Research Administrative Management System (RAMS)

Integration

System Design Document



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Department of Veterans Affairs

Revision History

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Artifact Rationale

The System Design Document (SDD) is a dual-use document that provides the conceptual design as well as the as-built design. This document will be updated as the product is built, to reflect the as-built product.

When to Complete Each Section of the SDD

| Section | Completed On or Before PMAS Phase | Rationale |
| --- | --- | --- |
| 1 – Introduction | MS 0 Review; updated thereafter | Conceptual design should inform evaluation of investments |
| 2 - Background | MS 0 Review; updated thereafter | Conceptual design should inform evaluation of investments |
| 3 – Conceptual Design | MS 0 Review; updated thereafter | Conceptual design should inform evaluation of investments |
| 4 – System Architecture | MS 0 Review; updated thereafter | Conceptual design should inform evaluation of investments |
| 5 – Data Design | MS 1 Review; updated thereafter | Design details should be elaborated upon during PMAS Planning phase and prior to development |
| 6 – Detailed Design | MS 1 Review; updated thereafter | Design details should be elaborated upon during PMAS Planning phase and prior to development |
| 7 – External System Interface Design | MS 1 Review; updated thereafter | Design details should be elaborated upon during PMAS Planning phase and prior to development |
| 8 – Human Machine Interfaces | MS 1 Review; updated thereafter | Design details should be elaborated upon during PMAS Planning phase and prior to development |
| Attachments | MS 1 Review; updated thereafter | Design details should be elaborated upon during PMAS Planning phase and prior to development |

A product’s system design should be defined conceptually prior to the allocation of personnel and resources that occur at project initiation. This gives the enterprise an opportunity to evaluate IT investments before project teams are stood up and funding is allocated. Sections 1- 4 that discuss the high-level design, should be completed prior to MS 0. All sections should be completed and updated before MS 1. Projects will need to address all SDD approval constraints prior to the MS 2 review. In addition, the SDD should reflect the as-built product going into the MS 2 review.

Instructions

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

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# Introduction

The Veterans Health Administration (VHA) Office of Research and Development (ORD) is responsible for the management and administration of the national Department of Veterans Affairs (VA) intramural research program. ORD has improved 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 the ORD Central Office. This tool supports the major business functions of the local offices and the Central Office as it pertains to administering and managing processes for the Research and Development Committee (RDC) and its subcommittees: the Institutional Review Board (IRB), Subcommittee for Research Safety (SRS), and Institutional Animal Care and Use Subcommittee (IACUC) as required for conducting research at the VA.

In the past, ORD used a variety of information systems and supplemental database applications to support research activities at the Central Office and field research facilities. The systems were not standardized and resulted in multiple inefficiencies such as:

* Inconsistent data management practices
* Central Office initiated data calls not addressed in a timely fashion
* Limited ability to respond to Congressional and Secretary-level inquiries
* Constrained capacity to review research progress
* Difficulty in meeting VA and industry-mandated compliance reporting requirements

The implementation of RAMS has eliminated many of the previous inefficiencies, and further enhancements will provide the capabilities necessary to expand the applicability and use of the tools beyond the areas of research, which are under the domain of the IRB. As a result, RAMS Integration will enhance the RAMS product so that other types of research, such as animal studies that are overseen by IACUC can also be managed in the system. Communications among local committees involved in research compliance will improve through the addition of the SRS. Committee oversight will improve with the introduction of functions for the RDC.

## Scope

RAMS serves as a multipurpose tool for the ORD Central Office and VA Medical Center (VAMC) field research offices. The system consists of a single front-end web-based data management and reporting application and a centralized back-end database. RAMS provides the capability to create and track administrative data for all projects in local research offices. RAMS can manage research oversight committees and subcommittees, track research personnel assignments, training requirements, and certifications. RAMS also manages laboratory facility data including space allocations and equipment, and support-required reporting to ORD.

This system serves as a communication portal accessible to ORD and local research offices. It requires sufficient server space to exchange numerous tools and resources, many of which are graphics-intensive and require large amounts of storage capacity. The RAMS Integration will expand and integrate additional features or additional software applications into the existing RAMS.

The scope of this document is to cover both functional and non-functional requirement specifications for the RAMS Integration that addresses the business needs as requested, including:

* Manage the research overseen by the IACUC
* Manage the activities of the Research and Development Committee (R&D)
* Manage the activities of the Safety Committee
* Provide communication portals among the various committees
* Provide easily-accessible reporting capability at the local facility level
* Enable the ORD Central Office to create reports covering enterprise-wide research activities

## User Profiles

RAMS supports major business functions of each local research office and the Central Office reporting to ORD. RAMS facilitates management of the local and central IRB, RDC, SRS, and IACUC and provides a common database for tracking and reporting of administrative research program data throughout the VA. The following table outlines the user profiles for the RAMS Integration project.

Table 1: User Profiles

| User Level | Role | Responsibilities | RAMS Access Level |
| --- | --- | --- | --- |
| Administrative Officer (AO) | Senior ORD official at each research station | Administrative functions of the research program | Read/Write |
| Associate Chief of Staff for Research (ACOS) | Chief Operational Officer for the research station | Oversees committees and subcommittees and is responsible for coordination with audit agencies as well as the day-to-day management of the research program at facilities with large active programs. | Read/Write |
| Committee Coordinator/ Committee Administrator | Manages all activities of the committee | Communication with Principal Investigators, assignment of projects to agendas, minutes, coordinator of reviewer comments, scheduling of meetings, tracking committee members and quorums. | TBD |
| Principal Investigator (PI) | Directs research project or program | Oversees scientific, technical, and day-to-day management of the research and is leader of research team. | Read/Write |
| Principal Investigator Designee | Assists in preparation of project/protocol | Completes entry of components associated with the protocol, submits to IRB. | TBD |
| Co-Principal Investigator (Co-PI) | Similar to Principal Investigator | Ensures project is conducted in compliance with applicable laws and regulations and institutional policy. | Read/Write |
| RDC Administrator | Conducts review process for considerations | Conducts reviews for items such as conflicts of interest, initial review of disclosure forms, and determining whether referrals are needed to specific committees. | TBD |
| RDC Chair | Determines if an application is complete | Determines if an application lacks any disqualifying features and forwards all application materials to members of the RDC. | TBD |
| RDC Member | A member of the RDC | Member of an elected board or other group formally designated by an institution to review, approve, require modification in, disapprove, and conduct continuing oversight of human research in accordance with laws and regulations. | TBD |
| RDC Staff | Assists the Administrative Officer, RDC Chair in administrative functions | Performs administrative functions. | TBD |
| IRB Administrator | Conducts review process for considerations | Conducts reviews for items such as conflicts of interest, initial review of disclosure forms, and determining whether referrals are needed to specific committees. | TBD |
| IRB Chair | Determines if an application is complete | Determines if an application lacks any disqualifying features and forwards all application materials to members of the IRB. | TBD |
| IRB Member | A member of the IRB | Member of an elected board or other group formally designated by an institution to review, approve, require modification in, disapprove, and conduct continuing oversight of human research in accordance with laws and regulations. | TBD |
| IRB Staff | Assists the Administrative Officer, IRB Chair in administrative functions | Performs administrative functions. | TBD |
| SRS Administrator | Conducts review process for considerations | Conducts reviews for items such as conflicts of interest, initial review of disclosure forms, and determining whether referrals are needed to specific committees. | TBD |
| SRS Chair | Determines if an application is complete | Determines if an application lacks any disqualifying features and forwards all application materials to members of the SRS. | TBD |
| SRS Member | A member of the SRS | Member of an elected board or other group formally designated by an institution to review, approve, require modification in, disapprove, and conduct continuing oversight of human research in accordance with laws and regulations. | TBD |
| SRS Staff | Assists the Administrative Officer, SRS Chair in administrative functions | Performs administrative functions. | TBD |
| IACUC Administrator | Conducts review process for considerations | Conducts reviews for items such as conflicts of interest, initial review of disclosure forms, and determining whether referrals are needed to specific committees. | TBD |
| IACUC Chair | Determines if an application is complete | Determines if an application lacks any disqualifying features and forwards all application materials to members of the IACUC. | TBD |
| IACUC Member | A member of the IACUC | Member of an elected board or other group formally designated by an institution to review, approve, require modification in, disapprove, and conduct continuing oversight of human research in accordance with laws and regulations. | TBD |
| IACUC Staff | Assists the Administrative Officer, IACUC Chair in administrative functions | Performs administrative functions. | TBD |
| Local Site Investigator (Central IRB (CIRB) Role Only) | Investigator at site participating in a multi-site research study | Oversees scientific, technical, and day-to-day management of the research at a local site. | TBD |
| Local RAMS Administrator | User with special privileges to establish and maintain local user accounts | Administrative functions. | Read/Write |
| Study Coordinator | Specialized research coordinator working under direction of the Principal Investigator | Facilitates the daily trial activities and conduct of the study, reports with administrative, scientific proposal preparation and review, budget, award acceptance, etc. | TBD |
| ORD Administrator | Determines whether a given project is a candidate for review by the VA CIRB | Administrative VA CIRB support. | TBD |
| Research Compliance Officer (RCO) | Ensures projects are in compliance with Federal, State, and Institutional regulations | Administrative VA support to ensure research regulations are enforced and ensures high standards of ethics, integrity, and responsibility in research programs | TBD |
| Office of Research Oversight (ORO) Reviewer | Supports research and manages research programs | Works alongside scientists and research team members to ensure the smooth functioning of research projects; Coordinates Peer Reviews and coordinates with other staff as necessary. Performs other related duties as assigned. | TBD |

# Background

The ORD is responsible for the management and administration of the national VA intramural research program. The VA research program currently uses a variety of information systems and supplemental database applications to support research activities at the ORD Central Office and field office level. The existing non-standard architecture has led to inconsistent data management processes across the national program. This has also resulted in delays from the field level when responding to ORD Central Office-initiated data calls. The goal is for RAMS to be a centralized management system and repository to enable ORD to capture and translate real-time data more rapidly and provide a higher level of responsiveness to governmental agencies monitoring research compliance issues, Congressional inquiries, and VA executive management concerns. RAMS will create a system enabling the VA research community to merge divergent business processes, increase knowledge sharing and efficiency, and reduce redundancy.

The RAMS Integration will extend the centralized management of administrative functions to the IACUC, the R&D committee, and the Subcommittee on Research Safety (SRS). This extension of functionality will serve to improve the VA Research Programs efficiency and capabilities.

## Overview of the System

RAMS supports business functions at the local research offices and the ORD Central Office as it pertains to administering and managing the IRB process required for conducting human research at the VA and provides a common centralized database for tracking and reporting on VA administrative research programs. The RAMS IRB Management functions to be implemented over two development increments include: project management, personnel management, committee management, and document management capabilities.

RAMS Integration will serve as a communication portal accessible by ORD and research offices. It requires sufficient server space to exchange numerous tools and resources, many of which contain multiple graphics and require large amounts of storage capacity.

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

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

The RAMS Integration employs a configurable technology based on Microsoft (MS) Structured Query Language (SQL) Server, SharePoint, a custom web user interface (e.g., Java, J2EE), and web services. This solution will deliver content management, workflow, and data quality assurance, and improve ORD’s ability to track and report research projects.

## Overview of the Business Process

The new functionality of the RAMS Integration will allow management of research projects and studies by the R&D Committee, the IRB, the IACUC, the SRS, and local research offices reporting to ORD.

The RAMS Integration will develop a Reporting Management Module standard reporting system for every committee to improve efficiencies in monitoring and reporting on committee activities. The reporting system in addition to other features, will allow users to be able to see a study listing by local site, retrieve an active study listing, retrieve a listing of closed projects and sites, receive an annual report from each committee member to the R&D Committee, and receive an annual report for Director's Certification.

## Overview of the Significant Requirements

All requirements for the RAMS Integration project are defined in the User Stories in the Requirements Specification Document (RSD). Business needs for the requirements are defined in the Business Requirements Document (BRD). Both of these documents as well as this SDD document can be found in RTC along the following path: Source Control > https://clm.rational.oit.va.gov/ccm/web/com/ibm/team/scm/web/graphics/icons/streams_obj.gifStreams > https://clm.rational.oit.va.gov/ccm/web/com/ibm/team/scm/web/graphics/icons/workspace_obj.pngRAMS Int CM > https://clm.rational.oit.va.gov/ccm/web/com/ibm/team/scm/web/graphics/icons/component_obj.pngRAMS Releases > https://clm.rational.oit.va.gov/ccm/web/com/ibm/team/scm/web/graphics/icons/fldr_obj.gifR2-0 >

The RAMS Integration project has the following objectives:

* Overview of significant functional requirements
* The objectives of the significant functional requirements are to incorporate the R&D Committee, the IACUC, and the SRS into the RAMS Integration. The integration will enable the tracking and management of research projects and studies in RAMS.
* Overview of the functional workload/performance requirements
* The objectives of the functional workload/performance requirements are to measure system performance, including response times, and to meet the user workload expectations
* Overview of operational requirements
* The objectives of the operational requirements are to ensure that RAMS is available 24/7, with 99.9% availability, and support hours are from 9 am to 6 pm Eastern Standard Time (EST).
* Overview of pivotal technical requirements
* Enhancements to RAMS must provide the capability to integrate additional committees and subcommittees without an inherent redesign of the platform, leveraging generic object-oriented modules, whereby new committees and subcommittees can be incorporated in the platform with minimal development effort
* Overview of the security and privacy requirements
* The objectives of the security and privacy requirements are to ensure all VA security and privacy policies are enforced throughout the interfaces and protect the Veteran’s security, including personal and authorization disclosure information

The design of the new functionality for the RAMS project will adhere to all VA security and privacy policies and guidelines

* Overview of system criticality and high availability requirements
* See Section 3.3.1, System Criticality and High Availability
* Overview of Single Sign On (SSO) requirements
* The RAMS SSO shall be in compliance with VA security and privacy standards.
* Overview of use of enterprise portals
* RAMS will support enterprise single sign on capabilities to facilitate any future integration with Enterprise portals by implementing IDentity Management (IDM) in a manner consistent with PD SharePoint design standards. Additionally, RAMS will be implemented using a SharePoint architecture that can be integrated with an enterprise SharePoint Farm as future business needs require
* Overview of special device requirements
* RAMS shall use digital signatures for certain study approval activities, which requires the user’s access devices to be capable of reading valid signatures from VA issued PIV smart cards

# Conceptual Design

This section of the SDD provides details about the following topics:

* Conceptual Application Design
* Conceptual Data Design
* Conceptual Infrastructure Design

## Conceptual Application Design

The RAMS conceptual application design offers an overview of core functional components for the RAMS Integration project without itemizing specific design characteristics or physical architecture. This is focused on logical design and what components and subcomponents of logical functionality are required to meet all RAMS requirements and gain user acceptance.

### Application Context

The following figure shows the location of relevant environments and the interfaces associated with RAMS.

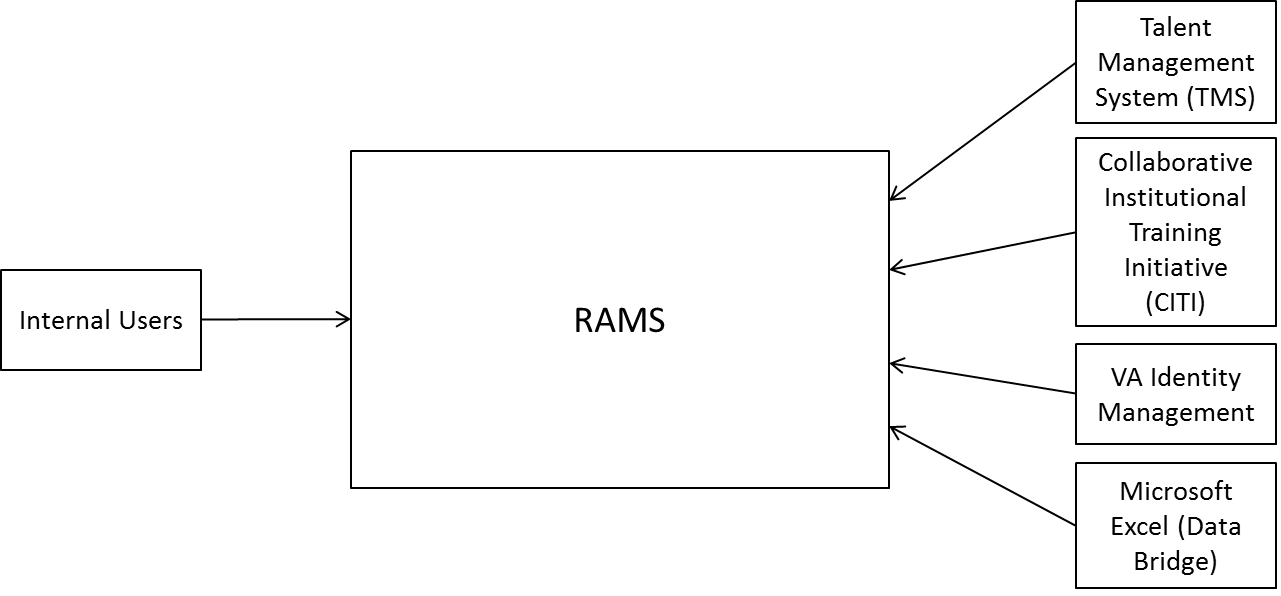


Figure 1: Application Context Diagram

### High-Level Application Design

The high-level application design identifies the major components of the Philadelphia Information Technology Center (PITC) solution and the relationship of the application components to each other and to the surrounding applications.

