

REDCap e-Docs Module Requirements Traceability Matrix

Document Version: 1.0

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REDCap eDocs Module
Requirements Traceability
Matrix

Document Version: 1.0

Prepared by:

Prepared by:

I have prepared the contents of this document and agree that the provisions contained herein are appropriate and consistent with current regulatory expectation for computer validation, internal policies and procedures and available FDA industry Guidance and I tender it for approval.

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I have reviewed the contents of this document and accept and approve of the provisions as stated herein are appropriate and consistent with current regulatory expectation for computer validation, internal policies and procedures and available FDA industry Guidance and I tender it for approval.

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Company: Vanderbilt University Medical Center

Paul Harris, Management, VUMC

Revision History

Date	Version	Description
31-Mar-2020	1.0	Original Release, New Document

1. Purpose

The purpose of this Requirements Traceability Matrix (RTM) is to ensure that all the requirements defined for eDocs Module within REDCap system are verified (tested) in the system qualification activities. The RTM is a document to map and trace user requirements with the qualification test cases to ensure adequate level of testing is being achieved. This requirements traceability refers to the ability to follow the life of a requirement, in both forwards and backwards direction, i.e., from its origins, through its development and specification, to its subsequent deployment and use, and through periods of ongoing refinement and iteration.

2. Scope

The scope of this document is limited to the association of the user requirements to the test cases executed in the validation activities of REDCap system. The traceability Matrix provides bi-directional traceability from the high-level user requirements to the functional specifications, configuration/design specifications to the test scripts executed during the system qualification activities.

3. References

The following reference documents were utilized to generate the Requirements Traceability Matrix.

Document/Deliverable	Version	Completion
REDCap eDocs Module User Requirements Specification	1.0	16 Feb 2020
REDCap eDocs IQ Test Protocol	1.0	17 Feb 2020
REDCap eDocs PQ Test Protocol	1.0	17 Feb 2020
SOPs/Release Training	1.0	31-Mar-2020

4. Acronyms and Definitions

TERM	DEFINITION
RTM	Requirement Traceability Matrix
URS	User Requirement Specification
FS	Functional Specification
CSDS	Configuration Specification / Design Specification

5. Requirements

Each requirement will include a proposed verification mechanism. This will be identified in the 'Verification' column below. Verification methods include:

- P - Procedural controls will be verified to satisfy these requirements.

- T - Formal testing will be executed to document that these requirements are satisfied.
- V - Verification will be performed and documented that these requirements are satisfied.
- N/A - Requirement may not be verified in the scope of this project.

Some requirements may have multiple verification methods.

This section shall state the requirements: installation, system, security, regulatory, user/functional, instrument interface and risk mitigation (if necessary). The contents of this section shall define the environment in which the system must operate, the interface, data and reporting, as applicable.

A set of criteria will also be applied resulting in a prioritization of each user requirement on a scale from 1-3.

The priority levels are defined as:

- Priority (3): the user requirement is mandatory and must be implemented in the scope of the project. Essential to business operations; a mandatory function or requirement.
- Priority (2): the user requirement is strongly expected and may be implemented after this project or highly desirable to business operations; would provide significantly enhanced benefit but is not critical.
- Priority (1): the user requirement is "Optional" and may not be implemented nor tested in the scope of the project ("Nice to have" requirement) or for future business operations; nice to have feature or requirement.

Priority 3 requirement is mandatory, and a functional solution must satisfy the requirement. Priority 2 or 1 requirements are optional and do not need to be tested or satisfied in this retrospective validation effort.

6. Traceability Matrix Table

Req#	Requirement	Verification	Priority	Traceability	Test Result
1	Data Requirements				
1.1	System shall allow a file upload size up to a maximum of 50 mb The file upload will generally have a size requirement of 10-100kb but can be as large as 50 mb.	T	3	PQ-eDocs Steps 4 and 5	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2	eDocs Core Functionality				
2.1	Basic Demographic form Development				
2.1.1	System shall permit inclusion of eDoc file upload process in any data collection instrument. System will allow for the inclusion of the eDocs file upload process in any data collection instrument created within the system framework.	T	3	PQ-eDocs Step 5	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.2	eDocs File Versioning				



