

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

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.

Gaurav Kumar (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.

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

Colleen Lawrence, System Owner

Joseph Franchetti, Quality Assurance
Representative, JAF Consulting, IncRob 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

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

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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):

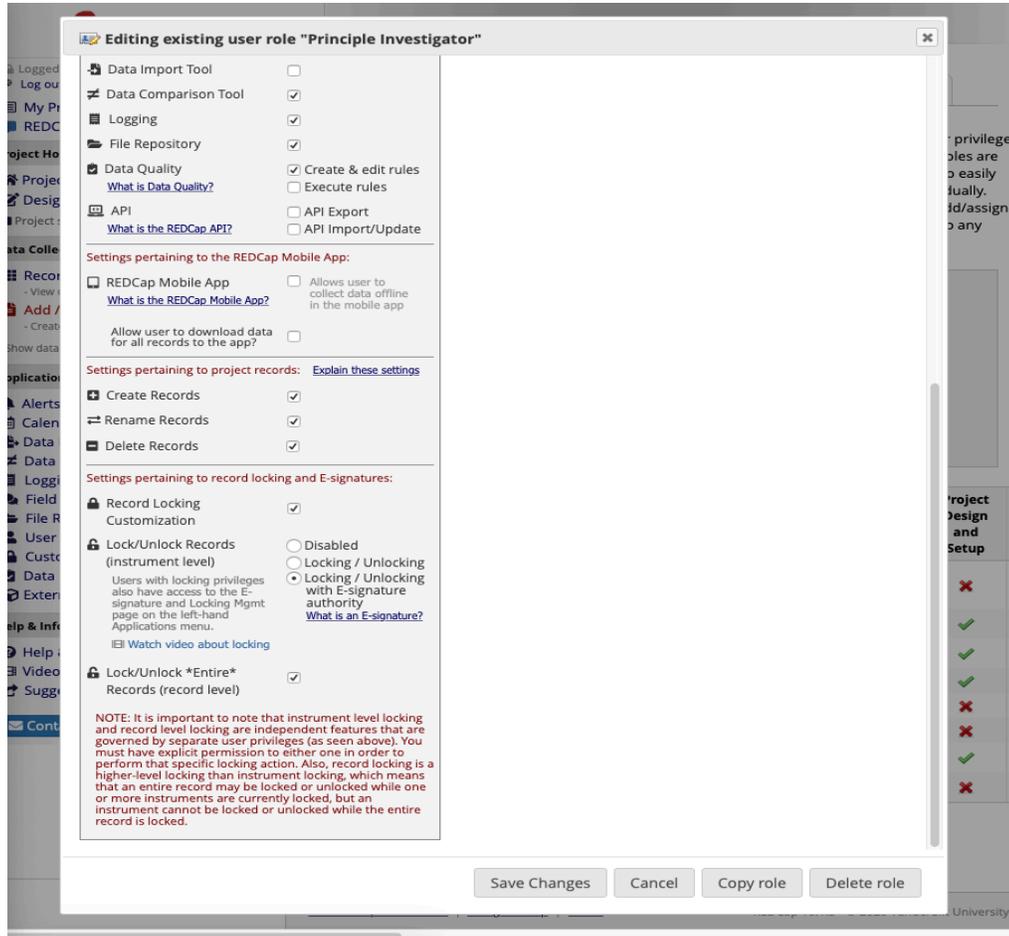
- Provides technical input in establishing, drafting, editing and approval of this procedure
- Review and Approves this procedure

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.

Attachment 001



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.