The RAMS solution will have the following components:

* **Content Management Server**

Includes an MS SharePoint 2013 serving as the document repository for the solution and provides content management, dashboard capabilities, and workflow

* **Application/Web Server**

A Tomcat Java Application Server for the RAMS application that will interface with SharePoint, the Content Management Server, through Representational State Transfer service (also known as RESTful service) calls

* **Database**

An SQL Server database backend for the RAMS solution, SharePoint, and the Server Reporting Services Server (SSRS)

* **Reporting Server**

An SQL SSRS for supporting reporting capabilities for the RAMS solution

* **Extract, Transform, and Load (ETL) Server**

For one time migration of data from field office applications into the new Centralized RAMS Database

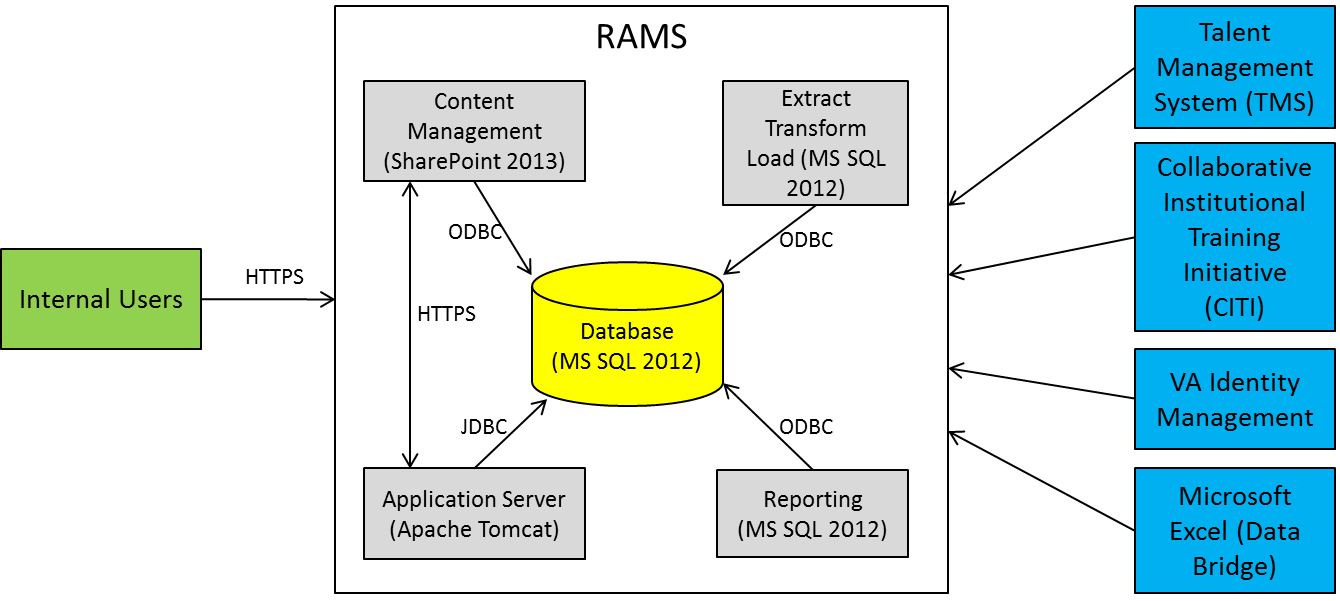


Figure 2: Sample High-Level Application Design of the RAMS Integration

The following is the general application context:

* The RAMS solution will interface with a customizable MS SQL Server database to support RAMS functionality.
* The RAMS solution will provide web-based forms capability deployable to various VA hardware platforms.
* The RAMS solution will have an interface with MS SSRS to provide letter/form generation and customized self-service reports.
* The RAMS solution will provide version control functionality to store source artifacts in the VA-compliant repositories.
* The RAMS solution will have an interface with MS SharePoint 2013 which serves as the document repository for the solution and provides content management, dashboard capabilities, and workflow.

**Internal Data Stores**

The RAMS database is comprised of two Schemas pertaining to the different functional architectures of the system:

* The RAMS Core Schema will provide the structured relational content and control data required for the RAMS expert system developed as the J2EE application. This system will store all aspects of study application metadata, dynamic forms, and stored user responses.
* The RAMS SharePoint Schema will provide the necessary data storage for all aspects of the SharePoint environment. Further detail about what is stored in this schema is available from MS and there is no additional information in this document. More information is available at SharePoint Database Types and Descriptions (SharePoint 2013).

Objects / Components to be Built or Modified

This table will be populated with additional details provided by the developer at a later date, pending VA input and review.

When available, the following table will list the Objects in the High-Level Application Design.

Table 2: Objects in the High-Level Application Design

| Name | Description | Service or Legacy Code | External Interface Name | External Interface ID | Internal Interface Name | Internal Interface ID | SDP Sections 1&2 |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Content Management Server | Document repository for the solution and provides content management, dashboard capabilities, and workflow | TBD | TBD | TBD | TBD | TBD | TBD |
| Web Server | Server that provides the HTTPS interface for the Content Management Server | TBD | TBD | TBD | TBD | TBD | TBD |
| Application Server | An application server that provides data and logical access to custom data and logic modules for RAMS | TBD | TBD | TBD | TBD | TBD | TBD |
| ETL Server | A stateless server that uses an SQL Server Database Engine to store metadata and object definitions | TBD | TBD | TBD | TBD | TBD | TBD |
| Report Server | SQL SSRS used to support reporting capabilities for the RAMS solution | TBD | TBD | TBD | TBD | TBD | TBD |
| 2012 SQL Database | SQL Server database backend for the RAMS solution, SharePoint, and the SSRS | TBD | TBD | TBD | TBD | TBD | TBD |
| Collaborative Institutional Training Initiative (CITI) | An educational tool used to support and train RAMS researchers | TBD | TBD | TBD | TBD | TBD | TBD |
| Talent Management System (TMS) | Web-based educational system intended for employees and staff of the VA | TBD | TBD | TBD | TBD | TBD | TBD |

The following table lists the Internal Data Stores for the RAMS Integration.

Table 3: Internal Data Stores

| Function | OS/bit | VM | CPU | RAM | OS GB C: | APP GB D: | DATA GB E: | BKUP GB B: | LOG GB L: | TEMP GB T: | Total GB |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SQL Database | W2012 x64 | 1 | 4 | 32 | 60 | 160 | 200 | 50 | 15 | 15 | 500 |
| SharePoint Content Management Server | W2008 R2x64 | 1 | 4 | 32 | 120 | 940 |  |  |  |  | 1060 |

### 

### Application Locations

The following table lists the Application Locations for the RAMS Integration.

Table 4: Application Locations

|  |  |  |
| --- | --- | --- |
| Application Component | Location | Type |
| Application/Web Server | PITC | Tomcat 7 Web Application Server |
| Database | PITC | MS SQL Server 2008 R2 Database |
| Content Management Server | PITC | MS SharePoint 2013 |
| ETL Server | PITC | SQL Server Integration Services (SSIS) |
| Reporting Server | PITC | MS SQL Server Reporting Services |

The following Application Locations listed below are identified in Section 3.3.3, Technology Locations.

* Development Environment - PITC
* Testing Environment – PITC
* Software Quality Assurance (SQA) Environment - PITC
* Pre-Production Environment - PITC
* Production Environment - PITC

The following table lists the Application Users for the RAMS Integration.

Table 5: Application Users

|  |  |  |
| --- | --- | --- |
| Application Component | Location | Users |
| RAMS Solution | Alpha Sites:  CIRB (DC)  Miami, FL  New Orleans, LA  Beta Sites:  Asheville, NC  Washington DC VA  ORD Field Offices  (eventual rollout) Chicago, IL | Principal Investigator (PI)  Co-Principal Investigator (Co-PI)  PI Designee  Co-Investigator  Study Coordinator  Site Investigator  Local Site Investigator  Associate Chief of Staff (ACOS) for R&D  R&D Administrative Officer (AO)  Committee Coordinator  VA Central IRB Administrator  RDC Chair  RDC Member  RDC Staff  IRB Chair  IRB Member  IRB Staff  SRS Chair  SRS Member  SRS Staff  IACUC Chair  IACUC Member  IACUC Staff  Privacy Officer/HIPPA  Information Security Officer Local System Administrator System Administrator  Research Compliance Officer  ORO Reviewer |

## Conceptual Data Design

The following sections will outline the conceptual data design for the RAMS project. All technical decisions concerning RAMS data models should be assessed with this proposed conceptual data architecture in mind.

### Project Conceptual Data Model

A project Conceptual Data Model (CDM) is a high-level representation of the data entities and their relationships. It is a first step to developing the more detailed Logical Data Model (LDM) during the Logical Data Design (LDD).

The RAMS Integration data model will consist of created and stored data in the Centralized RAMS Database required for generating study application instruments, study application instances, review and management forms from the RAMS web interface. Read/Write data will be transferred from/into the Centralized RAMS Database via the RAMS solution’s web services.

The figure below introduces the RAMS CDM and describes the high-level concepts as entities and their relationships.

Examples of the RAMS high-level concepts include:

* Institution
* Review Committees
* Study
* Project Association
* Project Funding (in future versions)
* Study Form
* Protocol
* Person
* Person Association
* User
* Person Institution Association
* Person Name
* Project Team Member

In general, each concept/entity in a CDM only contains a few important attributes. However, the entities in the RAMS CDM are fully attributed as they are part of the RAMS LDM.

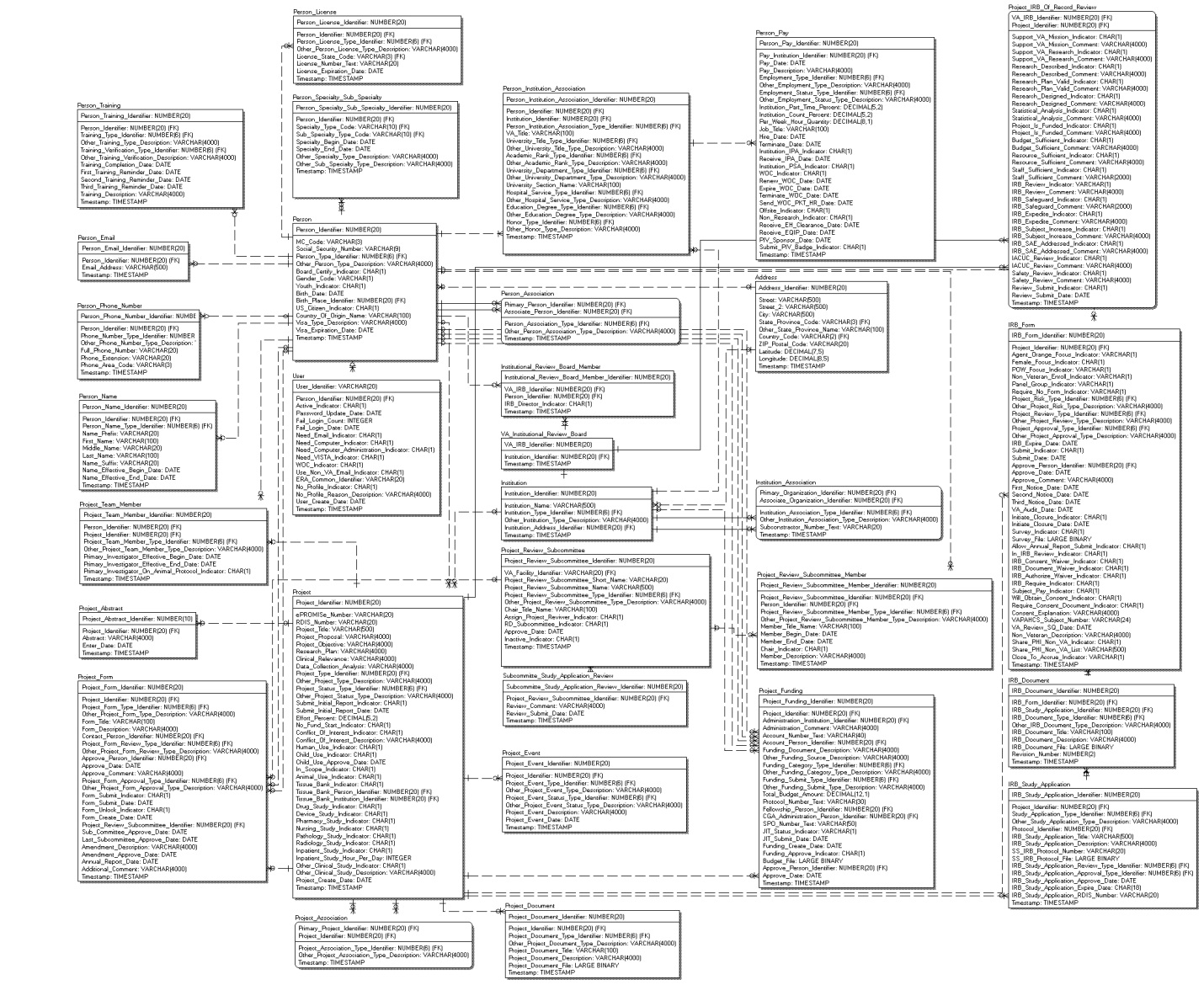


Figure 3: Sample Project Conceptual Data Model

Note: This diagram is not associated with the features being implemented in RAMS Integration.

### Database Information

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

The RAMS Integration will support major business functions of the IACUC, SRS, R&D, each local research office, and the Central Office reporting to the ORD. In addition, the RAMS application will facilitate management of the local and central IRB offices and provide a common database for tracking and reporting of administrative research program data throughout the VA.

RAMS serves as a single front-end web-based data management and reporting application framework hosted on an MS SharePoint 2013 server and a custom Java J2EE application on a separate Tomcat Server. An MS SQL Server 2012 R2 enterprise edition database is used for all data services for the RAMS environment, where all data access will be performed through the Server applications with no direct data access from the SQL Server. Accessing this data is a combination of services implemented in the MS SharePoint 2013, Tomcat J2EE, and SQL Server Integration Services (SSIS) platforms.

The SharePoint platform performs all functions of user access and administration, Committee Management, Document Storage, and workflow management, while the Java application implemented on SharePoint provides the unique functionality of creating and reviewing IRB applications. RESTful services integration of these two applications permits the Java component to initiate workflows for Committee Review, Amendments, Continuing Reviews, and interact with other aspects of the system allowing uniform role-based access across the entire study application lifecycle.

The table below identifies all databases that will be created, replaced, interfaced with, or whose structure will be modified, as part of this effort.

Table 6: Database Information

| Database Name | Description | Type | Steward |
| --- | --- | --- | --- |
| SharePoint Database | SharePoint Database (MS SQL) that will house metadata and support Document repository functions required of the SharePoint to perform as the Document repository for the RAMS Solution. | Existing | VA |
| Centralized RAMS Database | Microsoft SQL Server database that houses all VHA national research program input data for the RAMS Solution, Application meta data store and user management data store | Existing | VA |
| Staging Database | Staging Database for ETL operations | Existing | VA |

#### RAMS Database Testing and Modifications

**RAMS Database Testing**

The purpose of the RAMS testing is to measure the functional quality of the software against the specified user functional criteria prior to the system’s release into the production environment. The testing process will cover the major business functions for creation, review and approval of single and multi-site human or animal research projects. Testing will also provide the necessary traceability to the design and requirements artifacts to ensure increment components have been fully developed and will operate in a production environment.

**RAMS Database Modifications**

The Code that merges exists between Java applications and SharePoint applications. The code under development for each effort is compiled into distinct components that run in their own processes; though the code may not be shared, the data is shared.

The compiled applications are distinct, but they each connect to some of the same data sources. Hence, if there is going to be an area of merge conflicts or incompatible code, it is likely to be in the modifications made to the database in order to support new feature development.

To this end, developers must inform the Project Manager (PM) about any known database modifications to any of the following shared data stores prior to work beginning on those efforts:

* RAMS metadata
* RAMS user data

The development teams will plan for such changes, and provide an opportunity for development teams to design collaboratively a solution that will be compatible when the code is eventually integrated.

While collaboration is a good start, it does not solve the problem of tricky integration of database modifications. If there are a series of database changes that need to be sequenced just right, it will complicate the deployment process. Therefore, a database version control methodology will need to be established for each of these databases. This requires:

* Scripts that change the database schema or database objects being checked into source code version control system (Rational)
* The scripts are numbered in such a way that allows them to run in a specific order
* Each database maintains a table that stores the last successfully run script, which essentially becomes the revision of that database instance
* A tool such as DbDeploy is used to automatically run the un-run scripts in order, and update the revision in the database table during the deployment process

#### RAMS Dependencies

The RAMS databases will rely on MS Active Directory to create and authenticate user accounts.

RAMS will rely on VA PIV smart card authentication and PKI for digital signatures required for certain approval processes.

#### RAMS Scalability

The database engine on SQL Server 2012 R2 is scalable up, and supports the RAMS Solution and the growing data needs during the RAMS lifecycle. The SQL Server 2012 R2 Server hosting the database engine can be scaled up in the following three areas to improve and support its performance:

* Storage (hard disk capacity)
* CPU Cores (processing power)
* Memory (RAM)

#### RAMS Database Naming Conventions

The following table lists the RAMS database naming conventions.

Table 7: RAMS Database Naming Conventions

| Type | Guideline |
| --- | --- |
| Style | The first letter of each word will be capitalized with the remainder of the letters in lower case. No spaces will occur between words, e.g., “FirstName” |
| Table names | Table names with more than one word will use an underscore instead of spaces, e.g., “First\_Name”. |
| Field/Column names | No underscore in column names and no spaces |

#### RAMS Database Identification

The following table outlines the RAMS database identification information.

Table 8: RAMS Database Identification

| Element | Element Name | Meaning |
| --- | --- | --- |
| RAMS | RAMS | The database name for the VA RAMS system |
| C:\Program Files\Microsoft SQL Server\80 | 80, 90, 100 | Add 80, 90, to 100 to the end of the element to get to the directory. There are three total directories. |
| db\_location | Database Location | The location of the database in relation to the application |
| D:\SQLDATA\RAMS.mdf | Storage path | Full path of a location used by the database for placing automatic storage table spaces |

#### RAMS Storage

Sizing for the current database will accommodate approximately one year of production data assuming an equivalent storage requirement for content collected via the RAMS application, versus the document-based methodology currently in place.

#### Database Architecture and Integration Requirements

The RAMS database architecture will consist of a Microsoft (MS) SQL Server 2012 R2 enterprise edition installed on a Windows Server 2012 on a virtual server and will serve as a data repository for RAMS. The database server will interact with the RAMS application on a Tomcat application server via authenticated Java Database Connectivity (JDBC) connections. MS SQL Server Integration Services will perform all edit/transform/load activities to migrate any data into the RAMS database. MS SQL Server Reporting Services is the tool for meeting all the reporting requirements set forth in the RAMS RSD and will be exposed to the end user via direct role-based access from the SharePoint Server.

### User Interface Data Mapping

RAMS relies on web services to access and create customer data. The following figure displays the current homepage for RAMS.

