

Department of Veterans Affairs

Research Administrative Management System (RAMS) System Design Document



**July 2014
Version 1.1**

Revision History

Date	Version	Description	Author
July 10, 2014	1.0	Initial Draft	<div></div> Team
July 16	1.1	Corrected miscellaneous errata	<div></div> Team

Table of Contents

1. Introduction.....	1
1.1. Purpose of this document	1
1.2. Identification	1
1.3. Scope	2
1.4. Relationship to Other Plans.....	3
1.5. Methodology, Tools and Techniques	3
1.6. Policies, Directives and Procedures	3
1.7. Constraints.....	4
1.8. Design Trade-offs.....	4
1.9. User Characteristics.....	4
1.9.1. User Problem Statement	6
1.9.2. User Objectives	7
2. Background.....	8
2.1. Overview of the System	8
2.2. Business Benefits	9
2.3. Assumptions and Constraints	10
2.3.1. Design Assumptions	10
2.3.2. Design Constraints	10
2.4. Overview of the Significant Requirements	11
2.4.1. Overview of Significant Functional Requirements.....	11
2.4.2. Database Requirements.....	14
2.4.3. Disaster Recovery Requirements	19
2.4.4. Design Constraint Requirements	19
2.4.5. Performance Requirements	21
2.4.6. Operational Environment Requirements.....	22
2.4.7. Usability-User Interface Requirements.....	22

2.4.8.	User Access / Security & Privacy Requirements.....	25
2.4.9.	Reliability Requirements	28
2.4.10.	Auditing Requirements	28
2.4.11.	Training Requirements.....	28
2.4.12.	Enterprise Requirements	28
2.4.13.	Special Device Requirements.....	29
3.	Conceptual Design.....	30
3.1.	Conceptual Application Design	30
3.1.1.	Application Context.....	30
3.1.2.	Application Locations	32
3.1.3.	Application Users.....	32
3.2.	Conceptual Data Design.....	33
3.2.1.	Project Conceptual Data Model.....	33
3.2.2.	Database Information.....	33
3.3.	Conceptual Infrastructure Design.....	34
3.3.1.	System Criticality and High Availability.....	34
3.3.2.	Special Technology.....	34
3.3.3.	Technology Locations.....	34
3.3.4.	Conceptual Infrastructure Diagram.....	38
3.3.5.	Locations of Environments and External Interfaces	43
4.	System Architecture.....	44
4.1.	Hardware Architecture	45
4.2.	Software Architecture	51
4.3.	Communications Architecture.....	51
5.	Data Design.....	53
5.1.	Data Needs Assessment	57
5.2.	Use Cases	57
5.3.	Context/Collaboration Diagrams.....	58
5.4.	RAMS High Level Target “To-Be” Solution.....	60
5.5.	Database Management System Files.....	60
5.6.	Non-Database Management System Files.....	60

6. Detailed Design	61
6.1.1. Physical Architecture Design.....	61
6.2. Software Detailed Design.....	61
6.3. Communications Detailed Design.....	63
7. External Interface Design	65
7.1. Interface Architecture.....	65
7.2. Human Machine Interface.....	65
7.2.1. Interface Design Rules	65
7.2.2. Inputs.....	65
7.2.3. Outputs.....	65
8. System Integrity Controls	65
8.1. Requirements Traceability Matrix	66
8.2. Packaging and Installation	66
8.3. Design Metrics	66
Attachment A – Approval Signatures	67

1. Introduction

The Veterans Health Administration (VHA) Office of Research and Development (ORD) is responsible for the management and administration of the national VA intramural research program. The availability and efficient management of national research office program data are critical elements of the business process of ORD. As part of former Major Initiative 13, “Perform Research and Development,” the Office of Information & Technology (OI&T) and ORD aim to improve the efficiency and performance of the national VA research program by implementing an enterprise-wide Research Administrative Management System (RAMS) accessible by active field research offices and ORD Central Office.

The RAMS solution will support business functions at the ORD local research offices and ORD Central Office as it pertains to administering and managing the Institutional Review Board (IRB) process required for conducting research at VA, provide a common centralized database for tracking and reporting on VA administrative research program. The RAMS centralized data repository will enable ORD to capture and translate real time data more rapidly, which in turn will provide a higher level of responsiveness to governmental agencies monitoring research compliance issues, Congressional inquiries and VA executive management. The consolidated IT infrastructure and elimination of redundant information management systems will also translate into cost avoidance. RAMS will create a system enabling the VA research community to merge together divergent business processes, increase knowledge sharing and efficiency, and reduce redundancy and cost. RAMS will also provide data administration, management, and reporting capabilities to VA research and development organizations. Finally, RAMS will enable VA to comply with Executive Order 13563 of Jan. 18, 2011, which directs regulatory simplification.

1.1.Purpose of this document

The purpose of this document is to describe in sufficient detail, how RAMS is to be constructed. The System Design Document (SDD) translates the Requirement Specifications into a document from which the developers can create the actual system. It identifies the top level system architecture, and identifies hardware, software, communication, and interface components. This document will be reviewed and analyzed by relevant VA business stakeholders and key members of the RAMS project team.

1.2.Identification

This document describes the RAMS application and software. The following software applications are utilized in RAMS:

- Microsoft SQL Server 2008 R2
- Microsoft SQL Server Reporting Services
- Microsoft SharePoint 2013
- Microsoft Windows 2008 R2

- Scribe

The following open source software applications are utilized in RAMS

- Apache Tomcat 7.x (Latest Stable)

The following software development framework and platform is utilized in RAMS

- Java Enterprise Edition 7

In addition, the RAMS is comprised of the applications the VA uses in support of performing RAMS project development processes.

- Rational Tool Set

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

- VA Handbook 6500.3 Certification & Accreditation
- VA Handbook 6102 Internet/Intranet Web-Site requirements

1.3.Scope

This document covers the overall high level descriptions through the project perspectives, functions, characteristics, constraints, assumptions and dependencies as outlined in Section 3. The specific requirements are detailed by the external interface requirements, classes, performance requirements, design constraints, software system attributes and other requirements. 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 Solution will have the following functionalities:

Table 1: Scope of RAMS System

The RAMS Application Shall:	The RAMS Application Shall Not:
<ul style="list-style-type: none">• Create and track administrative data for each IRB Application assigned to the central and local research office	<ul style="list-style-type: none">• Provide access to Non-VA Credentialed users
<ul style="list-style-type: none">• Manage IRB committees and subcommittees processes	<ul style="list-style-type: none">• Collect or Maintain PHI/PII of enrolled subjects participating in VA research
<ul style="list-style-type: none">• Track research personnel assignments	
<ul style="list-style-type: none">• Create Consent Forms and Health Insurance Portability and Accountability Act (HIPAA) Authorization	
<ul style="list-style-type: none">• Provide for uploading of documents to support the IRB review process	
<ul style="list-style-type: none">• Track training requirements and certifications	

• Manage laboratory data including space allocations and equipment	
• Support required reporting to ORD.	

This system will serve as a communication portal that is accessible to ORD and 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.

1.4.Relationship to Other Plans

This SDD supports the requirements defined within the RAMS Requirements Specification Document (RSD). It also relates to the following documents:

- RAMS Configuration Management Plan
- RAMS Risk Log
- RAMS Risk Management Plan

1.5.Methodology, Tools and Techniques

For requirements, the RAMS project will utilize the International Business Machines (IBM) Rational Requirements Composer (RRC), Rational Team Concert (RTC), and the RAMS change control process plan. The RAMS project team is using the Program Management Accountability System (PMAS) processes and the latest ProPath templates for all artifacts, including design documents.

1.6.Policies, Directives and Procedures

The following standards and regulations apply to design of this system:

- Federal Information Security Management Act (FISMA) of 2002
- Federal Information Processing Standard (FIPS)
- Electronic and Information Technology Accessibility Standards (36 CFR 1194)
- VA Directive 6102
- VA Handbook 6102
- VA Handbook 6500 Standards
- VA Directive 6500, Information Security Program
- VHA Healthcare Identity Management Enterprise
- Office of Enterprise Development (OED) ProPath Process Methodology
- Program Management Accountability System (PMAS) portal
- Memorandum-VA Identity Management Policy (VA Internet Quorum (VAIQ) 701115
- National Institute Standards and Technology (NIST) Special Publications
- Technical Reference Model (RTM)

- Department of Veterans Affairs (VA) Information Technology (IT) Program Management (VA Handbook 6062)

1.7.Constraints

The following constraints are applied to the RAMS Solution:

- Some users will be accessing the system from VA affiliates and universities, but all are expected to have VA accounts.
- The system must comply with VHA Enterprise Architecture and Security

1.8.Design Trade-offs

- The RAMS Solution Environment and Components will be hosted on Microsoft Windows Operating Systems. This underscores the COTS versus Free and Open Source Software (FOSS) trade-off.
- Custom web applications will be hosted on the Apache Tomcat Application Server
 - Per requirements fulfillment the JEE 7 SDK can be used to develop custom web applications. This underscores the COTS versus custom development trade-off. The RAMS Solution will be developed based off the JEE 7 SDK custom developed web applications and will leverage out-of-the-box functionality of interfaced COTS components.
 - The Application development done using Java versus MS .NET is a trade-off for the following reasons:
 - RAMS Solution will be machine independent thanks to the applications and application server relying on the Java JVM
 - RAMS Solution can be developed with several widely available Free and Open Source Software (FOSS) Java libraries in Struts2
 - The Tomcat Application does not limit the environment due to any licensing restrictions
- The RAMS Solution will rely on web services to access and create customer data. The RAMS Solution will store a great deal of Research Project related data, activities and relevant user information within the RAMS Solution's Centralized Database and Document Repository.
- The RAMS Solution utilizes Java as the primary platform for user interaction in the View and Controller components of the Java Model View Controller (MVC) design framework in Struts2. The tradeoff of choosing Java development vs SharePoint development includes more ease of customization of the user front-end, graphics, functionality and easier interoperability between backend systems.

1.9.User Characteristics

- Administrative Officer (AO)

- The AO for R&D is responsible for the administrative functions of the research program.
- Associate Chief of Staff (ACOS)
 - The ACOS for R&D is responsible for the day-to-day management of the research program at facilities with large, active programs.
- Chief of Staff (COS)
- Chief Research and Development Officer (CRADO)
 - The CRADO is responsible for the overall policy, planning, coordination, and direction of R&D activities within VHA.
- Chief Veterinary Medical Officer (CVMO)
 - The CVMO is responsible for veterinary medical and animal research concerns and issues. The CVMO reports to the CRADO, or designee.
- Principal Investigator (PI)
 - The PI is a designated by an applicant institution to direct a research project or program and who usually writes the grant application.
 - The PI oversees scientific, technical, and day-to-day management of the research.
 - In the event of an investigation conducted by a team of individuals, the PI is the responsible leader of that team.
- Co-Principal Investigator (Co-PI)
 - A Co-PI is when one of two or more PIs share equally in the accountability for a study.
 - A Co-PI must meet the same qualifications of a PI.
- Information Security Officer (ISO)
 - The ISO and Privacy Officer must be involved in the review of human subjects research to address and mitigate potential concerns regarding privacy and confidentiality, and information security, respectively.
- Institutional Official (IO)
 - The IO is legally authorized, as Signatory Official, to commit an institution to an Assurance.
 - The IO serves as the official representative of the institution to external agencies and oversight bodies, and provides all written communication with external departments, agencies, and oversight bodies.
 - The Principal Deputy Under Secretary for Health is the IO for VHA Central Office, and VA facility Directors are the IOs for local VA facilities.
- Medical Center Director (MCD)
 - The MCD serves as the IO responsible for all aspects of the research program including but not limited to: human subjects protection, animal welfare care and use, privacy and security of VA data, and biosafety.
- Privacy Officer (PO)

- The PO and ISO must be involved in the review of human subjects research to address and mitigate potential concerns regarding privacy and confidentiality, and information security, respectively.
- Research Compliance Officer (RCO)
 - The primary responsibility of the RCO is to review research projects relative to requirements for the protection of human subjects, laboratory animal welfare, research safety, research laboratory security, research information protection, and other areas under the jurisdiction of ORO.
- Research Coordinator
 - Staff member at a CSP Coordinating Center who assists in the management of the non-protocol sections of a project.
- Site Investigator or Local Site Investigator (SI or LSI)
 - The Site Investigator or LSI is an investigator at a site participating in a multi-site research project.
 - The LSI oversees scientific, technical, and day-to-day management of the research at the local site.
- RAMS System/Station Administrator
 - Staff member at each research station responsible for adding users and any configuration actions required by the local installation of RAMS.
- VA Investigator
 - A VA investigator is any individual who conducts research approved by the VA R&D committee while acting under a VA appointment on VA time, including full and part-time employees, without compensation (WOC) employees, and individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970.
 - In addition, a VA investigator must comply with all applicable VA and VHA requirements, and comply with applicable local VA facility policies and procedures.

1.9.1. User Problem Statement

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 levels. 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.

Each field research office must be in compliance with federal and industry regulations. In the absence of an enterprise solution, the field offices expend excessive local resources to track critical data for ongoing projects to ensure that they are meeting all of the requirements of the law. In the absence of a uniform, standardized software solution, both ORD and their field research offices will continue to experience limited ability to efficiently respond to

Congressional and Secretary level inquiries, review progress of research portfolios to address current and future VA research needs and meet VA and industry mandated compliance reporting requirements

1.9.2. User Objectives

The implemented RAMS solution will support major business functions of each local research office and the Central Office reporting to ORD, facilitate management of the local and central IRB, and provide a common database for tracking and reporting of administrative research program data throughout VA.

