

VA Eye Injury Registry
Work Effort Unique Identifying #20130702
Business Requirements Document



December 2013

Revision History

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

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Table of Contents

1. Purpose	1
2. Overview.....	1
3. Customer and Primary Stakeholders.....	2
4. Scope.....	2
5. Goals, Objectives and Outcome Measures	2
6. Enterprise Need/Justification	3
7. Requirements	4
7.1. Business Needs/Owner Requirements	4
7.2. Non-Functional Requirements.....	10
7.2.1. Performance, Capacity, and Availability Requirements	12
7.2.2. Usability Requirements	14
7.3. Known Interfaces	17
7.4. Related Projects or Work Efforts.....	18
8. Other Considerations	18
8.1. Alternatives	18
8.2. Assumptions	19
8.3. Dependencies	19
8.4. Constraints.....	19
8.5. Business Risks and Mitigation	19
Appendix A References	21
Appendix B Models	22
Appendix C Stakeholders, Users, and Workgroups.....	24
Stakeholders	24
Stakeholder Support Team (BRD Development).....	24
Primary and Secondary Users	25
Appendix D Enterprise Requirements	27
Appendix E Acronyms and Abbreviations	26
Appendix F Sample Eye Note	32
Appendix G Approval Signatures	35

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) #[20130702](#) Department of Veterans Affairs (VA) Eye Injury Registry (EIR). 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 does not state the development methodology. The intended audience for this document is the Office of Information and Technology (OIT).

2. Overview

The Office of Specialty Care Services, Veterans Health Administration (VHA), is submitting this request. Dr. Mary G. Lawrence serves as the Business Owner of the VA Eye Injury Registry.

[The National Defense Authorization Act \(NDAA\) of 2008, Section 1623 of Public Law 110-181](#) mandated that the Secretary of Defense establish within the Department of Defense (DoD), a Vision Center of Excellence (VCE). The VCE's vision is to work in the prevention, diagnosis, mitigation, treatment, and rehabilitation of military eye injuries and to collaborate with the Secretary of VA as well as other institutions. In addition to establishing the VCE, the law required DoD to develop and implement an eye injury registry, now known as the DoD Defense and Veterans Eye Injury and Vision Registry (DVEIVR), to track diagnosis, treatment, and follow up care for each case of significant eye injury by a member of the Armed Forces and to ensure the registry has a secure electronic exchange of data with VA.

Section 1623 of Public Law 110-181 requires VA to collaborate with DoD to:

- Add VA data to the DVEIVR pertaining to the treatments, surgical procedures, and outcomes for Veterans who were entered into the registry.
- Gather longitudinal data on eye injuries for improved best practices and safety measures.
- Collect VA data to be shared with DoD to develop the Military Eye Vision Injury Registry, now known as the VA EIR. This registry was developed in 2010 and is a component of the Converge Registries project.

The DVEIVR was developed in 2011 by DoD, utilizing capabilities from the VA EIR. The DVEIVR tracks the diagnosis, surgical intervention, operative procedures, related treatments, and the follow up care for each active duty Service Member that sustained a significant eye injury. DoD ocular medical records are manually created and stored in a Portable Document Format (PDF) format in DoD medical systems; therefore, they require manual abstraction of relevant data for the DVEIVR. This manual data abstraction, from DoD medical record systems into the DVEIVR, was initiated in March 2012. Similar to DVEIVR, the VA EIR is the primary data source of ocular clinical and related data from Service members and Veterans treated in VA medical and rehabilitation facilities and will require manual data abstraction.

Currently, the VA EIR is in maintenance status and no future development is available. The VA EIR Cross Functional Workgroup was established between DoD and VA to review, provide guidance and make recommendations related to the Eye Injury Registry which may include data

requirements, data models, and functional requirements through an ongoing iterative consensus. The new requirements include (but are not limited to) the ability to make VA EIR eligibility determinations, identify relevant encounters, add data fields (e.g. medications, low vision, and blind rehabilitation care), and filter records of patients with serious eye injuries based on International Classification of Diseases (ICD) and Current Procedural Terminology (CPT) codes. Other requirements include system change requests for design changes to facilitate data abstraction processes and reporting capabilities.

These enhancements will support the harmonization of VA and DoD ocular and related clinical data and provide the system changes that will enhance data entry by the data abstractors. Specifically, the system improvements ensure that the same data format is shared between the DoD and VA systems, support eligibility determinations and relevance of data, expand the number and types of VA data fields and elements (e.g. pharmacy data), automate transmission of data on a regular schedule, as well as support accuracy in reporting which is essential for statistical results.

3. Customer and Primary Stakeholders

The primary stakeholder for this request is [REDACTED], MD, MPH, Interim Director of VCE, representing the Office of Specialty Care. Review [Appendix C](#) for the complete list of primary and secondary stakeholders.

4. Scope

Requested enhancements and modifications include:

- The ability to filter and identify eligible Veterans for the VA EIR
- Adding and capturing relevant ocular clinical and relevant data in the VA EIR that is harmonized with the DVEIVR by adding new data fields and modifying existing fields
- System enhancements to facilitate data abstraction.

Data collected must be shared with DoD. DoD will make available to VA the longitudinal data of Service members and Veterans who are cared for in both DoD and VA medical facilities and enrolled in the DVEIVR.

5. Goals, Objectives and Outcome Measures

Goal/Objective and Desired Outcome	Impact	Measurement
Filter list of potential registry enrollees in the VA EIR.	Identification of eligible Veterans (i.e., Veterans with significant eye injuries and visual dysfunction from Operation Enduring Freedom/Operation Iraqi Freedom [OEF/OIF] and Operation New Dawn [OND]) in the VA EIR.	80% of filtered new patients list are eligible for VA EIR.
Determine the eligibility of each enrollee for inclusion in the VA EIR.	Eligible Veterans will be enrolled in the VA EIR.	90% accuracy in eligibility determination.