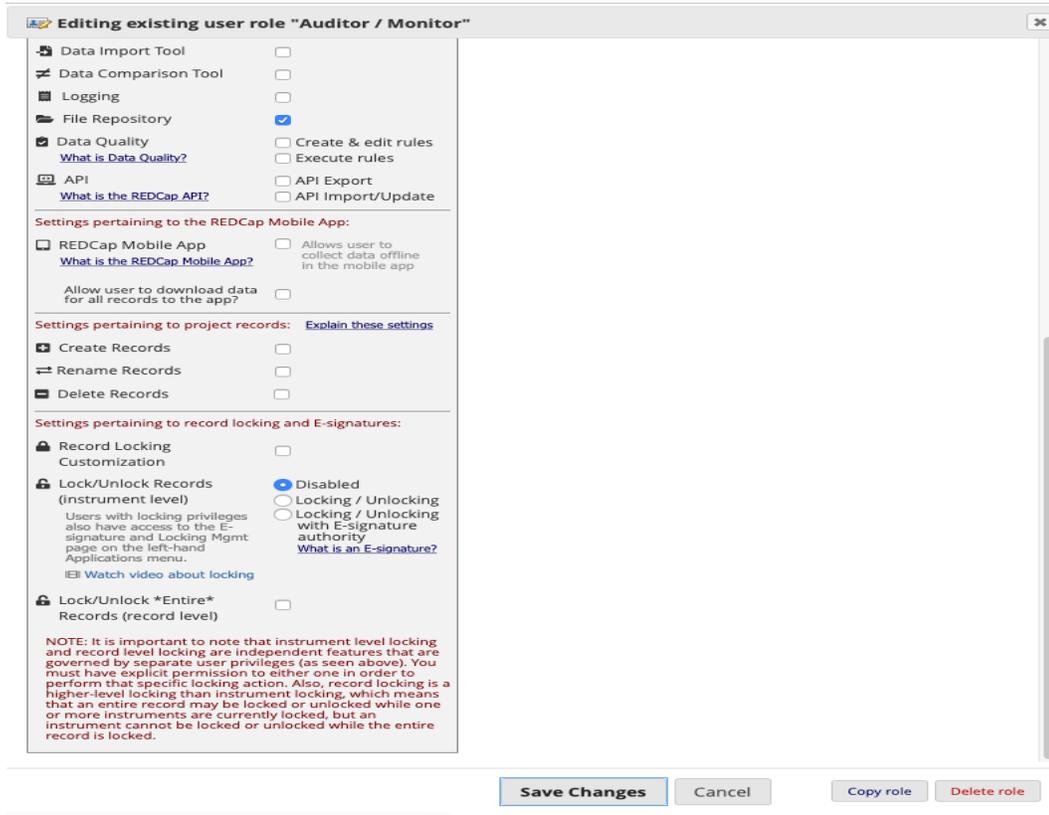
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Attachment 002



Editing existing user role "Auditor / Monitor"

- Data Import Tool
- Data Comparison Tool
- Logging
- File Repository
- Data Quality
 - [What is Data Quality?](#)
 - Create & edit rules
 - Execute rules
- API
 - [What is the REDCap API?](#)
 - API Export
 - API Import/Update

Settings pertaining to the REDCap Mobile App:

- REDCap Mobile App
 - [What is the REDCap Mobile App?](#)
 - Allows user to collect data offline in the mobile app
- Allow user to download data for all records to the app?

Settings pertaining to project records: [Explain these settings](#)

- Create Records
- Rename Records
- Delete Records

Settings pertaining to record locking and E-signatures:

- Record Locking Customization
- Lock/Unlock Records (instrument level)
 - Users with locking privileges also have access to the E-signature and Locking Mgmt page on the left-hand Applications menu.
 - [Watch video about locking](#)
 - Disabled
 - Locking / Unlocking
 - Locking / Unlocking with E-signature authority
 - [What is an E-signature?](#)
- Lock/Unlock *Entire* Records (record level)

NOTE: It is important to note that instrument level locking and record level locking are independent features that are governed by separate user privileges (as seen above). You must have explicit permission to either one in order to perform that specific locking action. Also, record locking is a higher-level locking than instrument locking, which means that an entire record may be locked or unlocked while one or more instruments are currently locked, but an instrument cannot be locked or unlocked while the entire record is locked.