2. Background

The mission of OI&T is to provide benefits and services to Veterans of the United States. In meeting these goals, OI&T strives to provide high quality, effective, and efficient information technology (IT) services to those responsible for providing care to the Veterans at the point-of-care as well as throughout all the points of the Veterans' health care in an effective, timely and compassionate manner. VA depends on Information Management/Information Technology (IM/IT) systems to meet mission goals.

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 levels. 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. RAMS is envisioned as 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. RAMS will create a system enabling the VA research community to merge together divergent business processes, increase knowledge sharing and efficiency, and reduce redundancy.

2.1. Overview of the System

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

The RAMS IRB management solution shall be developed to have the following functional capabilities over two increments:

- Add/Edit a Project/Protocol
 - User Log in and verification
 - Add/Update Project Proposal via web form entry
 - Add/Update General and Required Information
 - Upload documents related to project
 - Create Consent and Health Insurance Portability and Accountability Act (HIPAA) letters from templates
 - Manage project data provided by affiliate IRB
- Associate personnel to project
 - Add Project staff and assign role and permission
 - Add/edit user profile

- Preliminary Project Review
 - Online Communication between admin and PI(Principle Investigator)
 - Add project to selected agenda
 - Assign type of review
- Manage Committee Processes
 - Create and publish agenda
 - Role based notification system
 - Assign and receive reviews online
 - Upload and manage documents with version control
 - Create and publish minutes
 - Track unexpected events and deviations
 - Generate revision and rebuttal letters
 - Generate renewal notifications
 - Monitor calendar and continuing review deadlines for each project
 - Manage process unique to Central IRB (cIRB)
- Manage Project Status
 - Track project status
 - Develop project status reports and dashboard
 - Update the Project status dashboard
 - Generate data submission in MS Word format
 - Export data for local reports

The RAMS IRB management solution will employ a configurable technology based on MS SQL Server, SharePoint, a custom web user interface (e.g., Java, J2EE), and web services. . This solution will deliver content management, work-flow, and data quality assurance and improve ORD's ability to track and report research projects.

2.2.Business Benefits

The RAMS solution will support business functions at the ORD local research offices and ORD Central Office as it pertains to administering and managing the IRB process required for conducting research at VA, and provide a common centralized database for tracking and reporting on VA administrative research program. RAMS will automate business processes to improve communication, collaboration, and completion of IRB applications, consent and HIPAA Authorization documents, and other ancillary forms/documents required for IRB approval. By automating these processes, RAMS will help reduce process failures due to lost paperwork, difficulty in obtaining necessary forms and unavailability of IRB personnel.

RAMS will provide a standard architecture solution that will help to reduce variations in standards for review and approval of IRB applications. This includes data collection standards and a rules engine to help determine when an expedited review is appropriate, what forms and sections within those forms must be completed, approval chain, user roles, etc. The RAMS

solution will, thereby, improve efficiencies in monitoring and reporting out compliance with federal requirements and VA policies, including reporting of serious adverse events (SAEs), completed/incomplete informed consent documents, number of human research protocols with/without IRB approval and Research and Development Committee (R&DC) approval, for-cause suspension or termination protocols, lapse in continuing reviews, and research personnel scope of practice and training requirement completions.

RAMS will improve PI user experiences through implementing standard usability design principles for the user interface. Implementing standard usability design practices can help improve retention and communication issues between local site PIs, their local IRB and RD&C, and central IRB.

2.3. Assumptions and Constraints

The RAMS Solution is an implementation of the Service Oriented Architecture (SOA) to expose and consume data to and from multiple potential data consumers and providers. This approach is consistent with the VA-wide intention to move to the web services architecture based on SOA best practices.

2.3.1. Design Assumptions

The following assumptions influenced the design of this system:

- Documents are stored in Microsoft SharePoint 2013.
- User Interface style similar to Modern Expert Systems such as Turbo Tax.
- Single Sign on (SSO) capability provided Claims-Based and/or Kerberos Authentication
- The RAMS System will foster standardization of processes and data definitions across the enterprise
- The system will immediately increase efficiency of operations at the VAMC R&D offices.
- RAMS users may experience degraded performance when accessing RAMS capabilities from the disaster recovery site when in failure or recovery mode

2.3.2. Design Constraints

The following data integration conditions or constraints will limit the range of design choices that are available:

- Browser dependent web UI elements such as
 - DHTML/CSS
 - JQuery
 - JavaScript
 - AJAX

- Image Formats (jpg, gif, png etc.)
- Common Framework Elements
- Section 508 Amendment to the Rehabilitation Act of 1973 guidelines
- Records retention rules
- The system must comply with VHA Enterprise Architecture and security

2.4.Overview of the Significant Requirements

The material in this section is not to replace either the existing functional and technical requirements documents, nor serve as the basis for the Requirements Traceability Matrix (RTM). It should inform non-project personnel reading this document as to the basis for the design.

For more details on requirements, see the RAMS Requirements Specification Document (RSD).

2.4.1. Overview of Significant Functional Requirements

The following is an overview of the major functional requirements for the system. The goal is not to include the full set of requirements in this document or to replace the functional requirements documents, but to identify the major functions to be performed and the few major requirements that drive the design that is described in the sections below.

Table 2 Significant Functional Requirements

ID	Specific Requirements / Synopsis	Requirements
BRD Document BN 1	Adhere to Enterprise Level requirements within the Enterprise Requirements Repository (ERR) and as specifically addressed in Appendix D of the BRD Document	Security Requirements -FIPS 199, NIST SP 800-60, NIST SP 8000-53, VA Handbook 6500. Privacy Requirements. 508 Compliance. Executive Order Requirements. Identity Management Requirements.
FRD 2.1 to 2.15	Allow sites to track and manage research projects and studies	Enter and edit projects in database. Add users and set permissions. Provide searchable abstract for each project. Manage investigators and personnel related to research projects. Support auto fill reports and forms required by R&D and subcommittees. Attach review committee forms, including data security, COI, safety, radiation, and IRB forms

ID	Specific Requirements / Synopsis	Requirements
		<p>to project.</p> <p>Submit and track eligibility and off-site waivers.</p> <p>Track fiscal year expenditures by project.</p> <p>Track sponsorship and funding status for projects.</p> <p>Submit Annual and Final (or as needed) Project Report.</p> <p>Create project specific consent letter.</p> <p>Identify categories of human subjects involved in project.</p> <p>Manage project data provided by affiliate.</p> <p>Track project status and publish status reports.</p>
FRD 3.1 to 3.23	Automate the management of committees to ensure compliance	<p>Add members to committees and track appointment dates.</p> <p>Add projects, amendments, and other business to committee agenda and designate type of review.</p> <p>Provide portal/tools for local form creation and form-based collection of safety information.</p> <p>Automate creation of IRB protocol.</p> <p>Schedule meetings and notify members.</p> <p>Collect reviewer feedback from subcommittees and investigator responses.</p> <p>Provide a mechanism for the use of secure electronic signatures for the signing of all forms and correspondence.</p> <p>Publish and store minutes of meetings.</p> <p>Provide IRB management capability.</p> <p>Track reporting of adverse events, protocol deviations, and protocol exceptions.</p>

ID	Specific Requirements / Synopsis	Requirements
		<p>Track Data Safety Monitoring Board reports.</p> <p>Generate investigational drug information record (10-9012)</p> <p>Notify investigator when annual renewals of subcommittee reviews are due.</p> <p>Manage continuing reviews</p> <p>Track Federal Wide Assurances, IRB registrations, MOUs and other accreditations.</p> <p>Allow for site specific committee configurations and workflows.</p> <p>Automate creation of Research Protocol Safety Survey (RPSS)(VA Form 10-0398)</p> <p>Allow online communication between PI and Admin.</p> <p>Generate revision and rebuttal letters.</p> <p>Manage processes unique to the cIRB including site applications and notifications.</p>
FRD 4.1 to 4.8	Manage data about personnel engaged in research at VAMC facilities	<p>Add and edit profile for VA, In-Person Authentication (IPA), Without Compensation (WOC) and contractor employees engaged in research.</p> <p>Track training, scope of practice and all necessary certifications for PIs and other employees.</p> <p>Notify PI and employee when training is required including annual/biannual re-training</p> <p>Notify WOC/IP/VA employee and sponsor when appointment renewal is required.</p> <p>Track key, PC and badge assignments/issues.</p> <p>Track Conflict of Interest (COI) Disclosures.</p> <p>Add bio sketch or CV.</p>
FRD 6.1 to 6.12	Central Office reporting requirements	Provide query and reporting tools for administrative research

ID	Specific Requirements / Synopsis	Requirements
		<p>data.</p> <p>Define portfolio reporting categories of funded research projects, with tools for creating/editing categories.</p> <p>Support VA-specific portfolio categories.</p> <p>Export raw data in XML, which can be analyzed with third-party business intelligence, analysis, and visualizations tools.</p>
FRD 7.1 to 7.7	System will interface with VA Systems	<p>Support data exchange Manage IRB and/or other central database for ORD projects.</p> <p>Support data import from Collaborative Institutional Training (CITI).</p> <p>Support data import from Talent Management System (TMS).</p>

2.4.2. Database Requirements

Table 3 Database Requirements

Req ID	Requirement	Feature ID	Priority
DD-001	The RAMS Logical Data Model shall be in 3 rd Normal Form.	All	P1
DD-002	The RAMS Logical Data Model shall include all major entities and relationships to manage all aspects of RAMS.[6]	All	P1
DD-003	The RAMS shall confirm the integrity of all received data through the RAMS application data integrity check.	All	P1
DD-004	The RAMS shall confirm the integrity	All	P1

Req ID	Requirement	Feature ID	Priority
	of all received data through the RAMS database referential integrity.		
DD-005	The RAMS shall record the data for managing the RAMS Committees information.	3.1.1	P1
DD-006	The RAMS shall record the data for checking the RAMS Committees status information.	3.2	P1
DD-007	The RAMS shall record the Committee Reviewer Comment data.	3.10.2	P1
DD-008	The RAMS shall allow editing the recorded Committee Reviewer Comment data.	3.10.2	P1
DD-009	The RAMS shall record the correspondence prepared and sent to the Primary Investigator.	3.10.5	P1
DD-015	The RAMS shall record the data entered for Conducting a Convened Meeting.	3.7	P1
DD-016	The RAMS shall record the data entered for Assigning Reviewers for the protocol review and investigation of potentially reportable matters.	3.8.1	P1

Req ID	Requirement	Feature ID	Priority
DD-008	The RAMS shall allow editing of the recorded Committee Reviewer Comment data.	3.10.2	P1
DD-009	The RAMS shall record the correspondence prepared and sent to the Primary Investigator.	3.10.5	P1
DD-015	The RAMS shall record the data entered for Conducting a Convened Meeting.	3.7	P1
DD-016	The RAMS shall record the data entered for Assigning Reviewers for the protocol review and investigation of potentially reportable matters.	3.8.1	P1
DD-008	The RAMS shall allow editing of the recorded Committee Reviewer Comment data.	3.10.2	P1
DD-009	The RAMS shall record the correspondence prepared and sent to the Primary Investigator.	3.10.5	P1
DD-015	The RAMS shall record the data entered for Conducting a	3.7	P1

Req ID	Requirement	Feature ID	Priority
	Convened Meeting.		
DD-016	The RAMS shall record the data entered for Assigning Reviewers for the protocol review and investigation of potentially reportable matters.	3.8.1	P1
DD-020	The RAMS shall record the data entered for Categorizing Potentially Reportable Matters IRB.	3.13	P1
DD-021	The RAMS shall record the data entered for Managing Continuing Reviews.	3.16	P1
DD-026	The RAMS shall record the Compliance Data from Non-VA Committees.	3.21	P1
DD-028	The RAMS shall record the data for Managing Communications with R&D Committee.	3.23.1	P1
DD-029	The RAMS shall record the data for Managing Criteria for IRB Review.	3.23.2	P1
DD-033	The RAMS shall record the data for Managing Documents.	3.24	P1

Req ID	Requirement	Feature ID	Priority
DD-045	The RAMS shall record the data entered for Adding a New User.	4.1	P1
DD-046	The RAMS shall record the data entered for Self Registration.	4.1.1	P1
DD-047	The RAMS shall record the data entered for Editing Existing User profile.	4.2	P1
DD-048	The RAMS shall record the data entered for the person's Name, Contacts, and Affiliations.	4.2.1	P1
DD-049	The RAMS shall record the data entered for the person's Scope Practice.	4.2.2	P1
DD-050	The RAMS shall record the data entered for the person's Education, Licenses, and Credentials.	4.2.3	P1
DD-051	The RAMS shall record the data entered for Adding/Creating Pg 18, Biosketch, or CV.	4.2.4	P1
DD-052	The RAMS shall record the data entered for the person's Research Appointment.	4.2.5	P1
DD-053	The RAMS shall record the data entered for the person's Employment Profile.	4.2.6	P1

Req ID	Requirement	Feature ID	Priority
DD-055	The RAMS shall record the data entered for the Project Investigator Profile.	4.2.8	P1
DD-061	The RAMS shall record the data entered for Managing Projects.	2.1	P1
DD-063	The RAMS shall prepare and transform the data stored in the RAMS database into the formats suitable for Reporting and Analysis.	All	P1

