document committee review	P1	2 (5.6.C.iv)
<b>Feature ID F3.24.2.2: Correspondence between committees and researchers regarding committee project/protocol/application reviews.</b>			
FRD 3.24.2.2 -1	Coordinator shall have the ability to indicate from whom the correspondence was sent (choose all that apply): <input type="checkbox"/> Researcher: (choose name from drop-down list) <input type="checkbox"/> Committee Chair <input type="checkbox"/> Research Administrator <input type="checkbox"/> Committee Coordinator <input type="checkbox"/> Other, specify: _____	P1	2 (5.6.B.i)
FRD 3.24.2.2 -2	Coordinator shall have the ability to indicate to whom the correspondence was sent (choose all that apply): <input type="checkbox"/> Researcher: (choose name from drop-down list) <input type="checkbox"/> Committee Chair <input type="checkbox"/> Research Administrator <input type="checkbox"/> Committee Coordinator <input type="checkbox"/> Other, specify: _____	P1	2 (5.6.B.i)



Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
FRD 3.24.2.2 -4	Coordinator shall have the ability to determine what is the primary reason for the correspondence. (select one best response) <ul style="list-style-type: none"> <li>○ From committee, announce approval of a project/protocol/application</li> <li>○ From committee, provide review comments or request information for a project/protocol/application</li> <li>○ From committee, notify researcher of lapsed approval with directions to stop work</li> <li>○ From committee, correspondence regarding laboratories</li> <li>○ From committee, other correspondence</li> <li>○ From researcher, provide information requested by the committee regarding a review</li> <li>○ From researcher, correspondence regarding laboratories</li> <li>○ From researcher, provide other information</li> <li>○ Other, specify:_____</li> </ul>	P1	2 (5.6.B.i)
FRD 3.24.2.2 -5	RAMS System shall prompt coordinator to link the document to a specific project and protocol/application.	P1	2 (5.6.B.i)
FRD 3.24.2.2 -6	Coordinator shall have the ability to briefly describe this document- 150 words or less.	P1	2 (5.6.B.i)
FRD 3.24.2.2 -7	RAMS System shall ask the coordinator if this is the last document in file that needs to be described.	P1	2 (5.6.B.i)
FRD 3.24.2.2 -9	RAMS System shall allow file upload (browse for file).	P1	TBD
FRD 3.24.2.2 -10	RAMS System shall save the data into RAMS database.	P1	2 (5.6.B.i)
<b>Feature ID F3.24.2.4: Committee documents - agenda, minutes, project/protocol/application, LASIF, DSMB report, or other similar documents used for committee review or to document committee.</b>			
FRD 3.24.2.4 -1	Coordinator shall have the ability to Choose which document will be uploaded: <ul style="list-style-type: none"> <li>○ IRB Application or protocol documents, without HIPAA authorization and/or informed consent document</li> <li>○ IRB Application or protocol documents, with HIPAA authorization and/or informed consent document</li> <li>○ IRB DSMB report</li> <li>○ IRB agenda from Affiliate</li> <li>○ IRB minutes from Affiliate</li> <li>○ Other IRB document for review</li> <li>○ VA IRB Minutes</li> <li>○ VA IRB Agenda</li> </ul>	P1	2 (5.6.C.iv)
FRD 3.24.2.4 -2	RAMS System shall prompt Coordinator to link the document to a specific project and protocol/application.	P1	2 (5.6.C.iv)
FRD 3.24.2.4 -3	Coordinator shall have the ability to briefly describe	P1	2

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
	the document in 150 words or less.		(5.6.C.iv)
FRD 3.24.2.4 -4	RAMS System shall ask the Coordinator if they wish to describe another document.	P1	2 (5.6.C.iv)
FRD 3.24.2.4 -6	RAMS System shall allow file upload (browse for file).	P1	2 (5.6.C.iv)
FRD 3.24.2.4 -7	RAMS System shall save the data into RAMS database.	P1	2 (5.6.C.iv)