Save Changes **Cancel** **Copy role** **Delete role**

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Attachment 002

Editing existing user role "Data Entry Analyst"

 Data Import Tool	<input type="checkbox"/>
 Data Comparison Tool	<input type="checkbox"/>
 Logging	<input checked="" type="checkbox"/>
 File Repository	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> Data Quality What is Data Quality?	<input type="checkbox"/> Create & edit rules <input type="checkbox"/> Execute rules
 API What is the REDCap API?	<input type="checkbox"/> API Export <input type="checkbox"/> API Import/Update

Settings pertaining to the REDCap Mobile App:

<input type="checkbox"/> REDCap Mobile App What is the REDCap Mobile App?	<input type="checkbox"/> Allows user to collect data offline in the mobile app
Allow user to download data for all records to the app?	<input type="checkbox"/>

Settings pertaining to project records: [Explain these settings](#)

 Create Records	<input checked="" type="checkbox"/>
 Rename Records	<input type="checkbox"/>
 Delete Records	<input type="checkbox"/>

Settings pertaining to record locking and E-signatures:

 Record Locking Customization	<input type="checkbox"/>
 Lock/Unlock Records (instrument level) <small>Users with locking privileges also have access to the E-signature and Locking Mgmt page on the left-hand Applications menu. Watch video about locking</small>	<input checked="" type="radio"/> Disabled <input type="radio"/> Locking / Unlocking <input type="radio"/> Locking / Unlocking with E-signature authority What is an E-signature?
 Lock/Unlock *Entire* Records (record level)	<input type="checkbox"/>

NOTE: It is important to note that instrument level locking and record level locking are independent features that are governed by separate user privileges (as seen above). You must have explicit permission to either one in order to perform that specific locking action. Also, record locking is a higher-level locking than instrument locking, which means that an entire record may be locked or unlocked while one or more instruments are currently locked, but an instrument cannot be locked or unlocked while the entire record is locked.

Save Changes Cancel Copy role Delete role

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Attachment 002

Editing existing user role "Study Coordinator"

- Data Import Tool
- Data Comparison Tool
- Logging
- File Repository
- Data Quality
 - Create & edit rules
 - Execute rules
- API
 - API Export
 - API Import/Update

Settings pertaining to the REDCap Mobile App:

- REDCap Mobile App
 - Allows user to collect data offline in the mobile app
- Allow user to download data for all records to the app?

Settings pertaining to project records: [Explain these settings](#)

- Create Records
- Rename Records
- Delete Records

Settings pertaining to record locking and E-signatures:

- Record Locking Customization
- Lock/Unlock Records (Instrument level)
 - Locking / Unlocking
 - Locking / Unlocking with E-signature authority

Users with locking privileges also have access to the E-signature and Locking Mgmt page on the left-hand Applications menu.

[Watch video about locking](#)
- Lock/Unlock *Entire* Records (record level)

NOTE: It is important to note that instrument level locking and record level locking are independent features that are governed by separate user privileges (as seen above). You must have explicit permission to either one in order to perform that specific locking action. Also, record locking is a higher-level locking than instrument locking, which means that an entire record may be locked or unlocked while one or more instruments are currently locked, but an instrument cannot be locked or unlocked while the entire record is locked.

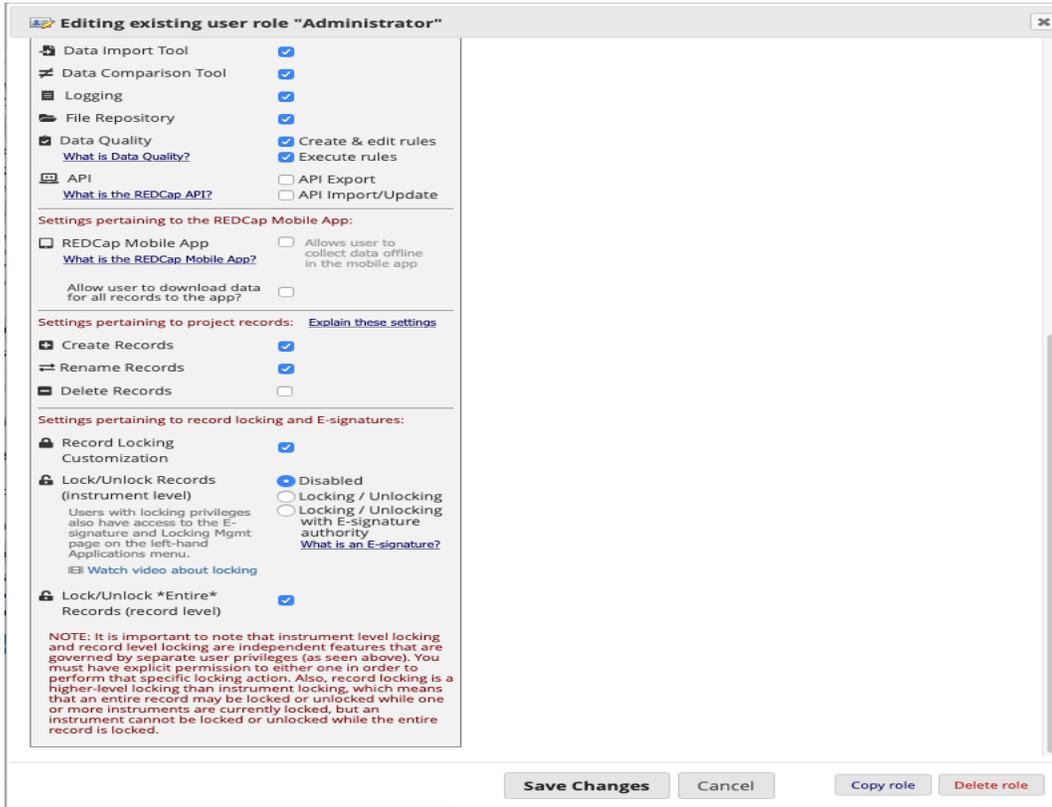
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Attachment 002