2.4.3. Disaster Recovery Requirements

Table 4 Disaster Recovery Requirements

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

2.4.4. Design Constraint Requirements

Table 5 Design Constraint Requirements

Req. ID	Requirement
---------	-------------

Req. ID	Requirement
DCS-001	The RAMS system shall be free of per person or per seat licenses.
DCS-002	The RAMS system shall comply with all VA Enterprise Architecture Standards.
DCS-003	The RAMS system shall be designed as a Service Oriented Architecture (SOA) as defined in “Principles of Service Oriented Architecture Version 1.31, Software Engineering – Standards Division, Office of Enterprise Development, Office of Information & Technology, Department of Veterans Affairs.”[4]
DCS-004	RAMS software interfaces built for new business functions, legacy applications, databases, middleware and other infrastructure components shall be implemented as services using SOAP/HTTP(S), XML/HTTP(S), SOAP/Java Message Service (JMS), or XML/JMS.
DCS-005	RAMS services shall be built using standards that promote interoperability.[5]
DCS-006	RAMS services shall be designed according to a technical service contract and a negotiated Service Level Agreement (SLA) that together comprise the service contract.
DCS-007	RAMS services implementation shall be loosely coupled to the service interface.
DCS-008	A RAMS service interface is the sole entry point into service logic and resources. Services shall be accessed only via the exposed, published interfaces.
DCS-009	All RAMS service interfaces shall be defined using a technical service contract that includes a WSDL (Web Services Description Language) definition, one or more XML schema definitions, and WS-Policy definitions as required.
DCS-010	RAMS services shall be designed so they can be monitored to determine whether services become unavailable, has a detectable security fault, and whether factors specified in the SLA portion of the Service Contract are out of the permitted range, including but not limited to, resource utilization and the fault behaviors and performance metrics.
DCS-011	No RAMS service shall use static (e.g. hard coded) service addresses.
DCS-012	RAMS service logic exposed by the service shall handle concurrent access without deadlock or loss of data integrity.
DCS-013	RAMS services shall be implemented in a manner that does not require

Req. ID	Requirement
	consumers to use a specific language (e.g. Java only) to access the service.
DCS-014	RAMS services, in the event of exceptions, shall provide fault content to the consumer and the audit log, without compromising security, which shall include sufficient information for consumer recovery.
DCS-015	RAMS shall use RESTful Web services (Representational State Transfer) for any service that is accessed through the user interface.

2.4.5. Performance Requirements

Table 6 Performance Requirements

Req. ID	Requirement
PERF-001	RAMS service consumers shall consume services offered by a service provider in accordance with the service contract.
PERF-002	The RAMS Service Level Agreement (SLA) component of the service contract shall be negotiated with the service provider.
PERF-003	RAMS shall implement standard SLA across all service consumers. .
PERF-004	RAMS shall have no anonymous service consumers.
PERF-005	RAMS shall support users at peak usage levels, where peak usage is defined in the users' Service Level Agreement.
PERF-006	RAMS hardware and software resources shall be sufficiently scalable to support increased workloads by adding equivalent resources.
PERF-007	RAMS shall process and use Coordinated Universal Time (UTC) for internal and external time synchronization.
PERF-008	RAMS shall support 1000 concurrent users at peak usage levels, where peak usage is defined in the users' Service Level Agreement.
PERF-009	The data in the RAMS datamart shall be refreshed from the RAMS operational database once a day.
PERF-011	RAMS users shall have consistent response times when accessing RAMS capabilities during normal operation.

Req. ID	Requirement
PERF-012	RAMS users may experience degraded performance when accessing RAMS capabilities from the disaster recovery site when in failure or recovery mode.

2.4.6. Operational Environment Requirements

Req. ID	Requirement
BRD 7.1.1.1.	The system will be web based and managed from a central server and database.
BRD 7.1.1.2.	The RAMS shall exceed 99.9 percent availability except during periods of scheduled maintenance.
BRD 7.1.1.3.	Maintenance shall be scheduled during off-peak hours during a time approved by the Office of Research and Development (ORD).
BRD 7.1.1.4.	A notification of scheduled maintenance periods that require the service to be offline or which may degrade system performance shall be disseminated to the user community a minimum of 48 hours prior to the scheduled event.
BRD 7.1.1.5.	Notification of unscheduled outages and events that degrade system functionality and/or performance shall be disseminated to the user community within 30 minutes of the occurrence. The business impact must be noted.
BRD 7.1.1.6.	The system shall be supported by a documented operations & maintenance (O&M) plan, continuity of operations (COOP) plan, and disaster recovery (DR) plan.
BRD 7.1.1.7.	The system shall receive ongoing IT operational system-level support 24x7x365
BRD 7.1.1.8.	An end-user support process shall be implemented and documented to enable users to report problems using the RAMS software and to get help.
BRD 7.1.1.9.	Data protection measures, such as backup intervals and redundancy, shall be consistent with systems categorized as mission essential.

2.4.7. Usability-User Interface Requirements

An overview of the Usability-User Interface Requirements are:

Req. ID	Requirement
BRD 7.1.2.1.	The RAMS application shall conform to common usability standards for CPRS.

Req. ID	Requirement
BRD 7.1.2.2.	The system shall respond to user actions when working with form data within 3 seconds or less 95% of the time under normal user loads of 1000 simultaneous user requests, and within 5 seconds or less 90% of the time under peak loads.
BRD 7.1.2.3.	The system shall provide context-sensitive help at the interface level for data entry and update screens.
BRD 7.1.2.4.	The system shall include the option to display definitions next to data entry fields, such as as a mouse-over pop-up.

Additional GUI specific requirements are as below:

Table 7 GUI Specific Requirements

Req. ID	Requirement
GUI-001	The RAMS GUI shall follow the design process and evaluation usability guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter1.pdf .
GUI-002	The RAMS GUI shall follow the optimize user experience usability guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter2.pdf .
GUI-003	The RAMS GUI shall follow the hardware and software usability guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter4.pdf .
GUI-004	The RAMS GUI shall follow the homepage usability guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter5.pdf .
GUI-005	The RAMS GUI shall follow the page layout usability guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter6.pdf .
GUI-006	The RAMS GUI shall follow the navigation usability guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter7.pdf .
GUI-007	The RAMS GUI shall follow the scrolling and paging usability guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter8.pdf .
GUI-008	The RAMS GUI shall follow the headings, titles, and labels usability guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter9.pdf .

Req. ID	Requirement
GUI-009	The RAMS GUI shall follow the links usability guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter10.pdf .
GUI-010	The RAMS GUI shall follow the text appearance usability guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter11.pdf .
GUI-011	The RAMS GUI shall follow the lists usability guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter12.pdf .
GUI-012	The RAMS GUI shall follow the screen based controls usability guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter13.pdf .
GUI-013	The RAMS GUI shall follow the Graphics, Images, and Multimedia usability guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter14.pdf .
GUI-014	The RAMS GUI shall follow the content organization guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter16.pdf .
GUI-015	The RAMS GUI shall follow the search guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter17.pdf .

Data Entry UI Requirements specifics are as follows:

Table 8 Data Entry UI Requirements

Req. ID	Requirement
DEUI-001	The RAMS GUI shall minimize user data entry fields.
DEUI-002	The RAMS GUI shall distinguish required and optional data entry fields.
DEUI -003	The RAMS GUI shall not make user-entered codes case sensitive.
DEUI-004	The RAMS GUI shall label data entry fields clearly.
DEUI-005	The RAMS GUI shall put labels close to data entry fields.
DEUI-006	The RAMS GUI shall allow users to see their entered data.
DEUI-007	The RAMS GUI shall use radio buttons for mutually exclusive selections.

Req. ID	Requirement
DEUI-008	The RAMS GUI shall allow users to stay with one entry method as long as possible for data entry transactions.
DEUI-009	The RAMS GUI shall use checkboxes to enable multiple selections.
DEUI-010	The RAMS GUI shall label units of measurement.
DEUI-011	The RAMS GUI shall not limit viewable list box options.
DEUI-012	The RAMS GUI shall display default values whenever a likely default choice can be defined.
DEUI-013	The RAMS GUI shall place (automatically) a blinking cursor at the beginning of the first data entry field when a data entry form is displayed on a page.
DEUI-014	The RAMS GUI shall use open lists rather than drop-down lists to select one from many.
DEUI-015	The RAMS GUI shall provide auto-tabbing functionality for frequent users with advanced Web interaction skills.

Other UI specific requirements are as follows:

Table 9 Other UI Requirements

Req. ID	Requirement
OUI-001	The RAMS UI shall follow the writing web content usability guidelines as specified in the usability.gov website: http://usability.gov/pdfs/chapter15.pdf .

2.4.8. User Access / Security & Privacy Requirements

Req. ID	Requirement
BRD 7.1.3.1.	The system shall provide a process for end user account management (i.e., create account, inactivate account, constrain access.
BRD 7.1.3.2.	The system shall reside wholly within VA firewalls as defined by VA operational guidelines.
BRD 7.1.3.3.	The system shall be accessible from within the VA intranet by all users with RAMS user access permission.

The following tables specify the Security Requirements

Table 10 Security Requirements

Req. ID	Requirement
SEC-001	At a minimum, the RAMS System Administrator shall have the capability to grant access and set user privileges.
SEC-002	RAMS access levels shall be configurable by the VA through role-based group privileges
SEC-003	RAMS shall utilize VA's Active Directory (LDAP) for user authentication.
SEC-004	RAMS shall use encrypted e-mail when distributing prescheduled reports.
SEC-005	RAMS shall comply with all applicable VA security standards and best practices.
SEC-006	RAMS service security architecture shall be aligned with the WS-I Basic Security Profile (Web Services Interoperability Organization) and the NIST Guide to Secure Web Services (National Institute of Standards and Technology).
SEC-007	RAMS shall provide single sign-on (SSO) to all end users and services.
SEC-008	RAMS shall use SAML Assertions to implement SSO and for authentication subject identification when the integration involves an intermediary web service.
SEC-009	RAMS shall use TLS (SSL 3.1 or greater) for all communication services as documented in NIST Special Publication 800-52, Guidelines for the Selection and Use of Transport Layer Security (TLS) Implementations .
SEC-010	RAMS security policies shall comply with the 44 U.S.C Federal Information System Security Act.
SEC-011	RAMS shall provide a standardized service interface layer for security policy enforcement.

Req. ID	Requirement
SEC-012	<p>RAMS shall comply with the US Government Agencies requirements about storing and handling Personally Identifiable Information (PII). The following PII data is identified in RAMS:</p> <ol style="list-style-type: none">1. SSN2. Last name, middle name and first name3. Gender4. Race5. College/University degree/academic rank6. Date of Birth7. Birth place8. Country of citizenship9. Visa10. Person_Pay table11. Person_Effect_Certification table
SEC-013	RAMS shall be designed with the access control and auditing capability at both application level and database level.
SEC-014	RAMS shall be designed with perimeter security control capability, such as firewall and intrusion detection.

The following tables specify the Privacy Requirements

Table 11 Privacy Requirements

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

2.4.9. Reliability Requirements

Table 12 Reliability Requirements

Req. ID	Requirement
REL-001	The RAMS shall maintain 99% uptime.
REL-002	The RAMS shall require no more than 24 hours of maintenance per month. Servicing and maintenance is expected to occur during nights and weekends.
REL-003	The RAMS shall be available from 8:00 am to 8:00 pm EST during weekdays.

2.4.10. Auditing Requirements

Req. ID	Requirement
BRD 7.1.4.1.	The System shall provide the capability to record and monitor each access to and modification of database contents.

2.4.11. Training Requirements

Req. ID	Requirement
BRD 7.1.5.1.	User training shall be designed concurrently with system development and shall be available prior to RAMS deployment.
BRD 7.1.5.2.	An end-user training manual and a user guide shall be provided in printed and searchable online formats.
BRD 7.1.5.3.	A system administrator training manual shall be provided in printed and searchable online formats.

2.4.12. Enterprise Requirements

Req. ID	Requirement
---------	-------------

Req. ID	Requirement
BRD 7.1.6.1.	All VA security requirements shall be adhered to. Based on Federal Information Processing Standard (FIPS) 199 and National Institute of Standards and Technology (NIST) SP 800-60, recommended Security Categorization is TBD. (The Security Category is the basis for determining the Certification and Accreditation (C&A) and other security requirements for the work effort. The Security Engineer (SE) assigned to the work effort will assist the stakeholders in the determination of the Security Categorization.)
BRD 7.1.6.2.	The Security Categorization shall drive the initial set of minimal security controls required for the information system. Minimum security control requirements are addressed in NIST SP 800-53 and VA Handbook 6500, Appendix D.
BRD 7.1.6.3.	All VA Privacy requirements shall be adhered to. Efforts that involve the collection and maintenance of individually identifiable information must be covered by a Privacy Act system of records notice.
BRD 7.1.6.4.	All Section 508 requirements shall be adhered to.
BRD 7.1.6.5.	All executive order requirements shall be adhered to. All Enterprise Identity Management requirements shall be adhered to. These requirements are applicable to any application that adds, updates, or performs lookups on persons.

