

iMedConsent Platform Migration
Work Effort Unique Identifying #20090711
Business Requirements Document



July 2014

Revision History

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

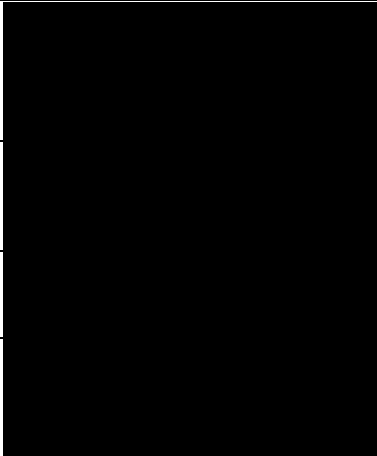
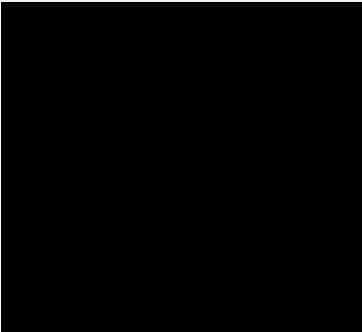
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1. Purpose

The Business Requirements Document (BRD) is authored by the business community for the purpose of capturing and describing the business needs of the customer/business owner identified within the New Service Request (NSR) #20090711¹, iMedConsent: Migration to a Web-Based Platform. The BRD provides insight into the AS-IS and TO-BE business area, identifying stakeholders and profiling primary and secondary user communities. It identifies what capabilities the stakeholders and the target users need and why these needs exist, providing a focused overview of the request requirements, constraints, and other considerations identified. This document is a business case and does not mandate a development methodology. The intended audience for this document is the Office of Information and Technology (OI&T).

2. Overview

Informed consent for clinical treatments and procedures is essential to high quality patient care. Clinicians are obligated by ethical standards of practice and are required by law, regulation, and policy that govern the Veterans Health Administration (VHA) to obtain patients' informed consent (see The Joint Commission Standard RI.2.4.0², VHA Handbook 1004.1³, Title 38 CFR § 17.32⁴, and Title 38 USC 7331⁵). The iMedConsent software package provides VHA physicians with essential tools to ensure that Veterans receive consistent, legible, high-quality information regarding the health care options proposed by the health care team. iMedConsent integrates informed consent into the electronic medical records process and reduces lost or misplaced forms. This improves patient safety by decreasing delayed or postponed procedures. The VHA National Leadership Board (NLB) approved purchase for the enterprise license in 2004 and mandated national implementation and usage of iMedConsent in VHA. Nationwide installation and training were completed in September 2005. An iMedConsent Handbook (VHA Handbook 1004.05), formally mandating use of iMedConsent, was released in August 2009.

iMedConsent is a Windows client/server software application. Each Department of Veterans Affairs Medical Center (VAMC) maintains an iMedConsent server and must expend resources to make quarterly patch updates to the application. Critical updates can only be applied when the next quarterly release is scheduled. The National Center for Ethics in Health Care (NCEHC, 10P6) has requested that iMedConsent be migrated to a centralized platform to permit updates to be more responsive and to reduce the work involved to apply those updates for all sites. This will provide consent form updates to all sites in a shortened timeframe, allowing all sites to have the latest version of all nationally standardized forms.

The ability to make timely updates to the iMedConsent software is extremely important from a patient care perspective. Veterans should receive the absolute latest information available regarding the risks, benefits, and alternatives of a treatment that is proposed by his/her health care team. However, under the current decentralized client-server model, it is often 3-6 months

¹ [REDACTED]

² http://depts.washington.edu/asaccp/dev/sites/default/files/prof/asa70_7_11_12.pdf

³ http://www.ethics.va.gov/docs/policy/VHA_Handbook_1004-01_Informed_Consent_Policy_20090814.pdf

⁴ <http://www.law.cornell.edu/cfr/text/38/17.32>

⁵ <http://www.law.cornell.edu/uscode/text/38/7331>

or more before a desired update is implemented in the system. This process is complicated by the Continuous Readiness in Information Security Program (CRISP) initiative, requiring additional security measures for updating software on the client computers. Providing system updates is now taking approximately 9 months, due to extensive System Center Configuration Manager (SCCM) development, testing, and deployment processes needed to install updates on every computer. Transition to a web-based platform will negate the need for SCCM client software updates. Migration to a web-based platform will ensure that practitioners have access to new forms and process wizards in a matter of days instead of months.

There are approximately 150,000 users of iMedConsent. Over 2.5 million consent forms were stored in Fiscal Year (FY) 2013. All medical centers and Community-Based Outpatient Clinics (CBOC) use iMedConsent.

3. Scope

The goal of this request is to reduce maintenance costs, eventually eliminate the need to maintain iMedConsent servers at each facility, and deploy iMedConsent updates in a timely manner by migrating the application from a decentralized to centralized platforms. The application's current functionality would not be changed. There would be no need for additional training since the functionality of the product would not change.

4. Customer and Primary Stakeholders

The primary customers/stakeholders for this request are business owner Virginia Ashby Sharpe, PhD, representing the Chief, Ethics Policy, NCEHC (10P6) and endorser Melissa Bottrell, PhD, Acting Deputy Executive Director for Ethics in Health Care, NCEHC (10P6). See [Appendix C](#) for the complete list of primary and secondary stakeholders.

5. Goals/Objectives and Outcome Measures

Goal/Objective and Desired Outcome	Impact/Benefit	Measurement
Application and content updates do not require individual deployment to 128+ sites.	Reduction in OI&T support needed to maintain system. This includes reduction in the need to resolve individual computer issues, since software will reside on the server instead of each computer. The vendor will be asked to provide an Application Program Interface (API), so no browser plug-ins are expected to be needed.	The iMedConsent application resides in 4-6 locations enterprise wide at regional data centers.
Reduced cost for maintaining iMedConsent.	Regionalizing servers will reduce OI&T support needs. This should consolidate server locations (instead of one at each facility) and decrease the number of servers.	<ul style="list-style-type: none"> • OI&T maintenance time will be reduced at least 75%. • Server maintenance (where the application resides) will be reduced 90%.