Goal/Objective and Desired Outcome	Impact	Measurement
Identify additional data fields and elements that will support longitudinal analysis of patient treatments and outcomes.	<ul style="list-style-type: none"> • Availability of relevant data fields and elements for data capture, either digitally or with manual abstraction. • Negative Impact: Limited ability or inability to conduct longitudinal analyses of enrolled Service members and Veterans with serious eye injuries will exist. 	100% compliance with VA required data fields and elements in DVEIVR.
Harmonize VA EIR data fields and elements with the DVEIVR data. Expanding VA EIR data elements for transfer of the data to DVEIVR.	<ul style="list-style-type: none"> • Harmonization of VA EIR and DVEIVR data for interpretation and analysis. • Improve reporting functionality for ocular injuries. • Facilitate timely and accurate reporting of data related to ocular injuries collected by VA and DoD. • Negative Impacts: <ul style="list-style-type: none"> ○ VA will not fully meet the NDAA Congressional 2008 mandate. ○ Significant and profound disparities of data terms between VA and DoD will exist. ○ Limits and prevents reporting capabilities due to missing data fields and elements resulting in non-harmonized data. 	<ul style="list-style-type: none"> • 100% compliance with data definitions and interpretation with VA and DoD data fields and elements. • 98% of data transfer and frequency schedule will meet Service Level Agreement (SLA). • 95% of role based reports will be available to authorized users.
Enhance data abstraction processes to enable statistical analysis of data elements for reporting (e.g., number of Veterans with eye injuries).	Data abstraction processes facilitate reporting on defined data fields and elements.	95% accuracy in the data abstraction of reviewed and manually entered data fields.
Electronically transfer VA EIR data in accordance with agreed upon format and schedule.	VA EIR data transfer is ingested into DVEIVR without conflict.	<ul style="list-style-type: none"> • 95% compliance with timeline for data transfer. • 100% compliance with ingestion of VA data fields and elements harmonized with DVEIVR data fields.

6. Enterprise Need/Justification

Section 1623 of Public Law 110-181, “National Defense Authorization Act of 2008”, established a congressional mandate for an exchange of data between VA and DoD to track the diagnosis, surgical interventions, other treatments, as well as follow up care for each eye injury case for the

purposes of encouraging and facilitating the conduct of research and development of best practices and clinical education.

Under [VHA Strategic Plan 2013-2018](#), this request supports the following goals:

- Facilitate Veterans' personalized, proactive, patient-driven health care.
- Achieve measurable improvements in health outcomes related to eye injuries.
- Align resources to deliver sustained value to Veterans between VA and DoD related to eye injuries.

7. Requirements

7.1. Business Needs/Owner Requirements

ReqPro Tag BN/OWNER Number	Business Need (BN)/Owner (OWNER) Requirement	OWNER Priority*
NEED1555 BN1	Adhere to the Enterprise Level requirements as specifically addressed in Appendix D of this document.	High
NEED2539 BN2	Utilize nationally standardized terminology for all VA Eye Injury Registry enhancements.	High
OWNER170 2.1	Provide the ability to express all content using nationally recognized reference and authoritative terminology standards (e.g., Logical Observation Identifiers, Names, and Codes [LOINC], Systematized Nomenclature of Medicine Clinical Terms [SNOMED CT], etc.).	High
OWNER8836 2.2	Ability to record observations using standardized terms.	High
OWNER8837 2.3	Provide the ability for users to submit a request to Standards and Terminology Services (STS) for new standardized terms (e.g., via New Term Rapid Turnaround [NTRT] process).	High
OWNER11851 2.4	Provide the ability for STS to distribute the newly standardized terms to each instance of VA Eye Injury Registry.	High
NEED2844 BN3	Provide the ability to manage data elements/fields throughout the registry.	High
OWNER11451 3.1	Provide the ability to select "Other" in the list of numeric values.	High
OWNER11452 3.2	Provide the ability to select "Other" in the list of alpha values in drop down list boxes.	High
OWNER12580 3.3	Provide the ability to annotate additional information in the annotation/comment box when "Other" is selected.	High
OWNER12581 3.4	Provide the ability to select the term "Other" within new and existing data element fields when applicable throughout VA EIR.	High
OWNER12582 3.5	Provide the ability to add comments/annotations in each data field annotation box.	High

ReqPro Tag BN/OWNER Number	Business Need (BN)/Owner (OWNER) Requirement	OWNER Priority*
OWNR12583 3.6	Provide the ability to select “Not Documented” in lieu of “Not Recorded” in the Exam Findings tab, and other tabs, to be determined.	Med
OWNR12584 3.7	Provide the ability to select “Unknown” as documented in the medical record.	Med
OWNR12585 3.8	Provide the ability to select one or more data element within a field.	High
NEED2848 BN7	Provide the ability to review registry records prior to submission for quality review.	High
OWNR11454 7.1	Provide the ability to add data to saved registry record prior to submission for quality review.	High
OWNR11455 7.2	Provide the ability to save new data to registry record prior to submission for quality review.	High
NEED2849 BN8	Provide the ability to filter the queue of patient records based on a defined set of data fields.	High
OWNR12586 8.1	Provide the ability to filter patient records based on patient eligibility.	High
OWNR12587 8.2	Provide the ability to filter patient records to determine relevancy of encounters.	High
NEED2852 BN11	Provide the ability to add data fields/elements as needed at the administrator level.	High
OWNR11462 11.1	Provide the ability to add data fields to the visit data.	High
OWNR11463 11.2	Provide the ability to add data fields to the exam findings.	High
OWNR11464 11.3	Provide the ability to add data fields to the treatments (e.g., medications, rehabilitation).	High
OWNR11465 11.4	Provide the ability to add data fields related to outcomes.	High
NEED2854 BN13	Provide the ability to select unilaterality and bilaterality of the eyes throughout the VA Eye Injury Registry.	High
OWNR11466 13.1	Provide the ability to select right eye in exam findings.	High
OWNR11467 13.2	Provide the ability to select right eye in treatment sections.	High