2.4.13. Special Device Requirements

There are no special device requirements

3. Conceptual Design

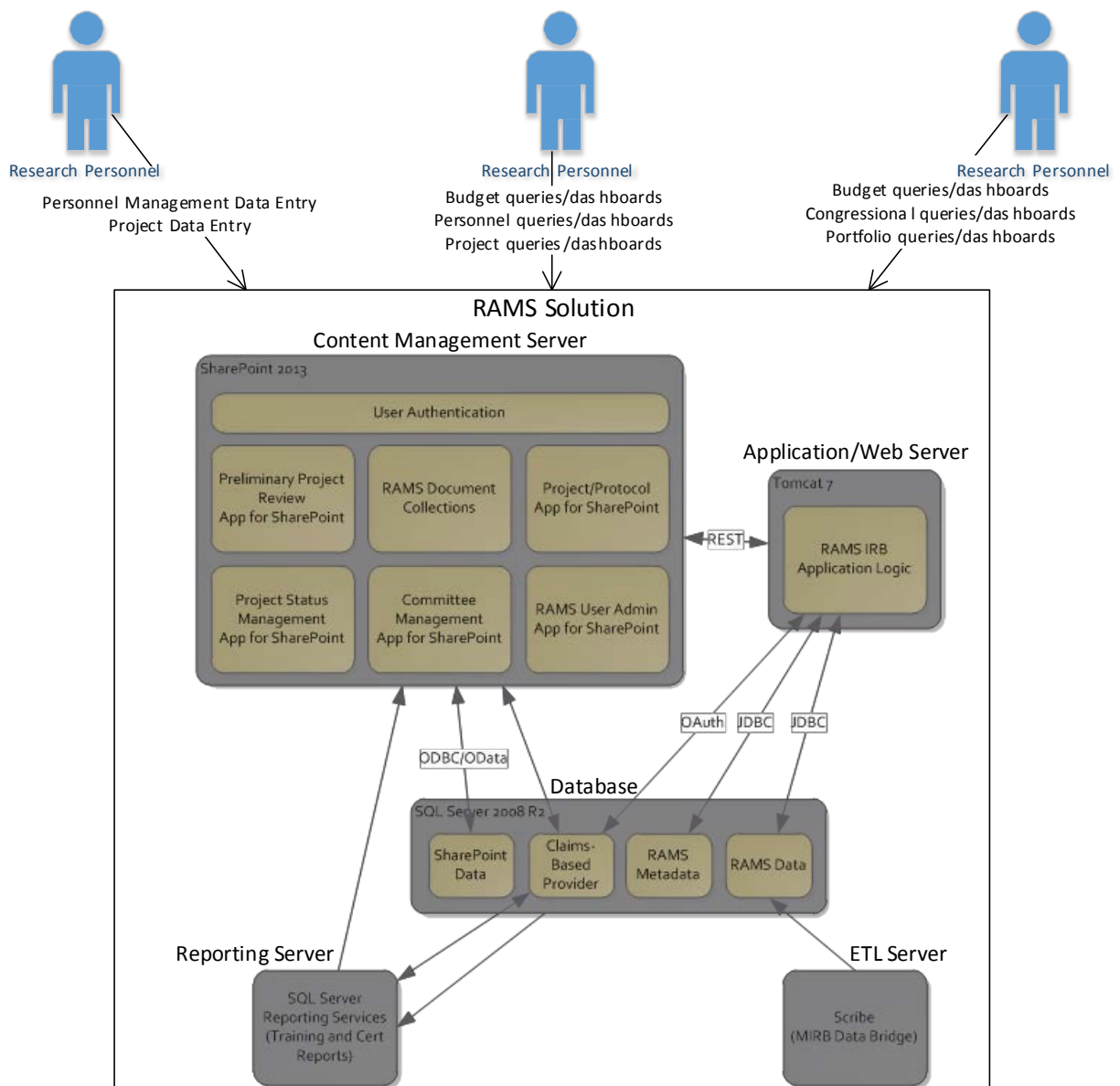
3.1. Conceptual Application Design

3.1.1. Application Context

The following is the general application context:

- i. RAMS Solution will interface with customizable Microsoft SQL Server database to support RAMS functionality
- ii. RAMS Solution will provide web based forms capabilities deployable to various VA hardware platforms
- iii. RAMS Solution will interface with Microsoft Report SSRS to provide letter/form generation and customized self-service reports
- iv. RAMS Solution will provide source control functionality to store source artifacts in VA compliant repositories
- v. RAMS Solution will interface with Microsoft SharePoint 2013 which serves as the document repository for the solution and provide content management, dashboard capabilities and workflow
- vi. RAMS Solution's database will support data migrations from a MIRB databases to the RAMS central database

Figure 1 Application Context Diagram



The RAMS Solution will have the following components:

Content Management Server

A Microsoft SharePoint 2013 which serves as the document repository for the solution and provide 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 RESTful service calls.

Database

An SQL Server database backend for RAMS Solution, SharePoint, and Server Reporting Services Server (SSRS).

Reporting Server

An SQL SSRS for supporting reporting capabilities for the RAMS Solution.

ETL Server

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

3.1.2. Application Locations

Table 13 Application Locations

Application Component	Location at which Component is Run	Type
Application/Web Server	On Site at VA Facility	Tomcat 7 Web Application Server
Database	On Site at VA Facility	Microsoft SQL Server 2008 R2 Database
Content Management Server	On Site at VA Facility	Microsoft SharePoint 2013
ETL Server	On Site at VA Facility	Scribe
Reporting Server	On Site at VA Facility	Microsoft SQL Server Reporting Services

3.1.3. Application Users

Table 14 Application Users

Application Component	Location	Users
RAMS Solution	Chicago, IL Miami, FL New Orleans, LA cIRB (DC)	Principle Investigator (PI) Co-Principle Investigator (Co-PI) PI Designee or Designee Co-Investigator Study Coordinator Site Investigator or Local Site Investigator Associate Chief of Staff (ACOS) for Research and Development (R&D) / R&D AO / R&D Administrative Officer for Research and Development Committee Coordinator ORD Manager VA Central IRB Administrator Institutional Review Board Chair Institutional Review Board Member Institutional Review Board Staff

Application Component	Location	Users
		Privacy Officer / HIPPA Information Security Officer Local System Administrator System Administrator

3.2. Conceptual Data Design

3.2.1. 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), which will be provided during the Logical Data Design (LDD).

The RAMS data model will consist of created and stored data in the Centralized RAMS Database required for document forms from the SharePoint Document Repository. Read/Write data will be transferred from/into the Centralized RAMS Database via the RAMS Solution's web services

3.2.2. Database Information

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

Network requirements, per MS recommendations - The bandwidth speed must be at least 1 gigabit per second.

Table 15 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.	Create	VA
Centralized RAMS Database	Microsoft SQL Server database that houses all VHA national research program input data for the RAMS Solution, Application meta data	Create	VA

Database Name	Description	Type	Steward
	store and user management data store.		
Staging Database	Staging Database for ETL operations	Create	VA
Microsoft SSRS Metadata Database	Metadata Database required for Microsoft SSRS to server reporting functionality of the RAMS Solution	Create	VA

3.3. Conceptual Infrastructure Design

3.3.1. System Criticality and High Availability

The RAMS shall be designed to facilitate database backups by the VA regular standards and procedures of the SQL Server database. The system will be designed 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 shall be designed to 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.

3.3.2. Special Technology

At this time, no special technology is used as part of this system.

3.3.3. Technology Locations

Table 16 Technology Locations for Development Environment

Technology Component	Location	Usage
DEVELOPMENT Environment	EDE Development Environment On the VA Production Network	Development environments in the VA Production Network and Environment serving as the RAMS Solution and environment Development Site for developers
Workstations	Multiple	User
Special Hardware	N/A	
Interface Processors	N/A	
MIRB (Microsoft Access)	[TBD]	One time data migration from MIRB to Centralized RAMS Database
Microsoft SQL Server	[TBD]	Centralized RAMS Database

Technology Component	Location	Usage
Microsoft SharePoint	[TBD]	Document Repository for the RAMS Database
Microsoft SSRS	[TBD]	Custom reporting services
Web Application Server	[TBD]	Java Application and Web Server

Table 17 Technology Locations for Testing Environments

Technology Component	Location	Usage
TESTING Environment (1 and 2)	(AITC/EDE) Testing Environment On the VA Production Network	Testing environments in the VA Production Network and Environment serving as the RAMS Solution and environment TEST Site
Workstations	Multiple	User
Special Hardware	N/A	
Interface Processors	N/A	
MIRB (Microsoft Access)	[TBD]	One time data migration from each station using MIRB to Centralized RAMS Database
Microsoft SQL Server	[TBD]	Centralized RAMS Database
Microsoft SharePoint	[TBD]	Document Repository for the RAMS Database
Microsoft SSRS	[TBD]	Custom reporting services
Web Application Server	[TBD]	Java Application and Web Server

Table 18 Technology Locations for Staging Environment

Technology Component	Location	Usage
STAGING Environment	Staging Environment On the VA Production Network	Staging environment in the VA Production Network and Environment serving as the RAMS Solution and environment Staging Site
Workstations	Multiple	User

Technology Component	Location	Usage
Special Hardware	N/A	
Interface Processors	N/A	
MIRB (Microsoft Access)	[TBD]	One time data migration from each station using MIRB to Centralized RAMS Database
Microsoft SQL Server	[TBD]	Centralized RAMS Database
Microsoft SharePoint	[TBD]	Document Repository for the RAMS Database
Microsoft SSRS	[TBD]	Custom reporting services
Web Application Server	[TBD]	Java Application and Web Server

Table 19 Technology Locations for Production Environment

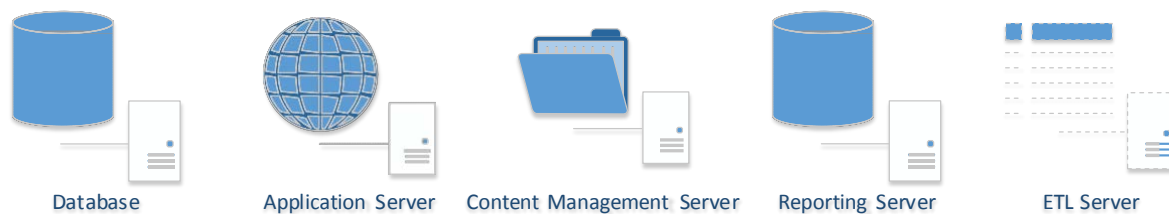
Technology Component	Location	Usage
PRODUCTION Environment	Production Environment? On the VA Production Network	Production environment in the VA Production Network and Environment serving as the RAMS Solution and environment Production Site
Workstations	Multiple	User
Special Hardware	N/A	
Interface Processors	N/A	
MIRB (Microsoft Access)	[TBD]	One time data migration from each station using MIRB to Centralized RAMS Database
Microsoft SQL Server	[TBD]	Centralized RAMS Database
Microsoft SharePoint	[TBD]	Document Repository for the RAMS Database
Microsoft SSRS	[TBD]	Custom reporting services
Web Application Server	[TBD]	Java Application and Web Server

Table 20 Technology Locations for Production Disaster Recovery Environment

Technology Component	Location	Usage
PRODUCTION DISASTER RECOVERY Environment	Production Disaster Recovery Environment? On the VA Production Network	Production Disaster Recovery environment in the VA Production Network and Environment serving as the RAMS Solution and environment Disaster Recovery Site
Workstations	Multiple	User
Special Hardware	N/A	
Interface Processors	N/A	
MIRB (Microsoft Access)	[TBD]	One time data migration from each station using MIRB to Centralized RAMS Database
Microsoft SQL Server	[TBD]	Centralized RAMS Database
Microsoft SharePoint	[TBD]	Document Repository for the RAMS Database
Microsoft SSRS	[TBD]	Custom reporting services
Web Application Server	[TBD]	Java Application and Web Server

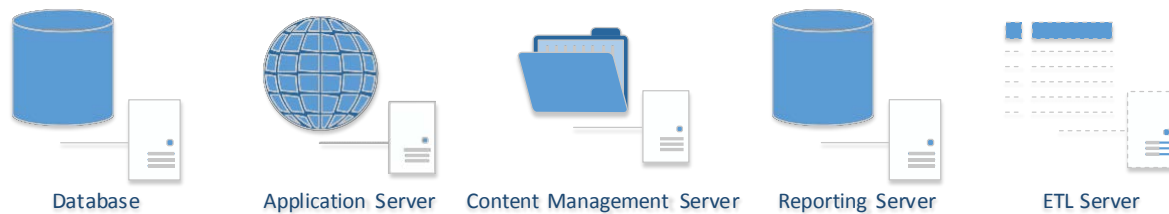
3.3.4. Conceptual Infrastructure Diagram

Figure 2 Development Environment



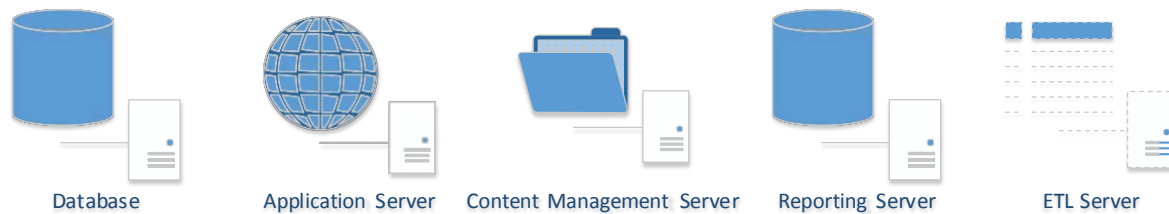
Purpose	Description	Operating Sytem	# of Cores	Memory	Storage
Database	SQL Server DB Backend for RAMS, Sharepoint and SSRS	Windows 2008 R2	4	8GB	250GB
Application Server	Java Application Server for the RAMS Application	Windows 2008 R2	4	4GB	160GB
Content Mgmt Server	SharePoint Server	Windows 2008 R2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