Goal/Objective and Desired Outcome	Impact/Benefit	Measurement
Updates to the application can occur more frequently.	Updates to software and content can be coordinated within weeks instead of months if VHA eliminates the need to push software to each computer using SCCM. Helps avoid patient safety issues associated with practice changes (e.g., identification of need to document contrast media risks in patients with liver disease).	Updates can be deployed in days or weeks, as compared to the current 3-9 month timeframe.
Software will be based on the same Commercial-Off-The-Shelf (COTS) program being developed for use by the Department of Defense (DoD).	Acquisition and development should help smooth transition to a joint Department of Veterans Affairs (VA)/DoD system in the future.	Achieve software deployment on a platform that can move toward a joint acquisition in the future.
Web-based software used in the vendor's COTS product will be supported by Microsoft.	Current client/server model of iMedConsent is based on Visual Basic 6, which is no longer supported by Microsoft.	Vendor has stated that their current software in their COTS product is supported by Microsoft. They have not specifically identified what they are using now.
Software will be compatible with handheld devices capable of running the Computerized Patient Record System (CPRS) (e.g., iPad)	Will be able to be incorporated on additional platforms, giving users and facilities flexibility in their hardware acquisition needs.	The iMedConsent application is accessible on multiple types of hardware.

6. Enterprise Need/Justification

These enhancements align with the Eight for Excellence strategy to continuously improve the quality and safety of health care for Veterans, particularly in those health issues associated with military service. They align with the Power of Performance goal of promoting improved business processes. They also align with the HealthVet strategic initiative for centralizing platforms. These enhancements will move the iMedConsent platform along the same development process as the U.S. Navy is taking at the Brooks Army Medical Center. It should help with future transition of this software product to a joint VA/DoD integration.

7. Business Requirements

7.1. Business Needs/Owner Requirements

Identifier	Business Need (BN) / Owner (OWNR) Requirement	OWNR Priority*
NEED1555 BN 1	Adhere to the Enterprise Level requirements as specifically addressed in Appendix D of this document.	

Identifier	Business Need (BN) / Owner (OWNR) Requirement	OWNR Priority*
NEED516 ARCH530 BN 2	Provide the ability to allow facilities to modify and create forms.	
OWNR2336 2.1	Provide the ability to customize portions of standard national forms.	High
OWNR2337 2.2	Provide the ability to create and store locally-developed forms.	High
OWNR2338 2.3	Provide the ability to use vendor's form builder tools for local forms development.	High
OWNR2339 2.4	Provide the ability to share locally-developed forms with other facilities.	High
NEED517 ARCH530 BN 3	Provide the ability to ensure that all sites are using the latest version of iMedConsent.	
OWNR2340 3.1	Provide the ability for all sites to access the same web-based iMedConsent program.	High
NEED3447 ARCH593 BN 4	Ability for software to pull data in from the Veterans Health Information Systems Technology Architecture (VistA) via Health Level 7 (HL7) messaging.	
OWNR14182 4.1	Provide ability to populate data and establish patient context using HL7 messaging – Automated Data Transfer.	High
OWNR14183 4.2	Provide the ability to auto-populate the patient consent forms with selected patient information that resides in the patient's EHR (e.g., demographics).	High

7.2. Non-Functional Requirements

Functional requirements describe what a system must be able to perform—that is, the system behavior. All other requirements are non-functional. This section describes the non-functional requirements from a business need perspective.

ReqPro Tag	Non-Functional Requirements (NONF) Category
	System Performance Reporting Requirements
NONF3414	The application shall be hosted within the VA firewall.
NONF3415	The application shall adhere to VA security policies.
NONF3416	The centralized application needs to perform as the current application does. Aggregated performance across facilities should be used to arrive at a baseline to compare the new system against.

ReqPro Tag	Non-Functional Requirements (NONF) Category
NONF3417	<p>Increase the speed with which iMedConsent can be updated so that end users have access to the latest software features and Veterans receive up-to-date information about their treatment.</p> <p>Note: (This will be a result of a decrease in the coordination/development time with OI&T. Patches can be locally installed instead of pulled down to the server. Removing the need to develop an SCCM package should increase deployment of updates by at least 2-3 months.)</p>
NONF3418	<p>Increase the speed with which software improvements are implemented.</p> <p>Note: (This will be a result of a decrease in the coordination/development time with OI&T. Patches can be locally installed instead of pulled down to the server. Removing the need to develop an SCCM package should increase deployment of updates by at least 2-3 months.)</p>
NONF3419	<p>Increase the speed with which clinical content can be updated nationwide.</p> <p>Note: (This will be a result of a decrease in the coordination/development time with OI&T. Patches can be locally installed instead of pulled down to the server. Removing the need to develop an SCCM package should increase deployment of updates by at least 2-3 months.)</p>
NONF3420	Minimal additional training will be needed for clinicians and other users.
NONF517	A Service Level Agreement (SLA) will be developed with the hosting site and all parties involved in supporting operations (i.e., Enterprise Operations, Dialog Medical, Office for Ethics, Clinical Application Coordinators [CAC], etc.) to meet the standards for a web-based application.
NONF2811	Include instrumentation to measure all performance metrics specified in the Non-Functional Requirements section of the BRD. At a minimum, systems will have the ability to measure reporting requirements for Responsiveness, Capacity, and Availability as defined in the Service Level Requirements section of this document.
NONF2812	Make the performance measurements available to the Information Technology (IT) Performance Dashboard to enable display of “actual” system metrics to customers and IT staff.
Operational Environment Requirements	
NONF3297	System response times and page load times shall be consistent with VistA Standards.
NONF3298	Maintenance, including maintenance of externally developed software incorporated into the iMedConsent application, shall be scheduled during off peak hours or in conjunction with relevant maintenance schedules. The business owner should provide specific requirements for establishing system maintenance windows when planned service disruptions can occur in support of periodic maintenance.
NONF1608	Information about response time degradation resulting from unscheduled system outages and other events that degrade system functionality and/or performance shall be disseminated to the user community within 30 minutes of the occurrence. The notification shall include the information described in the current Automated Notification Reporting (ANR) template maintained by the VA Service Desk. The specific business impact must be noted in order for OI&T to provide accurate data in the service impact notice of the ANR.
NONF1609	Provide a real-time monitoring solution that tracks and reports agreed upon critical system performance parameters.