ReqPro Tag BN/OWNER Number	Business Need (BN)/Owner (OWNER) Requirement	OWNER Priority*
OWNR11468 13.3	Provide the ability to select right eye in outcomes section.	High
OWNR11469 13.4	Provide the ability to select left eye in exam findings.	High
OWNR11470 13.5	Provide the ability to select left eye in treatment sections.	High
OWNR11471 13.6	Provide the ability to select left eye in outcomes section.	High
OWNR11472 13.7	Provide the ability to select both eyes in exam findings.	High
OWNR11473 13.8	Provide the ability to select both eyes in treatment sections.	High
OWNR11474 13.9	Provide the ability to select both eyes in outcomes section.	High
OWNR11475 13.10	Provide the ability to select "Not Specified" in the exam findings.	High
OWNR12588 13.11	Provide the ability to select "Not Specified" in treatment sections.	High
OWNR12589 13.12	Provide the ability to select "Not Specified" in outcome sections.	High
NEED2855 BN14	Provide the ability to perform quality review of the manually entered data in the VA EIR.	High
OWNR11476 14.1	Provide the ability to amend the data fields, if needed.	High
OWNR11477 14.2	Provide the ability to annotate for each "amended" data field.	High
NEED2856 BN15	Enable the ability to transmit VA EIR data to DVEIVR in accordance to the pre-defined format.	High
OWNR11479 15.1	Provide the ability to transmit VA EIR data to DVEIVR on a regular, scheduled basis.	High
NEED2857 BN16	Provide the ability for VA EIR to interface with VA systems.	High
OWNR11480 16.1	Provide the ability to interface VA EIR with Compensation and Pension Record Interchange (CAPRI) to obtain eligibility and clinical data.	High
OWNR11481 16.2	Provide the ability to interface VA EIR with the pharmacy package to obtain medication data.	High

ReqPro Tag BN/OWNER Number	Business Need (BN)/Owner (OWNER) Requirement	OWNER Priority*
OWNR11482 16.3	Provide the ability to interface VA EIR with DVEIVR to transfer VA ocular related patient data.	High
OWNR11483 16.4	Provide the ability to interface VA EIR with VA Authenticated Federation Infrastructure (VAAFI) in order to transfer data from VA EIR and DoD DVEIVR.	High
OWNR11484 16.5	Provide the ability to interface VA EIR with the VA authoritative source (e.g., Master Veteran Index [MVI], VA /DoD Identity Repository [VADIR]) to obtain patient demographic data that is consistent with DoD identification requirements.	High
OWNR11485 16.6	Provide the ability to interface VA EIR with the Implant Registry (e.g., Veterans Implant Tracking and Alert System [VITAS], Surgical Quality Workflow Manager [SQWM], or any other application/registry that may be applicable).	Medium
OWNR11486 16.7	Provide the ability to interface VA EIR with the prosthetics data source.	Medium
OWNR11487 16.8	Provide the ability to collect data from eye care point of service testing devices.	Medium
NEED2858 BN17	Provide the ability for voice recognition.	Low

*All listed requirements are needed by the business community. The Priority is merely a mechanism to suggest a sense of urgency and order to the technical community if the requirements are to be parsed into phases. The order of importance begins with those that are designated as High priority.

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 (Note: Each system developed by VA OIT <u>must</u> comply with the following mandatory requirements.)
	System Performance Reporting Requirements
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 non-functional requirements section of this document.
NONF2812	Make the performance measurements available to the IT Performance Dashboard to enable display of “actual” system metrics to customers and IT staff.
	Operational Environment Requirements
NONF2703	System response times and page load times shall be consistent with OIT standards (e.g. My HealtheVet or HealtheVet).

ReqPro Tag	Non-Functional Requirements (NONF) Category (Note: Each system developed by VA OIT <u>must</u> comply with the following mandatory requirements.)
NONF1780	Maintenance, including maintenance of externally developed software incorporated into the VA EIR, shall be scheduled during off peak hours or in conjunction with relevant Corporate Data Center Operations (CDCO) maintenance schedules.
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 OIT to provide accurate data in the service impact notice of the ANR.
NONF1609	Provide a real-time monitoring solution to report agreed/identified critical system performance parameters.
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 OIT performance dashboard display. If no such performance metrics are required or provided, there will be no program specific SLA created, nor shall there be any active/real time monitoring through the OIT 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.
	Documentation Requirements
NONF1612	A technical training curriculum shall be developed and delivered to all levels of staff users.
NONF2916	The training curriculum shall state the expected training time for primary users to become proficient at using the VA EIR.
NONF2913	All training curricula, user manuals and other training tools shall be developed/updated by VA EIR data abstractor contract, reviewed and approved by the Office of Specialty Care, and delivered to authorized users. The expected time for development of the initial training materials is four weeks and delivery will be via face-to-face training. These requirements are expected to be met two weeks in advance of the release of the enhancement through face-to-face sessions, user manuals, and PowerPoint presentations. The curricula shall include all aspects of the enhanced VA EIR and all changes to processes and procedures.
NONF3131	The training curriculum developed by the VA EIR data abstractor contract shall state the expected task completion time for primary users.
NONF2228	User manuals and training tools shall be developed. If they already exist, updates shall be made, as necessary, to them and they shall be delivered to all levels of users.