Figure 3 Test 1 Environment



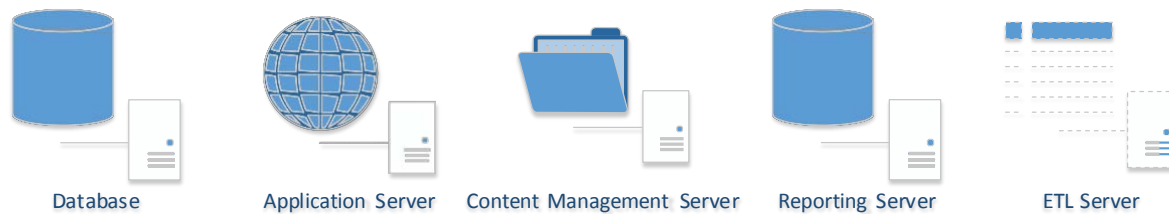
Purpose	Description	Operating Sytem	# of Cores	Memory	Storage
Database	SQL Server DB Backend for RAMS, Sharepoint and SSRS	Windows 2008 R2	4	8GB	250GB
Application Server	Java Application Server for the RAMS Application	Windows 2008 R2	4	8GB	160GB
Content Mgmt Server	SharePoint Server	Windows 2008 R2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

Figure 4 Test 2 Environment



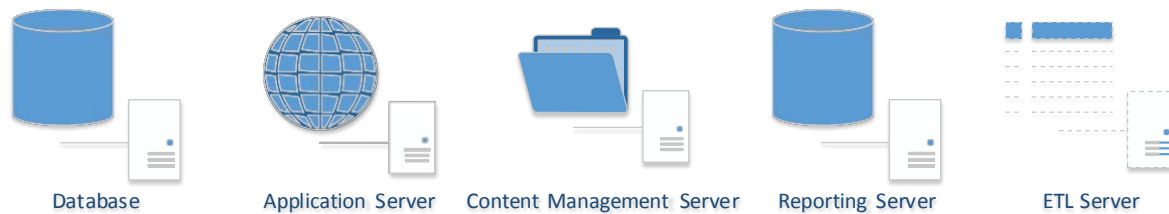
Purpose	Description	Operating Sytem	# of Cores	Memory	Storage
Database	SQL Server DB Backend for RAMS, Sharepoint and SSRS	Windows 2008 R2	4	8GB	250GB
Application Server	Java Application Server for the RAMS Application	Windows 2008 R2	4	8GB	160GB
Content Mgmt Server	SharePoint Server	Windows 2008 R2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

Figure 5 Staging Environment



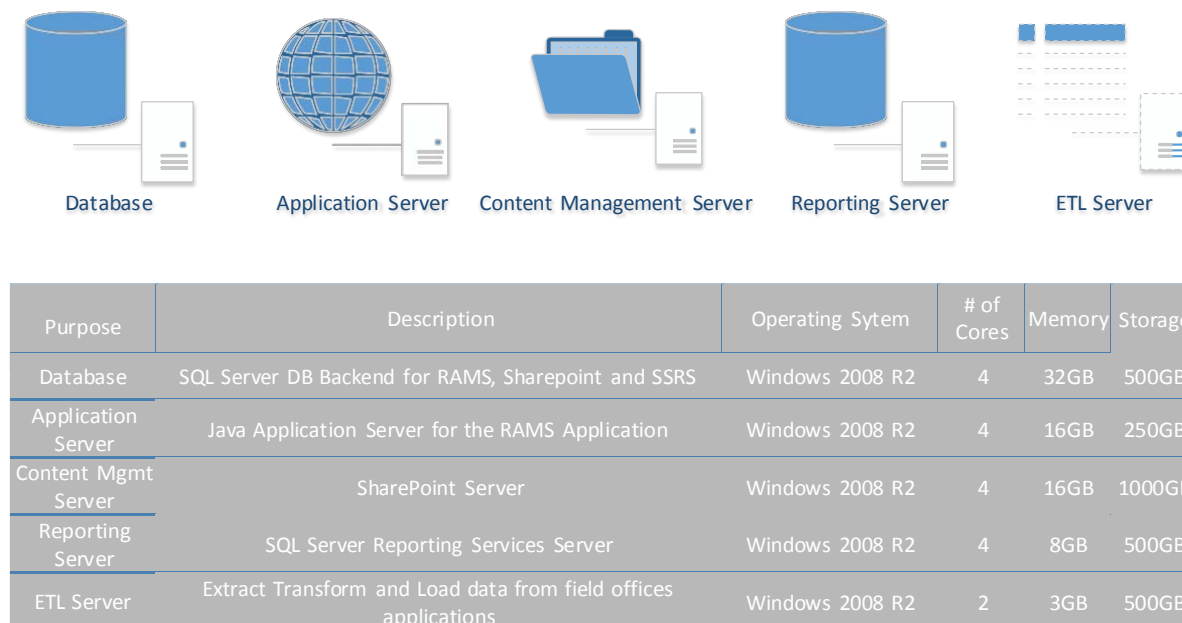
Purpose	Description	Operating Sytem	# of Cores	Memory	Storage
Database	SQL Server DB Backend for RAMS, Sharepoint and SSRS	Windows 2008 R2	4	8GB	500GB
Application Server	Java Application Server for the RAMS Application	Windows 2008 R2	4	8GB	250GB
Content Mgmt Server	SharePoint Server	Windows 2008 R2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

Figure 6 Production Environment



Purpose	Description	Operating Sytem	# of Cores	Memory	Storage
Database	SQL Server DB Backend for RAMS, Sharepoint and SSRS	Windows 2008 R2	4	32GB	500GB
Application Server	Java Application Server for the RAMS Application	Windows 2008 R2	4	16GB	250GB
Content Mgmt Server	SharePoint Server	Windows 2008 R2	4	16GB	1000GB
Reporting Server	SQL Server Reporting Services Server	Windows 2008 R2	4	8GB	500GB
ETL Server	Extract Transform and Load data from field offices applications	Windows 2008 R2	2	3GB	500GB

Figure 7 Production Disaster Recovery Environment



3.3.5. Locations of Environments and External Interfaces

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

- 1 Testing Environment
- 1 Development Environment

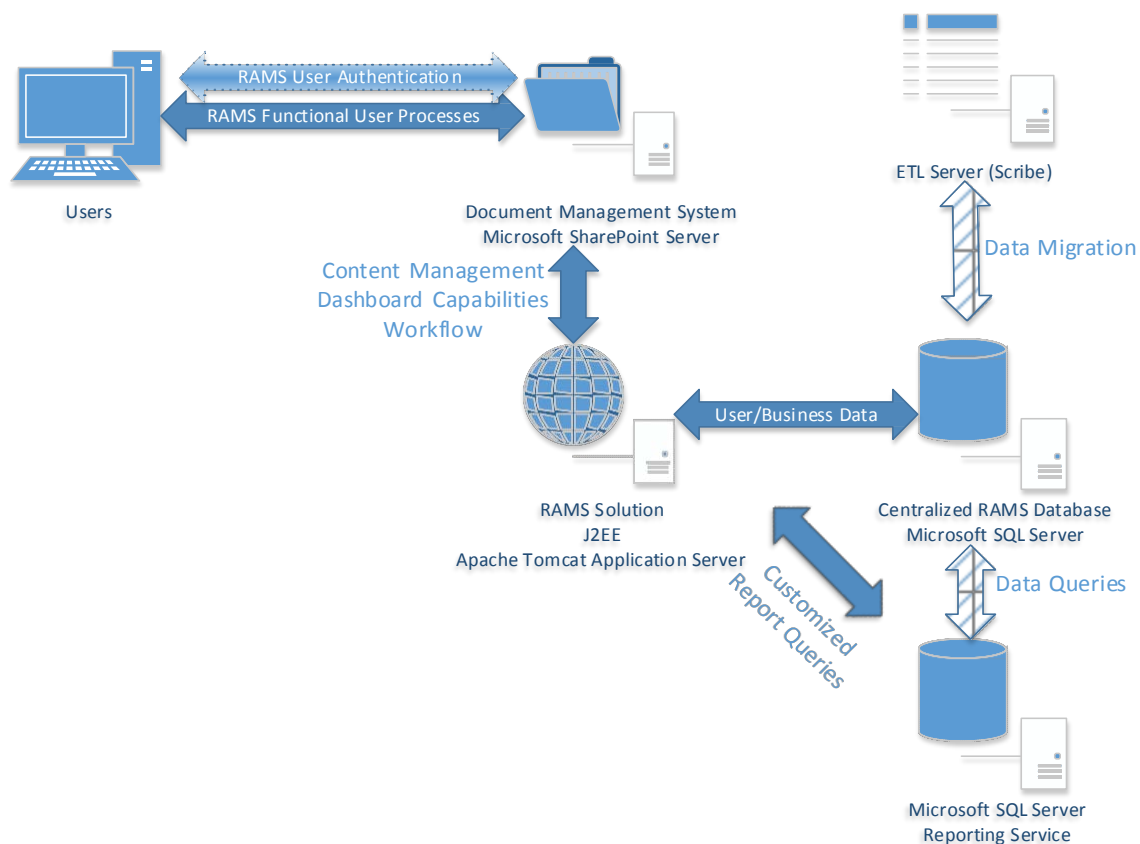
The VA will house the following environments in the AITC Hosting Infrastructure:

- 1 Testing Environment
- 1 Staging Environment located at
- 1 Production Environment at
- 1 Production DR Environment at

4. System Architecture

An outline of System Architecture and its Integration follows in the diagram below:

Figure 3 System Architecture



4.1. Hardware Architecture

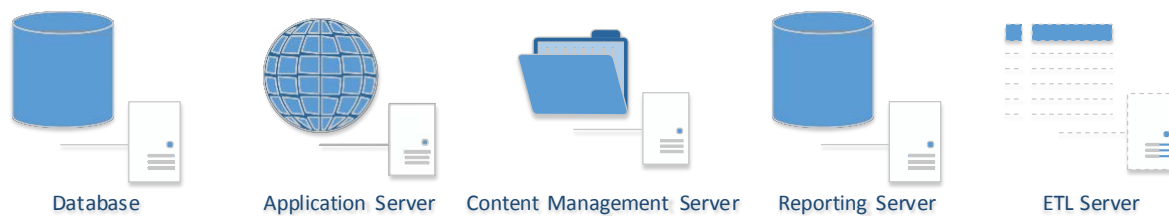
Hardware Detailed Architecture Diagrams

Figure 9 Development Environment



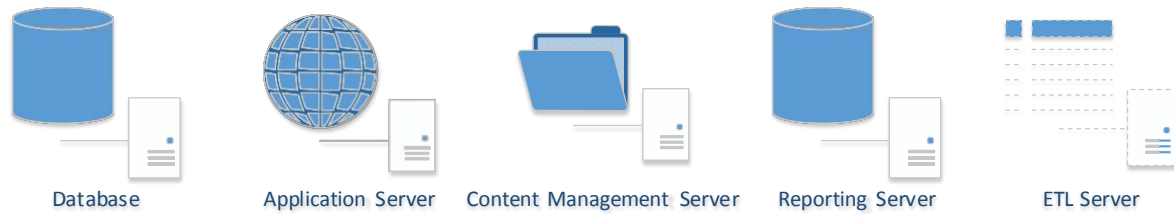
Purpose	Description	Operating Sytem	# of Cores	Memory	Storage
Database	SQL Server DB Backend for RAMS, Sharepoint and SSRS	Windows 2008 R2	4	8GB	250GB
Application Server	Java Application Server for the RAMS Application	Windows 2008 R2	4	4GB	160GB
Content Mgmt Server	SharePoint Server	Windows 2008 R2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

Figure 10 Test 1 Environment



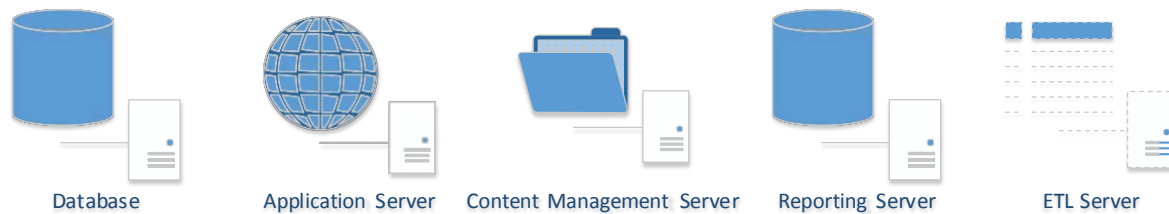
Purpose	Description	Operating Sytem	# of Cores	Memory	Storage
Database	SQL Server DB Backend for RAMS, Sharepoint and SSRS	Windows 2008 R2	4	8GB	250GB
Application Server	Java Application Server for the RAMS Application	Windows 2008 R2	4	8GB	160GB
Content Mgmt Server	SharePoint Server	Windows 2008 R2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