ReqPro Tag	Non-Functional Requirements (NONF) Category
NONF2820	Critical business performance parameters shall be identified, e.g. transaction speed, response time for screen display/refresh, data retrieval, etc. in a manner that data capture can occur to support metric reporting and support the OI&T performance dashboard display. If no such performance metrics are required or provided there will be no program specific SLAs created, nor shall there be any active/real time monitoring through the OI&T Performance Dashboard to provide the business owners any performance metrics.
NONF1610	Notification of scheduled maintenance periods that require the service to be offline or that may degrade system performance shall be disseminated to the business user community a minimum of 48 hours prior to the scheduled event. This should be done using a system such as posting of ANR and local email notifications to users/facilities. Notification of planned outages needs to be communicated to all medical practitioners and personnel with CPRS access.
Documentation Requirements	
NONF1612	A technical training curriculum shall be developed and delivered to all levels of staff users. This shall not be a requirement placed on the vendor, as it is outside the scope of the current contract. This will need to be accomplished using additional VA resources.
NONF3299	The training curriculum shall state the expected training time for primary users and secondary users to become proficient at using the iMedConsent application.
NONF3300	All training curricula, user manuals and other training tools shall be developed/updated by the designated VA or Contractor Developers, with input from the project business owners and Subject Matter Experts (SME). The finalized training tools will be delivered to the business owners and the CPRS team four weeks in advance of the release of the enhancement. The training tools will be delivered through various media, for example, nationwide conference calls and PowerPoint presentations. The curricula shall include all aspects of the enhanced iMedConsent application and all changes to processes and procedures.
NONF1613	The training curriculum developed by the Program Office shall state the expected task completion time for primary and secondary users and measurable goals and objectives for each training module.
NONF2228	User manuals and training tools developed for iMedConsent shall be updated to included new capabilities from iMedConsent.
NONF3301	IT will provide the level of documentation required to support the system and maintain operations and continuity. Documentation shall represent minimal programmatic and lifecycle operations support documentation artifacts as defined by VA standards in ProPath and as required by the VA Enterprise System Engineering Lifecycle and Release Management office for sustained operations, maintenance, and support (eie lifecycle/default.aspx) prior to approval by any VA change control board and release into production.
Implementation Requirements	
NONF3302	Technical Help Desk support for the application shall be provided for users to obtain assistance with iMedConsent. For issues involving the iMedConsent software, this will be provided by the vendor's service desk. For issues involving ancillary packages (e.g., Vista Imaging, CPRS Text Integration Utility [TIU]), this will be provided by the National Service Desk.

ReqPro Tag	Non-Functional Requirements (NONF) Category
NONF1614	The IT solution shall be designed to comply with the applicable approved Enterprise SLA.
NONF3303	The deadline for implementation has yet to be determined.
	Data Protection/Back-up/Archive Requirements
NONF1615	Based upon the criticality of the system, provide a back-up and data recovery process for when the system is brought off-line for maintenance or technical issues/problems.
NONF3304	This system is rated as mission essential because it impacts patient safety as it relates to iMedConsent.
NONF3413	A Continuity of Operations Plan will be published that includes performance/capacity requirements for backlog processing following Disaster Recovery (DR).
	Data Quality/Assurance Requirements
NONF2229	A monitoring process shall be provided to ensure that data is accurate and up-to-date and provides accurate alerts for malfunctions while minimizing false alarms.
	User Access/Security Requirements
NONF1617	Ensure the proposed solution meets all VHA Security, Privacy, and Identity Management requirements including VA Handbook 6500 (see Appendix E).
NONF3236	All VA security requirements as defined in VA Handbook 6500 shall be followed. To assist BRD development, the Security Requirements Steering Committee (SRSC) has made available an authoritative extract of those requirements.
NONF3237	All National Institute of Standards and Technology (NIST) SP 800-53 security control family requirements shall be followed. An extract of VA cross-cutting enterprise security and privacy requirements (categorized by current NIST SP 800-53 security control families) is available from the VA SRSC. Based on Federal Information Processing Standard (FIPS) 199 and NIST SP 800 60, recommended Security Categorization is High. The Security Categorization will 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.
NONF3238	Relevant Health Insurance Portability and Accountability Act (HIPAA) security and privacy requirements shall be followed. An extract of HIPAA requirements is available from the VA SRSC. VHA Health Care Security Requirements (HCSR) will determine applicable HIPAA security requirements for health care-related projects.
NONF3239	Provide data sensitivity and segmentation support for HL7 Version 3 Standard: Privacy, Access, and Security Service; Release 1, Section 6.1.1, table 5: Data Segmentation Business Requirements.

7.3. User Access Levels

User Level	Role	Responsibilities	iMedConsent Access Level
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User Level	Role	Responsibilities	iMedConsent Access Level
Primary Users	Physicians, Registered Nurses (RN), social workers, patient educators	Administering clinical care for patients and providing education.	Access needed to write to files in the database (may include Modify for some files and only "Access" for some. Determined by COTS software design)
Secondary Users	OI&T Regional or facility representatives/system administrators	Provide maintenance of the iMedConsent server.	Modify
Secondary Users	CACs	Maintain permissions, run reports provided by the software, and manage content.	Modify