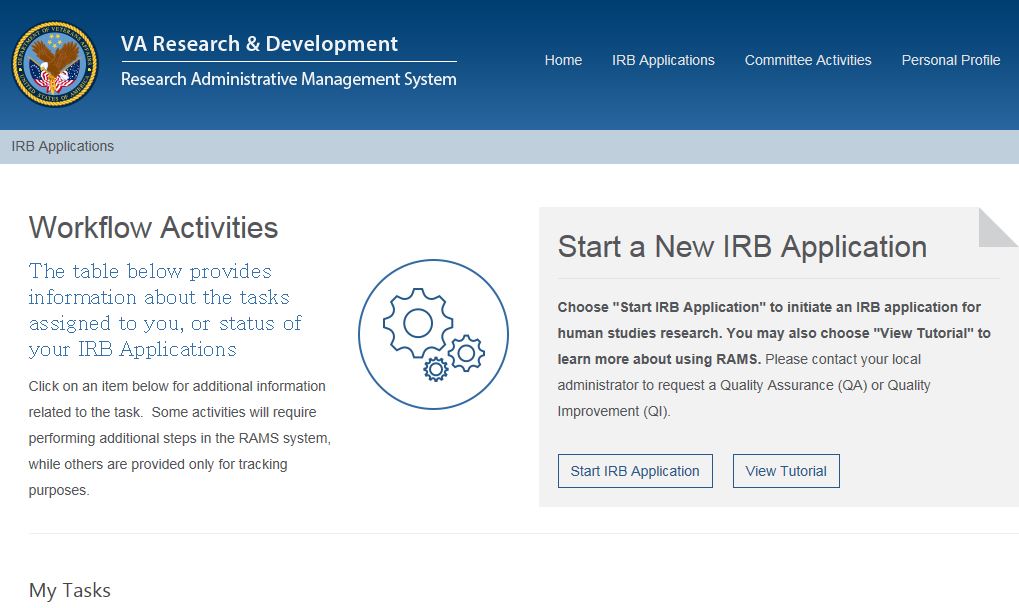


Figure 4: RAMS Homepage

Additionally, all RAMS data access will occur through the Server applications, with no data access directly from the SQL Server where it stores the majority of Research Project-related data, activities, and relevant user information within the RAMS solution’s Centralized Database and Document Repository. Based on these rules as defined within the metadata, the application layer displays the user interface accordingly. The RAMS solution Developers will write their own application methods using the JEE 7 Software Development Kit (SDK) and the SharePoint applications.

The trade-off of choosing Java development vs. SharePoint development includes more ease of customization for the user front-end, graphics, functionality, and easier interoperability between backend systems.

Additional Usability-User Interface (UI) Requirements are:

* The system shall respond to user actions when working with form data within three seconds or less, 95 percent of the time under normal user loads of 1000 simultaneous user requests and, within five seconds or less, 90 percent of the time under peak loads.
* The system shall provide context-sensitive help at the interface level for data entry and update screens.
* The system shall include the option to display definitions next to data entry fields, such as a mouse-over pop-up.

#### Application Screen Interface

The following requirements are related to the Application Screen Interface, also known as the Graphical User Interface (GUI).

* The RAMS Integration solution shall interface with a customizable MS SQL Server database to support RAMS functionality
* The RAMS Integration solution shall interface with MS Report SSRS to provide letter/form generation and customized self-service reports
* The RAMS Integration solution shall interface with MS SharePoint 2013 which serves as the document repository for the solution and provide content management, dashboard capabilities, and workflow

Table 9: Graphical User Interface Specific Requirements

| Req. ID | Requirement |
| --- | --- |
| GUI-001 | The RAMS GUI shall follow the design process and evaluation usability guidelines as specified in the US Health and Human Services (HHS) Web Standards and Usability Guidelines, Chapter 1. |
| GUI-002 | The RAMS GUI shall follow the optimize user experience usability guidelines as specified in the US Health and Human Services (HHS) Web Standards and Usability Guidelines, Chapter 2. |
| GUI-003 | The RAMS GUI shall follow the hardware and software usability guidelines as specified in the US Health and Human Services (HHS) Web Standards and Usability Guidelines, Chapter 4. |
| GUI-004 | The RAMS GUI shall follow the homepage usability guidelines as specified in the US Health and Human Services (HHS) Web Standards and Usability Guidelines, Chapter 5. |
| GUI-005 | The RAMS GUI shall follow the page layout usability guidelines as specified in the US Health and Human Services (HHS) Web Standards and Usability Guidelines, Chapter6. |
| GUI-006 | The RAMS GUI shall follow the navigation usability guidelines as specified in the US Health and Human Services (HHS) Web Standards and Usability Guidelines, Chapter 7. |
| GUI-007 | The RAMS GUI shall follow the scrolling and paging usability guidelines as specified in the US Health and Human Services (HHS) Web Standards and Usability Guidelines, Chapter 8. |
| GUI-008 | The RAMS GUI shall follow the headings, titles, and labels usability guidelines as specified in the US Health and Human Services (HHS) Web Standards and Usability Guidelines, Chapter 9. |
| GUI-009 | The RAMS GUI shall follow the links usability guidelines as specified in the US Health and Human Services (HHS) Web Standards and Usability Guidelines, Chapter 10. |
| GUI-010 | The RAMS GUI shall follow the text appearance usability guidelines as specified in the US Health and Human Services (HHS) Web Standards and Usability Guidelines, Chapter 11. |
| GUI-011 | The RAMS GUI shall follow the lists usability guidelines as specified in the US Health and Human Services (HHS) Web Standards and Usability Guidelines, Chapter 12. |
| GUI-012 | The RAMS GUI shall follow the screen-based controls usability guidelines as specified in the US Health and Human Services (HHS) Web Standards and Usability Guidelines, Chapter 13. |
| GUI-013 | The RAMS GUI shall follow the Graphics, Images, and Multimedia usability guidelines as specified in the US Health and Human Services (HHS) Web Standards and Usability Guidelines, Chapter 14. |
| GUI-014 | The RAMS GUI shall follow the content organization guidelines as specified in the US Health and Human Services (HHS) Web Standards and Usability Guidelines, Chapter 16. |
| GUI-015 | The RAMS GUI shall follow the search guidelines as specified in the US Health and Human Services (HHS) Web Standards and Usability Guidelines, Chapter 17. |

There are eight main GUI screens associated with the RAMS application and its main business functions. Details on the main screens are shown below. Information on database tables and field names will remain undecided until the design of the integrated RAMS database is available.

##### RAMS Landing Screen

The RAMS Landing Screen, shown in the figure below, represents the main screen that provides access to the application; the following table describes this screen.

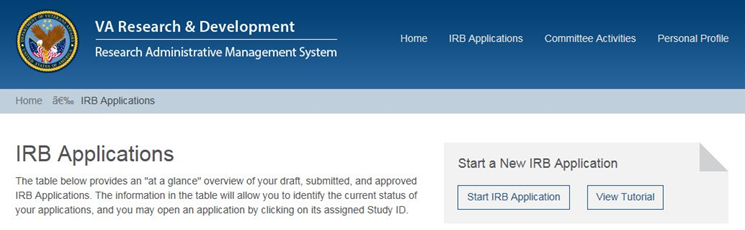


Figure 5: RAMS Landing Screen

Table 10: RAMS Landing Screen Description

| Graphical User Interface (GUI) Field | Table (Database Table that Field Connects to) | Field (Field in Table that the GUI Field Connects to) | Comments |
| --- | --- | --- | --- |
| Home | N/A | N/A | Home screen |
| IRB Applications | N/A | N/A | Navigation to IRB Application functions |
| Committee Activities | N/A | N/A | Navigation to Committee Activities functions |
| Personal Profile | N/A | N/A |  |

##### RAMS Homepage

The RAMS Homepage Screen, shown in the figure below, represents the screen that provides an overview of the user’s current tasks; the following table describes this screen.

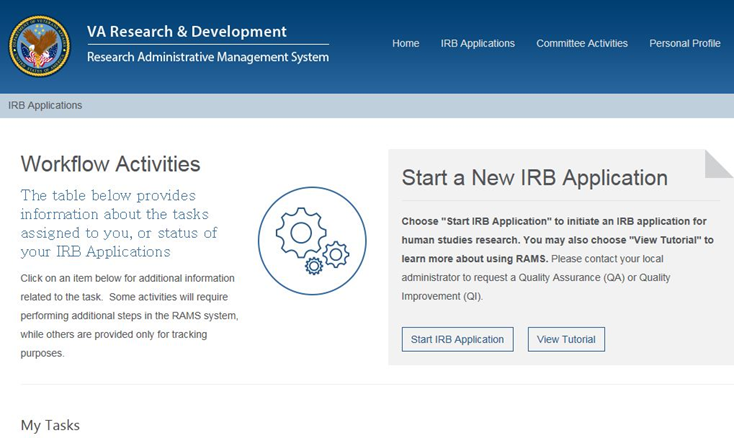


Figure 6: RAMS Homepage

Table 11: RAMS Homepage Screen

| Graphical User Interface (GUI) Field | Table (Database Table that Field Connects to) | Field (Field in Table that the GUI Field Connects to) | Comments |
| --- | --- | --- | --- |
| My Tasks | N/A | N/A | Displays the current tasks for the user with respect to his/her role on the IRB Application |
| Start IRB Application | N/A | N/A | Navigation to the IRB Application functions |
| View Tutorial | N/A | N/A | Navigation to RAMS Help area |

##### Edit Tasks

The Edit Tasks Screen, shown in the figure below, represents the screen that allows the user to maintain their tasks within RAMS; the following table describes this screen.

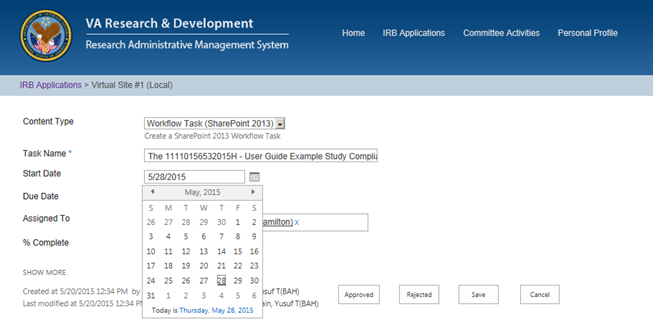


Figure 7: Edit Tasks Screen

Table 12: Edit Tasks Screen Description

| Graphical User Interface (GUI) Field | Table (Database Table that Field Connects to) | Field (Field in Table that the GUI Field Connects to) | Comments |
| --- | --- | --- | --- |
| Content Type | Tasks (SharePoint List) | Content Type | The generic label for the task type |
| Task Name | Tasks (SharePoint List) | Task Name | The name of the task |
| Start Date | Tasks (SharePoint List) | Start Date | Start date of the task |
| Due Date | Tasks (SharePoint List) | Due Date | Due date of the task |
| Assigned To | Tasks (SharePoint List) | Assigned To | Task assignment |
| % Complete | Tasks (SharePoint List) | % Complete | The percentage complete for the task |
| Edit Action Buttons | N/A | N/A | Type of action for the edits |

##### View Tutorial RAMS Help

The View Tutorial RAMS Help Screen, shown in the figure below, represents the screen that provides help on RAMS system functions; the following table describes this screen.

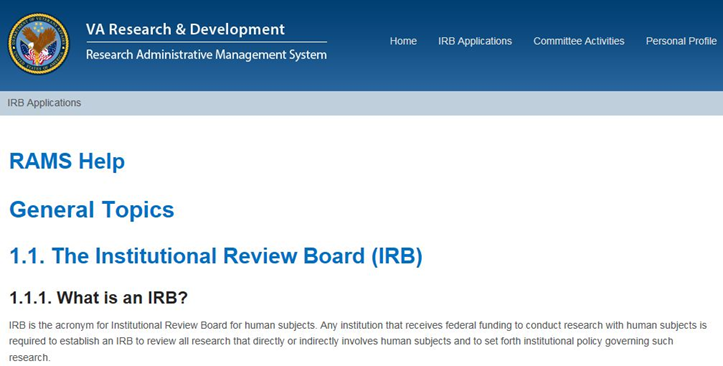


Figure 8: View Tutorial RAMS Help Screen

Table 13: View Tutorial RAMS Help Screen Description

| Graphical User Interface (GUI) Field | Table (Database Table that Field Connects to) | Field (Field in Table that the GUI Field Connects to) | Comments |
| --- | --- | --- | --- |
| General Topics | N/A | N/A | Lists RAMS Help topics. |
| Help Description | N/A | N/A | Description of RAMS functions from the user’s point-of-view. |

##### IRB Applications

The IRB Applications Screen, shown in the figure below, represents the screen that contains application profiles. This screen lists all applications on approved studies for which the RAMS user is granted access; the following table describes this screen.

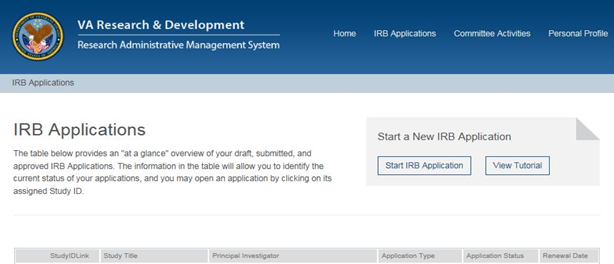


Figure 9: IRB Applications Screen

Table 14: IRB Applications Screen Description

| Graphical User Interface (GUI) Field | Table (Database Table that Field Connects to) | Field (Field in Table that the GUI Field Connects to) | Comments |
| --- | --- | --- | --- |
| StudyIDLink | Applications (SharePoint List) | StudyIDLink | System-generated ID and URL for Study Application |
| Study Title | Applications (SharePoint List) | Study Title | Title of the research study |
| Principal Investigator | Applications (SharePoint List) | Principal Investigator | Head investigator for the study |
| Application Type | Applications (SharePoint List) | Application Type | Type of application |
| Application Status | Applications (SharePoint List) | Application Status | Status of application |
| Renewal Date | Applications (SharePoint List) | Renewal Date | Renewal date for the application |

##### IRB Application

The IRB Application Screen, shown in the figure below, permits the user to enter data and submit a request for a new research study. Data elements are dynamically rendered on this screen from metadata contained in the RAMS database, whereby any arbitrary combination of questions and answers may be defined for a specific application type and is not statically defined anywhere in the system. The figure below represents one sample collection of questions as rendered from the database. The table describes the generic database fields, which contain the database elements that provide these questions.

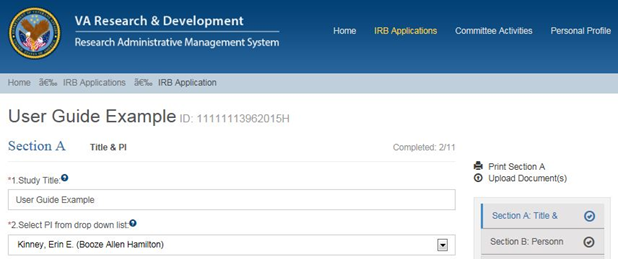


Figure 10: IRB Application Status Screen

Table 15: IRB Application Status Screen Description

| Graphical User Interface (GUI) Field | Table (Database Table that Field Connects to) | Field (Field in Table that the GUI Field Connects to) | Comments |
| --- | --- | --- | --- |
| Question | RAMS.Forms\_Questions | Title | System-generated study ID |
| Response | RAMS.Forms\_Reponses | Answer | Completion date for the application |

##### Committee Activities Screen

The Committee Activities Screen, shown in the figure below, represents the screen that tracks committee members, meetings past and present, meeting minutes, and submitted applications; the following table describes this screen.

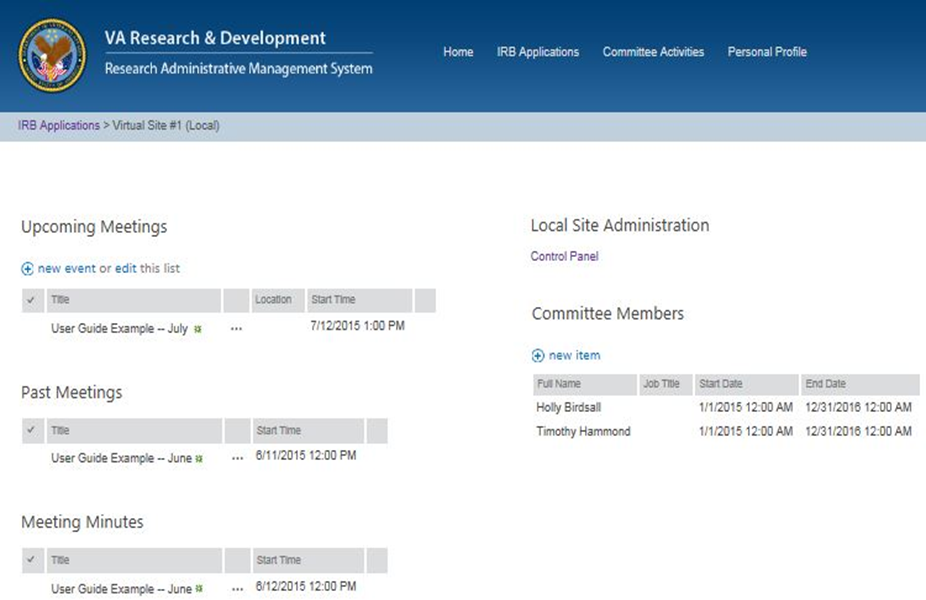


Figure 11: Committee Activities Screen

Table 16: Committee Activities Screen Description

| Graphical User Interface (GUI) Field | Table (Database Table that Field Connects to) | Field (Field in Table that the GUI Field Connects to) | Comments |
| --- | --- | --- | --- |
| Committee Member Full Name | Committee Members (SharePoint List) | Full Name | The full name of the committee member |
| Committee Member Job Title | Committee Members (SharePoint List) | Job Title | The job title of the committee member |
| Committee Member Start Date | Committee Members (SharePoint List) | Start Date | Committee Member Start Date |
| Committee Member End Date | Committee Members (SharePoint List) | End Date | Committee Member End Date |
| Upcoming Meeting Title | Agendas (SharePoint List) | Title | Upcoming Meeting Title |
| Upcoming Meeting Location | Agendas (SharePoint List) | Location | Upcoming Meeting Location |
| Upcoming Meeting Date and Start Time | Agendas (SharePoint List) | Date and Start Time | Upcoming Meeting Date and Start Time |
| Past Meeting Title | Agendas (SharePoint List) | Title | Past Meeting Title |
| Meeting Date and Start Time | Agendas (SharePoint List) | Date and Start Time | Meeting Date and Start Time |
| Meeting Minutes Title | Meeting Minutes (SharePoint List) | Title | Meeting Minutes Title |
| Meeting Minutes Date and Start Time | Meeting Minutes (SharePoint List) | Date and Start Time | Meeting Minutes Date and Start Time |

#### Application Report Interface

The following reports will be available via RAMS. Future versions of this design document will include report samples as they become available:

1. Committee Roster Reports
2. Training Report
3. Report on Without Compensation (WOC) Staff Report
4. Key, Badge, and Equipment Inventory Report
5. Lab Space Report
6. Laboratory Annual Self-Inspection Form (LASIF)

The developer will provide additional details at a later date, pending VA input and review.