#### Feature ID 3.21: Capture Compliance Data from Non-VA Committees.

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
<b>Feature ID F3.21: Capture Compliance Data from Non-VA Committees.</b>			
FRD 3.21 -1	Coordinator shall have the ability to enter data on study applications reviewed by non-VA committees that need to be tracked by the VA research office.	P1	1 (5.5.a.vi); 2 (5.6.C.iii)
FRD 3.21 -4	RAMS System shall save information into RAMS database.	P1	1 (5.5.a.vi); 2 (5.6.C.iii)

#### Feature ID 3.30: Manage Documents Received Locally.

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
<b>Feature ID F3.30: Manage Documents Received Locally.</b>			
FRD 3.30-1	Research Administration shall have the ability to receive communication from external oversight entity.	P1	2 (5.6.C.iv)
FRD 3.30-2	RAMS System shall notify PI, Chair of responsible Subcommittee: Communication received, review and respond.	P1	2 (5.6.C.iv)
FRD 3.30-3	RAMS System shall manage Documents– enter document, provide PI and Chair of responsible Subcommittee with access.	P1	2 (5.6.C.iv)
FRD 3.30-6	Subcommittee Coordinator shall have the ability to enter document into system, specify: <ul style="list-style-type: none"> <li>●Project/application/protocol to which it applies</li> <li>●Response required</li> <li>●Subcommittee(s) responsible for review/ response</li> </ul>	P1	2 (5.6.C.iv)

## 2.6.2.5. Communications Management

### Feature ID 3.20: Task List and Notification - Adding and Removing Items

Req. ID	Requirement Description	Priority (P1, P2, P3)	Increment (1, 2, Future)
<b>Feature ID F3.20.2: Set up Notifications in RAMS.</b>			
FRD 3.20.2 -1	IRB Coordinator shall have the ability to provide a description of the Notification to document its purpose for use by programmers and high level system admins. This notification lets the PI know that approval for an IRB Continuing Review has been granted by the IRB.	P1	2 (5.6.C.ii)
FRD 3.20.2 -2	IRB Coordinator shall have the ability to provide the stakeholder category that will be assigned to complete this task. Stakeholders shown this notice include the PI and the PI's designated study team [stakeholder class(s)=X, Y].	P1	2 (5.6.C.ii)
FRD 3.20.2 -3	IRB Coordinator shall have the ability to define when the notification start date will be calculated- calculated from another field, or via user input. Due date = [date of IRB approval].	P1	2 (5.6.C.ii)
FRD 3.20.2 -5	IRB Coordinator shall have the ability to define when the notification will expire, and no longer appear to the stakeholder. Remove form stakeholder notification list X days after it appears.	P1	2 (5.6.C.ii)
FRD 3.20.2 -6	IRB Coordinator shall have the ability to provide the description of the task the stakeholder will see. The IRB approved the continuing review for [Project Name] on [approval date]. Unless the project is closed, you will receive a task reminder to submit a request for additional continuing review on [expiration date- 90 days].	P1	2 (5.6.C.ii)
FRD 3.20.2 -7	IRB Coordinator shall have the ability to save the Notifications information into RAMS database.	P1	2 (5.6.C.ii)

### 2.6.3. Reporting Functionality

A key component of the RAMS is the Business Intelligence reporting functionality.

Req. ID	Requirement	Priority (P1, P2, P3)	Increment (1, 2, Future)
RF-001	RAMS shall provide report generation tools.	P1	2 (5.6.D.v)
RF-002	RAMS report generation tools shall provide the capability to perform ad-hoc queries and generate ad-hoc reports.	P1	2 (5.6.D.v)
RF-003	RAMS report generation tools shall provide all user functionality through web based user interfaces.	P1	2 (5.6.D.v)
RF-004	RAMS report generation shall provide extraction, transformation, and load (ETL) process capability to allow reporting through data marts.	P1	2 (5.6.D.v)

## 2.6.4. Role Based Functionality

Req. ID	Requirement	Priority (P1, P2, P3)	Increment (1, 2, Future)
RBF-001	RAMS data access levels shall be configurable by the VA through role-based group privileges.	P1	1