Figure 11 Test 2 Environment



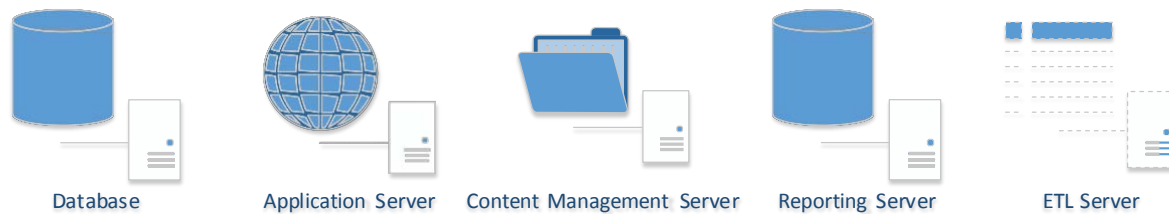
Purpose	Description	Operating Sytem	# of Cores	Memory	Storage
Database	SQL Server DB Backend for RAMS, Sharepoint and SSRS	Windows 2008 R2	4	8GB	250GB
Application Server	Java Application Server for the RAMS Application	Windows 2008 R2	4	8GB	160GB
Content Mgmt Server	SharePoint Server	Windows 2008 R2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

Figure 12 Staging Environment



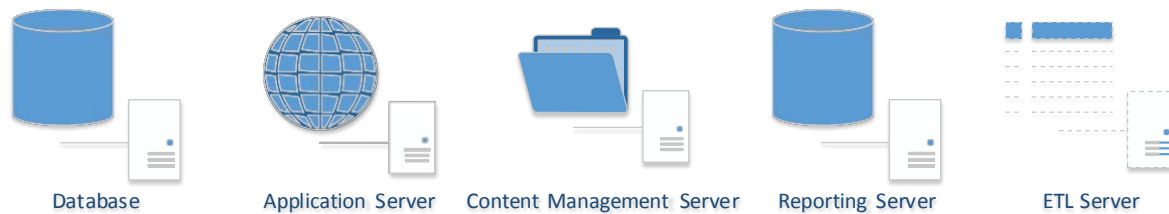
Purpose	Description	Operating Sytem	# of Cores	Memory	Storage
Database	SQL Server DB Backend for RAMS, Sharepoint and SSRS	Windows 2008 R2	4	8GB	500GB
Application Server	Java Application Server for the RAMS Application	Windows 2008 R2	4	8GB	250GB
Content Mgmt Server	SharePoint Server	Windows 2008 R2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

Figure 13 Production Environment



Purpose	Description	Operating Sytem	# of Cores	Memory	Storage
Database	SQL Server DB Backend for RAMS, Sharepoint and SSRS	Windows 2008 R2	4	32GB	500GB
Application Server	Java Application Server for the RAMS Application	Windows 2008 R2	4	16GB	250GB
Content Mgmt Server	SharePoint Server	Windows 2008 R2	4	16GB	1000GB
Reporting Server	SQL Server Reporting Services Server	Windows 2008 R2	4	8GB	500GB
ETL Server	Extract Transform and Load data from field offices applications	Windows 2008 R2	2	3GB	500GB

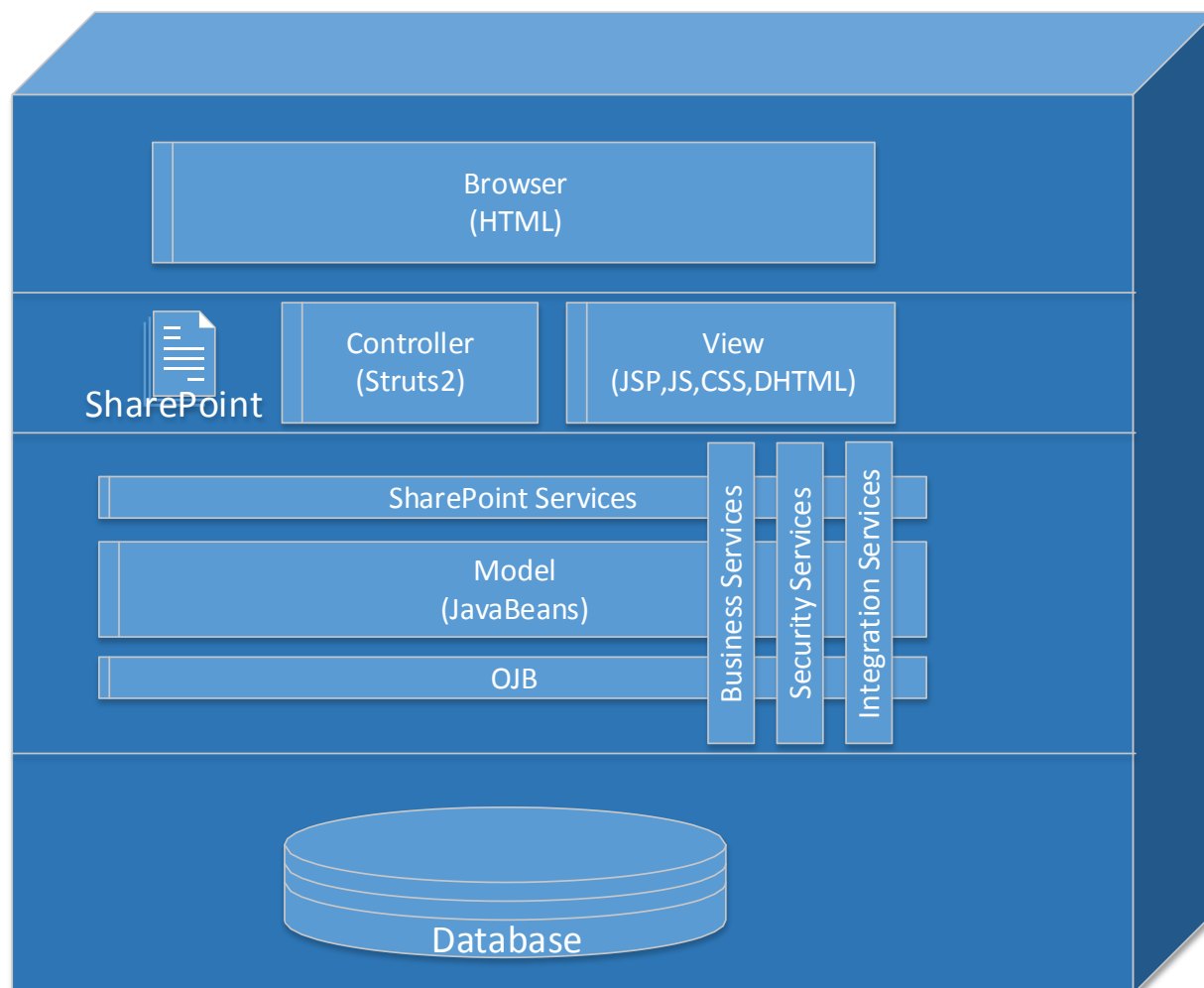
Figure 14 Production Disaster Recovery Environment



Purpose	Description	Operating Sytem	# of Cores	Memory	Storage
Database	SQL Server DB Backend for RAMS, Sharepoint and SSRS	Windows 2008 R2	4	32GB	500GB
Application Server	Java Application Server for the RAMS Application	Windows 2008 R2	4	16GB	250GB
Content Mgmt Server	SharePoint Server	Windows 2008 R2	4	16GB	1000GB
Reporting Server	SQL Server Reporting Services Server	Windows 2008 R2	4	8GB	500GB
ETL Server	Extract Transform and Load data from field offices applications	Windows 2008 R2	2	3GB	500GB

4.2. Software Architecture

Figure 15 RAMS Solution Multitier Software Architecture

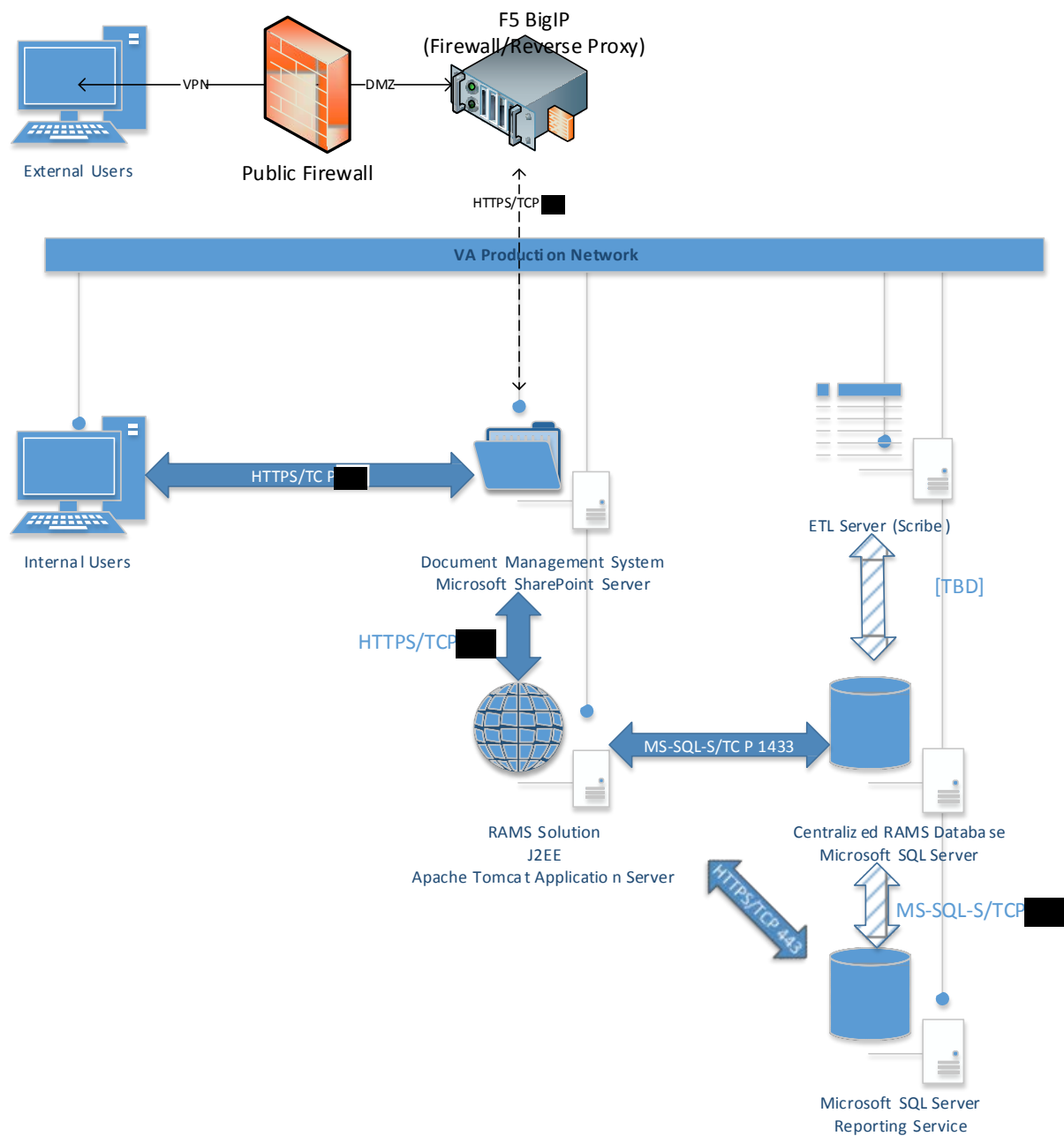


Further details of the Software Architecture can be found in section **6.2 Software Detailed Design**

4.3. Communications Architecture

The Communications Architecture Diagram below details communication within the RAMS Solution and users.

Figure 16 Communications Architecture



5. Data Design

The following data models are illustrative of commonly used data elements, but not considered final designs to be used with the RAMS application. Revised data designs will be incorporated into the document after further design sessions have concluded.