7.4. Known Interfaces and Data Sources

Name of Application	Description of current application	Interface Type	Existing Functionality	Deliverables
Master Veteran Index (MVI)	Source of VA person identity information	Automated	No	Demographic information will be automatically incorporated
CPRS	CPRS Version 29 and forward	HL7 interface - IBM Healthcare Pack; Sentillion Clinical Context Object Workgroup (CCOW)	Yes	Access and launch iMedConsent from within CPRS. CPRS will provide a Graphical User Interface (GUI) for viewing associated progress notes generated by iMedConsent
VistA	VistA Instances at each facility	HL7 interface - IBM Healthcare Pack	Yes	Application will store associated progress notes in VistA TIU, viewable through the CPRS GUI and any future electronic Health Management Platform (eHMP) built upon VistA
VistA Imaging	VistA Imaging provides a storage and retrieval capability for the images populated by iMedConsent	HL7 interface - IBM Healthcare Pack	Yes	Application will store associated images in VistA imaging, viewable through the VistA Imaging Viewer and any future eHMP built upon VistA

Name of Application	Description of current application	Interface Type	Existing Functionality	Deliverables
Web Browsers	Multiple web browsers are authorized for use within VA, per the Technical Reference Model	Automated	Yes	The iMedConsent web-based application will need to be able to run on multiple VA approved web-browsers, including those used by MAC OS.

7.5. Related Projects or Work Efforts

There are no active projects or other related work efforts to this request.

8. Service Level Requirements (SLR)

8.1. Availability

SLR Question	SLR Criteria	Description
1. How much time should the system be available (and how much down time is acceptable due to incident [unexpected] outage)?	99.5% (1.83 days down time) per year	After-hours downtime needed to maintain system and apply software/content updates.
2. When should the system be available (what will be the core operating hours of the system)?	24x7 (except as allowed for scheduled system updates)	Current contract requires this.
3. How soon should the system fully recover from an outage? (Includes Mean Time to Restore [MTRS])	2-8 hours	The contract with the vendor stipulates that calls or email requests for support from VA staff shall be returned within 2 hours. This leaves 6 hours for system restoration.
4. How much data will be restored when outage is recovered?	2-8 hours back	If the outage is on the VA interface side and the user generated data has made it to the iMedConsent server, then restoration should be 100%. If the data has not made it to the server, then paper will be required and no restoration of data using the application can be required.
5. What time period should be considered for maintenance periods?	After-hours	Maintenance periods should be after-hours, during low-usage periods after 5 PM and before 6 AM in the time zone where the consolidated servers are located by region.
6. What standard time zone will the system operate in?	All time zones	Local, depending on time zones of the region where the servers reside.

8.2. Capacity & Performance

SLR Question	SLR Criteria	Description
1. How many users will be on the system hourly?	>1000	Application is used at all facilities to obtain consent for every surgery/treatment/procedure requiring signature consent (3,300,000/year).
2. How many transactions will each average user perform each hour?	<1	3,300,000 transactions/year/365 days = average of 9,123 forms per day. Approximately 13 consent forms per year for each of the 118,799 providers.
3. What are the anticipated peak user times during the day?	Business day	Highest volume during the business day with peaks in the early morning (06:30-09:00) and afternoon (13:00-17:00) in the time zone where the consolidated servers are located by region.
4. What is the anticipated peak transaction load (when do you think that there will be the most transactions being performed on the system) during the day?	Other	Peaks in the early morning (06:30-09:00) and afternoon (13:00-17:00).
5. How many new users will be added in one year?	>1000	Every surgery, treatment/procedure requiring signature consents will have an associated provider/user.
6. How many more (if any) transactions will be added in one year?	>10	This is difficult to identify, as it is tied to overall enterprise growth. As we add hospitals and clinics, transactions should increase. Last year, the systems handled 3,300,000 forms. Increase will be a percentage, not a number. We don't have that percentage.
7. What kind of information will be stored? (Specify average of each kind per month)	Forms and documents that are formatted (example forms or documents with images)	A progress note in CPRS/eHMP and an image in VistA Imaging for each transaction.
8. What kind of search capacity is required?	Heavy (greater than 1,000 per hour)	Users need the ability to search for document templates.
9. What type of system(s) is/are required?	Intranet (All VA)	System will be web-based within the VA firewall.
10. Is there a need for heavy application reporting? If yes, when?	Other	Non-Protected Health Information (PHI) daily data roll up to vendor's data base. Daily data pull and administrator level report capability for usage data.

8.3. Interfaces and Security

SLR Question	SLR Criteria	Description
1. Does this system interact with other existing systems?	Yes	This system will interact with VistA, CPRS, VistA Imaging, and MVI.
2. Will this system require additional monitoring for IT system metrics?	Yes	Monitoring of downtime for system reliability will be needed.
3. Will this system contain personally identifiable information (PII), PHI, HIPAA information, or other confidential/regulated data?	Yes	The forms generated will remain on the system for at least a period of time (TBD) and they will contain ePHI. There will be ePHI permanently stored to allow for report building (usage, metrics, etc.) and document processing/tracking.
4. Who will be the anticipated users of this system?	<ul style="list-style-type: none">• Regional: OI&T Personnel for support• VA: All users of CPRS should have access to this software.• The Vendor: Dialog Medical• Business Owners: NCEHC	Any user of CPRS should have access to this software to generate patient specific consent forms, administrative forms, patient education documents, etc. The vendor and the NCEHC will need access for monitoring, management, maintenance, and development support.

9. Other Considerations

9.1. Alternatives

There are no alternatives that would satisfy the business needs.

9.2. Assumptions

- The iMedConsent application is scalable to the VHA architecture.
- The current vendor (Dialog Medical) will perform the work with appropriate VA staff support.
- Completed and signed consent forms will be stored in the patient record (with temporary backup in a separate iMedConsent database).

9.3. Dependencies

This request requires that the hardware and resources necessary to maintain a centralized platform(s) are available during development and after deployment.