## 2.7. Graphical User Interface (GUI) General Specifications

Req. ID	Requirement	Priority (P1, P2, P3)	Increment (1, 2, Future)
GUI-001	The RAMS GUI shall follow the design process and evaluation usability guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter1.pdf">http://usability.gov/pdfs/chapter1.pdf</a>	TBD	1, 2
GUI-002	The RAMS GUI shall follow the optimize user experience usability guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter2.pdf">http://usability.gov/pdfs/chapter2.pdf</a>	TBD	1, 2
GUI-003	The RAMS GUI shall follow the hardware and software usability guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter4.pdf">http://usability.gov/pdfs/chapter4.pdf</a>	TBD	1, 2
GUI-004	The RAMS GUI shall follow the homepage usability guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter5.pdf">http://usability.gov/pdfs/chapter5.pdf</a>	TBD	1, 2
GUI-005	The RAMS GUI shall follow the page layout usability guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter6.pdf">http://usability.gov/pdfs/chapter6.pdf</a>	TBD	1, 2
GUI-006	The RAMS GUI shall follow the navigation usability guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter7.pdf">http://usability.gov/pdfs/chapter7.pdf</a>	TBD	1, 2
GUI-007	The RAMS GUI shall follow the scrolling and paging usability guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter8.pdf">http://usability.gov/pdfs/chapter8.pdf</a>	TBD	1, 2
GUI-008	The RAMS GUI shall follow the headings, titles, and labels usability guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter9.pdf">http://usability.gov/pdfs/chapter9.pdf</a>	TBD	1, 2
GUI-009	The RAMS GUI shall follow the links usability guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter10.pdf">http://usability.gov/pdfs/chapter10.pdf</a>	TBD	1, 2
GUI-010	The RAMS GUI shall follow the text appearance usability guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter11.pdf">http://usability.gov/pdfs/chapter11.pdf</a>	TBD	1, 2
GUI-011	The RAMS GUI shall follow the lists usability guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter12.pdf">http://usability.gov/pdfs/chapter12.pdf</a>	TBD	1, 2

Req. ID	Requirement	Priority (P1, P2, P3)	Increment (1, 2, Future)
GUI-012	The RAMS GUI shall follow the screen based controls usability guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter13.pdf">http://usability.gov/pdfs/chapter13.pdf</a>	TBD	1, 2
GUI-013	The RAMS GUI shall follow the Graphics, Images, and Multimedia usability guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter14.pdf">http://usability.gov/pdfs/chapter14.pdf</a>	TBD	1, 2
GUI-014	The RAMS GUI shall follow the content organization guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter16.pdf">http://usability.gov/pdfs/chapter16.pdf</a>	TBD	1, 2
GUI-015	The RAMS GUI shall follow the search guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter17.pdf">http://usability.gov/pdfs/chapter17.pdf</a>	TBD	1, 2

### 2.7.1. Data Entry UI

Data entry User Interface (UI) requirements are defined below:

Req. ID	Requirement	Priority (P1, P2, P3)	Increment (1, 2, Future)
DEUI-001	The RAMS GUI shall minimize user data entry fields	TBD	1, 2
DEUI-002	The RAMS GUI shall distinguish required and optional data entry fields	TBD	1, 2
DEUI-003	The RAMS GUI shall not make user-entered codes case sensitive	TBD	1, 2
DEUI-004	The RAMS GUI shall label data entry fields clearly	TBD	1, 2
DEUI-005	The RAMS GUI shall put labels close to data entry fields	TBD	1, 2
DEUI-006	The RAMS GUI shall allow users to see their entered data	TBD	1, 2
DEUI-007	The RAMS GUI shall use radio buttons for mutually exclusive selections	TBD	1, 2
DEUI-008	The RAMS GUI shall allow users to stay with one entry method as long as possible for data entry transactions.	TBD	1, 2
DEUI-009	The RAMS GUI shall use checkboxes to enable multiple selections	TBD	1, 2
DEUI-010	The RAMS GUI shall label units of measurement	TBD	1, 2
DEUI-011	The RAMS GUI shall not limit viewable list box options	TBD	1, 2
DEUI-012	The RAMS GUI shall display default values whenever a likely default choice can be defined.	TBD	1, 2
DEUI-013	The RAMS GUI shall place (automatically) a blinking cursor at the beginning of the first data entry field when a data entry form is displayed on a page	TBD	1, 2
DEUI-014	The RAMS GUI shall use open lists rather than drop-down lists to select one from many	TBD	1, 2
DEUI-015	The RAMS GUI shall provide auto-tabbing functionality for frequent users with advanced Web interaction skills	TBD	1, 2