Editing existing user role "Administrator"

- Data Import Tool
- Data Comparison Tool
- Logging
- File Repository
- Data Quality
 - [What is Data Quality?](#)
 - Create & edit rules
 - Execute rules
- API
 - [What is the REDCap API?](#)
 - API Export
 - API Import/Update

Settings pertaining to the REDCap Mobile App:

- REDCap Mobile App
 - [What is the REDCap Mobile App?](#)
 - Allows user to collect data offline in the mobile app
 - Allow user to download data for all records to the app?

Settings pertaining to project records: [Explain these settings](#)

- Create Records
- Rename Records
- Delete Records

Settings pertaining to record locking and E-signatures:

- Record Locking Customization
- Lock/Unlock Records (instrument level)
 - Users with locking privileges also have access to the E-signature and Locking Mgmt page on the left-hand Applications menu.
 - [Watch video about locking](#)
 - Disabled
 - Locking / Unlocking with E-signature authority
 - [What is an E-signature?](#)
- Lock/Unlock *Entire* Records (record level)

NOTE: It is important to note that instrument level locking and record level locking are independent features that are governed by separate user privileges (as seen above). You must have explicit permission to either one in order to perform that specific locking action. Also, record locking is a higher-level locking than instrument locking, which means that an entire record may be locked or unlocked while one or more instruments are currently locked, but an instrument cannot be locked or unlocked while the entire record is locked.