Table 21 User and Self Registration Data (Illustrative)

Ref No	Data Element	Validation		Remarks
		Format/ Value	Rqrd	
1b.	First Name	Corporate Standard	Y	Manually Entered
1c.	Last Name	Corporate Standard	Y	Manually Entered
1d.	Middle Name	Corporate Standard	N	Manually Entered
1f.	Date of Birth	mm-dd-yyyy (Corporate Standard)	Y	Manually Entered
1g.	User email	Text	Y	Manually Entered
1h.	User Role	Drop Down	Y	Manually Entered
1i.	Self Register Flag	Y/N	Y	Manually Entered
1j.	User Registration Status	Corporate Standard	Y	Complete Submitted, In Progress Not Submitted (Desire: Auto populated- from XXX)
1k.	Department	Text or Code if within VA	Y	ex. Otolaryngology
1l.	Center	Text	Y	Not Required
1m	Contact Phone	Corporate Standard	Y	Manually Entered
1n	Contact Fax	Corporate Standard	Y	Not Required

Ref No	Data Element	Validation		Remarks
		Format/ Value	Rqrd	
1o	Contact Email	Corporate Standard	Y	Manually Entered
1p	Contact Mail Station	Corporate Standard	Y	Not Required

Table 22 Project/Study Information (Illustrative)

Ref No	Data Element	Validation		Remarks
		Format/ Value	Rqrd	
1b.	First Name	Corporate Standard	Y	Manually Entered
1c.	Last Name	Corporate Standard	Y	Manually Entered
1d.	Middle Name	Corporate Standard	N	Manually Entered
1f.	Date of Birth	mm-dd-yyyy (Corporate Standard)	Y	Manually Entered
1g.	User email		Y	Manually Entered
1h.	User Role	Drop Down	Y	Manually Entered
1i.	Academic Degrees	Drop Down	Y	Manually Entered
1j.	Board Certifications	Drop Down	Y	Manually Entered
1k.	Co-PI or Co-Study Chair	Y/N	Y	Manually Entered
1k.	Co-Pi or Co-Study Chair SSN	999999999	Y	Only Required if 1k=Y
1k.	Co-PI or Co-Study Chair First Name	Corporate Standard	Y	Only Required if 1k=Y
1k.	Co-PI or Co-Study Chair Last Name	Corporate Standard	Y	Only Required if 1k=Y

Ref No	Data Element	Validation		Remarks
		Format/ Value	Rqrd	
2	Employment Status	Drop Down	Y	Manually Entered, Text if Other
3	VA Facility Name	Text Field	Y	Generated from VA Station Number
4a.	VA Station Number	Numeric	Y	Manually Entered
4b.	VA Facility Address	Text	Y	Generated from VA Station Number
4c.	Phone	9999999999	Y	Manually Entered
4d	Fax	9999999999	Y	Manually Entered
4e	VA E-mail		Y	Manually Entered
5a	Project Coordinator First Name	Corporate Standard	Y	Manually Entered
5b	Project Coordinator Last Name	Corporate Standard	Y	Manually Entered
5c	Project Coordinator Phone	9999999999	Y	Manually Entered
5d	Project Coordinator Fax	9999999999	Y	Manually Entered
5e	VA E-mail		Y	Manually Entered
6	Qualifications	Text	Y	Manually Entered, Biosketch Attached
7	Current Projects	Drop Down	Y	Manually Entered
8a	Date of Education	mm-dd-yyyy (Corporate Standard)	Y	Manually Entered
8b	Conflict of Interest Review	Drop Down	Y	Manually Entered, If yes check if COI Form Attached
9a	Coordinating Center Requirement	Y/N	Y	Manually Entered, If yes answer 9b-e
9b	Name of Coordinating	Text	Y	Only required if 9a=Y

Ref No	Data Element	Validation		Remarks
		Format/ Value	Rqrd	
	Center			
9c	Contact First Name	Text	Y	Only required if 9a=Y
9d	Contact Last Name	Text	Y	Only required if 9a=Y
9e	Contact Phone Number	9999999999	Y	Only required if 9a=Y
9f	Contact Email Address		Y	Manually Entered
10a	Local Site Investigator App Requirement	Y/N	Y	Manually Entered
10b	List of Personnel	Text	Y	Only required if 10a=Y
10c	Project Team Members First Name	Text	Y	Only required if 10a=N
10c	Project Team Members Last Name	Text	Y	Only required if 10a=N
10d	VA Status	Text	Y	
10e	Degrees	Text	Y	Only required if 10a=N
10f	5% Effort	Y/N	Y	Only required if 10a=N
10g	Project Role	Text	Y	Only required if 10a=N
10h	Access to Identifiable Data	Y/N	Y	Only required if 10a=N
10i	Obtaining Informed Consent	Y/N	Y	Only required if 10a=N
10j	Date of Latest VA HSP Training	mm-dd-yyyy (Corporate Standard)	Y	Only required if 10a=N
10k	Any applicable state laws	Y/N	Y	Only required if 10a=N
10l	Description of laws	Text	Y	Only required if 10k=Y

Ref No	Data Element	Validation		Remarks
		Format/ Value	Rqrd	
10m	Is there an appropriately credentialed and privileged clinician designated	Y/N/NA	Y	Only required if 10a=N

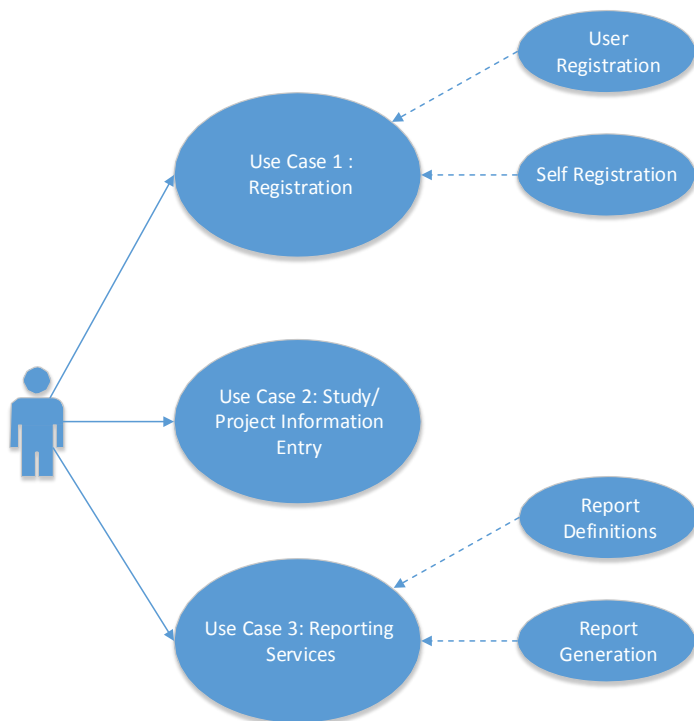
5.1. Data Needs Assessment

[TBD]

5.2. Use Cases

These are the understood Use Cases for RAMS that depend on data services:

Figure 18 Use Cases



5.3.Context/Collaboration Diagrams

Figure 19 Use Case 1 Registration

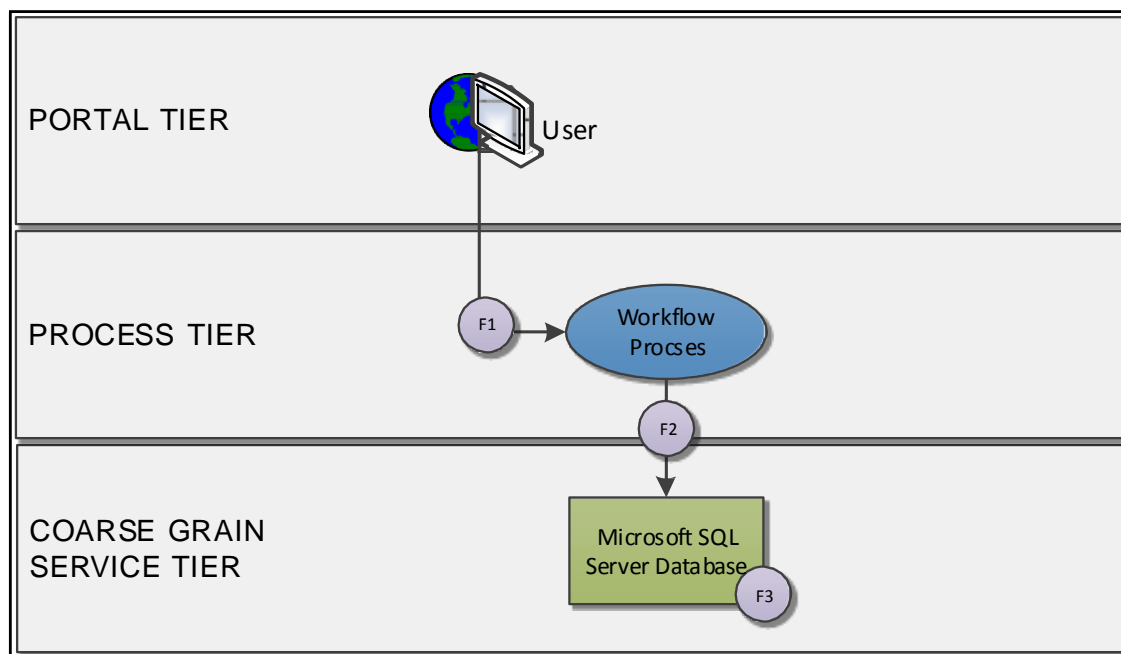


Figure 20 Use Case 2 Project/Study Entry

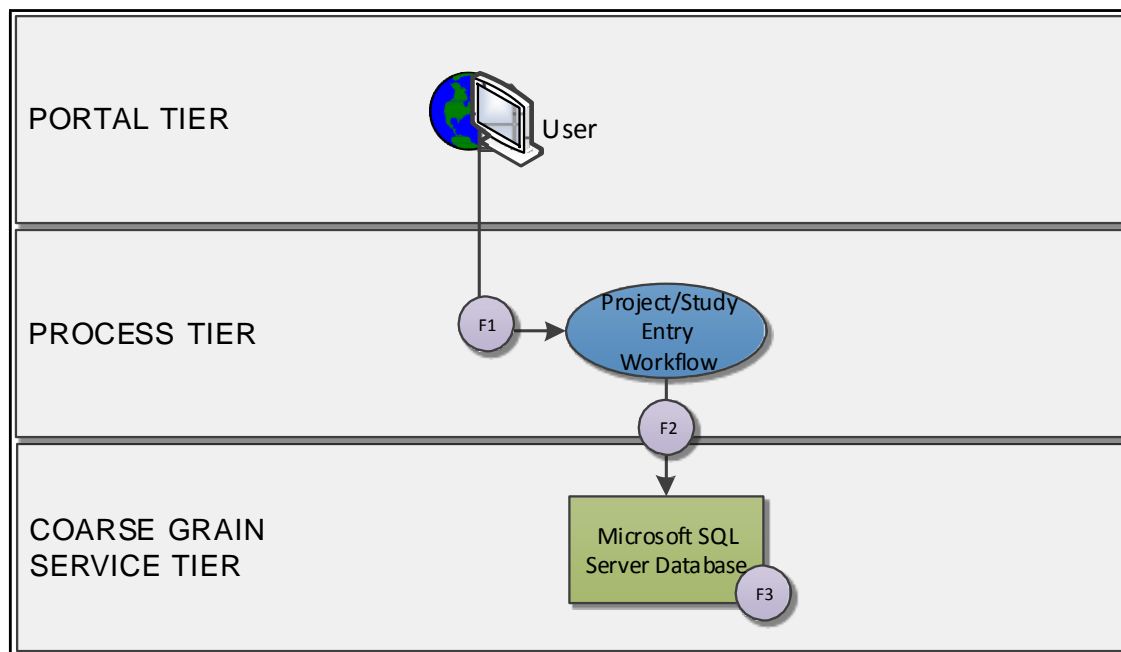
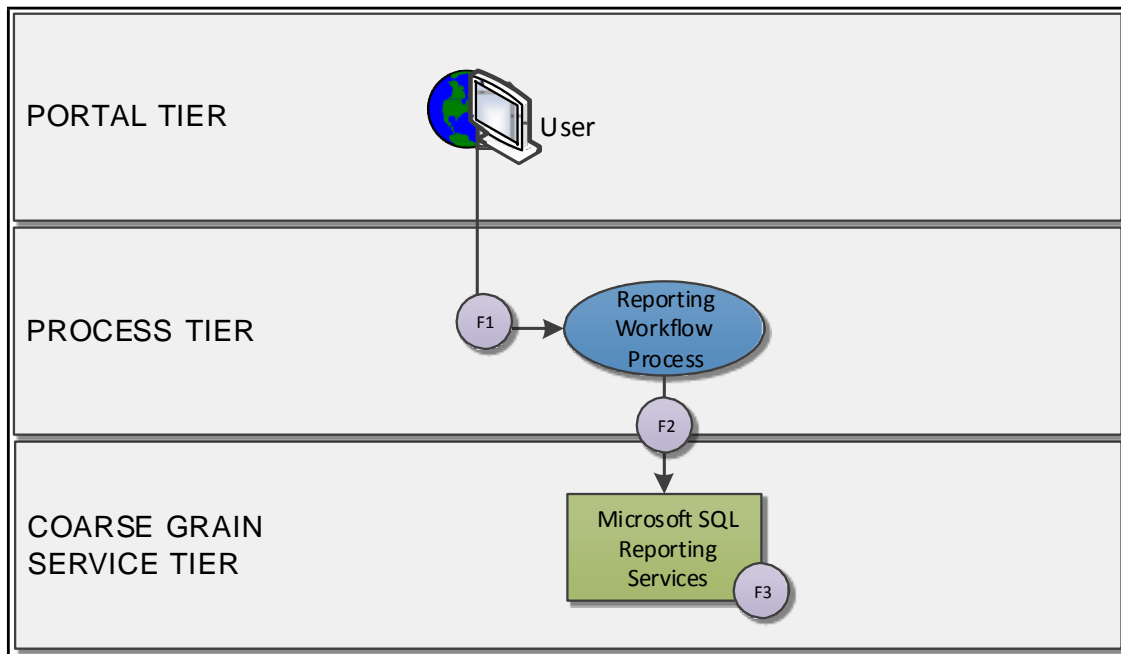
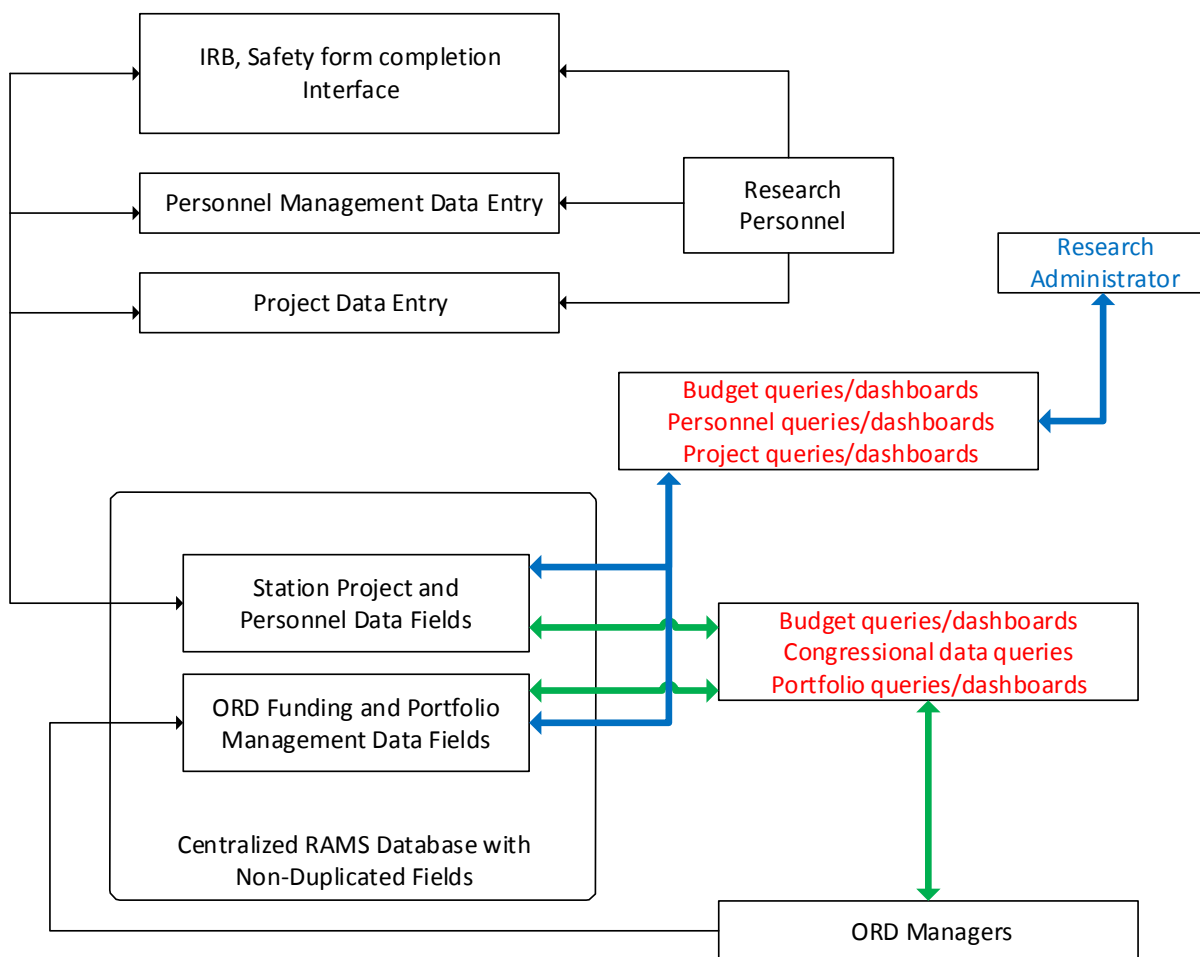


