

Title: User Administration and operation of Record Lock functionality in REDCap application

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Document	Number:

Revision: 001

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Signature Page

Prepared by:

I have prepared the contents of this document and agree that the provisions contained herein are appropriate and consistent with business processes, user requirements and I tender it for approval.

(umar (Aug 21, 2020 11:58 EDT)

Gaurav Kumar

Validation Representative, JAF Consulting, Inc

Reviewed and Approved by:

I have reviewed the contents of this document and accept and approve of the provisions as stated herein are appropriate and consistent with business processes, user requirements and I tender it for approval.

Colou E. haven

Colleen E. Lawrence (Aug 21, 2020 11:10 CDT) Colleen Lawrence, System Owner

Joseph a. Junchette

Joseph Franchetti, Quality Assurance Representative, JAF Consulting, Inc

Rob Taylor (Aug 21, 2020 11:06 CDT) Rob Taylor, Technical Owner, VUMC

Revision History

Date	Version	Description
21-AUG-2020	1.0	Original Release, New Document



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Purpose

This procedure describes User Administration and operation of the record lock functionality within REDCap application.

Scope

This procedure applies to the following record lock functionality business processes:

- User Permissions and management.
- Record Lock Operation

References

The table below lists the applicable references within the Vanderbilt University's Quality System.

Document Title	version	Date of approval
REDCap "Project / Record Lock" User Requirements Specification	1.0	15JUN2020



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Definitions

N/A

Responsibilities

Quality Assurance Representative:

Provide Compliance input in this procedure

Review and approve this procedure

Business System Owner (BSO):

Provides technical input in establishing, drafting, editing and approval of this procedure

Review and Approves this procedure

Information Technology (IT) Representative:

Provides technical input in establishing, drafting, editing and approval of this procedure

Follows this Standard Operating Procedure to ensure users are setup correctly in the system

Review and Approves this procedure

Subject Matter Expert (SME):

Provides technical input in establishing, drafting, editing and approval of this procedure Review and Approves this procedure

Procedure

1.0 User Role Setup and verification for record lock functionality

- 1.1. Login to eConsent Module as an Administrator and, within REDCap application and access the appropriate project to configure the record lock permission settings.
- 1.2. Navigate to the Applications Expandable Menu for the and Select the User Rights link.
- 1.3. Open the Principle Investigator user role and verify the Lock/Unlock *Entire* Records (record level) checkbox is checked following attachment 001.



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- 1.4. Select Save Changes and ensure the record lock functionality is turned on for the Principle Investigator role.
- 1.5. Following attachment 002, verify the record locked permission is disabled for every other user except for Principle Investigator and Administrator.

NOTE: User Administration shall be handled outside of the Operation group for this module.

1.6. Following attachment 002, verify the User Rights and Data Access group permissions are disabled for every user except for Administrator.



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 Data Import Tool Data Comparison Tool Logging File Repository Data Quality What is Data Quality? Mat is the REDCap API? Settings pertaining to the REDCap I What is the REDCap Mobile App What is the REDCap Mobile App? REDCap Mobile App What is the REDCap Mobile App? Allow user to download data for all records to the app? Settings pertaining to project recor Create Records Tename Records Delete Records 	Create & edit rules Execute rules API Export API Import/Update Mobile App:		
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🖞 Data Import Tool			
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Logging			
File Repository			
Data Quality What is Data Quality?	Create & edit rules		
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Attachment 002



1.7. Logout of the system as an administrator.



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2.0 Record Lock

- 2.1. Upon receiving request from the appropriate group that requires the record lock for all survey instruments, login to the system under Principle Investigator user role.
- 2.2. Open the applicable project, and navigate to the Record Status Dashboard.
- 2.3. Select and open the applicable record that is required to be locked.
- 2.4. Using attachment 003, select the Lock entire record.
- 2.5. Verify the entire record for accuracy.
- 2.6. Select the checkbox next to I approve the data that is contained in this record.
- 2.7. Select Locked entire record.
- 2.8. The entire record gets locked at a record level.
- 2.9. Logout of the system