##### Report on Without Compensation (WOC) Staff Report

The developer will provide additional details will at a later date by, pending VA input and review.

##### Key, Badge, and Equipment Inventory Report

The developer will provide additional details at a later date, pending VA input and review.

##### Lab Space Report

The developer will provide additional details at a later date, pending VA input and review.

##### Committee Roster Reports

The developer will provide additional details at a later date, pending VA input and review.

##### Training Report

The developer will provide additional details at a later date, pending VA input and review.

##### Laboratory Annual Self-Inspection Form (LASIF)

The developer will provide additional details at a later date, pending VA input and review.

#### Unmapped Data Element

The developer will provide additional details at a later date, pending VA input and review.

### Data Transfer Requirements

System architecture designs, and system and infrastructure requirements will determine data transfer requirements. Requirements will be determined based on the necessary hardware, software, networking, and connectivity specifications of the production systems with key requirements such as functionality, performance, safety, security, capacity, cost, and time constraints being crucial in order to determine the correct infrastructure for the environments.

All machines are hosted in the VA development and test environments, which is an elastic network environment that hosts tools and servers that support this development project. Instances will be necessary for a testing team to support the various types of functional and user acceptance testing that will be required for compatibility of any data transfer to take place.

Parallel development will take place on the RAMS codebase, as the platform is comprised of many interoperating components in Java (RESTful Services, Business Logic) and SharePoint (multiple custom Applications [Apps]). The development effort will coordinate this type of parallel development by creating branches in a source code Version Control System (VCS) to isolate the changes from one another until ready to be integrated. Isolation allows for scoping changes only where needed, allowing developers to sustain a higher velocity because they can focus only on their changes, and defer the interference of peripheral changes, until the developers stabilize and verify the code.

### Data Formats

The following table lists the format and data types for the RAMS Integration.

Table 17: Data Formats

| Format | Data Type |
| --- | --- |
| Exact Numerics | bigint, bit, decimal, int, money, numeric, smallint, smallmoney, tinyint |
| Approximate Numerics | float, real |
| Date and Time | date, datetime2, datetime, datetimeoffset, smalldatetime, time |
| Character Strings | char, varchar, text |
| Unicode Character Strings | nchar, nvarchar, ntext |
| Binary Strings | binary, varbinary, image |

New data can be appended to an existing database table. This option is off by default and must be turned on by using the Append to Access and Open Database Connectivity (ODBC) Tables option in the ODBC/Access Options section of the Options dialog box or the SET command DB-TABLE-APPEND in the command processor.

Stat/Transfer will match as many variables as possible to those already in the table and add your data to the matching columns. Obviously, at least one column must match exactly and, in addition, the table must be free of constraints, such as those requiring unique keys, that would prohibit a simple "append” operation.

### ETL Server Functionality and Interface Connections

The following is the Extract, Transfer, and Load (ETL) process defined in the RAMS Integration:

**Extract**– The first step in the ETL process, is extracting the data from various sources. Each of the source systems may store its data in a completely different format from the rest. The sources are usually flat files or Relational Database Management System (RDBMS), but almost any data storage is usable as a source for an ETL process.

**Transform** – After extracting the data and converting it into the expected format, it’s time for the next step in the ETL process, which is transforming the data according to a set of business rules. The data transformation may include various operations including, but not limited to, filtering, sorting, aggregating, joining data, cleaning data, generating calculated data based on existing values, validating data, etc.

**Load** – The final ETL step involves loading the transformed data into the destination target, which might be a database or data warehouse.

For migration of data from field office applications into the new Centralized RAMS Database, the following are factors that have influenced its current implementation, including:

* **Application Architecture:** requires an assessment of the software and hardware components that make up the application, how they are organized, and how they interface with and depend on one another.
* **Data Architecture:** requires an assessment of how requisite data for the application is modeled, governed, stored, structured, and used.
* **Integration Architecture:** requires an assessment of the mechanisms by which the application is connected to other systems or applications and the means by which data is exchanged between them.
* **Deployment Architecture:** requires an assessment of the way in which the application is made accessible to its users, as well as how new versions of the application or its data are made available.
* **Security Architecture:** requires an assessment of the approach to protecting application data, securing the application, and managing risks associated with their use.

#### RAMS Integration Tools

##### ETL Platform

SSIS is an MS SQL platform that will be used for building a high-performance RAMS solution to include:

* Extraction
* Transformation
* Load (ETL) packages for data warehousing.

Additional RAMS ETL Tool (SSIS) functionality includes:

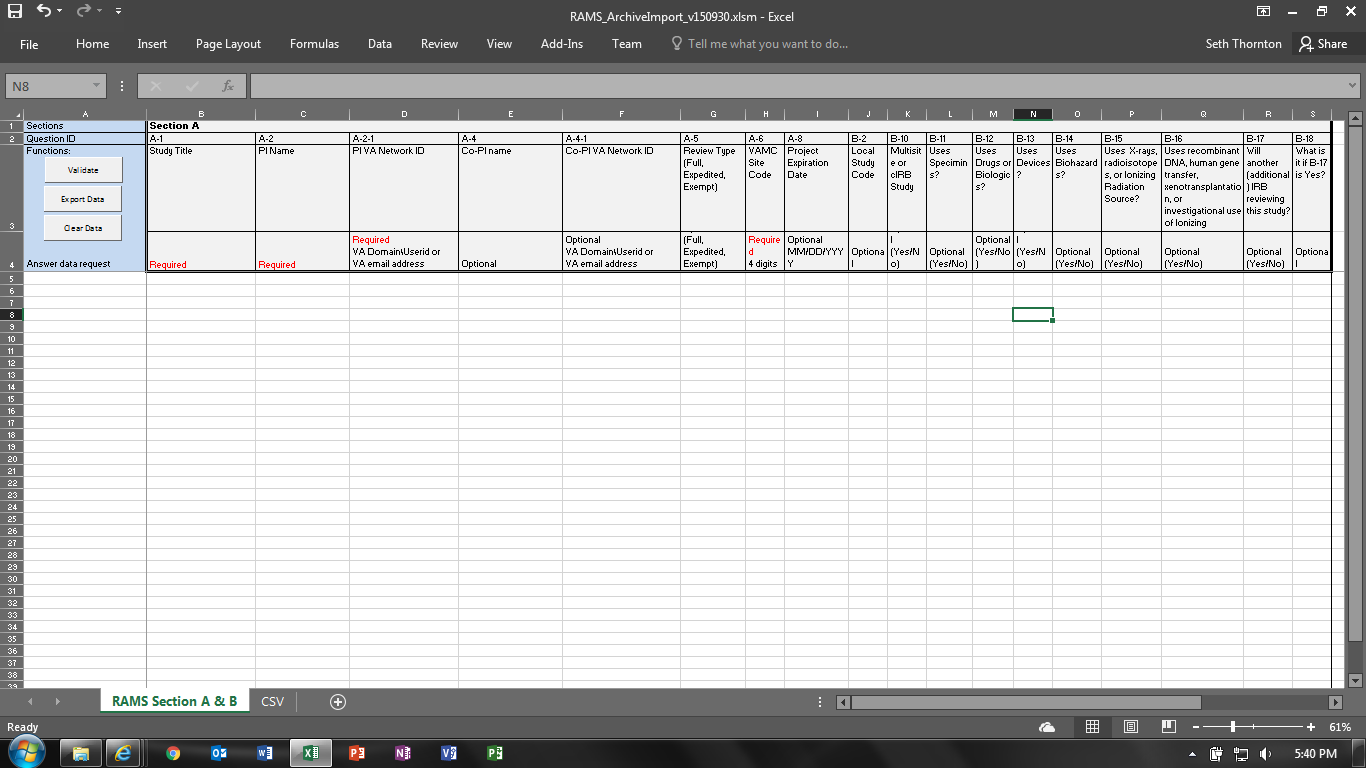
* Graphical tools and wizards for building and debugging packages
* Tasks for performing workflow functions such as File Transfer Protocol (FTP) operations, executing SQL statements, and sending e-mail messages
* Data sources and destinations for extracting and loading data
* Transformations for cleaning, aggregating, merging, and copying data
* Integration Services for administering package execution and storage
* Application programming interfaces (APIs) for programming the Integration Services object model

##### RAMS Data Bridge

RAMS provides the ability to enter new Study applications through the web interface using only manual entry methods. To support Research Offices, which may have existing approved studies, the RAMS design includes a function referred to as the “Data Bridge” which leverages a customized spreadsheet template designed to collect the essential data elements to create a Study record in both the custom RAMS database used by Apache Tomcat and the Application List in SharePoint. By creating data elements in these two collections, a user may perform the basic functions necessary to track and update studies as if they had been entered the system using manual methods (i.e., Create adverse or Reportable events, Submit Amendments, update study personnel, etc.)

Components of the Data Bridge:

1. RAMS\_ArchiveImport\_v150930.xls



1. Apache Tomcat Service Façade  
   In order to facilitate uploading the RAMS data bridge file in a programmatically controlled manner (to ensure file are processed in order, collisions are avoided, etc.), a file upload process was developed on the Apache Tomcat server. The Tomcat server, which receives the multipart data from HTTPS, and transfers the file to a Samba share which connects to the Incoming file directory on the SSIS server. As all files are uploaded with the same filename from the browser, the file is renamed before being written to the filesystem in order to avoid file collisions. The files accumulate in the Samba share until the SSIS Server retrieves them via a scheduled task.
2. SSIS Server File Import Scheduled Task  
   The SSIS Server has a scheduled task, which runs after a configured number of minutes elapse (configurable in the Windows Task Scheduler). This job moves files from the incoming Samba share directory, processes the SSIS import procedure, and relocates the file to an archive directory. This scheduled task is a DOS shell script, which logs all activity to .log files for archive history. SSIS is invoked from the command line along with any T/SQL procedures required to normalize the data to RAMS data standards.
3. SSIS Import Package  
   This procedure parses the CSV file generated by the Excel tool, and maps file elements to the staging table columns. The script imports any data included in the file as long as the datatypes are correct and includes all required columns.
4. SQL Server T/SQL Procedures  
   Data imported into the staging tables must be normalized to RAMS data standards, and a study ID must be generated for the file. Multiple stored procedures work together to format the data, assign synthetic values (such as study ID) and insert records into the target tables. Any data, which does not adhere to RAMS standards is inserted into an error table for analysis by the DBA or engineering team.
5. SharePoint rams\_archive\_import.html page  
   The final stage to importing data into the RAMS platform is to synthesize the SharePoint objects required to register the study in the platform. The archive\_insertion.js JavaScript procedures are used in the rams\_archive\_import page, which reads any staged data that does not exist in the Application list and renders it for the current user with the option to select which studies to import. A button is used on the page to permit the user to initiate the functions, which automate the creation of SharePoint list objects, folders, etc. A progress bar shows the user a relative indication of overall progress, and dynamically generates a log of activities on the page to capture and display any relevant errors that may occur during the process.

#### RAMS Database Interfaces

The following MS database Interfaces used during the RAMS Integration will consist of SSIS, SSRS, and SharePoint.

Microsoft SQL Server Native Client OLE DB Provider

The MS SQL Server Native Client Object Linking and Embedding (OLE) DB Provider offers an OLE DB interface to MS SQL Server databases. By using the SQL Server Native Client OLE DB Provider, SQL Server-distributed queries can query data in remote instances of the SQL Server.

And

Microsoft OLE DB Provider for ODBC

The OLE DB Provider for ODBC offers an OLE DB interface to ODBC data sources. By using the OLE DB Provider for ODBC, distributed queries can access all ODBC data.

The following figure displays the RAMS System Interface Diagram.

\\bylighthealthcare.sharepoint.com@SSL\DavWWWRoot\RAMSIntegration\Shared Documents\Design\Updated SDD Working Folder\Derived Files\Figure 21.wmf

Figure 12: RAMS System Interface Diagram

**NOTE**: Generic JDBC drivers will be consumed for the J2EE based UI.

#### JDBC Interface

The following table lists the details of the JDBC interface connection.

Table 18: JDBC Interface

|  |  |
| --- | --- |
| Interface | Details |
| Purpose | The JDBC API is the industry standard for database-independent connectivity between Java programming language and a wide range of databases |
| Characteristics | The JDBC API provides a call-level API for SQL-based database access. |
| Interface Architecture | See Figure 13 below. |
| API and Error Conditions | When JDBC encounters an error during an interaction with a data source, it throws an instance of SQLException as opposed to Exception |
| Security | Kerberos  Secure Sockets Layer (SSL) |

The figure below displays the Interface Architecture for the JDBC Interface connection.

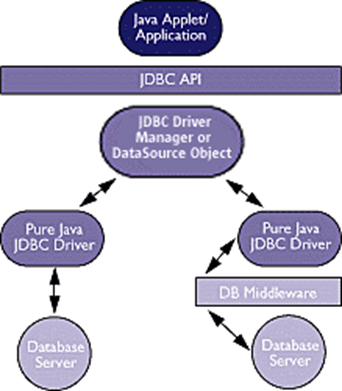


Figure 13: Interface Architecture

## Conceptual Infrastructure Design

The conceptual infrastructure design is a high-level overview of the infrastructure that supports the RAMS Integration.

The RAMS application is a web-based application accessible from behind the VA network via a client workstation with a VA-approved Internet browser. RAMS will serve as a single front-end web-based data management and reporting application framework and centralized back-end database system.

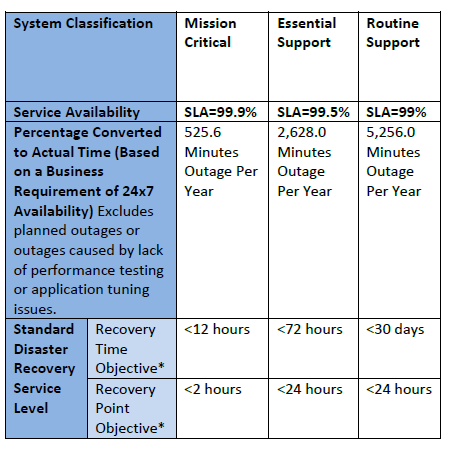
The deployment architecture implements an N-tiered model consisting of an Internet browser based GUI serviced by an MS Windows server(s), a NET-based business logic-service-processing layer, and an MS SQL-based data access tier. Conceptual infrastructure design for RAMS involves Concept Development, System Integration, and Infrastructure that is crucial to the success of the RAMS integration.

Conceptual Development is a set of activities carried out early in the systems engineering lifecycle to collect and prioritize operational needs and challenges, develop alternative concepts to meet the needs, and select a preferred concert as the basis for subsequent system or capability development, and implementation.

* The RAMS Integration requirement should identify integration and interoperability challenges and with all-purpose intentions of developing and creating integration strategies that meet the business/mission needs of end users and their stakeholders. RAMS engineers will develop and evaluate integration and interoperability options and observe and assess integration testing. As such, RAMS engineers should address integration and interoperability issues associated with the system, including technical, programmatic, social, and business dimensions.
* Infrastructure engineering ensures that the IT infrastructure is sufficiently robust, scalable, and efficient to deliver the integrated services underlying the physical environment that supports the processes, physical resources, and operators required for developing, integrating, operating, and sustaining IT applications and support services. Physical resources include facilities, hardware, software, and tools. Operators include engineers, programmers, administrators, and help/service desk personnel, and users. The RAMS infrastructure engineering supports objectives to ensure that a reliable, consistent level of service is available to infrastructure customers and IT service consumers—both human and machine.
* Infrastructure operations address the day-to-day management and maintenance of IT services, systems, and applications, as well as the infrastructure, the geographic location, the facilities in which they are housed, and the energy and hardware usage.

Skilled support resources and defined processes are the key to the Conceptual Infrastructure Design and Operations. This includes systems and network administration, data center operations, help/service desks, network operations centers, and service level management.

### System Criticality and High Availability



The RAMS Integration project’s Disaster Recover Plan (DRP) is covered by the Philadelphia Information Technology Center (PITC). Additionally, must facilitate database backups by the VA regular standards and procedures of the SQL Server database. The system will be able to be reloaded from a backup image and placed back into service by the VA’s standard Operating System backup and restore procedures. The RAMS Architecture must separate the operational site from the disaster recovery site. The RAMS system shall be able to replicate the RAMS data from the operational site to the disaster recovery site in near real-time.

The RAMS software application is a critical component that needs to be available 24 hours per day and 7 days a week. The RAMS software application has existing software and hardware components that support the planned design.

The VA hosting environment supporting the application will handle the Disaster Recovery (DR) procedures. If there is a need for the RAMS software to go offline, the following will need to occur:

* A notification will be disseminated to the user community, within 30 minutes of an unscheduled outage and/or system degradation, with details from the Automated Notification Reporting (ANR) template maintained by the VA Service Desk.
* A notification will be disseminated to the user community, within 30 minutes of an event that poses a risk of extending a scheduled maintenance period, which may require that the service be offline, or result in system degradation.

In the event manual intervention is necessary, all support documentation for the RAMS software will be stored in a document repository containing the most current officially approved document versions.

### Special Technology

At this time, the system does not include any special technology.

### Technology Locations

The tables below provide information on the environment, location, and usage for the RAMS Integration solution.