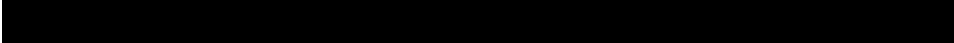
9.4. Constraints

None

9.5. Business Risks and Mitigation

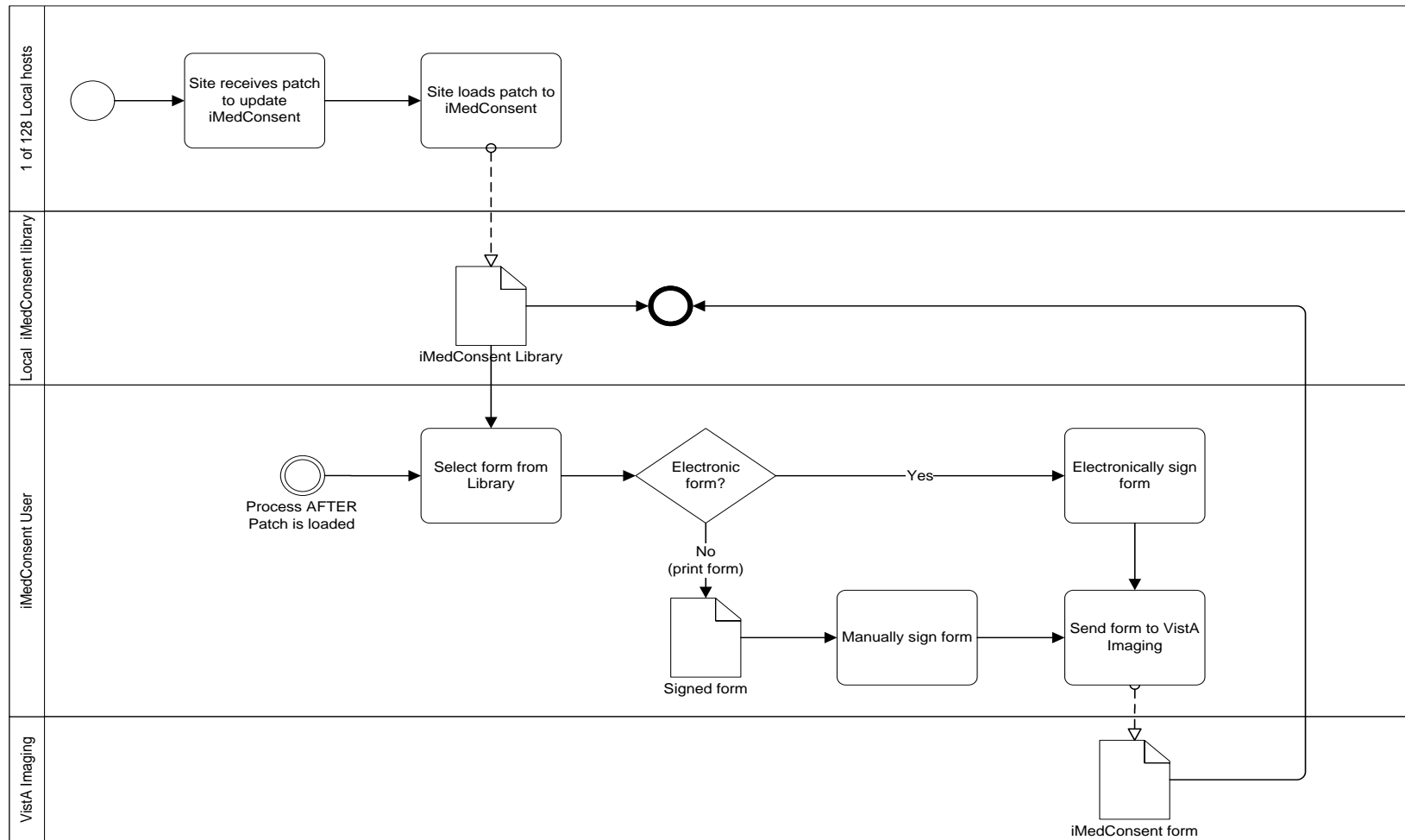
Business Risks	Mitigation
Due to the compressed time frames used to elicit and document the requirements for this NSR, there is the inherent risk that the requirements do not capture the full scope of the request.	Coordinate with users, SMEs, Business Owners, and Leadership to ensure all requirements are captured.
The bandwidth required for a centralized platform has not been completely researched.	Coordinate with SMEs and perform extensive research to ensure bandwidth requirement is obtained.
The number of resources required to maintain the new platform is unknown (network availability, redundancy, back-up, support, etc.).	Coordinate with SMEs and perform research analysis to ensure number of resources required to maintain new platform is available.

Appendix A References

- An iMedConsent Handbook (VHA Handbook 1004.05), formally mandating use of iMedConsent, was released in August 2009.
http://www.ethics.va.gov/docs/policy/VHA_Handbook_1004-05-ImedConsent_20090319.pdf
- Informed consent and advance care planning - Title 38 CFR § 17.32
<http://www.law.cornell.edu/cfr/text/38/17.32>
- Informed Consent for Clinical Treatments and Procedures - VHA Handbook 1004.1
http://www.ethics.va.gov/docs/policy/VHA_Handbook_1004-01_Informed_Consent_Policy_20090814.pdf
- Informed Consent - Title 38 USC 7331
<http://www.law.cornell.edu/uscode/text/38/7331>
- The Joint Commission Standard RI.2.4.0
http://depts.washington.edu/asaccp/dev/sites/default/files/prof/asa70_7_11_12.pdf
- VA Handbook 6500 – Information Security Program