### 2.7.2. Other UI

Other UI requirements are as outlined below:

Req. ID	Requirement	Priority (P1, P2, P3)	Increment (1, 2, Future)
OUI-001	The RAMS UI shall follow the writing web content usability guidelines as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter15.pdf">http://usability.gov/pdfs/chapter15.pdf</a>	TBD	1, 2

## 2.8. Multi-Divisional Specifications

From the perspective of the end user, there is no functional difference between user location and the functionalities provided by the RAMS.

## 2.9. Performance Specifications

The performance specification requirements are as outlined below:

Req. ID	Requirement	Priority (P1, P2, P3)	Increment (1, 2, Future)
PERF-001	RAMS service consumers shall consume services offered by a service provider in accordance with the service contract.	TBD	1, 2
PERF-002	The RAMS Service Level Agreement (SLA) component of the service contract shall be negotiated with the service provider.	TBD	1, 2
PERF-003	The RAMS SLA shall not be unique to the service consumer and it is preferable that it not be unique.	TBD	1, 2
PERF-004	RAMS shall have no anonymous service consumers.	TBD	1, 2
PERF-005	RAMS shall support users at peak usage levels, where peak usage is defined in the users' Service Level Agreement.	TBD	1, 2
PERF-006	RAMS hardware and software resources shall be sufficiently scalable to support increased workloads by adding equivalent resources.	TBD	1, 2
PERF-007	RAMS shall process and use Coordinated Universal Time (UTC) for internal and external time synchronization.	TBD	1, 2
PERF-008	RAMS shall support 1000 concurrent users at peak usage levels, where peak usage is defined in the users' Service Level Agreement.	TBD	1, 2
PERF-009	The data in the RAMS datamart shall be refreshed from the RAMS operational database once a day.	TBD	1, 2
PERF-011	RAMS users shall have consistent response times when accessing RAMS capabilities during normal operation.	TBD	1, 2
PERF-012	RAMS users may experience degraded performance when accessing RAMS capabilities from the disaster recovery site when in failure or recovery mode.	TBD	1, 2

## 2.10. Quality Attributes Specifications

The quality attribute specification requirements are as outlined below:

Req. ID	Requirement	Priority (P1, P2, P3)	Increment (1, 2, Future)
QAS-001	RAMS services shall apply open data standards where possible. Examples include <a href="#">W3C/IETF</a> and <a href="#">OASIS standards</a> .	TBD	1, 2
QAS-002	RAMS services shall apply open schemas instead of creating new schema definitions where possible. Examples include the <a href="#">CDISC Study Design Model in XML (SDM-XML) standard, version 1.0</a> and the <a href="#">FEA TRM</a> .	TBD	1, 2
QAS-003	RAMS services shall apply open standards for message interfaces where possible, instead of creating new schema definitions. Examples include <a href="#">W3C/IETF</a> and <a href="#">OAGiS Standards</a> .	TBD	1, 2

## 2.11. Reliability Specifications

The reliability specification requirements are as outlined below:

Req. ID	Requirement	Priority (P1, P2, P3)	Increment (1, 2, Future)
REL-001	The RAMS shall maintain 99% uptime.	TBD	1, 2
REL-002	The RAMS shall require no more than 24 hours of maintenance per month. Servicing and maintenance is expected to occur during nights and weekends.	TBD	1, 2
REL-003	The RAMS shall be available from 8:00 am to 8:00 pm EST during weekdays.	TBD	1, 2

## 2.12. Scope Integration

Please refer to information in Section 2.3 Design Constraints Specifications.