Table 19: Technology Locations for Production Environment

| Technology Component | Location | Usage |
| --- | --- | --- |
| Workstations | Multiple | User |
| Special Hardware | N/A |  |
| Interface Processors | N/A |  |
| MS SQL Server 2012 | PITC | Centralized RAMS Database |
| MS SharePoint 2013 | PITC | Document Repository for the RAMS Database |
| MS SSRS 2012 | PITC | Custom reporting services |
| MS SSIS 2012 | PITC | Custom ETL Services |
| Apache Tomcat 7.x | PITC | Java Application and Web Server |

Table 20: Technology Locations for Pre-Production Environment

| Technology Component | Location | Usage |
| --- | --- | --- |
| Workstations | Multiple | User |
| Special Hardware | N/A |  |
| Interface Processors | N/A |  |
| MS SQL Server 2012 | PITC | Centralized RAMS Database |
| MS SharePoint 2013 | PITC | Document Repository for the RAMS Database |
| MS SSRS 2012 | PITC | Custom reporting services |
| MS SSIS 2012 | PITC | Custom ETL Services |
| Apache Tomcat 7.x | PITC | Java Application and Web Server |

Table 21: Technology Locations SQA Environment

| Technology Component | Location | Usage |
| --- | --- | --- |
| Workstations | Multiple | User |
| Special Hardware | N/A |  |
| Interface Processors | N/A |  |
| MS SQL Server 2012 | PITC | Centralized RAMS Database |
| MS SharePoint 2013 | PITC | Document Repository for the RAMS Database |
| MS SSRS 2012 | PITC | Custom reporting services |
| MS SSIS 2012 | PITC | Custom ETL Services |
| Apache Tomcat 7.x  Server | PITC | Java Application and Web Server |

Table 22: Technology Locations for Test Environments\*

| Technology Component | Location | Usage |
| --- | --- | --- |
| Workstations | Multiple | User |
| Special Hardware | N/A |  |
| Interface Processors | N/A |  |
| MS SQL Server 2012 | PITC | Centralized RAMS Database |
| MS SharePoint 2013 | PITC | Document Repository for the RAMS Database |
| MS SSRS 2012 | PITC | Custom reporting services |
| MS SSIS 2012 | PITC | Custom ETL Services |
| Apache Tomcat 7.x | PITC | Java Application and Web Server |

Table 23: Technology Locations for Development Environments\*

| Technology Component | Location | Usage |
| --- | --- | --- |
| Workstations | Multiple | User |
| Special Hardware | N/A |  |
| Interface Processors | N/A |  |
| MS SQL Server 2012 | PITC | Centralized RAMS Database |
| MS SharePoint 2013 | PITC | Document Repository for the RAMS Database |
| MS SSRS 2012 | PITC | Custom reporting services |
| MS SSIS 2012 | PITC | Custom ETL Services |
| Apache Tomcat 7.x | PITC | Java Application and Web Server |

Note: There will be two Development and Test environments to support ongoing sustainment and development activities.

Table 24: Disaster Recovery Locations

| Technology Component | Location | Usage |
| --- | --- | --- |
| System Quality Assurance (SQA) | PITC | BackUps Performed |
| Pre-Production Environment | PITC | BackUps Performed |
| Production Environment | PITC | BackUps Performed |
| Development Environment | PITC | BackUps Performed |
| Test Environment | PITC | BackUps Performed |

### Conceptual Infrastructure Diagram

For information on the location of environments and external interfaces, see Section 3.1, Conceptual Application Design.

#### Location of Environments and External Interfaces

The RAMS Integration solution serves as a multi-purpose administrative tool for the ORD Central Office and VAMC research offices. RAMS provides the capability to create and track administrative data for each research project, e.g., required staff training.

The diagram below depicts the following:

1. All planned RAMS functionality at this time is located within the VA/VHA universe.
2. RAMS users may be internal or external to the VA firewall.
3. Collaborative Institutional Training Initiative (CITI) and Talent Management System (TMS), both VA internal systems, interface with the RAMS functions that track required staff training.



Figure 14: RAMS Future View, System, and Interfaces

The following figure outlines the locations of environments and external interfaces.

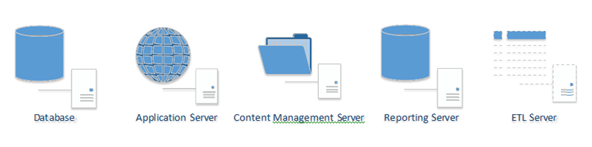


Figure 15: Locations of Environments and External Interfaces

Table 25: Development Environment

| Purpose | Description | Operating System | # of Cores | Memory | Storage |
| --- | --- | --- | --- | --- | --- |
| SQL Database | SQL Server DB Backend for RAMS, SharePoint, and SSRS | Windows 2012 x64 | 4 | 32GB | 500GB |
| JAVA Application Server | Java Application Server for the RAMS Application | Windows 2012 x64 | 4 | 8GB | 250GB |
| SharePoint Content Management. Server | SharePoint Server | Windows 2012 x64 | 4 | 32GB | 1060GB |
| SQL Reporting Server | SQL Server Reporting Services Server | Windows 2012 x64 | 4 | 8GB | 440GB |
| ETL Server | ETL data from the field offices applications | Windows 2012 x64 | 2 | 8GB | 440GB |

| **Purpose** | **Description** | **Operating System** | **# of Cores** | **Memory** | **Storage** |
| --- | --- | --- | --- | --- | --- |
| SQL Database | SQL Server DB Backend for RAMS, SharePoint and SSRS | Windows 2012 x64 | 4 | 8GB | 250GB |
| JAVA Application Server | Java Application Server for the RAMS Application | Windows 2012 x64 | 4 | 8GB | 160GB |
| SharePoint Content Management Server | SharePoint Server | Windows 2012 x64 | 4 | 8GB | 250GB |
| SQL Reporting Server | SQL Server Reporting Services Server | Windows 2012 x64 | 4 | 8GB | 160GB |
| ETL Server | ETL data from the field offices applications | Windows 2012 x64 | 2 | 3GB | 250GB |

Table 26: Test Environment

Table 27: SQA Environment

| Purpose | Description | Operating System | # of Cores | Memory | Storage |
| --- | --- | --- | --- | --- | --- |
| SQL Database | SQL Server DB Backend for RAMS, SharePoint and SSRS | Windows 2012 x64 | 4 | 8GB | 250GB |
| JAVA Application Server | Java Application Server for the RAMS Application | Windows 2008 R2 | 4 | 8GB | 160GB |
| SharePoint Content Management Server | SharePoint Server | Windows 2008 R2 | 4 | 8GB | 250GB |
| SQL Reporting Server | SQL Server Reporting Services Server | Windows 2008 R2 | 4 | 8GB | 160GB |
| ETL Server | Extract, Transform, and Load data from the field offices applications | Windows 2008 R2 | 2 | 3GB | 500GB |

Table 28: Pre-Production Environment

| Purpose | Description | Operating System | # of Cores | Memory | Storage |
| --- | --- | --- | --- | --- | --- |
| SQL Database | SQL Server DB Backend for RAMS, SharePoint and SSRS | Windows 2012 x64 | 4 | 32GB | 500GB |
| JAVA Application Server | Java Application Server for the RAMS Application | Windows 2008 R2 | 4 | 16Gb | 250GB |
| SharePoint Content Management. Server | SharePoint Server | Windows 2008 R2 | 4 | 16GB | 1000GB |
| SQL Reporting Server | SQL Server Reporting Services Server | Windows 2008 R2 | 4 | 8Gb | 500GB |
| ETL Server | ETL data from the field offices applications | Windows 2008 R2 | 2 | 3GB | 500GB |

Table 29: Production Environment

| Purpose | Description | Operating System | # of Cores | Memory | Storage |
| --- | --- | --- | --- | --- | --- |
| SQL Database | SQL Server DB Backend for RAMS, SharePoint and SSRS | Windows 2012 x64 | 4 | 32GB | 500GB |
| JAVA Application Server | Java Application Server for the RAMS Application | Windows 2008 R2 | 4 | 16GB | 250GB |
| SharePoint Content Management Server | SharePoint Server | Windows 2008 R2 | 4 | 16GB | 1000GB |
| SQL Reporting Server | SQL Server Reporting Services Server | Windows 2008 R2 | 4 | 8GB | 500GB |
| ETL Server | ETL data from the field offices applications | Windows 2008 R2 | 2 | 3GB | 500GB |

The VA will house the following environments in the PITC Hosting Infrastructure:

* 2 Development Environment
* 2 Testing Environment
* 1 SQA Environment
* 1 Pre-Production Environment
* 1 Production Environment

#### Conceptual Production String Diagram

The figure below shows the configuration of a single string production environment and the components that are required.

\\bylighthealthcare.sharepoint.com@SSL\DavWWWRoot\RAMSIntegration\Shared Documents\Design\Updated SDD Working Folder\Derived Files\Figure 21.wmf

Figure 16: Conceptual Production String Diagram

# System Architecture

This section describes the system and/or subsystem(s) architecture for the project. An outline of System Architecture and its Integration follows in the diagram below:

\\bylighthealthcare.sharepoint.com@SSL\DavWWWRoot\RAMSIntegration\Shared Documents\Design\Updated SDD Working Folder\Derived Files\Figure 17.wmf

Figure 17: System Architecture Diagram

The RAMS system is a web application accessed via a web browser. The system is hosted on Virtual Machines (VMs) in PITC that is comprised of a complete and modern hosting facility.

The RAMS application serves as a communication portal that is accessible to the ORD and research offices as it pertains to administering and managing the IRB, IACUC, SRS, R&D, local research offices reporting to ORD, and provides a common database for tracking and reporting of administrative research program data throughout the VA.

## Hardware Architecture

The diagram below and the following table will show the hardware architecture, connectivity, and location of servers within the RAMS solution.

\\bylighthealthcare.sharepoint.com@SSL\DavWWWRoot\RAMSIntegration\Shared Documents\Design\Updated SDD Working Folder\Derived Files\Figure 18.wmf

Figure 18: Hardware Architecture

Table 30: RAMS Hardware Architecture

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Function | OS/bit | VM | CPU | RAM | OS GB C: | Description | Total GB |
| SQL Database | W2012 x64 | 1 | 4 | 32 | 60 | SQL Server DB Backend for RAMS, SharePoint and SSRS | 500 |
| Java Application | RHEL 6.5 | 1 | 4 | 8 | 60 | Java Application Server for the RAMS Application | 250 |
| SharePoint Content Management Server | W2012 x64 | 1 | 4 | 32 | 120 | Content Management Server | 1060 |
| SQL Reporting | W2012 x64 | 1 | 4 | 8 | 60 | SQL Server Reporting Services Server | 440 |
| ETL | W2012 x64 | 1 | 2 | 8 | 60 | ETL data from field office applications | 440 |

## Software Architecture

**RAMS Solution Multi-Tiered Software Architecture**

Software used for the RAMS application is shown in the figure below.

\\bylighthealthcare.sharepoint.com@SSL\DavWWWRoot\RAMSIntegration\Shared Documents\Design\Updated SDD Working Folder\Derived Files\Figure 19.wmf

Figure 19: Software Architecture

Technology Name:

* MS SQL Server 2012
* MS SQL Server Reporting Services 2012
* MS SharePoint 2013 SP1
* MS Windows Server 2012 x64
* Red Hat Enterprise Linux 7.0.57
* SQL Server Integration Services 2012

RAMS uses five VMs for software development and a separate, identical collection of five VMs for testing and integration. RAMS is currently using Windows 2012 Server VMs as the base for each environment. The five VMs consist of a database VM with SQL Server 2012 that hosts an instance of every database for each virtual application instance. Other VMs run the SharePoint 2013 application server, Tomcat 7 Java Application Server, SSRS, and SSIS.

The figure below shows the various machines that make up the RAMS VM Infrastructure.

\\bylighthealthcare.sharepoint.com@SSL\DavWWWRoot\RAMSIntegration\Shared Documents\Design\Updated SDD Working Folder\Derived Files\Figure 20.wmf

Figure 20: RAMS Virtual Machine Infrastructure

The table below lists the core components of the Server VMs.

Table 31: Virtual Machine Core Components

| Software | Version |
| --- | --- |
| Windows Server | 2012 R2 64-bit |
| IIS | 7.5 |
| SQL Server | 2012 R2 |
| SharePoint | 2013 SP1 |
| SQL Server Reporting Services | 2012 |
| .NET Framework | 4.5.1 - .Net Framework will be upgraded before the end of the Divest period in Q4 CY2018 |
| SQL Server Integration Services | 2012 |
| Apache/Tomcat | 7.0.62 – Tomcat will be updated to 9.0.x before Q1 2018 |

## Network Architecture

* All UI logic resides on a Windows 2012 Server hosting SharePoint 2013
* All custom application logic resides on a Red Hat Enterprise Linux 7 server hosting Apache Tomcat 7.
* The database portion of the application resides on a separate Windows 2012 Server hosting SQL Server 2012.
* Custom reporting services are delivered using a Windows 2012 Server hosting SQL Server 2012 Reporting Services.
* Extract/Transform/Load services are delivered using a Windows 2012 Server hosting SQL Server 2012 Integration Services.

The figure below displays the network architecture for the RAMS Integration.

\\bylighthealthcare.sharepoint.com@SSL\DavWWWRoot\RAMSIntegration\Shared Documents\Design\Updated SDD Working Folder\Derived Files\Figure 21.wmf

Figure 21: Network Architecture

## Service Oriented Architecture / ESS

The following Service Oriented Architecture (SOA) design considerations apply to the enhanced RAMS application when completed and installed:

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

The open source software application is:

* Apache Tomcat 7.x (Latest Stable)

The Software Development framework and platform is:

* Java Enterprise Edition 7
  + RAMS Integration made no changes in this area so what is in place has been inherited from any previous work in place
  + Tomcat 7 is running on Tomee which is a certified Java EE 1.6 implementation
  + Oracle has delayed the release of Java EE 1.8 until the end of 2017
  + This RAMS update will follow the current guidance of the TRM but it is recommended that the TRM be updated
  + RAMS will update Tomcat by Q4 2017 prior to the current version approval expiring if at that time it complies with TRM guidance

The following figure displays the RAMS Conceptual Architecture.

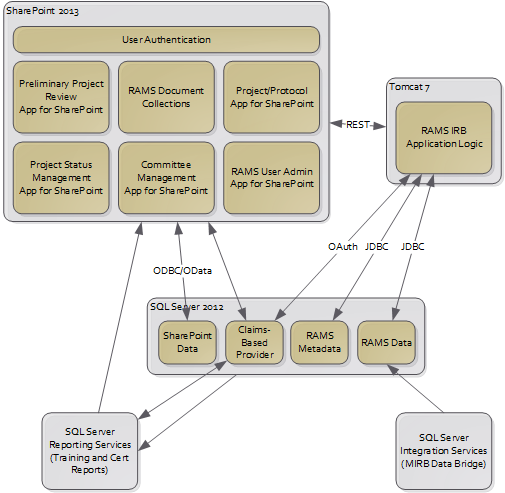


Figure 22: RAMS Conceptual Architecture

## Enterprise Architecture

The RAMS system integration will comply with the VA Technical Reference Model (TRM) standards and One-VA Enterprise Architecture standards. The RAMS Integration will utilize SOA principals as encouraged within the VA TRM and One-VA standards.

The One-VA Enterprise Architecture (One-VA EA) is a comprehensive picture of the VA’s operations, capabilities, and services and the business processes and IT capabilities that support them. The VA's architecture is an evolving entity built through ongoing collaboration between business and technology leaders and staff across the administration. As the organization evolves and strives to meet change, its architectural picture changes.

The VA One-VA TRM is one component within the overall Enterprise Architecture (EA) that establishes a common vocabulary and structure for describing the information technology used to develop, operate, and maintain enterprise applications. Moreover, the One-VA TRM, which includes the Standards Profile and Product List, serves as a technology roadmap and tool for supporting the Office of Information & Technology (OI&T).

The RAMS Application Architecture adheres to these core VA EA principles:

* Compliance with VA EA
* Use of approved Tools on the VA TRM
* Compliance with the VA SOA Design Principles
* Compliance with the VA Security Patterns
* Extensibility
* Flexible application design to support the adding of new IRB legacy capabilities
* Flexible data model design to support future data migrations
* Scalability
* Ability to support a growing user base
* Ability to support a growing data/transaction capacity

# Data Design

The RAMS database is comprised of two Schemas pertaining to the different functional architectures of the system:

1. RAMS IRB Schema will provide the structured relational content and control data required for the RAMS expert system developed as the J2EE application. This system will store all aspects of IRB applications metadata, dynamic forms, and stored user responses.
2. RAMS SharePoint Schema will provide the necessary data storage for all aspects of the SharePoint environment. Further detail about what is stored in this schema is available from Microsoft and this document includes no additional details. More information can be found at: http://technet.microsoft.com/en-us/library/cc678868(v=office.15).aspx

## DBMS Files

The developer will provide additional details at a later date, pending VA input and review.

| Script | Description |
| --- | --- |
| VA\_RAMS.SQL | Base Schema located at https://SERVER:PORT/projects/RAMS/repos/rams-java-source/browse/db/RAMS.sql |

The proposed RAMS physical structure will consist of one SQL data file and one SQL log file on separate drives on the DB server. The system databases will reside in the data drive and not in the OS partition. The file layout will be as below.

Name = RAMS, FILENAME = 'd:\SQLDATA\RAMS.mdf')

Name = RAMS\_Log, FILENAME = 'd:\SQLDATA\RAMSlog.ldf

***SharePoint 2013 Data***

The proposed SHAREPOINT physical structure will consist of one SQL data file and one SQL log file on separate drives on the DB server. The system databases will reside in the data drive and not in the OS partition. The file layout will be as below.

Name = SHAREPOINT, FILENAME = 'd:\SQLDATA\SHAREPOINT.mdf')

Name = SHAREPOINT \_Log, FILENAME = 'd:\SQLDATA\ SHAREPOINT log.ldf

## Non-DBMS Files

The RAMS design does not utilize any non-DBMS files in the current design.

## Data View

The RAMS database will be in 3rd Normal Form (3NF). The initial schema will consist of 17 tables each with a primary key. The database will facilitate the storage of all of the RAMS’ forms and their pertaining questions and answers provided by the applicant.