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Req#	Requirement	Verification	Priority	Traceability	Test Result
2.2.1	System shall maintain version history of a file upload field or a form on the survey. File version history shall maintain previous version(s) of a file upload field or a form on the survey.	T	3	PQ-eDocs step 40	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.2.2	System shall allow a user to delete file from the data collection field. NOTE: This is an administrative function. The file will be deleted on REDCap instance but retained in the 'Vault'.	T	3	PQ-eDocs step 42	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.2.3	System shall allow a user to overwrite and upload a new version of the current file while maintaining the current version in the file upload field.	T	3	PQ-eDocs step 40	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation



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Req#	Requirement	Verification	Priority	Traceability	Test Result
2.2.4	System shall provide an ability to download files from previous versions of an uploaded file.	T	3	PQ-eDocs step 41	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.2.5	System shall create a version of a file only when the file is saved.	T	3	PQ eDocs step 26	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.2.6	System shall maintain version history for files that will be Uploaded.	T	3	PQ-eDocs step 40	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation



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Req#	Requirement	Verification	Priority	Traceability	Test Result
2.2.7	System shall maintain a version history which shall include the following: <ul style="list-style-type: none">• Date/Time of Upload• User• File Uploaded• File Version• Information / Action NOTE: <i>Information / Action includes information about deleted files</i>	T	3	PQ-eDocs step 40	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.2.8	Logging history shall include the following: <ul style="list-style-type: none">• Date and time of the activity• Username performing the action• File information and action block	T	3	PQ eDocs step 21 PQ-eDocs step 47 PQ-eDocs step 48	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.2.9	System shall allow a user to download a file from the file history in the Information / action field.	T	3	PQ-eDocs step 41	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation



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Req#	Requirement	Verification	Priority	Traceability	Test Result
2.2.10	System shall allow a user to delete a file from the file history in the Information / action field.	T	3	PQ-eDocs step 41	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.2.11	System shall retain deleted eDocs from REDCap database into the vault storage,	T	3	PQ eDocs step 14 PQ-eDocs step 44	<input type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Deviation (eDocs - I/PQ - 004)
2.2.12	System shall enforce a mechanism to provide a reason for deletion prior to deletion of file.	T	3	PQ eDocs step 21 PQ-eDocs step 41	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation



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Req#	Requirement	Verification	Priority	Traceability	Test Result
2.2.13	System shall store date and time of the deleted file.	T	3	PQ eDocs step 21 PQ-eDocs step 42	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.2.14	System shall retain reason of deletion of the deleted file.	T	3	PQ eDocs step 21 PQ-eDocs step 48	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.2.15	System shall be able to export entire data collection instrument into a CSV file format.	T	2	PQ eDocs step 27	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation



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Req#	Requirement	Verification	Priority	Traceability	Test Result
2.2.16	System shall provide a capability to download documents from eDocs module from Data Exports, Reports, and Stats.	T	2	PQ-eDocs step 49 PQ-eDocs step 50 PQ-eDocs step 51	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.2.17	System shall provide a capability to upload documents into eDocs module from Data Exports, Reports, and Stats.	T	2	PQ-eDocs step 52	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.2.18	System shall be capable of performing the following: <ul style="list-style-type: none">• Upload New File• Remove File• Send file as an email	T	3	PQ eDocs step 4 PQ eDocs step 7 PQ eDocs step 9	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.3	Password verification & automatic external file storage				



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2.3.1	The system will allow any given project to utilize extra functionality regarding the use of file upload fields in the project.	T	3	PQ eDocs step 4	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.3.2	The system will ask to confirm that the file is correct while uploading and additionally ask the user to enter the REDCap password for the verification process	T	3	PQ eDocs step 5	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
4.3.4	The system will notify to save the changes or leave without saving the changes or stay on the page if the user proceeds without saving the record.	T	3	PQ eDocs step 28	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.4 4.4.	Post Signature Form Updates and Versioning				



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2.4.1	All versions of the files will be maintained within the project “vault.”	T	3	PQ eDocs step 14	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.4.2	System shall maintain all versions of the files on REDCap servers	T	3	PQ-eDocs step 53	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.5	Executed eDocs Storage				
2.5.1	An appropriate “vault” will be set-up for each project.	T	3	IQ-eDocs Step 8 PQ eDocs step 14	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation



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2.5.2	The Vault will have limited access only to administrators of the Local Network.	T	3	IQ-eDocs Step 11	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.5.3	The Vault will have write once read many configurations.	T	3	IQ-eDocs Step 11	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.5.4	The Vault environment will be backed up daily.	T	3	IQ-eDocs Step 12	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation



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2.5.5	The Vault will have data encryption enabled.	T	3	IQ-eDocs Step 13	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.6	SFTP storage				
2.6.1	eDocs will interface with an SFTP storage location.	T	3	IQ-eDocs Step 10	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.6.2	eDocs will not interface with any other systems directly other than the storage SFTP or "vault."	T	3	IQ-eDocs Step 9	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
Non-Functional Requirements					
All non-functional requirements not specified in this document are defined by data and application architectures and SOPs.					
Regulatory Information					



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2.6.3	This system is subject to FDA 21 CFR Part 11, Electronic Records; Electronic Signatures and other global system regulations.	T / P	3	PQ-eDocs Step 3 & 6 Operation SOP Section 1 step 7	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.7	Special Remote Use				
2.7.1	eDocs does not allow for off-line usage.	T	3	PQ-eDocs Step 34	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.8	Documentation and Training				
2.8.1	The eDocs validation documentation will be maintained by Stride program at Vanderbilt University.	V	3	Validation Plan	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation



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2.8.2	The eDocs validation package will provide the basic design and associated functionality and testing to demonstrate that the application performs in an accurate and reliable manner.	V	3	Validation Plan	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.8.3	Training for eventual users of the eDocs module will be provided in association with the REDCap training modules.	V	3	PQ-eDocs Step 36	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.8.4	There WILL BE training on regulated use of the eDocs and configuration considerations necessary for compliant use and control of the product.	V	3	PQ-eDocs Step 36	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.9	Availability and Recoverability				



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2.9.1	Disaster recovery and business continuity planning along with testing evidence will be developed and executed for the eDocs system and environment, effectively demonstrating the ability to recover and not lose data in the event of an outage or issues with the system or hosting environment.	T	2	IQ and PQ REDCap Database backup and restore procedure	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.10	Performance				
2.10.1	There are no known performance risks or limitations with the eDocs module within the REDCap application. The system supports concurrent users.	V	3	Administra tion SOP Section 5	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.11	Capacity				
2.11.1	eDocs storage and performance, because it is leveraging REDCap system and functionality, will be based on the REDCap system performance. The system will allow for concurrent users within the system without degradation of system performance.	V	3	Administra tion SOP Section 5	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.12	Installation Considerations				



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2.12.1	For all supporting infrastructure or hardware (both for test and production implementation), a formal Installation Qualification including any noted configuration points will be executed to document the infrastructure and associated components necessary to run the application.	T	3	IQ Test Protocol	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
FDA 21 CFR Part 11 and Associated Global Regulatory Requirements					
2.13	Security				
2.13.1	21 CFR Part 11 (g) The system should have effectively defined roles and access controls. Access should be granted to the system via appropriate entry of an acceptable User ID and password combination.	T / P	3	PQ eDocs Step 31 PQ eDocs Step 32 PQ eDocs Step 33 Administration SOP section 1 and 2	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation



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Req#	Requirement	Verification	Priority	Traceability	Test Result
2.13.2	21 CFR Part 11 (g) (d) The system will enforce role-based authorization to various parts of the system. Refer to the matrix below for a list of roles supported by the system and the activities that each role is authorized to perform. Roles will have effective checks and balances on use, as well as, a process for granting access with appropriate authorization (may be non-testable, but confirmed with procedures).	T / P	3	PQ eDocs Step 31 PQ eDocs Step 32 PQ eDocs Step 33 Administra tion SOP section 1 and 2	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.13.3	User Roles and Permissions: eDocs User Roles are based on Data entry so every user regardless of the roles and permission can view and edit the records.	T / P	3	Administra tion SOP section 1 and 2	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.14	Audit Trail				
2.14.1	21 CFR Part 11 (g) (e) Actions performed within the system should be recorded within the audit trail and the role/user performing the action is included within the audit trail record.	T / P	3	PQ-eDocs step 40 PQ-eDocs step 46 Administra tion SOP section 1 and 2	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation



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Req#	Requirement	Verification	Priority	Traceability	Test Result
2.14.2	eDocs will leverage the Logging, history and audit trail capabilities of the REDCap application framework.	T	3	PQ-eDocs step 21 PQ-eDocs step 40 PQ-eDocs step 46	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.14.3	21 CFR Part 11 (e) The system will provide secure, computer-generated audit trails to independently record all changes made to electronic records. The audit trail must contain the date and time of operator entries, the action performed (create, update, delete), the username of the operator performing the action, and the data elements affected. Record changes will not obscure previously recorded information.	T	3	PQ-eDocs step 21 PQ-eDocs step 48	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.14.4	An audit trail record will be created for every data process entry in the system.	T	3	PQ-eDocs step 21 PQ-eDocs step 40 PQ-eDocs step 46 PQ-eDocs step 48	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation



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2.14.5	Audit trail documentation will be retained and will be available for review and export.	T	3	PQ-eDocs step 21	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.14.6	Audit trail can be maintained with the data records for the length of the data retention requirements.	T	3	PQ-eDocs step 21	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.15	Process or Procedural Control				
2.15.1	All user interactions with the system will occur over an encrypted channel.	T	3	IQ-eDocs Step 14	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation



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2.15.2	21 CFR Part 11.30 For open systems, the application will demonstrate that an appropriate encryption standard is employed.	T	3	IQ-eDocs step 14	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.15.3	CFR Part 11.30 Systems should demonstrate that encryption is in effect for data in transit and while at rest.	T	3	IQ-eDocs step 14	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
2.15.4	Encryption Keys are maintained by VUMC	T	3	Administration SOP	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
3	Hardware and Software Requirements				



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3.1	A standard installation qualification document, defining the version of the software, the additional software and hardware components (i.e. PDF rendering software, etc.) and versions leveraged for the system to work, will be executed to capture these requirements.	V	1	IQ and PQ	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation																														
4	User Groups																																		
4.1.1	User Groups and accounts for eDocs are managed per project and utilize functionality associated with the REDCap application. The associated screen shots included here is of the REDCap User Rights module, which will be utilized for eDocs account and role set-up:	T / P	N/A	Administration SOP section 1 and 2	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation																														
4.1.2	<div>User Roles and Permissions Matrix for e-Docs:<table><tr><th>Activity</th><th>Administrator</th><th>Principle Investigator</th><th>Site Coordinator</th><th>Monitor / Auditor</th><th>Data Entry Analyst</th></tr><tr><td>Development of e-Docs Form</td><td>X</td><td>X</td><td>X</td><td></td><td></td></tr><tr><td>e-Docs Form Execution</td><td>X</td><td>X</td><td>X</td><td></td><td>X</td></tr><tr><td>Vaulting of Executed e-Consent Form</td><td>X</td><td>X</td><td>X</td><td></td><td></td></tr><tr><td>Read Only access to review e-Docs forms</td><td></td><td></td><td></td><td>X</td><td></td></tr></table></div>	Activity	Administrator	Principle Investigator	Site Coordinator	Monitor / Auditor	Data Entry Analyst	Development of e-Docs Form	X	X	X			e-Docs Form Execution	X	X	X		X	Vaulting of Executed e-Consent Form	X	X	X			Read Only access to review e-Docs forms				X		T	3	PQ e-Docs Step 31 PQ e-Docs Step 32 PQ e-Docs Step 33	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
Activity	Administrator	Principle Investigator	Site Coordinator	Monitor / Auditor	Data Entry Analyst																														
Development of e-Docs Form	X	X	X																																
e-Docs Form Execution	X	X	X		X																														
Vaulting of Executed e-Consent Form	X	X	X																																
Read Only access to review e-Docs forms				X																															