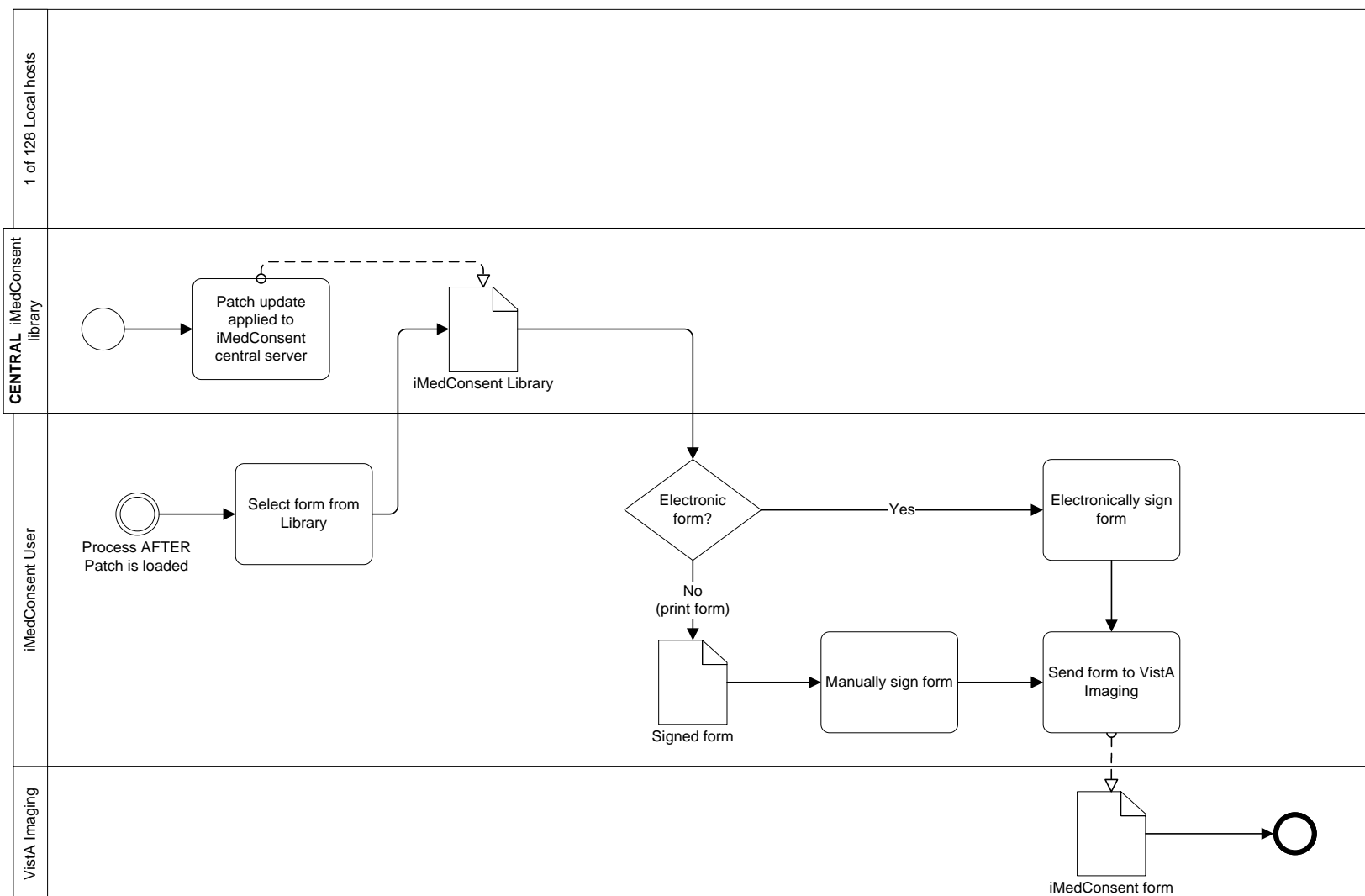
Appendix B Models

Migrate iMedConsent to a Centralized Platform NSR 20090711 As-Is process



Migrate iMedConsent to a Centralized Platform

NSR 20090711 To-Be process



Appendix C Stakeholders, Users, and Workgroups

Stakeholders

Type of Stakeholder	Description	Responsibilities
Requester	[REDACTED]	Submitted request. Submits business requirements. Monitors progress of request. Contributes to BRD development.
Endorser	[REDACTED] Director for Ethics in Health Care, NCEHC (10P6)	Endorsed this request. Provides strategic direction to the program. Elicits executive support and funding. Monitors the progress and time lines.
Business Owner/Program Office	[REDACTED] 10P6)	Provides final approval of BRD with sign-off authority. Provides strategic direction to the program. Elicits executive support and funding. Monitors the progress and time lines.
Business SME	[REDACTED]	Provides background on current system and processes. Describes features of current systems, including known problems. Identifies features of enhancement.
Technical SME	[REDACTED] [REDACTED] by (Contracting Officer)	Provides technical background information about the current software and requested enhancements.
User SME	[REDACTED] Pittsburgh VAMC	Ensures that the enhancements will account for current business processes and existing software capabilities.

Stakeholder Support Team (BRD Development)

Type of Stakeholder	Description	Responsibilities
Security Requirements SME	[REDACTED] Requirements Compliance	Responsible for determining and providing guidance on compliance with HIPAA.
Service Coordination SME	[REDACTED]	Responsible for ensuring all aspects of non-functional requirements have been accurately recorded for this request.

Type of Stakeholder	Description	Responsibilities
Business Liaison Staff	<div data-bbox="475 281 878 344" style="background-color: black; width: 248px; height: 30px;"></div> <div data-bbox="475 344 878 407" style="background-color: black; width: 248px; height: 30px;"></div> <div data-bbox="475 407 878 470" style="background-color: black; width: 248px; height: 30px;"></div> <div data-bbox="475 470 878 533" style="background-color: black; width: 248px; height: 30px;"></div> <div data-bbox="475 533 878 596" style="background-color: black; width: 248px; height: 30px;"></div> <div data-bbox="475 596 878 659" style="background-color: black; width: 248px; height: 30px;"></div> <div data-bbox="475 659 878 722" style="background-color: black; width: 248px; height: 30px;"></div> <div data-bbox="475 722 878 785" style="background-color: black; width: 248px; height: 30px;"></div> <div data-bbox="475 785 878 848" style="background-color: black; width: 248px; height: 30px;"></div> <div data-bbox="475 848 878 911" style="background-color: black; width: 248px; 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Requirements Analyst	<div data-bbox="475 422 894 485" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 485 894 548" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 548 894 611" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 611 894 674" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 674 894 737" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 737 894 800" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 800 894 863" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 863 894 926" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 926 894 989" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 989 894 1052" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1052 894 1115" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1115 894 1178" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1178 894 1241" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1241 894 1304" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1304 894 1367" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1367 894 1430" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1430 894 1493" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1493 894 1556" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1556 894 1619" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1619 894 1682" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1682 894 1745" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1745 894 1808" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1808 894 1871" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1871 894 1934" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1934 894 1997" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 1997 894 2060" style="background-color: black; width: 258px; height: 30px;"></div> <div data-bbox="475 2060 894 2100" style="background-color: black; width: 258px; height: 19px;"></div>	Responsible for working with all stakeholders to ensure the business requirements have been accurately recorded for this request.