Save Changes **Cancel** **Copy role** **Delete role**

1.7. Logout of the system as an administrator.

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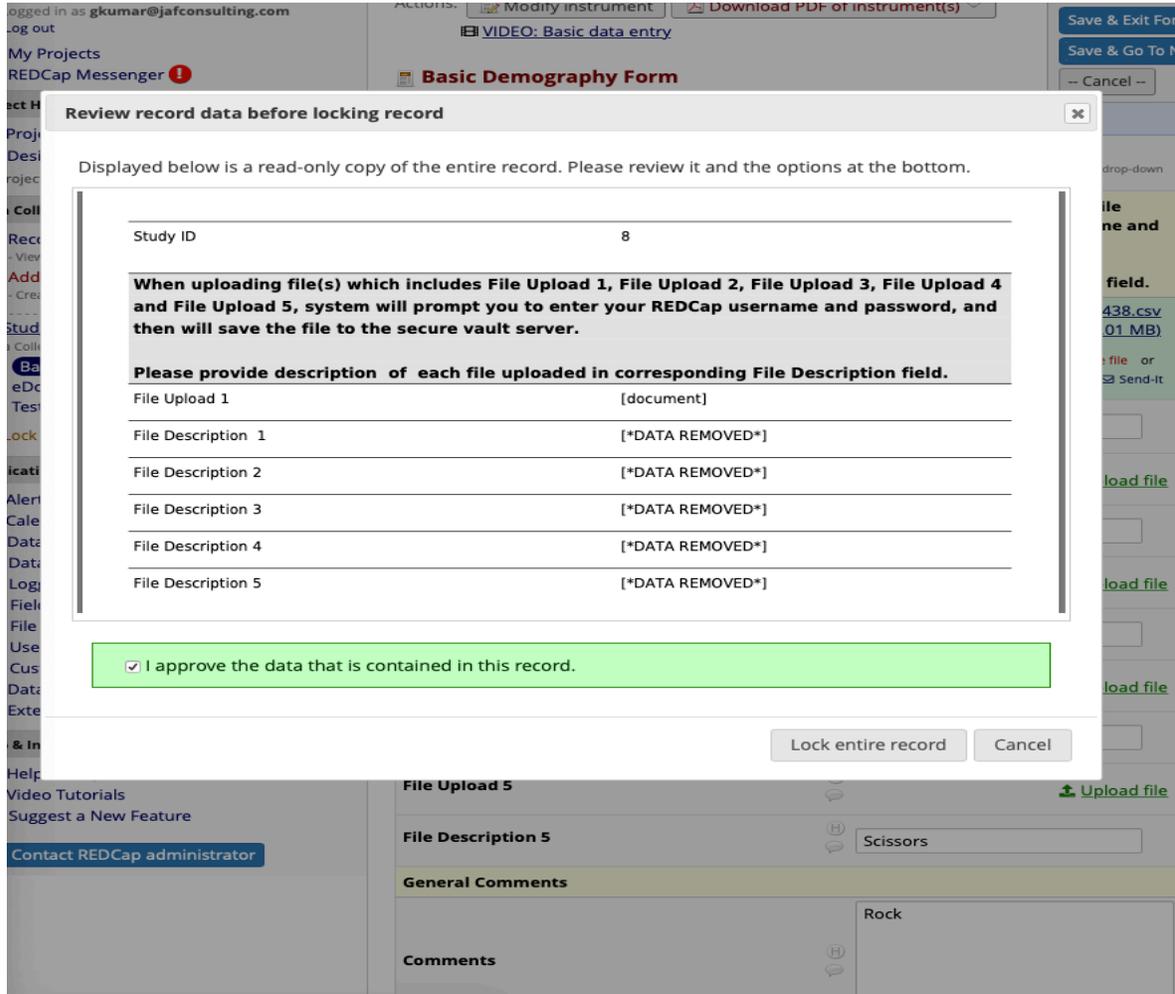
2.0 Record Lock