ReqPro Tag	Non-Functional Requirements (NONF) Category (Note: Each system developed by VA OIT <u>must</u> comply with the following mandatory requirements.)
NONF2910	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 [REDACTED]. This documentation shall be provided prior to approval by any VA change control board and release into production.
	Implementation Requirements
NONF2645	Technical Help Desk support for the application shall be provided for users to obtain assistance with access and errors.
NONF1614	The IT solution shall be designed to comply with the applicable approved Enterprise SLA.
NONF2914	The implementation must be completed one year from the contract award date.
	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.
NONF2915	Data protection measures, such as backup intervals and redundancy shall be consistent with systems categorized as a patient registry.
	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 D).

7.2.1. Performance, Capacity, and Availability Requirements

7.2.1.1. Performance

If this is a system modification, how many users does the current system support?
The current VA EIR has been limited to developers, testers, and stakeholders responsible for user acceptance testing. Therefore, the existing system supports 12 users and 2 transactions simultaneously. VA EIR currently has 15 authorized users; 12 active users and 3 inactive users.
How many users will the new system (or system modification) support?
The estimated number of users is 80, which includes an initial ramp up of 30-32 data abstractors, one database administrator, two quality reviewers, a trainer, and two Subject Matter Experts (SMEs). The estimated number of concurrent users in the ramp up is 35. Stakeholders and other authorized staff are expected to increase to 80 users.
What is the predicted annual growth in the number of system users?
The estimated number of users may increase by 25% in Fiscal Year (FY) 15, dependent on availability of funding for data abstractors.

7.2.1.2. Capacity

What is the predicted size (average) of a typical business transaction?
The current size of a typical business transaction is equivalent to an outpatient medical encounter. Because the majority of ocular/vision encounters are outpatient encounters, the predicted size is based on the encounter stored in CPRS. The transaction requires data entry in check boxes, drop down boxes, and manual documentation in an annotation box. The annotation box size is 4000 characters; however, business rules are expected to limit the number of characters for data entry.
What is the predicted number of transactions per hour (day, or other time period)?
A transaction for the data abstraction process is defined as completion of an encounter and submission for quality review and submission for transfer to the DVEIVR. An estimated one encounter per hour, per work day, per data abstractor. Due to start up requirements, security clearances, and training in FY14, an estimated average of 4 data abstractors will abstract ocular and related data from CAPRI into the VA EIR.
Is the transaction profile expected to change (grow) over time?
An increase in the number of data abstractors will increase the number of transactions. An increase of 25% is expected in FY15 depending on funding, time to receive security clearances, and staff training.
What is the process for planning/adjusting capacity?
The process planned for planning/adjusting capacity will include developing and periodically reviewing and analyzing VA EIR management reports of utilization by type of user, length of time to save/review/submit records, number of records submitted, number of records in the queue, system issues, and implementation of requested capabilities and system change requests. In parallel, there will be discussions with VA leadership on any need for additional funds.
Does the update require a surge capacity that would be different from the base application?
Based on the application, there should not be a need for surge capacity.

7.2.1.3. Availability

Describe when the envisioned system will need to be available (business hours only, weekends, holidays, etc.) to support the business.
<p>The hours of operation for data abstraction are expected to be Monday through Friday, based on flex time, from 7 am - 5 pm EST. The holiday schedule will be consistent with the vendor's holiday policies. The data abstraction support services are performed in contractor space. The vendor is expected to provide a Continuity of Operations Plan (COOP) for emergencies. Data abstraction will not be performed outside of the contractor designated workspace without the express permission of the Government. System maintenance should not occur during data abstraction time; preferred times are either after hours or weekends. The system needs to be available in accordance with VA access requirements for non-medical record systems.</p> <p>The VA EIR would require ongoing OIT operational system-level support, including:</p> <ul style="list-style-type: none">• A formal agreement between the Austin Information Technology Center (AITC) and OIT to support operations• Security Accreditation and Certification• System availability of 10 hours per day / 5 days per week• A Service Desk response time of 12 Hours• Daily incremental backups

- | |
|--|
| <ul style="list-style-type: none">• A maintenance window of 8 hours, scheduled monthly• Routine support of business continuity levels |
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7.2.2. Usability Requirements

User Experience encompasses the entire interaction between the user and the system. This includes direct interaction with the system, as well as other interactions, understanding, awareness, perceptions, beliefs, feelings, and actions that result from that interaction. One key component of the user experience is the usability of the system. Improving usability over the prior version is a key requirement for the VA EIR.

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).

In order for the VA EIR to achieve a good user experience for users who interact with it, the system must meet the requirements outlined in this section. These involve attributes of the application as well as the process that is 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 (ONCHIT) Meaningful Use (MU) 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 (NISTIR) 7741, ISO/International Electrochemical Commission (IEC) 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 data abstraction processes and workflow

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 (GUI) 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 filtering capabilities, to include:

- 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 data abstractor use of the prior version
- Address the specific findings reported from usability testing of the prior version or relevant prototypes

The application design should be modified to address the following UI guidelines provided in the table below, as applicable:

ReqPro Tag	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.
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.

ReqPro Tag	Usability/User Interface Requirements
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).
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.

ReqPro Tag	Usability/User Interface Requirements
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.

7.3. Known Interfaces

This is the business community’s best understanding of known interfaces and may not be a comprehensive listing. All required interfaces will be stated as Business Needs in [Section 7.1](#).