Appendix D Usability Requirements

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 VA’s 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 Graphical User Interface that allows the user to view data from multiple sources and include:

- 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 factors 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

Identifier	Usability/User Interface Requirements
NONF2661	Left align content in table cells to facilitate quick visual scan.
NONF2662	Left align text for column headers to facilitate visual scan and make columns and content appear more organized.

Identifier	Usability/User Interface Requirements
NONF2663	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.
NONF2664	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.
NONF2665	Left align page/section titles to anchor titles in consistent locations regardless of window sizing.
NONF2666	Labels for fields should be left aligned to facilitate quick visual scan and make forms and field groupings appear more organized.
NONF2667	Avoid using acronyms or abbreviations unless (a) they are widely understood/well known or (b) there is very limited space to display the full meaning. This supports naïve user understanding. If limited space results in using a non-common acronym/abbreviation, ensure it is specified within “Help” and/or as a tooltip.
NONF2668	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.
NONF2669	Provide visual separation between the navigation space and the main content area.
NONF2670	Add field level validation and notification of missing information on the same page without launching a new window or navigating to another page.
NONF2671	Make all text hyperlinks appear consistent in style.
NONF2672	Make drop-down selection box widths appropriate for content and visual appeal.
NONF2673	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.
NONF2674	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.
NONF2675	Provide standard sort behavior and visual indications on columns in all tables.
NONF2676	Define and adhere to a standard model for use and design of controls, buttons, hyperlinks, and navigation elements.
NONF2677	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).
NONF2678	Place common navigation elements in consistent locations.
NONF2679	Place critical information “above the fold” (i.e., in the top portion of the screen that is immediately viewable).

Identifier	Usability/User Interface Requirements
NONF2680	Use consistent screen flow models, elements, and terms to support similar workflows.
NONF2681	Use consistently named buttons when actions are the same (e.g., Add vs. Save vs. Submit).
NONF2682	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.
NONF2683	Provide field entry tool tips at the field location. Ensure consistency across the application in field labels, formats, location of tooltips, and tool tip text.
NONF2684	Provide visual indication of required fields.
NONF2685	Display field labels in close proximity to entry elements.
NONF2686	Use consistent elements to filter data.
NONF2687	Use consistent elements to sort data.
NONF2688	Use a consistent model for display, layout, and grouping of data entry fields.
NONF2689	Provide alternate row shading in lengthy tables of data, form elements, etc.
NONF2690	Ensure that icons are recognized by users.
NONF2691	Provide some “white space” between status icons in report views, white board views, etc.
NONF2692	Auto-populate default values in entry/selection fields when possible and appropriate.
NONF2693	Visually differentiate status icons from clickable icons, when appropriate.
NONF2694	Define and support the appropriate user tab sequence through fields in forms in order to support keyboard navigation when entering data in forms.
NONF2695	Define and adhere to standard action button placement on screens, forms, etc.
NONF2696	Visually distinguish the primary action button on a page.
NONF2697	Consistently use screen elements, action elements, workflow sequences within/across screens, language, etc.
NONF2698	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.
NONF2699	Provide context-specific Help.
NONF2700	Do not use the term “sex” or any like abbreviations of that to represent gender.

Appendix E Enterprise Requirements

Below is a subset of Enterprise-level Requirements that are of particular interest to the business community. These requirements **MUST** be addressed within each project resulting from this work effort. If OI&T cannot address these Enterprise-level requirements, the Business Owners responsible for each area **MUST** be engaged in any waiver discussions prior to any decisions being made. This section is not meant to be a comprehensive list of all Enterprise-level requirements that may apply to this work effort and should not preclude the technical community from reviewing all Enterprise-level requirements and identifying others that should apply to this work effort as well.

ReqPro Tag	Requirement Type	Description
ENTR99	Security	<p>All VA security requirements will be adhered to. Based on FIPS 199 and NIST SP 800-60, recommended Security Categorization is High.</p> <p>The Security Categorization will 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.</p>
ENTR10	Privacy	All VA Privacy requirements will 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.
ENTR95	508 Compliance	<p>All Section 508 requirements will be adhered to. Compliance with Section 508 will be determined by fully meeting the applicable requirements as set forth in the VHA Section 508 checklists (1194.21, 1194.22, 1194.24, 1194.31 and 1194.41) located at: http://www.ehealth.va.gov/508/resources_508.html or as otherwise specified. Checkpoints will be established to ensure that accessibility is incorporated from the earliest possible design or acquisition phase and successfully implemented throughout the project.</p>
ENTR7	Executive Order	All executive order requirements will be adhered to.
ENTR8	Identity Management	All Enterprise Identity Management requirements will be adhered to. These requirements are applicable to any application that adds, updates, or performs lookups on persons.
ENTR103	Terminology Services	Application/services shall reference the Standard Data Services (SDS) as the authoritative source to access non-clinical reference terminology.
ENTR104	Terminology Services	Application/Services shall use the VA Enterprise Terminology Services (VETS) as the authoritative source to access clinical reference terminology.

ReqPro Tag	Requirement Type	Description
ENTR105	Terminology Services	Applications recording the assessments and care delivered in response to an Emergency Department visit shall conform to standards defined by the VHA-endorsed version of C 28 – Health Information Technology Standards Panel (HITSP) Emergency Care Summary Document Using Integrating the Healthcare Enterprise (IHE) Emergency Department Encounter Summary (EDES) Component.
ENTR106	Terminology Services	Applications exchanging data summarizing a patient's medical status shall conform to standards defined by the VHA-endorsed version of C 32 – HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component.