- 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

Attachment 003



Attachment 003



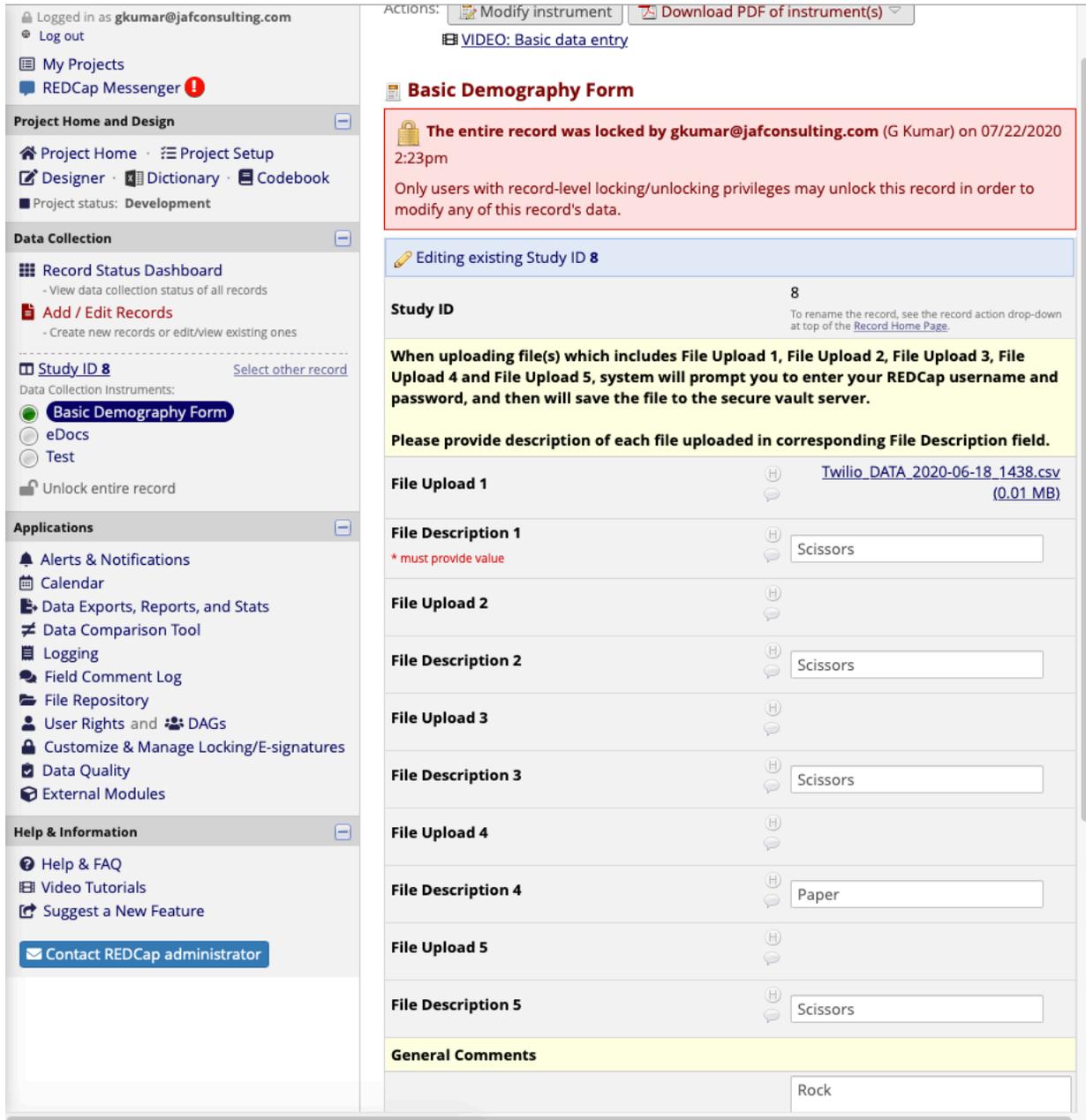
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Attachment 003