Figure 23: Data View



# Detailed Design

RAMS Integration is built on the original RAMS application, inheriting most of the original requirements and design specifications, and subsequently the basic paradigms of user interaction with the system are unchanged for most users. More specifically, the largest user community on the RAMS platform belongs to the primary security group, which provide the majority of system data entry, comprised of Study Personnel (including Investigators), will see no significant change to their responsibilities and capabilities on the system.

The sections below describe the implementation of functionalities intended to support the creation of additional committees in the RAMS platform. The initial set of committees as described previously will include the Research and Development Committee, Institutional Review Board (including the Central IRB), Subcommittee for Research Safety and the Institutional Animal Care and Use Committee. The nature of the changes to RAMS implemented for this version will also provide the ability to include additional committees with minimal effort on the part of the business and sustainment teams through implementation of a core module called the “Committee Broker”, which uses configurations rather than software code to define the Committees within the platform. This paradigm shift allows configuration of additional committees on the platform where they will reuse the same templates and data structures. This approach significantly simplifies the additional of new committees which in the past required significant software development to perform, and would require additional effort to maintain and configure over time. RAMS Integration will provide the Office of Research and development with a platform designed to grow over time and incorporate all aspects of Research Administration into the platform as configurable components with lower cost of ownership and sustainment effort.

## Hardware Detailed Design

There are no changes to the hardware required to implement this version of RAMS.

## Software Detailed Design

The sections below describe the approach and configuration for incorporating the new modules into RAMS during the Integration development effort. These descriptions should provide a comprehensive framework for the implementation of approved requirements. As the core architecture of the RAMS platform will remain unmodified, the focus of attention is places on the modifications and additional software elements being developed into the existing platform.

### Conceptual Design

The original implementation of RAMS Integration supported the Institutional Review Board subcommittee without consideration for the broader Office of Research and Development procedural requirements to support multiple committees at each research office. The “Committee Broker” functionality will eliminate this design limitation and provide the framework to support the RDC and its subcommittees including IRB, IACUC, SRS and any future subcommittees. RAMS Integration will add additional workflows and review actions as reusable objects using this framework to support the individual needs of each committee. An extension of the IRB Application database using additional metadata to drive protocol specific questions and logic, supporting the additional data capture required to identify the target Committee(s) for reviewing a Study. The addition of security groups will support the new roles required for the additional committees, permitting (but not requiring) overlap between group memberships and consolidated oversight at smaller and regional Research Offices.

The Committee Broker will also feature a Research/Protocol “Condition Library” that permits data driven definition of the specific logic required to identify the target committees that should be involved in the review process. This extensible library will initially support definition of conditions from a variety of sources, including:

* **Protocol** – Has the Principal Investigator described some aspect of the study that determines the scope of review?
* **Decision Based** – Have additional or alternate committees been identified in the initial review?
* **Supplemental** **Review** – Does the outcome of review by a specific committee require another committee?

The process objects, workflows and data objects in the Committee Broker are scalable to add new functionality as well as keep up with Technology updates mandated by TRM and other environmental factors. The page and report templates are reusable to permit future committees to take advantage of existing functionality without significant redesign.

#### Product Perspective

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

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

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

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

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

##### User Interfaces

RAMS is a web-based application and all regular interaction with the application will be via a VA-approved web browser.

##### Hardware Interfaces

There are no new hardware interfaces that will support the RAMS application.

##### Software Interfaces

For RAMS Data Bridge, see Section 3.2.6.1.2.

##### Memory Constraints

There are no significant memory constraints inherent with the RAMS system design and its intended method of implementation. As with most session-based web applications, there is a linear increase in memory and processor demand based on the number of concurrent users and the quantity of data that they will access. The application should be installed on enterprise class server hardware which supports the memory, processor, disk, and network configurations necessary to support a large number of concurrent users. As a result, there are no intended uses on systems or architectures that will inherently limit the ability to allocate resources necessary to support the VA ORD research user community.

#### Product Features

Please see the latest approved Requirements Specification Document.

#### Dependencies and Constraints

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

**Memory Constraints and Database Requirements**

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

**Dependencies and Constraints**

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

**Constraints**

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

**Additional Identified Design Constraints**:

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

The following table lists the technology used for RAMS Integration.

**Table 32: List of Technologies**

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

The open-source software application is:

* Apache Tomcat 7.x (Latest Stable)

The Software Development framework and platform is:

* Java Enterprise Edition 7

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

* Rational Tool Set
* Microsoft (MS) Visual Studio 2015.3

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

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

### Specific Requirements

The following sections describe the features to be implemented in the RAMS platform to support the Integration feature set. Please refer to the RAMS SDD for core features implemented during the previous software development efforts. The Integration development effort is additive, whereas any features not described in this document are assumed to be fully documented as within the scope of the prior efforts. At a future date, a single document may encompass all functionality contained within the RAMS platform.

#### System Features

RAMS Integration is an evolution of the functionality delivered in the first version of RAMS where the focus of the application was to provide a standardized methodology for collecting Study data and Protocols for research performed at the VA. The instruments used for data collection from Principal Investigators (PI) and Study Personnel was converted from flat file formats (typically stored as Word documents) into an intelligent, logic driven, series of forms which would ensure completeness and accuracy of the study application being delivered to the committees for review. This main feature is a critical aspect of RAMS for both the past and present context of development, where the bulk of data collection from the PI uses a consistent, standards-based methodology, enforced across all study applications, and using questionnaires developed by and for the ORD community.

The development of the original version of RAMS used only the context of an Institutional Review Board review of the data entered by the PI in order to limit the functionality to the initial highest priority of use cases. However, this design decision prevented the majority of Research Offices from adopting the platform due to the need to incorporate additional committee reviews, and the additional work required to manage both legacy and RAMS based processes in parallel. To resolve this, RAMS Integration will incorporate a significant transformation from the single Committee model to one where many committees may be configured in the system and have reviews of a single Application coordinated among the many. This transformation required a significant improvement to the model for identifying which applications will require the review of different committees, as the original design implicitly expected all applications to only be reviewed by the IRB. This change is captured through a number of improvements to the platform, which together are referred to as the “Committee Broker”.

The implementation of the Committee Broker on RAMS is through a collection of main site level objects, lists, and workflows, which allow for the definition of a controlling mechanism required to specify the target committees for a review to be performed on any given study. Additionally, changes to the subsite structure will allow many subcommittees to share the same data collections, via lists and workflows, such that an organized collaborative effort can be coordinated between multiple facets of the ORD organization at a regional and multi-regional level. The sections below describe the major application specifications for the changes to the main site collection and the subsite collections, which together implement the Committee Broker and other features included in the RAMS Integration platform.

#### Application Diagrams

First, to understand the general user flow between the constituent parts of the RAMS application during the operations, which are being modified for RAMS Integration, we will review the activities in Flow Diagrams.

##### Submit a Study

In the following flow diagram, we see that the main components of submitting a study will utilize most of the RAMS Platform architecture (database calls are implicit in any interaction with SharePoint or Tomcat and thus not rendered in this diagram). 

Figure 24: Submit Study Flow Diagram

The following logic diagram provides the steps performed during the process of submitting a new application.



Figure 25: Submit Study Logic Diagram

The first process performed after submission of the study will determine which committees will be required to review the study based on how the PI answers certain questions. Creation of a “Committee Rules” list , which will contain the specific trigger questions that indicate a specific committee will be involved in the review of a study. When any rule matches for the study, the application will retrieve the designated facility performing the committee review on behalf of the user. This will allow sites, which do not have adequate resources to staff their own committee, to utilize resources at another site. As a result, the platform will retrieve the ID from the “Configured Committees” list for the Operating Facility, which will review the study based on the user’s designated Facility. The identified Facilities and committees along with the addition of Facility URL to a HASH, means there will be only one record for each facility, but may be multiple values for the committees at that facility which will review the study. This process is repeated for each rule, which evaluates as true, but will include logic to ensure that no facilities are repeated, and no committees within that facility are repeated. Once complete the next operation is executed which will populate the Facilities with the necessary objects to perform a review. During this process, the Hash and REST calls will generate Committee Topics for each target facility, and will assign the list of committees for that facility to the Required Reviews Committee Topic attribute. Before iterating to the next Facility in the hash, the Committee value will be iterated and items will be created in the “Committee Reviews” list. This process is performed by looking up the “Committee Group” list item for the specified committee and retrieving the value of the Administrator group. A notification is created for the Administrators and the loop will iterate to the next committee. Once all committees are complete, the outer loop will iterate to the next Facility and repeat the process until done.

Note: All notifications processed by the system are performed using the shared workflow swf\_NotifyUser.

##### Review a Study

The following flow diagram illustrates the interactions between the various components of the RAMS platform during the review of an application.



Figure 26: Perform Review Application Flow Diagram

The following diagram describes the logic required to evaluate a study review process. This process repeats for each of the committees assigned to review the Study application, and operate in isolation until complete. Committees still have the opportunity to review the status of reviews, and administrators may review the comments provided by reviewers of another committee, however there is no explicit requirement for one committee to conclude activity before the other. The only instance where committee review completion has any bearing on the overall approval of a study is a process performed when the final committee approved the study. At that point, a notification will be sent to the PI to indicate that the process is complete.



Figure 27: Perform Review Logic Diagram

As illustrated above, the review process is only a loose collection of processes being managed by the Committee Administrators Group, where there is no explicit correlation between a step in the process and the approval of a Study. This design decision was made to support the variations of process followed by each Committee, where although the steps are common, there can be flexibility in regards to the management of the approval process for any given study.

The initial step for any review process is the assignment of a lead administrator, the person who will shepherd the study through the review process and conduct communication with the PI when necessary. The assignment of a lead administrator also provides the opportunity to conduct more targeted communication during the review process and allowing each lead administrator to focus on specific tasks for which they have been assigned. Once assigned, additional options are available to the lead administrator (LA) to assign reviewers, review comments and provide feedback or request revisions, to designate that a study is ready for committee review (through a committee meeting and the Agenda/Meeting Minutes functions), and designate approval or rejection by a committee. Any of these logic branches may be executed at any time after the LA has been assigned.

The key technical element designating the status of a study during this process is the “Committee Review” List item for this study for the specified committee. Metadata about the study review is captured in this list item, with attributes for the Committee, Lead Administrator, Reviewers, Status, and Version. Updates to the list item are made from the Reviewer toolbar from within the application, using REST calls to update SharePoint at the appropriate time.

Note: All notifications processed by the system use the shared workflow swf\_NotifyUser.

#### SharePoint Design Elements

The Committee Broker is a collection of functionality implemented on RAMS permits the implementation of additional subcommittees and facilitates the routing of study applications to the correct facility based on logic contained in the protocol submission and rules defined in the platform. As illustrated in the flow diagrams above, the coordination of relational data across multiple Main and Subsite Collection lists and workflows are required to manage the overall process of each study. The specifications of these elements are in the following sections.

##### SharePoint Lists

Additional lists and changes to current lists will be required at both the Main and Subsite collections. Changes to the different collections are in the following two sections.

###### Main Site Collection Lists

These lists defined at the main site collection will be used in the general context of RAMS users, for system configuration, and to assist with populating lookup values of other lists in the RAMS site.

Committees

The purpose of Committees is to store the basic set of committees configured in RAMS, used as a lookup when creating instantiated values for specific facilities and when defining rules.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| Committee Name | String | No | Stores the Verbose Name for a Committee, primarily used for readability. |
| Committee Code | String | No | Stores a short version of the committee name, which will be used in lookups that require reference to the Committee type |

Constraints

All records should contain unique values in every column.

Committee Roles

Committee Roles identify the standard roles of a committee.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| RoleName | String | No | Lookup value for use in other lists for the standard roles across all committees. |

Constraints:

Unique values only

Facilities

Facilities functionality identify all Facilities configured in RAMS, and the location of the subsite supporting the facilities subsites.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| Facility Name | String | No | Verbose version of the facility name for easy reference |
| Facility Code | String | No | Facility code, may also be used as mailstop |
| URL | URL | No | Location of the Facility subsite where users should be redirected for facility/committee activities. |
| Facility Group | Group | No | Group name for the facility which users must belong in order to associate studies with the correct target facility. |

Constraints:

All records should contain unique values in every column.

Configured Committees

Configured Committees capture what committees exist in the system and what facility they are configured for so that a review can be assigned to the correct Committee even if it is being operated by another Facility other than the one which the PI is assigned.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| Committee | ID | Committees.ID | Committee identifier to associate the relationship to a specific Committee |
| Operating Facility | ID | Facilities.ID | Associates the committee to a specific facility which will be performing the role |
| Facility | ID | Facilities.ID | Associates the record with the Facility for which the committee will be reviewing studies (This will be different from Operating facility in cases where another facility performs the role) |

Constraints:

All records should contain a unique combination of Committee and Facility.

Committee Rules

The purpose of Committee Rules is to store the rules used to determine what committees will review a particular application.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| Form | String | No | This is the form ID for the rule being implemented. Older forms may have different rules than the current form and can be used to ensure that reviews in progress do not become invalid if the form is incremented. |
| Section | String | No | Section ID for the triggering logic |
| Question | String | No | Specific question for the triggering logic |
| Answer | String | No | Specific answer for the triggering logic |
| Committee | ID | Committees.ID | Committee which should review the study if the application contains a match for the logic included in the preceding list elements. |

Constraints:

None.

Note: Define the rules so that a committee trigger can only be hit once per application per committee.

Applications (Modified Columns)

The applications list provides the main element for tracking and organizing studies on the RAMS system. The changes being made will support the review of multiple committees.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| ReviewRequired | String | No | Will contain a delimited string of the committees which will be required to review the application. |
| ReviewCompleted | String | No | Will contain a delimited string of the committees who have completed their review. |

Constraints:

None.

Note: Ensure that values are valid committee codes to avoid conditions where committees cannot be invoked due to lack of existence.

Laboratories

Laboratories store the laboratories in use by ORD research.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| Lab Name | String | No | Name of the laboratory |
| Address | String | No | Location of the laboratory |
| Last Inspection Date | DateTime | No | Last Inspection Date for the laboratory |

Constraints:

None.

###### Facility Subsite Lists

The following lists are defined as part of the Facility subsite solution, where these generic objects will be used to define the Facility level characteristics of system use as well as to contain the standardized solutions which much interoperate with the main site collection.

Reviews

The purpose of this list is to provide a mechanism for assigning reviews and reviewers for the various committees active at a facility, such that a generic container is usable regardless of the number of reviewing committees active at that site.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| CommitteeTopic | ID | CommitteeTopics.ID | ID value for a study application to create reference to the study, which is ready for review. |
| Version | Int | No | To correspond to the version of the study under review, will differentiate past reviews from current reviews, or for multiple concurrent amendments. |
| Committee | ID | CommitteeGroups.ID | Reference to the specific implemented committee at the facility, which is performing the review; this creates correct associations to the security groups |
| Lead Administrator | Person | No | Person who will be the lead committee administrator for the review |
| Primary Reviewer | Person | No | Person assigned to perform primary review |
| Assigned reviewers | People | No | People assigned to perform noon-primary review of application |
| Status | String | No | Current status of the application review (New, Assigned, Under Review, Ready for Committee, Approved, Rejected, Cancelled) |
| Active | Boolean | No | Default is “TRUE”, set to “FALSE” when reviews are complete or study is rejected. |

Constraints:

Unique values for combination of CommitteeTopicsID, Committee and Version

Committee Groups

Used to store the group names for the various roles of the committees as standardized objects across committees

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| Committee | ID | Committees.ID | Reference to a valid committee type as defined in the main site |
| RoleName | ID | CommitteeRoles.ID | Reference to a valid committee role as defined in the main site. |
| Group | Group |  | Valid reference to a configured committee group as defined in the security settings for the subsite. |

Constraints:

Unique values for combination of Committee and Role Name across all rows.

CommitteeTopics (New Columns)

CommitteeTopics store the facility specific instance of the applications.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| ReviewRequired | String | No | Will contain a delimited string of the committees, which will be required to review the application. |
| ReviewCompleted | String | No | Will contain a delimited string of the committees, who have completed their review. |
| Version | Int | No | Current version of the Committee Topics list item to ensure correct reference to the reviews, which are required. |

Constraints:

None.

Note: Be cautious to ensure that the ReviewRequired and ReviewCompleted do not contain more than one instance of a committee to avoid logic errors when determining the number of reviews remaining to complete.

CommitteeRoster (New Columns)

CommitteeRoster captures the roles of users on the various committees and to control the workgroup memberships.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| CommitteeID | ID | Committees.ID | Contain a Reference to the Available Committees for the facility |
| RoleID | ID | CommitteeRole.ID | Will contain a reference to the role for a committee member |
| Start Date | DateTime | No | Date when the User Became active in the committee |
| Expiration Date | DateTime | No | Date when the user’s role in the committee will expire |
| Active | Boolean | No | Default True |

Constraints:

None

Property

Property stores the property issued to study personnel, including PCs, Badges, and Keys.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| Person | Person | RAMS Users | People picker to capture identity of the user, who has received property. |
| Property Type | String | No | Description of the Property |
| Issued Date | DateTime | No | Date the property was issued |
| Expiration Date | DateTime | No | Date the property (badge) will expire |
| Return Date | DateTime | No | Date the property was returned |

Constraints:

None.

Appointments

Appointments store the appointment renewals for study personnel and committee members.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| Person | Person | RAMS Users | Person for whom the appointment pertains. |
| Person Type | Choice | Employee, WOC, IPA | Type of appointment held by the user |
| VA Sponsor | Person | RAMS Users | VA Employee who sponsors the appointed person |
| Date Appointed | DateTime | No | Date the appointment becomes active |
| Date Expires | DateTime | No | Date the appointment will expire |

Constraints:

None.

Laboratory Space

Laboratory Space stores the laboratories.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| Laboratory | ID | Laboratories.ID | Laboratory in which space is allocated |
| Study | ID | CommitteeTopics.ID | Study for which space is assigned |
| Contact Person | Person | RAMS Users | Person who should be contacted about lab space |
| Description of Use | String | No | Description of the use of the laboratory for this study |
| Start Date | DateTime | No | Date lab became used for this study |
| End Date | DateTime | No | Date Lab was/will no longer be used by study. |

Constraints:

None.

Agenda (New Columns)

This is an additional column to store the Committee to which the agenda item belongs.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| Committee | ID | Committees.ID | Committee Type for the meeting agenda |

Constraints:

None.