## 2.13. Privacy and Security Specifications

The security specification requirements are as defined in the following table:

Req. ID	Requirement	Priority (P1, P2, P3)	Increment (1, 2, Future)
SEC-001	At a minimum, the RAMS System Administrator shall have the capability to grant access and set user privileges.	TBD	1, 2
SEC-002	RAMS access levels shall be configurable by the System Administrator through role-based group privileges	TBD	1, 2
SEC-003	RAMS shall utilize VA's Active Directory (LDAP) for user authentication.	TBD	1, 2
SEC-004	RAMS shall use encrypted e-mail when distributing prescheduled reports.	TBD	Future
SEC-005	RAMS shall adhere to all VA security requirements based on Federal Information Processing Standard (FIPS) 199, National Institute of Standards and Technology SP800-60, directives, guidance, standards and best practices.	TBD	1, 2

Req. ID	Requirement	Priority (P1, P2, P3)	Increment (1, 2, Future)
SEC-006	RAMS service security architecture shall be aligned with the WS-I Basic Security Profile (Web Services Interoperability Organization) and the NIST Guide to Secure Web Services (National Institute of Standards and Technology).	TBD	TBD
TBDSEC-007	RAMS shall provide single sign-on (SSO) to all end users and services.	TBD	1, 2
SEC-008	RAMS shall use SAML Assertions to implement SSO and for authentication subject identification when the integration involves an intermediary web service.	TBD	1, 2
SEC-009	RAMS shall use TLS (SSL 3.1 or greater) to provide a protected channel for the transmission of data between the server and client (web browser) for all communication services as documented in <a href="#">NIST Special Publication 800-52, Guidelines for the Selection and Use of Transport Layer Security (TLS) Implementations</a> .	TBD	1, 2
SEC-010	RAMS security policies shall comply with: <ul style="list-style-type: none"> <li>• Federal Information Security Management Act (FISMA) of 2002</li> <li>• Federal Information Processing Standard (FIPS) 199</li> <li>• Electronic and Information Technology Accessibility Standards (36 CFR 1194)</li> <li>• VA Directive 6102</li> <li>• VA Handbook 6102</li> <li>• VA Handbook 6500 Standards</li> <li>• VA Directive 6500, Information Security Program</li> <li>• National Institute of Standards and Technology SP800-600 and sp800-53</li> </ul>	TBD	1, 2
SEC-011	RAMS shall provide a standardized service interface layer (Platform) for security policy enforcement. The Platform Layer shall also control access to data through security, control access to the database, and raise events for workflow processes and custom business logic implementation.	TBD	1, 2
SEC-012	RAMS shall comply with the US Government Agencies requirements about storing and handling Personally Identifiable Information (PII). The following PII data is identified in RAMS: <ol style="list-style-type: none"> <li>1. SSN</li> <li>2. Last name, middle name and first name</li> <li>3. Gender</li> <li>4. Race</li> <li>5. College/University degree/academic rank</li> <li>6. Date of Birth</li> <li>7. Birth place</li> <li>8. Country of citizenship</li> <li>9. Visa</li> <li>10. Person_Pay table</li> <li>11. Person_Effect_Certification table</li> </ol>	TBD	1, 2
SEC-013	RAMS shall be designed with the access control and auditing capability at both application level and database level.	TBD	1, 2
SEC-014	RAMS shall be designed with perimeter security control capability, such as firewall and intrusion detection.	TBD	1, 2



## 2.13.1. Privacy Specifications

The privacy specification requirements are as defined in the following table:

Req. ID	Requirement	Priority (P1, P2, P3)	Increment (1, 2, Future)
PRI-001	RAMS shall be designed to label and protect Personally Identifiable Information (PII) at both application level and database level.	TBD	1, 2
PRI-002	RAMS shall be designed to obscure selected PII, such as a person's Social Security Number (SSN) and salary on the RAMS application screens.	TBD	1, 2
PRI-003	RAMS shall be designed to encrypt PII stored data as defined in RSD paragraph 2.12, Security Specifications, requirement SEC-012 .	TBD	1, 2
PRI-004	RAMS shall comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules.	TBD	1, 2
PRI-005	RAMS shall comply with the PRIVACY ACT OF 1974 and other federal privacy regulations.	TBD	1, 2

## 2.14. System Features

System features are derived from the business needs. User stories and Process flows are captured for each system features and sub-features. RAMS system features are grouped into six major processes:

- Projects Management Process
- Document Management Process
- Personnel Management Process
- Committees Management Process
- Communications Management Process
- Logistics Management Process - Future

Please see Section 2.6.2 “Functional Process Requirements” for detailed requirements of these system features.