Appendix F Acronyms and Abbreviations

Term	Definition
10P6	National Center for Ethics in Health Care
ANR	Automated Notification Reporting
API	Application Program Interface
BITS	Business Information Technology Solutions
BN	Business Need
BRD	Business Requirements Document
CAC	Clinical Application Coordinator
CBOC	Community-Based Outpatient Clinic
CCD	Continuity of Care Document
CCOW	Clinical Context Object Workgroup
COTS	Commercial-Off-The-Shelf
CPRS	Computerized Patient Record System
CRISP	Continuous Readiness in Information Security Program
DoD	Department of Defense
DR	Disaster Recovery
EDES	Emergency Department Encounter Summary
eHMP	electronic Health Management Platform
ENTR	Enterprise Requirement
ESM	Enterprise Systems Management
FIPS	Federal Information Processing Standard
FY	Fiscal Year
GUI	Graphical User Interface
HCSR	Health Care Security Requirements
HI	Health Informatics (10P2A)
HIG	Health Information Governance
HIPAA	Health Insurance Portability and Accountability Act
HITSP	Health Information Technology Standards Panel
HL7	Health Level 7
HSI	Health Systems Informatics
IHE	Integrating the Healthcare Enterprise
ISO	International Organization for Standardization
IT	Information Technology
MTRS	Mean Time to Restore

Term	Definition
MVI	Master Veteran Index
NCEHC	National Center for Ethics in Health Care
NIST	National Institute of Standards and Technology
NLB	National Leadership Board
NONF	Non-Functional Requirements
NSR	New Service Request
OI&T	Office of Information and Technology
OIA	Office of Informatics and Analytics
OWNR	Owner Requirement
PHI	Protected Health Information
PII	Personally Identifiable Information
ReqPro	Rational© RequisitePro©
RN	Registered Nurse
SCCM	System Center Configuration Manager
SDS	Standard Data Services
SLA	Service Level Agreement
SLR	Service Level Requirement
SME	Subject Matter Expert
SRSC	Security Requirements Steering Committee
TBD	To Be Determined
TIU	Text Integration Utility
UCD	User Centered Design
UI	User Interface
VA	Department of Veterans Affairs
VAMC	Department of Veterans Affairs Medical Center
VETS	VA Enterprise Terminology Services
VHA	Veterans Health Administration
VistA	Veterans Health Information Systems and Technology Architecture

Appendix G Approval Signatures

The requirements defined in this document are the high level business requirements necessary to meet the strategic goals and operational plans of the National Center for Ethics in Health Care. Further elaboration to these requirements may be done in more detailed artifacts.

Business Owner

Signifies that the customer approves the documented requirements, that they adequately represent the customers desired needs, and that the customer agrees with the defined scope.

Signed: [REDACTED] 01/26/10

[REDACTED] Date

[REDACTED]

Subject: Re: NSR 20090711 iMedConsent Platform Migration - CBJ Business Owner concurrence

Approved

[REDACTED]

Business Liaison

Signifies appropriate identification and engagement of necessary stakeholders and the confirmation and commitment to quality assurance and communication of business requirements to meet stakeholder expectations.

Signed: [REDACTED] 01/08/10

[REDACTED] Date

Sent:

To:

Cc:

Subject: RE: NSR 20090711 iMedConsent Platform Migration - ESM final sign-off

Approved.

Office of Information and Technology

Indicates agreement that the requirements have been received, are clear, understandable, and are documented sufficiently to facilitate project planning when the project is approved and funded. It is understood that negotiations may need to occur with the Business Owner during project planning as a result of technical reviews and feasibility.

Signed:



Appendix H Post Sign-Off Additions

The following additional requirements were identified subsequent to the approval of this document. These requirements were not included in the project scope estimates when this request was considered for approval.

Business Need (BN)	OWNR Number	Owner Requirement (OWNR)	Ranking R=Required O=Optional
BN #4: Software can pull data in from VistA via HL7 messaging.			
	4.1	Provide ability to populate data and establish patient context using HL7 messaging – Automated Data Transfer.	R
	4.2	Provide the ability to auto-populate the patient consent forms with selected patient information that resides in the patient's EHR (e.g., demographics).	R

[Redacted]
Date: _____

<<Business Owner Name and Title>>

[Redacted]
Cc: Frazier, Raymond

Subject: RE: NSR 20090711 iMedConsent Migration - BRD.docx

[Approved via email message above.](#)

Signed: _____

Date: _____

[Redacted]
Subject: RE: NSR 20090711 iMedConsent Migration - BRD.docx

[Ok, thanks.](#)

Appendix I Approval Signatures

The requirements defined in this document are the high level business requirements necessary to meet the strategic goals and operational plans of the National Center for Ethics in Health Care. Further elaboration to these requirements may be done in more detailed artifacts.

Business Owner

Signifies that the customer approves the documented requirements, that they adequately represent the customers desired needs, and that the customer agrees with the defined scope.

Signed:

7/16/14

[Redacted Signature]

Date

[Redacted Signature]

Subject: RE: Approval of NSR Requirements Documents - NSR 20090711 iMedConsent: Migration to a Web-Based Platform

Thank you very much and nice to have spoken with you. I approve this version of the BRD and the updated draft Quad Chart.

Virginia Ashby Sharpe, Ph.D.

[Redacted Signature]

Business Liaison

Signifies appropriate identification and engagement of necessary stakeholders and the confirmation and commitment to quality assurance and communication of business requirements to meet stakeholder expectations.

Signed:

7/21/14

[Redacted Signature]

Date

[Redacted Signature]

Subject: RE: Approval of NSR Requirements Documents - NSR 20090711 iMedConsent: Migration to a Web-Based Platform

I approve.

/r

[Redacted Signature]

[Redacted Signature]

Office of Information and Technology

Indicates agreement that the requirements have been received, are clear, understandable, and are documented sufficiently to facilitate project planning when the project is approved and funded. It is understood that negotiations may need to occur with the Business Owner during project planning as a result of technical reviews and feasibility.

Signed:

<<OI&T Name and Title>>

Date

Include approval message attachments [HERE](#)