Meeting Minutes (New Columns)

This is an additional column to store the committee to which the meeting minutes will belong.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| Committee | ID | Committees.ID | Committee Type for the meeting minutes |

Constraints:

None.

Shared Documents

This is a document library, which will be used for each of the committees in use at a facility.

| Column Name | Data Type | Lookup | Purpose |
| --- | --- | --- | --- |
| N/A |  |  | All columns will be default for the SharePoint document library content type. |

Constraints:

None.

**Folder Structure**:

The following diagram depicts the structure of the folders and subfolders for the facility Shared Documents library.



Figure 28: Facilities Shared Documents Library Content Structure

##### SharePoint Workflows

The RAMS Integration Solution will incorporate additional workflows to facilitate the automation of data flow and business logic.

###### Shared Workflows

Notify User

| Attributes | Value |
| --- | --- |
| Workflow Name | swf\_NotifyUser |
| Description | This Site Workflow provides a template as a method for conveying information about a study to a RAMS user. This approach will permit a single object to be used to make modifications to the notification message template. |
| Called By | Multiple |
| List Workflow | No |
| Active List | None |
| Dependencies | None |
| Parameters | p\_Recipient (string) not null,  p\_Subject (string) not null,  p\_Title (string) not null,  p\_Description (string) not null,  p\_PageLink (string) not null,  p\_Date (datetime) |
| Output Value | None |
| Success Criteria | An email message is sent to the specified |

Appointment Renewal

| Attributes | Value |
| --- | --- |
| Workflow Name | swf\_AOApptExpiring |
| Description | This workflow relies on a timer to run every day for each of the Facility AO Appointment Lists. The job identifies which appointments are nearing expiration and sends a notification to the AO. |
| Called By | Timer |
| List Workflow | No |
| Active List | Appointments |
| Dependencies | Timer, Appointments.ExpirationDate, swf\_NotifyUser |
| Parameters | None |
| Output Value | None |
| Success Criteria | An email is generated for each of the Appointment lists in each of the Facilities for each list item where the expiration date is within the threshold value (30 days) and sends an email notification to the AO of the corresponding Facility, VA Sponsor and Expiring Individual. |

Personnel Change

| Attributes | Value |
| --- | --- |
| Workflow Name | swf\_personnelChange |
| Description | This workflow is manually invoked to provide a notification message to required Committee Coordinators when changes are made to a Study which is not in a DRAFT state. The workflow will traverse the configuration of required committee groups and notify all members of that group with a single message containing all personnel changes made to the study application. |
| Called By | Manual (Invoked via REST call from dynamicGeneration.js) |
| List Workflow | No |
| Active List | Applications |
| Dependencies | ConfiguredCommittees, CommitteeGroups, swf\_NotifyUser |
| Parameters | p\_Facility, p\_RequiredCommittees, p\_Message |
| Output Value | None |
| Success Criteria | An email is generated for each member of the Committee Coordinators group for each required committee for a given study application which notifies them of changes to assigned personnel. |



Figure 29: Personnel Change Workflow

###### List Workflows

Lead Administrator Assigned

| Attributes | Value |
| --- | --- |
| Workflow Name | lwf\_CmteLeadAdmin |
| Description | This list workflow will notify the assigned committee administrator when they have been assigned to review a study. This workflow calls the swf\_NotifyUser site workflow to generate the message notification. |
| Called By | Changed Item(CurrentItem.Lead Administrator) |
| List Workflow | Yes |
| Active List | CommitteeReviews |
| Dependencies | swf\_NotifyUser |
| Parameters | CurrentItem |
| Output Value | None |
| Success Criteria | Email Notification sent to assigned Lead Administrator notifying of new study. |

Primary Reviewer Assigned

| Attributes | Value |
| --- | --- |
| Workflow Name | lwf\_CmtePrimaryReview |
| Description | This list workflow will notify the assigned Primary Reviewer when they have been assigned to review a study. This workflow calls the swf\_NotifyUser site workflow to generate the message notification. |
| Called By | Changed Item(CurrentItem.Primary Reviewer) |
| List Workflow | Yes |
| Active List | CommitteeReviews |
| Dependencies | swf\_NotifyUser |
| Parameters | CurrentItem |
| Output Value | None |
| Success Criteria | Email Notification sent to assigned Primary Reviewer notifying of new study |

Secondary Reviewer Assigned

| Attributes | Value |
| --- | --- |
| Workflow Name | lwf\_CmteSecondaryReview |
| Description | This list workflow will notify the assigned Secondary Reviewer when they have been assigned to review a study. This workflow calls the swf\_NotifyUser site workflow to generate the message notification. |
| Called By | Changed Item(CurrentItem.Secondary Reviewer) |
| List Workflow | Yes |
| Active List | CommitteeReviews |
| Dependencies | swf\_NotifyUser |
| Parameters | CurrentItem |
| Output Value | None |
| Success Criteria | Email Notification sent to assigned Secondary Reviewer notifying of new study |

Notify Study Ready for Committee Review

| Attributes | Value |
| --- | --- |
| Workflow Name | lwf\_CmteReviewReady |
| Description | This workflow will notify the Committee Coordinator when a Committee Topic (Study) is ready for review and should be assigned to a Committee agenda. |
| Called By | ChangedItem(CurrentItem.Status) when value is changed to “Ready for Committee” |
| List Workflow | Yes |
| Active List | CommitteeReviews |
| Dependencies | CommitteeGroups.Group is retrieved based on CurrentItem.Committee to associate the group, which needs to receive the notification.  swf\_NotifyUser is used to generate the notification message. |
| Parameters | None |
| Output Value | None |
| Success Criteria | Committee Coordinator users for the correct committee receive an email notifying them that the study is ready for committee review. |

Study Approved

| Attributes | Value |
| --- | --- |
| Workflow Name | lwf\_ApplApproved |
| Description | This workflow executes when all of the required committees have completed their approvals of the Study |
| Called By | List Item Change (CurrentItem.RequiredReviews = CurrentItem.ReviewsCompleted) |
| List Workflow | Yes |
| Active List | Applications |
| Dependencies | swf\_NotifyUser |
| Parameters | None |
| Output Value | None |
| Success Criteria | Principal Investigator receives a notification message related to the approval of the current study by all required committees. |

Study Rejected

| Attributes | Value |
| --- | --- |
| Workflow Name | lwf\_ApplRejected |
| Description | This list is called when the study application is rejected by any of the required committees. A cascading update occurs which deactivate any of the remaining reviews and sets the status of the local Committee Topics lists to “Rejected” |
| Called By | Changed List Item (CurrentItem.Status = “Rejected”) |
| List Workflow | Yes |
| Active List | Committee Reviews |
| Dependencies | Applications, Facilities, Configured Committees, Committee Topics |
| Parameters | None |
| Output Value | None |
| Success Criteria | Principal Investigator Receives Notification of Rejection/Revisions Required  Application List Item is set to DRAFT status  All Committee Review List Items for all coordinated facilities are set to active=FALSE  All Committee Topics list items for all coordinated facilities are set back to Rejected |



Figure 30 Study Rejected Workflow

New Committee Roster Item

| Attributes | Value |
| --- | --- |
| Workflow Name | lwf\_CmteRosterNew |
| Description | This system call this list workflow when a new item is added to the committee roster. It will retrieve the security group required for the selected role and add the specified user to that group. |
| Called By | New Item |
| List Workflow | Yes |
| Active List | Committee Roster |
| Dependencies | CommitteeGroups |
| Parameters | None |
| Output Value | None |
| Success Criteria | Committee Member receives an email notification welcoming them to the security group on RAMS and can access the desired webpages for the group. |



Figure 31 Committee Roster SharePoint Workflows

Change Committee Roster Item

| Attributes | Value |
| --- | --- |
| Workflow Name | lwf\_CmteRosterChange |
| Description | The system calls this list workflow when an item on the committee roster has a changed value for active from TRUE to FALSE. It will retrieve the security group required for the selected role and remove the specified user from that group. |
| Called By | Changed Item |
| List Workflow | Yes |
| Active List | Committee Roster |
| Dependencies | CommitteeGroups |
| Parameters | None |
| Output Value | None |
| Success Criteria | Committee Member is removed from the appropriate security group on RAMS and can no longer access the functions for the group. |



Figure 32 Committee Roster SharePoint Workflows

Deleted Committee Roster Item

| Attributes | Value |
| --- | --- |
| Workflow Name | lwf\_CmteRosterDelete |
| Description | The system calls this list workflow when an item on the committee roster is deleted. It will retrieve the security group required for the selected role and remove the specified user from that group. |
| Called By | Deleted Item |
| List Workflow | Yes |
| Active List | Committee Roster |
| Dependencies | CommitteeGroups |
| Parameters | None |
| Output Value | None |
| Success Criteria | Committee Member is removed from the appropriate security group on RAMS, can no longer access the group functions, and is no longer listed in the committee roster for that role. |



Figure 33 Committee Roster SharePoint Workflows

##### Application Pages

###### Main Site Collection

The following changes pertain to the main site collection.

Master Page Template

In order to permit the evaluation of committees for which the user should be allowed to navigate, the Master Page template used by RAMS must be modified. There is currently a process in place when the user selects the Committee Activities link where a special page is called. This invokes a javascript library, dynamicCommitteeSwapper.js, which evaluates the memberships of committees and redirects users to the committee/facility subsite in which they have a “XXX committee user” membership (where XXX is the name of the facility for which the committee is configured). This script will need to be revised to ensure that the modified structure of committee memberships permits the user to access any committees, which they are assigned.

Note: Currently it is not supported for a user to have more than one Facility/Committee membership where there may be more than one option for the user to select as a destination Subsite (e.g. User1 is a member of both Facility1 Committee1 and Facility2 Committee1). It will be important to preserve this limitation initially, but to ensure that the limitation is only at the Facility level, where regardless of the number of committees memberships a user may have, they should be limited to a single facility such that only one target subsite will be identified.

Irb-applications-general.html

RAMS Integration will require modification to the irb-applications.general.html page and corresponding JavaScript files used to render Study Applications in both Draft and Submitted forms. The changes will activate support for the additional functionality developed in SharePoint Lists and Workflows, allowing an arbitrary number of committee reviews across any Facilities necessary to support the study. The following sections describe the changes required to the different components of the irb-applications-general.html page and it’s required JavaScript libraries.

dynamicGeneration.js

The dynamicGeneration.js library provides the functionality required by RAMS to read from the various data sources, either from SharePoint or the RAMS.war file, and render the study application for the target user audience.

The system currently supports the following Modalities of dynamicGeneration.js:

* Parent
* Local
* Read-only
* Amendment
* Closeout
* Continuing Review
* Adverse Event
* Administrative Update

The Following Changes will be required to support the features of the Committee Broker.

Implementation of Committee Rules Validation:

Refactor JavaScript to utilize the Reviews list item for identification of Lead Administrator, Primary and Secondary Reviewers

The dynamicGeneration.js library currently uses the assumption that there is only one collection of reviews for a given study, as such, the values for the IRB committee are hardcoded as elements in the Committee Topics list. This will need to be refactored such that the Reviews list is evaluated and the value for the current version of the study is retrieved for the current committee.

Evaluation of Committee Rules Logic to Determine the Required Committees

The implementation of Committee Rules logic will be inserted into the dynamic Generation.js file in the submitIRB() portion of the code which prepares the study data for submission to the WAR.js rest service.

|  |
| --- |
| Pseudocode Implementation |
| // Get Committee Rules  l\_CommitteeRulesArray = REST(get, <committee\_rules\_list\_items\_URL>)  l\_CommitteeRulesCount = length(l\_ConfiguredCommitteeRulesArray)  // Get configured committees for the user’s Facility  l\_ConfiguredCommitteesArray = REST(get, <committee\_rules\_list\_items\_URL, filter=”Facility = currentUser.Facility”>)  l\_FacilityCommittees = new Hash(Facility as String, Committees as Array, URL as String)  // Loop through the Committee Rules  for (i=1, i>= l\_CommitteeRulesCount, i++) {  // If the form responses contains a validated rule  if(study.Form[l\_CommitteeRulesArray[i].Form].Section[l\_CommitteeRulesArray[i].Section].Question[l\_CommitteeRulesArray[i].Question].answersID == l\_CommitteeRulesArray[i].Answer) {  // If the Operating Facility doesn’t have a Hash record yet  if(l\_FacilityCommittees[l\_ConfiguredCommitteesArray[l\_CommitteeRulesArray[i].Committee].OperatingFacility].URL == null){  // Push a value into the Hash  l\_FacilityCommittees.push(l\_ConfiguredCommitteesArray[l\_CommitteeRulesArray[i].Committee].OperatingFacility, l\_CommitteeRulesArray[i].Committee, l\_ConfiguredCommitteesArray[l\_CommitteeRulesArray[i].Committee].URL)  else {  // Add another Committee value to the existing Hash for the  // Operating Committee  l\_FacilityCommittees[l\_ConfiguredCommitteesArray[l\_CommitteeRulesArray[i].Committee].OperatingFacility].Committees.push(l\_CommitteeRulesArray[i].Committee)  }  }  } |

Creation of Facility Specific Committee Topic and Review List Items

Also to be included in the submitIRB() function of dynamicGeneration.js is the feature to traverse the identified Facility Committees which will be used to review the Study Application. For this new functionality, the code will traverse the hash values and generate Committee Topics and Committee Review list items for each Facility committee that will review the study.

Please reference Figure 25: Submit Study Logic Diagram for further illustration of the implementation of this feature.

Note: The aggregate list of all required committees must be inserted into the Required Committees attribute of the Applications List for the study. Subset values specific to each Facility as contained in the Hash record for that facility must be inserted into the Committee Topics List Item for the study.

Personnel Change Notification

To implement the personnel change notification, modifications will be made to the insertStudyMember() function to evaluate the changes between stored values and the values being submitted to the RAMS.war. Similar to the function for evaluating Committee Rules, the function will need to traverse the Configured Committees list, however because changes to DRAFT application personnel do not require notification, a SharePoint workflow can be invoked to traverse the necessary relationships to identify the target audience for notification. Differences between the two collections will be aggregated into a message body, which indicates the named personnel and the action taken and the function will invoke a REST call to the SharePoint swf\_PersonnelChange workflow.

RAMS\_tools.js

The RAMS\_tools.js library provides support for rendering the toolbars used by various roles involved in the review and approval of a RAMS Study Application. The library currently supports the following modalities:

* Preliminary Review
* Reviewer
* Committee
* Approved

The following changes will be required.

Refactor RAMS\_tools.js to Utilize Reviews List Items

Similar to the modifications made to refactor dynamicGeneration.js, the RAMS\_tools.js will also need to be modified to utilize the Reviews list item to capture the values of Lead Administrator, Primary Reviewer, and Secondary Reviewers. The function names currently include references to the IRB, whereas they should be updated to reflect the generic nature of the functions as they pertain to the current committee accessing the Study Application. Functionality rendered on the page shall not change despite refactoring of the JavaScript functions.

dynamicMembers.js

The dynamicMembers.js library provides the functionality for both uploading files for a RAMS Study Application as well as the management of study personnel.

File Upload Tagging

To enable tagging on documents uploaded to a study, Enterprise Keywords will be enabled on the relevant document libraries and a collection of terms will be added to the Term Store. This will enable RAMS to capture any keywords associated with file uploads. Standard Terms may be defined in JavaScript if they are immutable values, rather than retrieving the Term Collection form SharePoint, when uploading specific files specified in Form questions.

Add relevant terms to the Term Store Management Tool. Some examples would be:

* Device Brochure
* Protocol Document
* HIPAA form
* Informed Consent Form
* Reviewer Checklist
* Lab Safety Report
* Etc.

For the Main Site Collection Shared Document Library and the Facility Subsites Template, add an Enterprise Keywords column to the Library and enable Keyword Synchronization.

It will be necessary to render the list of applicable Terms to the user on the file upload page rendered by the dynamicMembers.js, which is achievable by using the managed metadata functions and JSOM. For example:

function defaultTermStore() {

session = SP.Taxonomy.TaxonomySession.getTaxonomySession(context);

termStore = session.getDefaultSiteCollectionTermStore();

context.load(session);

context.load(termStore);

context.executeQueryAsync(successDefaultTermStore, failedListTaxonomySession);

}

Note: When the user has selected a term along with the file for upload, it will be necessary to add the term attribute to the library list item. The upload function is included in the dynamicGeneration.js library

New List Item Script for Facilities List

Currently the RAMS application uses a Committees List object to describe the relationships between a facility and the members of various roles in the IRB subcommittee, it also contains a script which will automate the creation of a new subsite and the required Lists, Pages and Groups. With the addition of the Committee Broker, the context of some main site level lists will change, and additional relationships will be required to facilitate the accurate routing of Study Applications to the various Committees, which may include traversing multiple subsites to generate all the required list items. The standardized configuration of the Main site collection Lists and data contained within them, as well as the standardization of Subsites will enable workflow driven and relational lookup across all collections when performing Study reviews and oversight. This standardization increases the need for highly controlled system taxonomies and consistent use of list values to identify the targets when generating new list items and when executing workflows. As a result, it will be advantageous to use an automated script to create subsites to ensure accuracy, consistency, and reduce overall effort when implementing RAMS across the 110 Research Offices at the VA.

The following Diagram illustrates the sequence of activities, which will be performed when creating a new Facility subsite:



Figure 34 Script Activity Logic Diagram

###### Facility Subsite

The following screens and changes are defined for the Facility subsite collections, which will need to be generically applied in the subsite template in such a way that the template can be customized through automated means when generating a new facility instance.

Master Page Template

The master page template for the facilities subsite is currently inherited from the main site collection. This paradigm will be broken for the implementation of RAMS Integration, where the template will now need to be customized to fulfill the needs of the specific facility, which the template is being applied.

Note: It is not necessary to include the Facility lookup in this page, as the user has already navigated to this portion of the site. It can still be incorporated, but from a purely functional perspective, will not be necessary for the user to reload the main Facility page assuming that the toolbar context permits the user a method of switching between the various committees configured for that Facility.

The Master Page Template for committee subsites will be modified to include a navigation element, which permits users to quickly and easily change between modes/committees in the Facility. This will provide the opportunity for Committee members to locate easily activities in their assigned Committee as well as for Administrative Officers or other committees to review the activities and studies being reviewed by all Committees. Locations to each function are relative paths to predefined pages as described in the sections below, so a database or application lookup will not be mandatory in order to render the navigation elements. This solution increases the usability of the Facility subsite without creating an additional requirement for system resources.