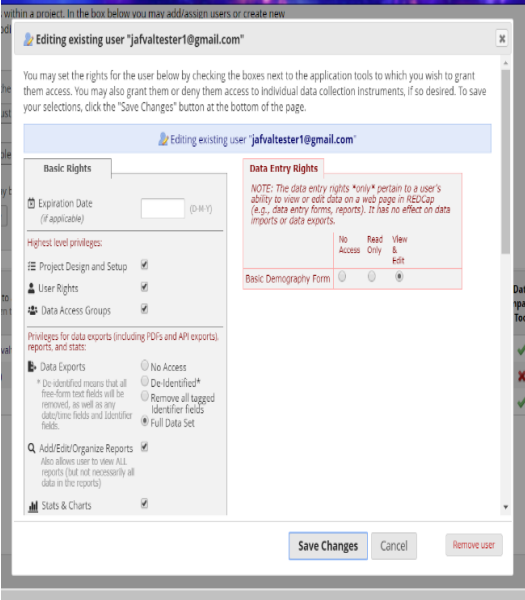


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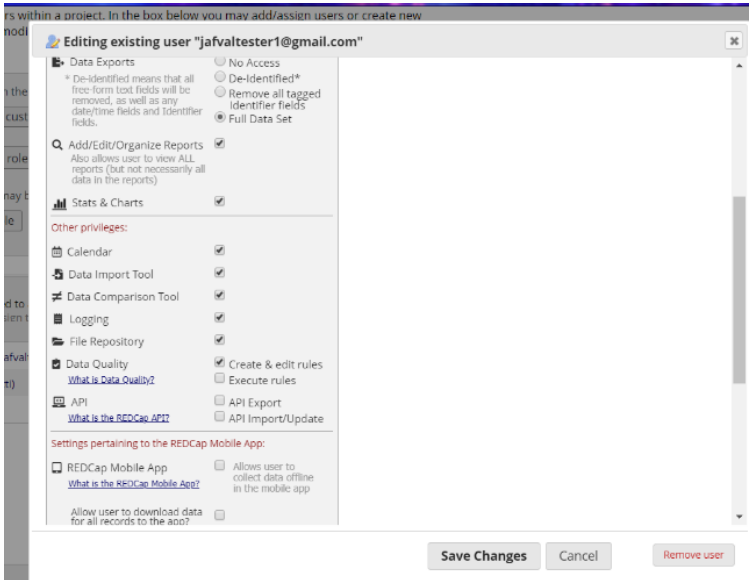
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Req#	Requirement	Verification	Priority	Traceability	Test Result
4.1.4		T / P	3	Administration SOP section 1 and 2	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation



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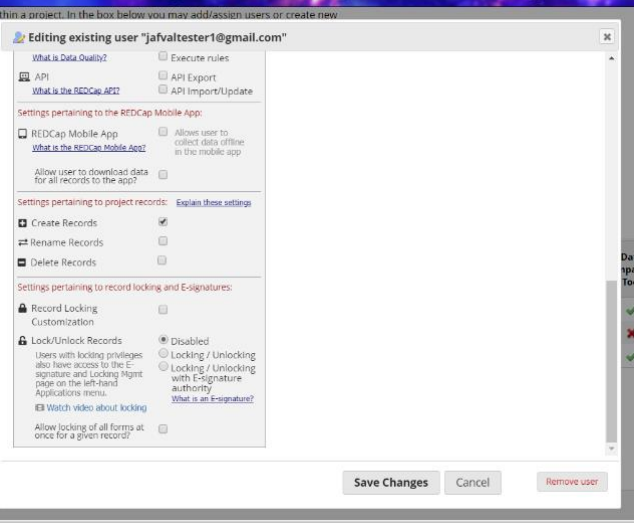
Document Version: 1.0

Req#	Requirement	Verification	Priority	Traceability	Test Result
4.1.5		T / P	3	Administration SOP section 1 and 2	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation



REDCap eDocs Module Requirements Traceability Matrix

Document Version: 1.0

Req#	Requirement	Verification	Priority	Traceability	Test Result
4.1.6		T / P	3	Administration SOP section 1 and 2	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
5	Other Requirements				
5.1	There shall be an operation and administration procedure	V	1	Operation and Administration SOP	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation
5.2	Computing Environment				



**REDCap eDocs Module Requirements
Traceability Matrix**

Document Version: 1.0

Req#	Requirement	Verification	Priority	Traceability	Test Result
5.2.1	System shall be developed and validated in test environment	V	1	PQ-eDocs step 36	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> N/A <input type="checkbox"/> Deviation











REDCap eDocs Requirements Traceability Matrix - Final v01

Final Audit Report

2020-03-31


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