Name of Application	Description-of current application	Interface Type	Existing Functionality	Deliverables
CAPRI, Vista Web/VistA	Source of ocular and related medical data	Automated and Manual	Yes	Medical records of eligible VA EIR enrollees
Electronic Eye Note Application	Source of ocular and related medical data	To Be Determined (TBD)	No	Eye/vision medical records of eligible VA EIR enrollees
Eye Clinic Point of Service (POS) devices (visual field analytics)	Source of ocular or vision testing data	TBD	No	Test data and variables
Pharmacy	Source of enrollees’ medication list	Automated or Manual	No	Pharmacy data of eligible VA EIR enrollees

Name of Application	Description-of current application	Interface Type	Existing Functionality	Deliverables
DVEIVR	Source of VA and DoD ocular and related data	Automated	Yes	VA EIR data ingested into DVEIVR, VA and DoD reports
AITC	Source to manage hardware process	Automated	Yes	Hardware support
VA Authentication Federation Infrastructure	Source used to transfer data to DoD Registry	Automated	Yes	Protocol/gateway used between VA and DoD to transmit VA EIR data
VA Authoritative source of demographic data (e.g. MVI, VADIR) Actual source TBD	Source of demographic data	Automated	Yes	Patient demographic will automatically populated as computable data
VA Implant Registry data source	Source of data related to implant devices	Automated	No	Eye Implant device data for eligible VA EIR enrollees
Prosthetics Device data source	Source of prosthetic data	Automated	No	Prosthetic eye/vision device data for eligible VA EIR enrollees

7.4. Related Projects or Work Efforts

VA-DoD Joint Eye Injury Registry (NSR# [20080213](#))

In March 2008, VA created the Military Eye/Vision Injury Registry BRD for this NSR. The objective of the initial BRD stated the need for an ability to identify Veterans with significant eye injuries in OEF/OIF/OND and then document short and long term visual outcomes. Data collected must be shared with DoD to longitudinally document visual outcomes for these Veterans.

8. Other Considerations

8.1. Alternatives

In 2008, VA reviewed the analysis of alternatives for compliance with the NDAA requiring the establishment of a military eye injury registry. VA and DoD stakeholders determined at that time that there would be one Military Eye Injury Registry and that DoD would develop and manage that application. In order for VA to provide data to the DoD registry, VA identified the need to develop the VA EIR. In the VA, the ocular and related data on eye injuries and vision dysfunctions are stored in a Text Integration Utility (TIU) note in the Computerized Patient Record System (CPRS) which is not standardized throughout the organization. (See [Appendix F](#) for a sample Eye Exam Note.) The VA EIR allows VA digital data and annotations to be electronically transferred to the DVEIVR. The ingestion of VA data with DoD data allows reporting of VA and/or DoD data for analysis of long-term outcomes of the eye injuries and vision dysfunction as required by legislation.

8.2. Assumptions

It is assumed that the registry and its components will:

- Derive digital and/or manually extracted data from the VA medical record (accessed through CAPRI/VistA) necessary to populate the VA EIR.
- Securely transmit data in a unidirectional manner from VA to DoD on a regular, recurring basis.
- Provide role-based access to authorized users of the VA EIR through an easy, user-friendly interface with the ability to read, write, edit, delete, and/or query data.
- Provide a connection to other VA data sources, such as the Pharmacy applications or Traumatic Brain Injury (TBI) registry based on specific functional requirements. Details of this request have yet to be fully analyzed for functionality.
- Conform to VA data standards and information technology and management best practices.
- It is anticipated that the business needs and requirements identified in this document will be developed by OIT in the VA EIR.

8.3. Dependencies

- The VA EIR data transfer is dependent upon maintaining the VA and DoD agreements that allow for abstraction of data by contracted staff (data use agreement) and data transfer agreement that permits the electronic transfer of data from VA EIR to the DEIVR.
- CAPRI/VistA must be operational in order to transmit computable data to the VA EIR and accessible to the data abstractors to manually extract other ocular and related data into the VA EIR.
- If the VA pharmacy application is selected, it must be operational in order to transmit the data for the display of medications and related data.
- Data abstractors, quality reviewers, database administrators, and SMEs must meet and receive security clearances from the Office of Personnel Management (OPM).
- Data abstractors must have access to the training resources dependent upon a VA email account.
- AITC and VAAFI support is dependent upon an SLA between VCE and VA.
- Lack of funding for this project would not meet the requirements of the NDAA for VA sharing data with DoD and would be a lost opportunity to harmonize data between VA and DoD for ocular injured Veterans. Funding for this project could impact Veteran health care by limiting the ability to access longitudinal record of treatments and outcomes in order to identify opportunities to develop best practices to enhance vision outcomes.

8.4. Constraints

This registry will only contain pre-determined data that is provided from VA source medical systems, such as CAPRI/VistA, pharmacy, and other ocular clinical data.

8.5. Business Risks and Mitigation

Business Risks	Mitigation
Funding	Prioritize the functional requirements to first address critical capabilities, enabling complete and accurate longitudinal data collection. When additional funding is available, complete development of the remaining requirements.