## 2.15. Usability Specifications

Usability specification requirements are as outlined below:


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 <a href="http://usability.gov/methods/process.html">http://usability.gov/methods/process.html</a>	TBD	1, 2
USA-002	RAMS shall follow the usability testing as specified in the usability.gov website <a href="http://usability.gov/pdfs/chapter18.pdf">http://usability.gov/pdfs/chapter18.pdf</a>	TBD	1, 2
USA-003	RAMS shall follow a User-centered design (UCD)	TBD	1, 2
USA-004	RAMS shall allow the users to access the RAMS data back to five years in history.	TBD	1, 2


## 3. Applicable Standards

All applicable standards have been noted in this document and are compiled in Section 1.4 References.

## 4. Interfaces

### 4.1. Communications Interfaces

Interface Description 1	Public Web Interface
Port(s)	
Source	Web Tier
Destination	VA Network

Interface Description 2	Remote Desktop Protocol
Port(s)	
Source	Development workstations/laptops on VA network/VPN
Destination	All Servers

Interface Description 3	SQL Server
-------------------------	------------

<b>Interface Description 3</b>	<b>SQL Server</b>
<b>Port(s)</b>	■
<b>Source</b>	Development workstations/laptops on VA network, Application Servers, SharePoint Server, ETL Server
<b>Destination</b>	Database Tier

## 4.2. Hardware Interfaces

Hardware interface requirements for RAMS are as follows:

<b>Req. ID</b>	<b>Requirement</b>	<b>Priority</b> (P1, P2, P3)	<b>Increment</b> (1, 2, Future)
HWIN-001	RAMS shall be capable of running on virtual server(s).	TBD	1, 2
HWIN-003	The RAMS software shall be developed so that it is independent of the hardware operating system (e.g., Windows, LINUX, or UNIX).	TBD	1, 2

## 4.3. Software Interfaces

Software interface requirements for RAMS are as follows:

<b>Req. ID</b>	<b>Requirement</b>	<b>Priority</b> (P1, P2, P3)	<b>Increment</b> (1, 2, Future)
SWIN-001	See Section 2.3 Design Constraints Specifications above.	TBD	1, 2

## 4.4. User Interfaces

For information about user interfaces, see Section 2.7 Graphical User Interface (GUI) General Specifications.

# 5. Legal, Copyright, and Other Notices

No legal disclaimers, copyright notices, warranties, patent notice, word mark, 508 disclaimer, or trademark compliance issues for the system/project apply.

# 6. Purchased Components

<b>#</b>	<b>Product Name</b>	<b>Version</b>	<b>TRM Approved (Y/N)</b>	<b>Description/Use/TRM link</b>
----------	---------------------	----------------	-----------------------------------	---------------------------------

#	Product Name	Version	TRM Approved (Y/N)	Description/Use/TRM link
1	SharePoint 2013 - (FARM INSTALLATION OPTION)	2010	Y	SharePoint. Approved. ████████████████████ ToolPage.asp?tid=5448^
2	SQL Server	2008 R2	Y	Database engine. Approved w/Constraints. ████████████████████ ToolPage.asp?tid=5020^
3	SQL Report Viewer		Y	Reporting from SQL Server data. Approved w/Constraints. ████████████████████ ToolPage.asp?tid=6403^
4	Apache Tomcat	7	Y	Web server. Approved w/Constraints. ████████████████████ ToolPage.asp?tid=7
8	Rational Tool Suite (Rational RequisitePro)		Y	████████████████████ ToolPage.asp?tid=41
9	Adobe Acrobat Pro		Y	████████████████████ ToolPage.asp?tid=5532^
10	MS Visual Studio 2005		Y	The "Express" editions of Visual Studio are not to be used for national development efforts. ████████████████████ ToolPage.asp?tid=5670^
15	Winzip		Y	Approved w/Constraints. This Technology can be used within the specified constraints. Only instances of this technology that have been deployed may continue to use this technology. No further expansion or use of this technology is permitted without a waiver from AERB.
16	*WinSCP		Y	████████████████████ ToolPage.asp?tid=299^
18	*Snagit		Y	Approved w/Constraints. This Technology can be used within the specified constraints. Versions 10 and 11 before 11.1 are prohibited due to a NIST high severity security vulnerability. ████████████████████ ToolPage.asp?tid=5122^
20	*UltraEdit		Y	Approved w/Constraints. This Technology can be used within the specified constraints. Only version 18 and higher are approved for use ████████████████████ ToolPage.asp?tid=6299^
21	*XML Spy		Y	████████████████████ ToolPage.asp?tid=5093^
22	Java 2 Enterprise Edition		Y	Java Platform. Approved. ████████████████████ StandardPage.asp?tid=8