A visual depiction of the navigation bar is listed below without embellishments to provide an understanding of the basic concept.

Note: The diagram shows all menu items as expanded, but this should only be activated by a mouse-over event during normal system use.



Figure 35: Facility Subsite Master Page Menu Wireframe

The table below provides an embellished description of the navigation elements to provide a mapping to the target pages.

Table 33: Description of Master Page Menu Links and Targets

| Main Menu Context | Menu Item | Title | Description/Assistive Text | URL |
| --- | --- | --- | --- | --- |
| Committees | Home | Home | Facility Home Page | ./Home.aspx |
| Committees | Research & Development | Research & Development | Research and Development Committee | ./RDC.aspx |
| Committees | Institutional Review Board | Institutional Review Board | Institutional Review Board | ./IRB.aspx |
| Committees | Research Safety | Research Safety | Subcommittee for Research Safety | ./SRS.aspx |
| Committees | Institutional Animal Care & Use | Institutional Animal Care & Use | Institutional Animal Care and Use Committee | ./IACUC.aspx |
| Administrative Office | Home | Home | Administrative Office Home Page | ./AO.aspx |
| Administrative Office | Appointments | Appointments | Appointments | ./Appointments.asp.x |
| Administrative Office | Property | Property | Property | ./Property.aspx |
| Administrative Office | Agreements & Memorandi | Agreements & Memorandi | Agreements & Memorandi | ./Agreements.aspx |
| Administrative Office | Laboratory Sapce | Appointments | Appointments | ./Labs.aspx |
| Local Site Administration | Home | Home | Home | ./LSACP.aspx |
| Local Site Administration | Archive Import | Archive Import | Archive Import | ./RAMS\_Archive\_import.html |
| Local Site Administration | Group Configuration | Group Configuration | Group Configuration | ./GroupConfiguration.aspx |

Home.aspx

The following table describes the elements of the Home.aspx page. This page already exists in RAMS under subsite and will largely require no changes to implement in Integration. The new functionality provided by the subsite master page template will provide the additional features required.

Table 34: Home.aspx Specification Table

|  |  |
| --- | --- |
| Purpose | The Facility home page contains an unfiltered view of all data contained in the specific Facility subsite. This generic view contains all the same elements of any of the Committee pages without using filtered lists. |
| Title | Home |
| Filename | Home.aspx |
| Location | /IRBApplications/<subsite>/Site Pages/ |
| Webparts | Agenda List View, Meeting Minutes List View, Committee Members List View, Committee Topics List View |
| Security | Members of the “<facility> Users” group |
| Wireframe | See Figure 39 Facility/Committee Home Page Wireframe |

RDC.aspx

RDC.aspx is a filtered version of the Home.aspx page. The only editable elements will be the Agenda, Meeting Minutes, and Committee Roster lists, however as these are all shared elements, there is no functional difference between invoking a new item page from any of Committee pages, rather the pages are intended to provide a preconfigured set of filters across all lists relative to the Committee.

Table 35: RDC.aspx Specification Table

|  |  |
| --- | --- |
| Purpose | The RDC home page contains a filtered view of RDC data contained in the specific Facility subsite. |
| Title | Research and Development Committee |
| Filename | RDC.aspx |
| Location | /IRBApplications/<subsite>/Site Pages/ |
| Webparts | Agenda List View, Meeting Minutes List View, Committee Members List View, Committee Topics List View  (All using list views where Committee = RDC) |
| Security | Members of the “<facility> Users” group |
| Wireframe | See Figure 39 Facility/Committee Home Page Wireframe |

IRB.aspx

IRB.aspx is a filtered version of the Home.aspx page. The only editable elements will be the Agenda, Meeting Minutes, and Committee Roster lists, however as these are all shared elements, there is no functional difference between invoking a new item page from any of Committee pages, rather the pages are intended to provide a preconfigured set of filters across all lists relative to the Committee.

Table 36: IRB.aspx Specification Table

|  |  |
| --- | --- |
| Purpose | The IRB home page contains a filtered view of IRB data contained in the specific Facility subsite. |
| Title | Research and Development Committee |
| Filename | IRB.aspx |
| Location | /IRBApplications/<subsite>/Site Pages/ |
| Webparts | Agenda List View, Meeting Minutes List View, Committee Members List View, Committee Topics List View  (All using list views where Committee = IRB) |
| Security | Members of the “<facility> Users” group |
| Wireframe | See Figure 39 Facility/Committee Home Page Wireframe |

SRS.aspx

SRS.aspx is a filtered version of the Home.aspx page. The only editable elements will be the Agenda, Meeting Minutes, and Committee Roster lists, however as these are all shared elements, there is no functional difference between invoking a new item page from any of Committee pages, rather the pages are intended to provide a preconfigured set of filters across all lists relative to the Committee.

Table 37: SRS.aspx Specification Table

|  |  |
| --- | --- |
| Purpose | The SRS home page contains a filtered view of SRS data contained in the specific Facility subsite. |
| Title | Subcommittee for Research Safety |
| Filename | SRS.aspx |
| Location | /IRBApplications/<subsite>/Site Pages/ |
| Webparts | Agenda List View, Meeting Minutes List View, Committee Members List View, Committee Topics List View  (All using list views where Committee = SRS) |
| Security | Members of the “<facility> Users” group |
| Wireframe | See Figure 39 Facility/Committee Home Page Wireframe |

IACUC.aspx

IACUC.aspx is a filtered version of the Home.aspx page. The only editable elements will be the Agenda, Meeting Minutes, and Committee Roster lists, however as these are all shared elements, there is no functional difference between invoking a new item page from any of Committee pages, rather the pages are intended to provide a preconfigured set of filters across all lists relative to the Committee.

Table 38 IACUC.aspx Specification Table

|  |  |
| --- | --- |
| Purpose | The IACUC home page contains a filtered view of IACUC data contained in the specific Facility subsite. |
| Title | Institutional Animal Care and Use Committee |
| Filename | IACUC.aspx |
| Location | /IRBApplications/<subsite>/Site Pages/ |
| Webparts | Agenda List View, Meeting Minutes List View, Committee Members List View, Committee Topics List View  (All using list views where Committee = IACUC) |
| Security | Members of the “<facility> Users” group |
| Wireframe | See Figure 39 Facility/Committee Home Page Wireframe |

AO\_Home.aspx

The Administrative Office Home page provides an at-a-glance overview of activities requiring the AO’s attention, either in newly created items, or those that will need attention (nearing expiration, etc.).

Table 39 AO\_Home.aspx Specification Table

|  |  |
| --- | --- |
| Purpose | The AO landing page provides the AO with direct access to view the four major components of the AO function as implemented in RAMS Integration. The modular page can support additional functions in the future as requirements expand and additional data elements are specified. |
| Title | Administrative Office |
| Filename | AO\_Home.aspx |
| Location | /IRBApplications/<subsite>/Site Pages/ |
| Webparts | Appointments List View, Property List View, Labs List View, Agreements List View (potentially in future version of RAMS) |
| Security | Restricted to Members of the “<facility> AO” group |
| Wireframe | See Figure 40 Administrative Office Home Wireframe |

Property.aspx

This page provides the standard list view for the Property List.

Table 40: Property.aspx Specification Table

|  |  |
| --- | --- |
| Purpose | Provides a standard list view page for the Property list, with standard editing controls enabled; allows the AO to assign new property items and update existing items. |
| Title | Issued Property and Badges |
| Filename | Property.aspx |
| Location | /IRBApplications/<subsite>/Site Pages/ |
| Webparts | Property List View |
| Security | Restricted to Members of the “<facility> AO” group |
| Wireframe | See Figure 43 Administrative Office Property Wireframe |

Appointments.aspx

This page provides the standard list view for the Appointments List.

Table 41: Appointments.aspx Specification Table

|  |  |
| --- | --- |
| Purpose | Provides the standard list view of the Appointments list with editing controls enabled; the AO can manage existing or create new appointments on this page. |
| Title | Appointed Personnel |
| Filename | Appointments.aspx |
| Location | /IRBApplications/<subsite>/Site Pages/ |
| Webparts | Appointments List View |
| Security | Restricted to Members of the “<facility> AO” group |
| Wireframe | See Figure 41 Administrative Office Appointments Wireframe |

Labs.aspx

This page provides the standard list view for the Laboratory Space List.

Table 42: Labs.aspx Specification Table

|  |  |
| --- | --- |
| Purpose | Allows the AO to track the space allocations for studies performed at their Facility. Standard list view with edit controls |
| Title | Laboratory Space Allocations |
| Filename | Labs.aspx |
| Location | /IRBApplications/<subsite>/Site Pages/ |
| Webparts | Laboratory Space |
| Security | Restricted to Members of the “<facility> AO” group |
| Wireframe | See Figure 44 Administrative Office Lab Space Wireframe |

LSACP.aspx

The Local Site Administrator Control Panel (LSACP) provides the facility site administrator with easy access to tools used to perform the function. As most of the committee memberships are now managed through the Committee Roster workflow this page is simplified compared to the version implemented in RAMS.

Table 43: LSACP.aspx Specification Table

|  |  |
| --- | --- |
| Purpose | Direct access to tools used by the Local Site Administrator |
| Title | Local Site Administration |
| Filename | LSACP.aspx |
| Location | /IRBApplications/<subsite>/Site Pages/ |
| Webparts | Content (Link to Archive Import), Content (Link to Training Data Import), Configured Workflows List View |
| Security | Restricted to Members of the “<facility> Site Administrators” group |
| Wireframe | See Figure 45 LSA Control Panel Home Wireframe |

rams\_archive\_import.html

Provides the functionality required to finish the import of a study (or studies) imported using the Data Bridge Excel tool. This page contains JavaScript which performs the final import of data into SharePoint objects.

Note: This is a preexisting page. The only requirement for this page is to update the navigational elements to include the subsite master page navigation elements.

Table 44: rams\_archive\_import.html Specification Table

|  |  |
| --- | --- |
| Purpose | Perform the SharePoint functions to complete the import of archived objects into RAMS. |
| Title | Import Archive Data |
| Filename | rams\_archive\_import.html |
| Location | /IRBApplications/<subsite>/Site Pages/ |
| Webparts | None |
| Security | Restricted to Members of the “<facility> Site Administrators” group |
| Wireframe | See Figure 46 LSA Archive Import Wireframe |

Note: The JavaScript library for this page does not need to adhere to the same complicated logic for generating facility specific. Committee Review records should not be required, and only one facility Committee Topics record is required to ensure committee oversite is available for renewal. When the PI amends or renews the study, any missing data elements will be required and Committee Rules logic will apply and generate any other facility-level data elements required at that time.

GroupConfiguration.aspx

This page permits the LSA to review the configuration of any committee groups configured for the Facility. This page will permit the LSA to manage some group memberships that will not be performed through the Committee Roster (i.e., users who need access but do not have explicit committee roles).

Table 45: GroupConfiguration.aspx Specification Table

|  |  |
| --- | --- |
| Purpose | To permit access to the configuration of committee roles at the current facility; Standard list view of the Committee Groups list |
| Title | Committee Group Configuration |
| Filename | GroupConfiguration.aspx |
| Location | /IRBApplications/<subsite>/Site Pages/ |
| Webparts | Committee Group List View |
| Security | Restricted to Members of the “<facility> Site Administrators” group |
| Wireframe | See Figure 47 LSA Workflow Configuration Wireframe |

## Network Detailed Design

No specific requirements related to the network design for RAMS are included in this release. An exhaustive network design is documented in the XXX document.

## Security and Privacy

### Security

The RAMS system shall remain behind the VA firewall and subject to VA security initiatives and protocols. RAMS will not exchange PII or other data that would be deemed sensitive; therefore, there is a need for encryption of the data that is exchanged between RAMS and external databases. RAMS Sign-on must comply with VA security and privacy standards.

### Privacy

RAMS does not contain any PII or PHI related to its users or otherwise. As such, there are no specific privacy requirements that are part of RAMS Integration at this time.

# External System Interface Design

No new interfaces are being defined at this time.

## Interface Architecture

No new interfaces are being defined at this time.

## Interface Detailed Design

No new interfaces are being defined at this time.

# Human-Machine Interface

The human-machine interactions between the RAMS user and the platform are constrained by the design limitations of standard VA computational platforms and peripherals. All interaction is via a VA-standard web browser (potentially enhanced with usability features to comply with Section 508 regulations).

## Interface Design Rules

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

Usability specification requirements are as outlined below.

Table 46: Usability Specification Requirements

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

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

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

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

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

* Adhere to an industry-recognized User Interface (UI) Best Practices Guideline or Style Guide. For example, first follow UI guidelines for the development platform. In instances where platform guidelines are not available, adhere to the VA Best Practices Guidelines/Style Guide.
* Inform requirements and designs with detailed human factors work products that have been/will be completed for the specific project. Examples of specific human factors activities might include heuristic evaluations, site visits, interviews, application-specific design guides, and usability testing on existing systems or prototypes.

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

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

To demonstrate high usability, the application should be:

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

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

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

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

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

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

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

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

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

The application design should be modified to:

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

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

Table 47: Usability/User Interface Requirements

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

## Inputs

The developer will provide additional details at a later date by, pending VA input and review.

## Outputs

The developer will provide additional details at a later date, pending VA input and review.

## Navigation Hierarchy

The RAMS Application supports multiple role based user types, which depending on their access and assignments may have different navigation options available to them, however two major areas may be depicted graphically which represent the two largest user communities on the system: 1) Study Personnel and 2) Committee Members.

Study personnel who are not also members of any committees will only be able to navigate the main section of the RAMS application, which is hosted on the main site collection of the RAMS SharePoint 2013 application (see Figure 36). The user’s security context in this area is the most generic, and any user who has been added to the RAMS Users security group can access these functions. In this portion of the RAMS application, users may browse through any studies, which they are associated (either as Investigators or as Staff), review any workflow activities assigned to them, and access their personal profile. Committee activities will not be available to them and will not be a navigable option until they have been added to one of the Committee security groups.



Figure 36: Main Site Navigation Hierarchy

Committee Members who have been added to one of the security groups defined for a specific Research Office, will be able to navigate the second area of the RAMS application, the Facility Subsite(s). These are deployed as subsites of the main site collection, and each has a localized copy of the RAMS Facility template, configured with specific security groups and web pages which can only be accessed by members of those teams. Every subsite is designed to provide standardized Committee and Subcommittee activities and secure data storage for each Research Office. The site hierarchy for the Committee is shown below in Figure 37.



Figure 37: Facility Subsite Navigation Hierarchy

### Facilities Subsite – Navigation Bar

The developer will provide additional details at a later date, pending VA input and review.



Figure 38 Facility/Committee Master Page Wireframe

### Committee/Subcommittee Home Screen

Additional details will be provided at a later date by the developer, pending VA input and review.



Figure 39: Facility/Committee Home Page Wireframe

### Administrative Office Home Screen

The developer will provide additional details at a later date, pending VA input and review.



Figure 40: Administrative Office Home Wireframe

### Administrative Office - Appointments Screen

The developer will provide additional details at a later date, pending VA input and review.



Figure 41: Administrative Office Appointments Wireframe

### Administrative Office Agreements and Memoranda Screen

The developer will provide additional details at a later date, pending VA input and review.



Figure 42: Administrative Office Agreements Wireframe

### Administrative Office - Property Screen

The developer will provide additional details at a later date, pending VA input and review.



Figure 43: Administrative Office Property Wireframe

### Administrative Office – Laboratory Space Allocations Screen

The developer will provide additional details at a later date, pending VA input and review.



Figure 44: Administrative Office Lab Space Wireframe

### LSA Control Panel – Home Screen

The developer will provide additional details at a later date, pending VA input and review.



Figure 45: LSA Control Panel Home Wireframe

### LSA Control Panel – Archive Import Screen

The developer will provide additional details at a later date, pending VA input and review.



Figure 46: LSA Archive Import Wireframe

### LSA Control Panel – Workflow Configuration Screen

The developer will provide additional details at a later date, pending VA input and review.



Figure 47: LSA Workflow Configuration Wireframe

# Attachment A – Approval Signatures

This section is for documenting the approval of the System Design Document. The review should be conducted face to face where signatures can be obtained ‘live’ during the review. If unable to conduct a face-to-face meeting, then it should be held via LiveMeeting and concurrence captured during the meeting. The Scribe should add /es/name by each position cited.

The Business Sponsor and Project Manager are required to sign.

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Glenda Miller, Project Manager Date

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James Breeling, M.D., Business Sponsor Date

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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Kimberly Nix, IT Program Manager Date

1. Additional Information

The developer will provide additional details at a later date, pending VA input and review.

* 1. Identification of Technology and Standards

This is the primary standard adhered to in the design of this system is the VA TRM. This governance body maintains a list of approved software and systems authorized to operate within the VA network. The system components that are part of this design are in the table below.

Table 48: System Components

| Purpose | Description | Version | Release |
| --- | --- | --- | --- |
| Database | SQL Server DB Backend for RAMS, SharePoint and SSRS | 2012 | 12 |
| Application Server | Java Application Server for the RAMS Application | 7 | 2 |
| Content Management Server | SharePoint Server | 2013 | SP 1 |
| Reporting Server | SQL Server Reporting Services Server | 2012 | 4 |
| Linux | Red Hat | 7.0.57 | N/A |

The open-source software application is :

* Apache Tomcat 7.x (Latest Stable) Will be updated to 9.0 before Q1 2018

The Software Development framework and platform is:

* Java Enterprise Edition 7

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

* Rational Jazz Team Server 6.0.1; Rational Team Concert 6.0, Rational Doors Next Generation 6.0, Rational Quality Manager 6.0, Rational Performance Tester 8.7.1.
* MS Visual Studio 2015.3
  1. Constraining Policies, Directives and Procedures

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

* VA Handbook 6500.3 Certification & Accreditation
* VA Handbook 6102 Internet/Intranet Services
  1. Requirements Traceability Matrix

The developer will provide additional details at a later date, pending VA input and review.

* 1. Packaging and Installation

The developer will provide additional details at a later date, pending VA input and review.

* 1. Design Metrics

The developer will provide additional details at a later date, pending VA input and review.