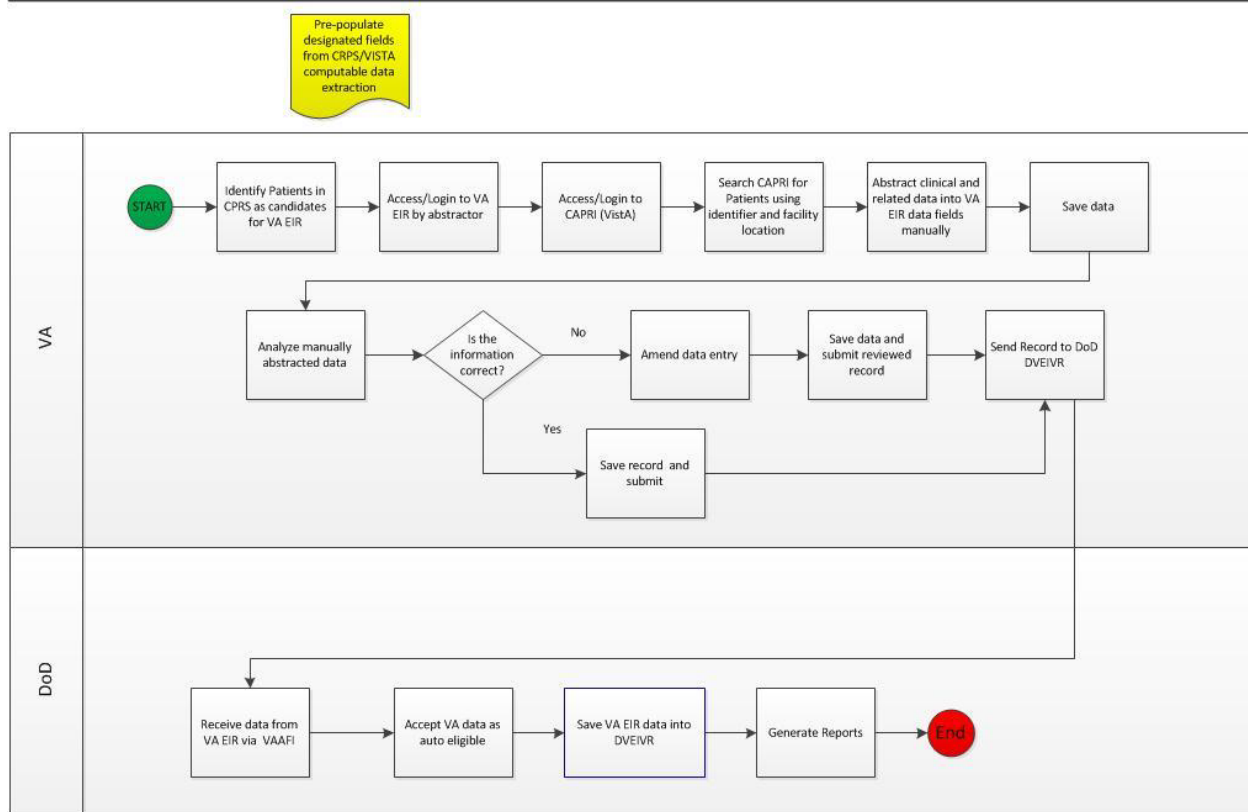
Business Risks	Mitigation
Inability to harmonize data	Limit transfer of VA EIR data to DVEIVR so that only “As-Is” harmonized data is available for reporting and analysis.
Inability to add new registry capabilities	Clinicians, researchers, and policy makers seeking longitudinal data will be required to request access to CPRS VA medical records in order to collect the additional ocular and related clinical data of VA patients with eye injuries or vision impairment.

Appendix A References

- Public Law 110-181-January 28, 2008
<http://www.gpo.gov/fdsys/pkg/PLAW-110publ181/pdf/PLAW-110publ181.pdf>
- VA Handbook 6500 – Information Security Program
[REDACTED]
- VHA Strategic Plan 2013-2018
[REDACTED]