Figure 21 Use Case 3 Reporting Services



5.4. RAMS High Level Target “To-Be” Solution

Figure 22



5.5. Database Management System Files

[TBD]

5.6. Non-Database Management System Files

- Forms
 - Review-Committee Forms
 - IRB Forms
 - Project Submission Forms
 - Agenda Forms
- Notification Letters/templates
- System notification letters/templates for:
 - User Administration
 - Platform Administration

6. Detailed Design

This section describes the proposed design in detail. Updates will be made as necessary.

6.1.1. Physical Architecture Design

The VA provides a virtualized computing environment to host the RAMS Solution. The VA procures implements and maintains the underlying hardware required to provide this virtualized environment. The VA RAMS support team has the ability to manage the virtualized network, server and storage environment. The VA has the ability to allow authorized systems, database, applications, and security administrators to securely log in to manage the physical environments.

6.1.1.1. Servers

The VA leverages Virtualization Technology for the RAMS Solution's Server Infrastructure. All Server machines within the proposed environment are virtualized, to ensure the server resources are used more efficiently while allowing for seamless load balancing of the application servers and clustering for the database servers.

The foundation of the RAMS Solution is Microsoft Windows Server 2008 R2. It will be used to run all physical host servers, supporting scalability of the virtual server sizes to accommodate requested virtual CPUs and memory that will allow for larger workloads.

Performance metrics can be utilized to trigger virtual machine migrations with no downtime (such as CPU utilization, disk queue length, etc.). Copying, cloning, and exporting virtual machines for use in testing or other environments are also a native capability.

6.2. Software Detailed Design

The RAMS Solution architecture can be divided into the following conceptual layers:

- Presentation
- Application
- Platform
- Data

The Presentation layer is the top layer of the RAMS Solution architecture and represents the way a user interacts with the RAMS Solution. RAMS Solution interface is presented through the following client components:

- Standard Web Browsers
 - Via Standard Web content generated by the Application Layer such as
 - HTML
 - CSS
 - DHTML
 - JavaScript

The Application layer represents the RAMS Solution web application. In the Application layer, most application logic revolves around data validation, generation and presentation such as Dynamic Forms Generation and Completion, Grid, Menu and Dashboard layouts.

There is almost no business logic within the application layer. Instead, most of the business logic is provided at the platform layer using attribute metadata. Metadata is information about the elements of a set of data. The attribute metadata captures the following:

- All the rules about data context
- Business-defined rules

Based on these rules that are defined within the metadata, the application layer displays the user interface accordingly. RAMS Solution Developers will write their own application methods using the JEE 7 SDK and the SharePoint applications.

The platform layer is the core of the RAMS Solution. The platform layer consists of:

- Apache Tomcat Application Server
 - Web Applications Deployed by the Apache Tomcat Application Server
- Microsoft IIS Server
 - SharePoint requires the Windows Server to have the IIS Server role installed

The security model protects the platform from unauthorized access across the web. Applications that interface with the RAMS Solution platform use standard VA standardized web services to communicate with.

The platform does not impose business-specific logic. This layer imposes only generic constraints such as security and limiting values for attributes. It contains the building blocks for an application, but by itself is nothing more than a collection of related objects. However, the interaction between those objects is used to implement more extensible logic such as dynamic form generation and user generated customized report definitions.

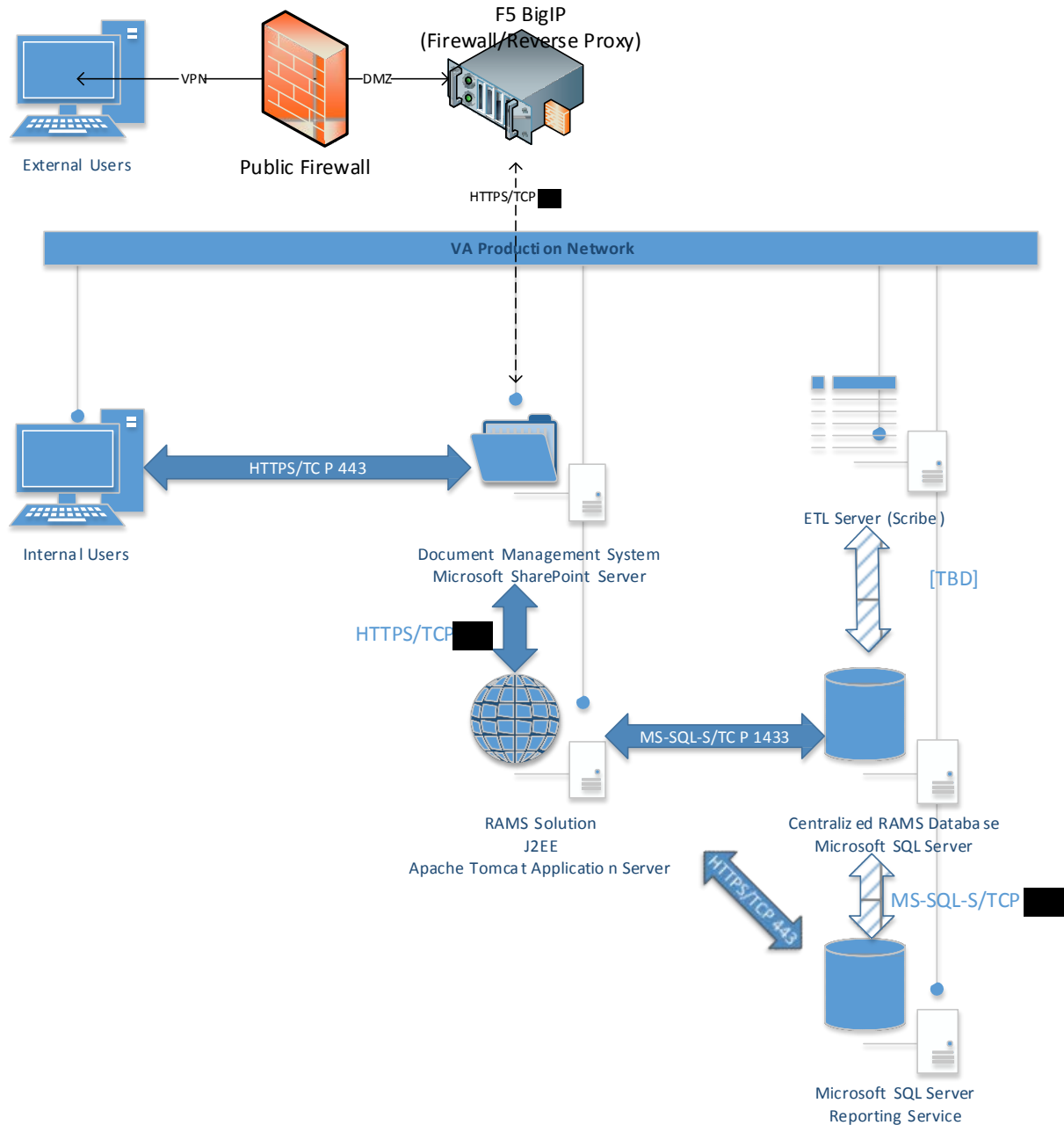
The platform also controls access to data through security, controls access to the database and raises events for workflow processes and custom business logic implementations.

The Data layer, the lowest layer in the architecture, provides the Centralized databases for storing the RAMS Solution data. The Data layer also consists of the Document Repository, which serves content management, dashboard capabilities, and workflow management used by the platform layer.

6.3. Communications Detailed Design

An end user connects to the RAMS Solution via standard Web Application ports over HTTPS. All communication between the RAMS Solution and its components is through its standard and VA approved communication protocols. No special network measures access are needed as the environment is hosted on site in the VA Production Network. Access to the RAMS Solution is controlled by the VA using firewall rules and ACLs

Figure 29 Communications Detailed Design



7. External Interface Design

7.1. Interface Architecture

RAMS will integrate with the following interfaces per the RAMS **BRD BN 7.1-7.7**:

[TBD]

Collaborative Institutional Training (CITI)

RAMS will support data import from Collaborative Institutional Training

Talent Management System (TMS)

RAMS will support data import from Talent Management System

Management IRB (MIRB) System

RAMS System will support a one-time data migration from the MIRB for historical IRB data.

7.2. Human Machine Interface

7.2.1. Interface Design Rules

The conventions and standards used for designing the user interface are incorporated from the RAMS BRD detailed in section above “**2.4.6. Usability-User Interface Requirements**”

7.2.2. Inputs

Input media used by the user would be the keyboard and mouse

7.2.3. Outputs

The users input will result in following type of application output: reports, data display screens and query results

8. System Integrity Controls

The System Security Plan describes controls in more detail. However, the controls being applied to the RAMS system include at a minimum:

- Physical Security
 - RAMS is a Web based application therefore, no install required.
- Configuration Management
 - Roles are defined in RAMS granting access to the appropriate users.
- Certification, Accreditation and Security assessments
 - All VA security requirements shall be adhered to. Based on Federal Information Processing Standard (FIPS) 199 and National Institute of Standards and Technology (NIST) SP 800-60, recommended Security Categorization is TBD. (The Security Category is the basis for determining the Certification and

Accreditation (C&A) and other security requirements for the work effort. The Security Engineer (SE) assigned to the work effort will assist the stakeholders in the determination of the Security Categorization)

- Identification and authentication
 - RAMS will utilize claims based authentication to authenticate users into the RAMS Solution.
- Access controls
 - RAMS will use standard RBAC access controls to provide web applications level access to users
- Audits
 - RAMS shall provide the capability to record and monitor each access to and modification of database contents
- Training
 - Training will be provided to end users prior to the first release of RAMS
- Systems and Communications Protection controls
 - RAMS will use standard VA ports and protocols for communication purposes

8.1. Requirements Traceability Matrix

The RTM can be found in the RAMS RSD.

8.2. Packaging and Installation

There are no special considerations for software packaging and installation.

- SP packages are in .wsp format
- SP deployments require PowerShell scripts

8.3. Design Metrics

The design activity will maintain compliance with IT Infrastructure Standards and compliance with Enterprise Infrastructure Engineering (EIE) standards. It will also be in compliance with C&A and other security standards.

Attachment A – Approval Signatures

Signed:

Date:

< *Integrated Project Team (IPT) Chair* >

Signed:

Date:

< *Business Sponsor* >

Signed:

Date:

< *IT Program Manager* >

Signed:

Date:

, Project Manager, RAMS

Signed:

Date:

Co-Chair of Architecture & Engineering Review Board (AERB)

Architecture, Strategy, and Design (ASD)

Signed:

Date:

Co-Chair of AERB

Service, Delivery, and Engineering (SDE)