#	Product Name	Version	TRM Approved (Y/N)	Description/Use/TRM link
23	Scribe		Y	Approved w/Constraints. Certified encryption must be used in transit and at rest if PII or PHI is involved. Must be implemented within the VA Production network (DMZ not allowed). [REDACTED]ToolPage.asp?tid=6490
24	SQL Server Reporting Services		Y	Approved w/Constraints. This Technology can be used within the specified constraints. Product must remain patched and operated in accordance with Federal and Department security and privacy policies and guidelines. Configuration and deployment standards for SQL server images and their host Windows Server images which are defined and maintained by the Core Systems Engineering organization within VA Enterprise Systems Engineering (ESE) must be followed and adhered to unless an appropriate waiver is granted.

## 7. User Class Characteristics

The table below identifies the various user classes that are anticipated to use this product. User class and characteristics have been differentiated based on frequency of use, process functions used, and access levels.

USER	ACRONYM	USER DESCRIPTION	USER CLASS AND CHARACTERISTICS		
			Frequency of Use	Process Functions	Access Levels
Administrative Officer	AO	Senior ORD official at each research station. The AO for R&D is responsible for the administrative functions of the research program.	Maximum	Projects Committees Personnel Laboratory Documents Communications	Read/Wr ite Read/Wr ite Write Read
Associate Chief of Staff for Research	ACOS	The chief operational officer for the research station. Oversees the committees and subcommittees and is responsible for coordination with audit agencies. The ACOS for R&D is responsible for the day-to-day management of the research program at	Maximum	Projects Committees Personnel Laboratory Documents Communications	Read Read Read/Wr ite

USER	ACRONYM	USER DESCRIPTION	USER CLASS AND CHARACTERISTICS		
			<i>Frequency of Use</i>	<i>Process Functions</i>	<i>Access Levels</i>
		facilities with large, active programs.			
Committee Coordinator	TBD	Also referred to as the Committee Administrator. Manages all activities of the committee including communication with PIs, assignment of projects to agendas, distribution of minutes, coordination of reviewer comments, scheduling of meetings, and tracking of committee members and quorums.	TBD	TBD	TBD
Co-Principal Investigator	Co-PI	Key personnel who have responsibilities similar to that of a PI on research projects. While the PI has ultimate responsibility for the conduct of a research project, the Co-PI is also obligated to ensure the project is conducted in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research	Average	Projects Committees Personnel Laboratory Documents Communications	Write Read/Wr ite Write
Information Security Officer	ISO	See Privacy Officer	Average	Projects Committees Personnel	Read Read Write
IRB Administrator	TBD	Responsible for conducting the review process for considerations such as conflicts of interest, including initial review of the disclosure forms prior to IRB Committee review and determines whether a referral to the specific Committee (e.g., COI) is necessary.	TBD	TBD	TBD