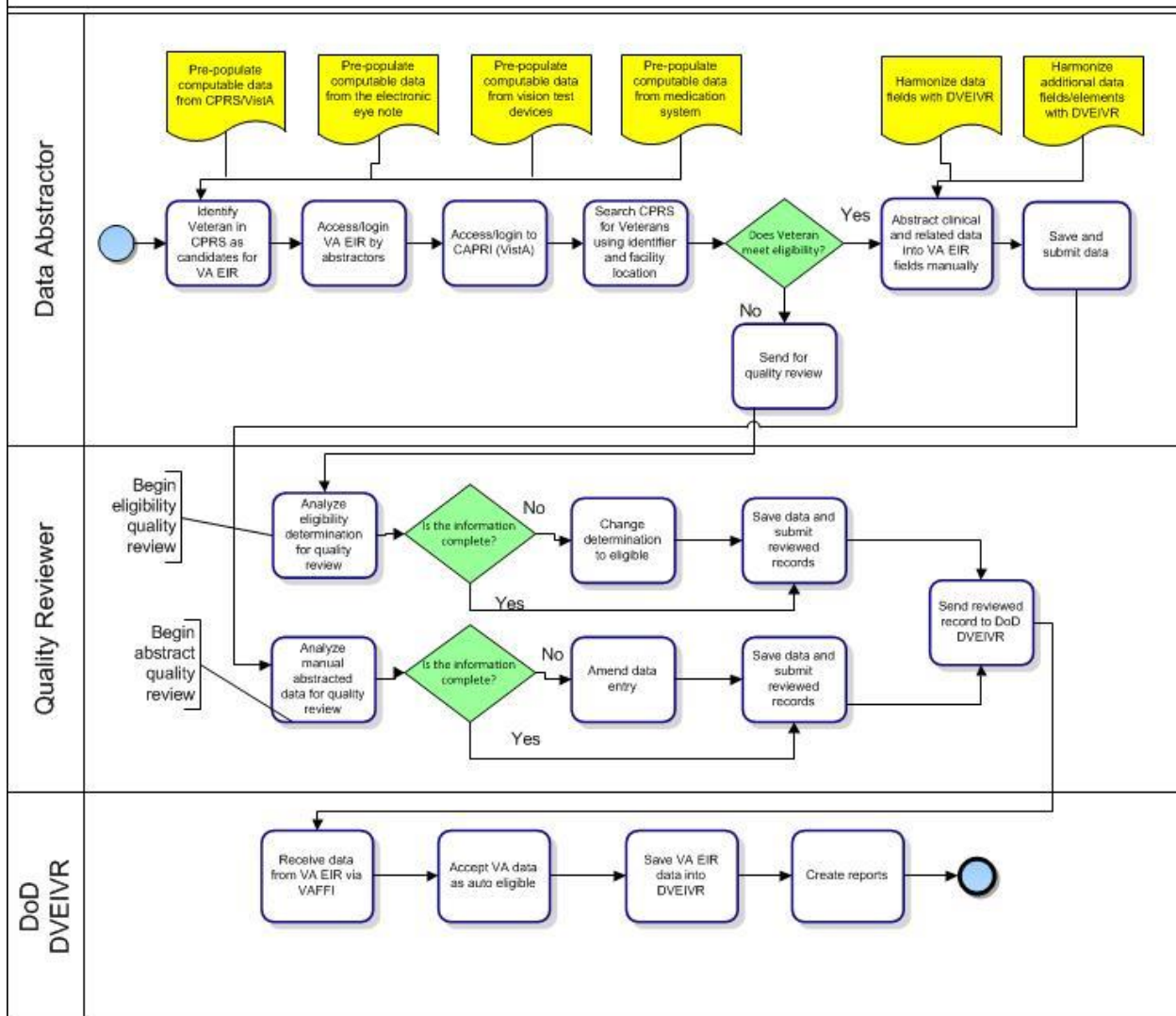
Appendix B Models

NSR #20130702 VA Eye Injury Registry
Name of Process (As-Is)



Created by [REDACTED]
Date: 11/23/2013

NSR 20130702 – VA Eye Injury Registry
Name of Process (To-Be)



Appendix C Stakeholders, Users, and Workgroups

Stakeholders

Type of Stakeholder	Description	Responsibilities
Requester	██████████ Interim Executive Director, VCE	Submitted request. Submits business requirements. Monitors progress of request. Contributes to BRD development.
Endorser	██████████ Principal Deputy Under Secretary for Health	Endorsed this request. Provides strategic direction to the program. Elicits executive support and funding. Monitors the progress and time lines.
Business Owner/ Program Office	██████████ Interim Executive Director, VCE	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	██████████ Physician Informaticist, Health Service Provider Management	Provides background on current system and processes. Describes features of current systems, including known problems. Identifies features of enhancement.
Technical SMEs	<ul style="list-style-type: none"> • ██████████ ██████████ Project Manager, VA OIT • ██████████ Director of Informatics and Information Management, VCE • ██████████ Director of Technology, VCE 	Provide technical background information about the current software and requested enhancements.
User SMEs	<ul style="list-style-type: none"> • ██████████ National Program Director, VA Ophthalmology Services • ██████████ Clinical Quality Specialist, Office of Informatics and Analytics • ██████████ Assistant Director of Informatics, VCE • ██████████ Interim Executive Director, VCE 	Ensure 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	██████████ Program Analyst, Health Care Security Requirements	Responsible for determining the Assessment & Authorization (A&A) and other security requirements for the request.
Service Coordination SME	██████████ Management Analyst, Office of Health Information	Responsible for ensuring all aspects of non-functional requirements have been accurately recorded for this request.
Health Enterprise Systems Portfolio Management Staff	<ul style="list-style-type: none"> • ██████████ Health Systems Manager, Health Systems Provider Management • ██████████ Program Analyst, Health Systems Provider Management • ██████████ Clinical Informaticist, Health Systems Provider Management 	Serve as the liaison between the Program Office (Business Owner) and Product Development throughout the lifecycle.
Strategic Investment Management (SIM), Requirements Development and Management (RDM)	██████████ Program Analyst, Requirements Development and Management	Responsible for working with all stakeholders to ensure the business requirements have been accurately recorded for this request.
User Acceptance Testers	<ul style="list-style-type: none"> • ██████████ Interim Director, VCE • ██████████ Assistant Director of Informatics, VA Central Office • ██████████ National Program Director, VA Ophthalmology Services • ██████████ Quality Specialist, Office of Informatics and Analytics 	Responsible for the incremental testing of the application throughout the project.

Primary and Secondary Users

Type of User	Description	Responsibilities
Primary Users	VCE Management Staff	Administrative and management responsibility for VCE and Data Abtractor Support Services Contract for DoD and VA. Establish policies and procedures. Manage and oversee quality assurance processes. May be authorized to read Eye Registry records.
Primary Users	VCE/VA EIR Database Administrator(s)	Maintain integrity on VA EIR system. Purge records based on policy. Manages access, roles and responsibilities of VA EIR.

Type of User	Description	Responsibilities
Primary Users	VHA VA EIR Management Staff	Administrative responsibility for VA EIR. Establishes VA registry policies and procedures. May be authorized to read Eye Registry records.

Appendix D 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 OIT 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 Federal Information Processing Standard (FIPS) 199 and National Institute of Standards and Technology (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	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.
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 Health Level Seven (HL7) Continuity of Care Document (CCD) Component.