Data Collection	
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Logged in as gkumar@jafconsulting.com Log out	Actions: Modify instrument Download PDF of instrument(s)		
III My Projects	El <u>VIDEO: Basic data entry</u>		
REDCap Messenger 1	Basic Demography Form		
Project Home and Design □ ☆ Project Home · 注 Project Setup □ ☑ Designer · III Dictionary · II Codebook ■ ■ Project status: Development □	The entire record was locked by gkumar@jafconsulting.com (G Kumar) on 07/22/2020 2:23pm Only users with record-level locking/unlocking privileges may unlock this record in order to		
Data Collection	modify any or this record's data.		
Record Status Dashboard - View data collection status of all records	Editing existing Study ID 8	8	
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3.0 Record Unlock

- 3.1. Upon receiving request from the appropriate group that requires the record unlock for all survey instruments, login to the system under Principle Investigator user role.
- 3.2. Open the applicable project, and navigate to the Record Status Dashboard.
- 3.3. Select and open the applicable record that is required to be unlocked.
- 3.4. Using attachment 004, select the Unlock entire record.
- 3.5. Verify the entire record for accuracy.
- 3.6. Select Unlock entire record.
- 3.7. The entire record gets unlocked at a record level.
- 3.8. Notify the appropriate users, for updates that needed to be performed on the unlocked study ID.
- 3.9. Logout of the system



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Logged in as gkumar@jafconsulting.com Log out	UDEO: Basic data entry	
 My Projects REDCap Messenger 	🖪 Basic Demography Form	
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Alerts & Notifications Calendar Data Exports, Reports, and Stats Data Comparison Tool Data Comparison	* must provide value File Upload 2 File Description 2	
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Logged in as gkumar@jafconsulting.com	Actions: Modify instrument	Download PDF of instrument(s) Save & Evit For
Log out	B VIDEO: Basic data entry	
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Project Home and Design 📃	Editing existing Study ID 8	
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Designer · E Dictionary · Codebook	Study ID	To rename the record, see the record action drop-down
Project status. Development	When unleading file(a) which includes	at top of the <u>Record Home Page</u> .
Data Collection	Upload 4 and File Upload 5, system w	ill prompt you to enter your REDCap username and
Record Status Dashboard	password, and then will save the file	to the secure vault server.
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- Create new records or edit/view existing ones		Twilio DATA 2020 06 19 1428 cm
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4.0 eConsent form storage

- 4.1. All versions of the patient's consent forms and all applicable survey instruments will be maintained within the project "vault."
- 4.2. An appropriate "vault" will be set-up for each project to house the locked consent forms and all applicable survey instruments.
- 4.3. The Vault will have limited access only to administrators of the Local Network.
- 4.4. The Vault will have write once read many configurations.
- 4.5. The Vault environment will be backed up daily.
- 4.6. The Vault will have data encryption enabled
- 4.7. SFTP/ "vault" for secure storage of the locked consent forms and all applicable survey instruments will provide for an un-editable file, but retrieval for reading/reviewing.
- 4.8. A copy of the locked record will be rendered to REDCap project for active use (viewing, etc.) in a Read Only format.
- 4.9. Standard encryption will be employed for the locked record files. Will be employed in transit and at rest.
- 4.10. The viewing of the e-Consent file will generally be device agnostic



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Attachments

Attachment 001

Attachment 002

Attachment 003

REDCap Record Lock Operation and Administration SOP v 1.0

Final Audit Report

2020-08-21

Created:	2020-08-21
Ву:	Gaurav Kumar (gkumar@jafconsulting.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAWl2f1WM8h-OV4Ry6udA3sq1dHXa4XzDF

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Adobe Sign

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Signed document emailed to Gaurav Kumar (gkumar@jafconsulting.com), Colleen E. Lawrence (colleen.lawrence@vumc.org), Rob Taylor (rob.taylor@vumc.org), and Joseph Franchetti (jfranchetti@jafconsulting.com)

2020-08-21 - 4:21:12 PM GMT