USER	ACRONYM	USER DESCRIPTION	USER CLASS AND CHARACTERISTICS		
			<i>Frequency of Use</i>	<i>Process Functions</i>	<i>Access Levels</i>
IRB Chair	TBD	The IRB Chair determines if an application is complete and or lacks any disqualifying features and is responsible for forwarding all application materials via email to the members of the IRB Committee	TBD	TBD	TBD
IRB Member	TBD	An elected board committee, or other group formally designated by an institution to review, approve, require modification in, disapprove, and conducting continuing oversight of human research in accordance with 38 CFR Part 16 and other applicable VA and Federal requirements.	TBD	TBD	TBD
IRB Staff	TBD	Assist the AO, IRB Chair and IRB Administrator in administrative functions.	TBD	TBD	TBD
Local Site Investigator (CIRB role only)	LSI	The Site Investigator or LSI is an investigator at a site participating in a multi-site research project. The LSI oversees scientific, technical, and day-to-day management of the research at the local site.	TBD	TBD	TBD
Local RAMS Administrator	TBD	User with special privileges to establish and maintain local user accounts.	TBD	TBD	TBD

USER	ACRONYM	USER DESCRIPTION	USER CLASS AND CHARACTERISTICS		
			<i>Frequency of Use</i>	<i>Process Functions</i>	<i>Access Levels</i>
ORD Administrator	TBD	The ORD Administrator determines whether or not a given project is a candidate for review by the VA Central IRB.	TBD	TBD	TBD
Principal Investigator (PI) Designee	TBD	An individual designated by the PI or CO-PI to assist in the preparation of the project/protocol as well as perform ongoing support to the approved project/protocol. Whoever the person is that the PI designates to complete entry of components associated with the protocol, only the PI or Co-PI however is permitted to submit the research protocol to the IRB for initial full review.	TBD	TBD	TBD
Principal Investigator	PI	A qualified person or persons designated by an applicant institution to direct a research project or program and who usually writes the grant application. The PI oversees scientific, technical, and day-to-day management of the research. In the event of an investigation conducted by a team of individuals, the PI is the responsible leader of that team	Maximum	Projects Personnel Documents Communications	Write Read/Wr ite Write
Privacy Officer	PO	Privacy Officer and ISO must be involved in the review of human subjects research to address and mitigate potential concerns regarding privacy and confidentiality, and information security, respectively.	Average	Projects Committees Personnel Laboratory Documents Communications	Read Read Write



USER	ACRONYM	USER DESCRIPTION	USER CLASS AND CHARACTERISTICS		
			<i>Frequency of Use</i>	<i>Process Functions</i>	<i>Access Levels</i>
Study Coordinator	SC	Specialized research professional working under the direction of the PI, facilitating the daily trial activities and the conduct of the study. Reports directly to the PI with administrative, scientific proposal preparation and review, budget, award acceptance, etc.	TBD	TBD	TBD
System Administrator (Sys Admin)	SA	User with special privileges to establish and maintain user accounts for all of RAMS.	Average	Projects Committees Personnel Laboratory Documents Communications	Write Write Write

## 8. Estimation

N/A – No formal estimation has been done for this system/project.

## Appendix A    User Stories Specification

This section refers to User Stories developed by the RAMS Project Team, including business process owner functional subject matter experts. **Please refer to the RAMS Increment 1 User Stories file dated 7/17/2014 and named: “RAMS\_User\_Stories\_IRB Management\_Inc1\_20140717.pptx”.**

## 9. Approval Signatures

*This section is used to document the approval of the RSD during the Formal Review. The review should be ideally conducted face to face where signatures can be obtained 'live' during the review, however the following forms of approval are acceptable:*

- *Physical signatures obtained face to face or via fax*
- *Physical signature obtained in person or via fax*
- *Digital signature tied cryptographically to the signer*

*/es/ in the signature block, provided that a separate digitally signed e-mail indicating the signer's approval is provided and kept with the document*

*The Chair of the governing Integrated Project Team (IPT), Business Sponsor, IT Program Manager, and the Project Manager are required to sign. Please annotate signature blocks accordingly.>*

**NOTE: This Requirements Specification Document is subject to change due to the iterative nature of Agile development.**

REVIEW DATE: *<date>*

SCRIBE: *<name>*

Signed:

---

Integrated Project Team (IPT) Chair

Date

---

Business Sponsor

Date

---

IT Program Manager

Date

---

Project Manager

Date