Appendix E Acronyms and Abbreviations

OIT Master Glossary:

Term	Definition
A&A	Assessment & Authorization
AITC	Austin Information Technology Center
ANR	Automated Notification Reporting
BN	Business Need
BRD	Business Requirements Document
CAPRI	Compensation and Pension Record Interchange
CCD	Continuity of Care Document
CDCO	Corporate Data Center Operations
COOP	Continuity of Operations Plan
CPRS	Computerized Patient Record System
CPT	Current Procedural Terminology
DoD	Department of Defense
DVEIVR	Defense and Veterans Eye Injury and Vision Registry
EDES	Emergency Department Encounter Summary
EIR	Eye Injury Registry
ENTR	Enterprise Requirements
FIPS	Federal Information Processing Standard
FY	Fiscal Year
GUI	Graphical User Interface
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
ICD	International Classification of Diseases
IEC	International Electrochemical Commission
IHE	Integrating the Healthcare Enterprise
IPT	Integrated Project Team
ISO	International Organization for Standardization
IT	Information Technology
LOINC	Logical Observation Identifiers, Names, and Codes
MU	Meaningful Use
MVI	Master Veteran Index

Term	Definition
NDA	National Defense Authorization Act
NIST	National Institute of Standards and Technology
NISTIR	National Institute of Standards and Technology Interagency Report
NONF	Non-Functional Requirement
NSR	New Service Request
NTRT	New Term Rapid Turnaround
OEF	Operation Enduring Freedom
OIF	Operation Iraqi Freedom
OIPT	OIT Integrated Project Team
OIT	Office of Information and Technology
ONCHIT	Office of the National Coordinator for Health Information Technology
OND	Operation New Dawn
OPM	Office of Personnel Management
OWNR	Owner Requirement
PDF	Portable Document Format
POS	Point of Service
RDM	Requirements Development and Management
ReqPro	Rational® RequisitePro®
SDS	Standard Data Services
SIM	Strategic Investment Management
SLA	Service Level Agreement
SME	Subject Matter Expert
SNOMED CT	Systemized Nomenclature of Medicine Clinical Terms
SQWM	Surgical Quality Workflow Manager
STS	Standards and Terminology Services
TBD	To Be Determined
TBI	Traumatic Brain Injury
TIU	Text Integration Utility
UCD	User Centered Design
UI	User Interface
VA	Department of Veterans Affairs
VAAFI	VA Authentication Federation Infrastructure
VADIR	VA/DoD Identity Repository

Term	Definition
VCE	Vision Center of Excellence
VETS	VA Enterprise Terminology Services
VHA	Veterans Health Administration
VistA	Veterans Health Information Systems and Technology Architecture
VITAS	Veterans Implant Tracking and Alert System

Appendix F Sample Eye Note

Note: Eye notes are not a standardized template throughout VA.

Template: EYE Comprehensive Exam

COMPREHENSIVE EYE EXAM:

☐ Type of Visit:

☐ HISTORY:

☐ Hemoglobin A1C:
HEMOGLOBIN A1c, INTEGRA - NONE FOUND

☐ VISUAL ACUITY:

FAR NEAR (this will line up properly in the note)

OD: 20/ OS: 20/

OD: 20/ OS: 20/

☐ ADWEKAE/FACE/LIDS: ☒ External unremarkable

☐ Motilities:

Prism Diopters:

☐ Confrontation Fields:

☐ Pupils: OD: Size: React:
OS: Size: React:

☐ Relative APD:

☐ Slit Lamp Exam

☐ Lids: OD: OS:

☐ Conjunctiva: OD:
OS:

☐ Cornea: OD:
OS:

☐ Topography: OD: ☐ Normal ☐ Abnormal
OS: ☐ Normal ☐ Abnormal

☐ Pachymetry: OD:
OS:

☐ Ant. Chamber: OD:
OS:

All None * Indicates a Required Field Preview OK Cancel

Template: EYE Comprehensive Exam

☐ Iris: OD: OS:

☐ Lens: OD: Grade:
OS: Grade:

☐ Tonometry: OD: OS:

☐ Meds:

☐ DFE:

☐ See Drawing

☐ NDPE

☐ (Check here to include in the note)
(----- IMPRESSION/PLAN -----)
IMPRESSION/ASSESSMENT:
(List: All symptoms or definitive diagnosis evaluated - including stability.
List: Management, new medications/med changes, tests ordered with indication.
List: F/U, consults, and diagnostic procedures ordered with indication)
*** Include stability and management options ***

1.
2.
3.
4.
5.

MANAGEMENT/PLAN:
(Include:
Tests and diagnostic procedures ordered - including indications
New medications and changes to existing medications
Follow up appointments and consults to be scheduled)

1.
2.
3.
4.
5.

(REMEMBER: Update the electronic problem list as needed.)

☐ Return to Clinic in ☐ days ☐ weeks ☐ months ☐ years .

* Indicates a Required Field

Template: EYE Comprehensive Exam

☐ Lens: OD: Grade:
 OS: Grade:

☐ Tonometry: OD: OS:

☐ Meds:

☐ DFE:

☐ See Drawing

☐ NDFE

☐ (Check here to include in the note)

(----- IMPRESSION/PLAN -----)

IMPRESSION/ASSESSMENT:
 (List: All symptoms or definitive diagnosis evaluated - including stability.
 List: Management, new medications/med changes, tests ordered with indication.
 List: F/U, consults, and diagnostic procedures ordered with indication)
 *** Include stability and management options ***

1.
 2.
 3.
 4.
 5.

MANAGEMENT/PLAN:
 (Include:
 Tests and diagnostic procedures ordered - including indications
 New medications and changes to existing medications
 Follow up appointments and consults to be scheduled)

1.
 2.
 3.
 4.
 5.

(REMEMBER: Update the electronic problem list as needed.)

☐ Return to Clinic in ☐ days ☐ weeks ☐ months ☐ years .

☐ Discussed with Dr.

☐ Discussed with and examined by Dr.

All None * Indicates a Required Field Preview OK Cancel

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 Program Office of Specialty Care. Further elaboration to these requirements will 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 Signature]

[Redacted Title]

[Redacted Position]

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], Health Systems Manager, VHA

Date

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 during project planning as a result of technical reviews and feasibility.

Signed:

[Redacted], VA OIT Project Manager

Date