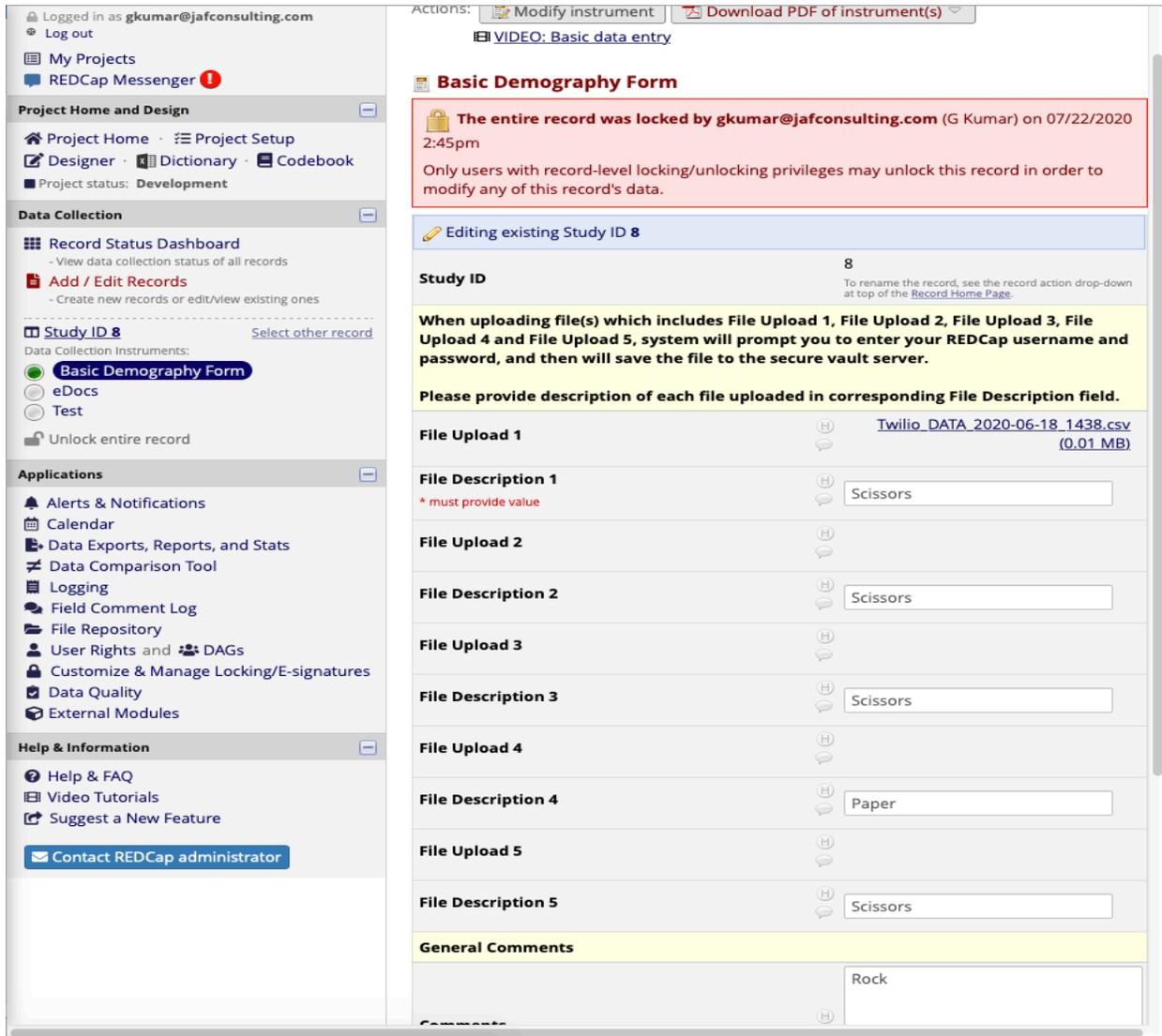


The screenshot displays the REDCap user interface. On the left is a navigation sidebar with sections for 'Project Home and Design', 'Data Collection', 'Applications', and 'Help & Information'. The 'Data Collection' section is active, showing 'Study ID 8' and 'Basic Demography Form' selected. The main content area shows a record lock notification: 'The entire record was locked by gkumar@jafconsulting.com (G Kumar) on 07/22/2020 2:23pm'. Below this, it indicates 'Editing existing Study ID 8'. A yellow warning box states: 'When uploading file(s) which includes File Upload 1, File Upload 2, File Upload 3, File Upload 4 and File Upload 5, system will prompt you to enter your REDCap username and password, and then will save the file to the secure vault server. Please provide description of each file uploaded in corresponding File Description field.' The interface lists five file uploads with their descriptions: 'File Upload 1' (Twilio_DATA_2020-06-18_1438.csv, 0.01 MB), 'File Upload 2', 'File Upload 3', 'File Upload 4' (Paper), and 'File Upload 5'. A 'General Comments' field at the bottom contains the text 'Rock'.

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

Attachment 004



Logged in as **gkumar@jafconsulting.com**
 Log out
 My Projects
 REDCap Messenger

Project Home and Design

- Project Home · Project Setup
- Designer · Dictionary · Codebook
- Project status: **Development**

Data Collection

- Record Status Dashboard - View data collection status of all records
- Add / Edit Records - Create new records or edit/view existing ones
- Study ID 8 [Select other record](#)
- Data Collection Instruments:
 - Basic Demography Form**
 - eDocs
 - Test
- Unlock entire record

Applications

- Alerts & Notifications
- Calendar
- Data Exports, Reports, and Stats
- Data Comparison Tool
- Logging
- Field Comment Log
- File Repository
- User Rights and DAGs
- Customize & Manage Locking/E-signatures
- Data Quality
- External Modules

Help & Information

- Help & FAQ
- Video Tutorials
- Suggest a New Feature
- Contact REDCap administrator

ACTIONS: [Modify instrument](#) [Download PDF of instrument\(s\)](#)
 VIDEO: [Basic data entry](#)

Basic Demography Form

The entire record was locked by gkumar@jafconsulting.com (G Kumar) on 07/22/2020 2:45pm
 Only users with record-level locking/unlocking privileges may unlock this record in order to modify any of this record's data.

Editing existing Study ID 8

Study ID 8
To rename the record, see the record action drop-down at top of the Record Home Page.

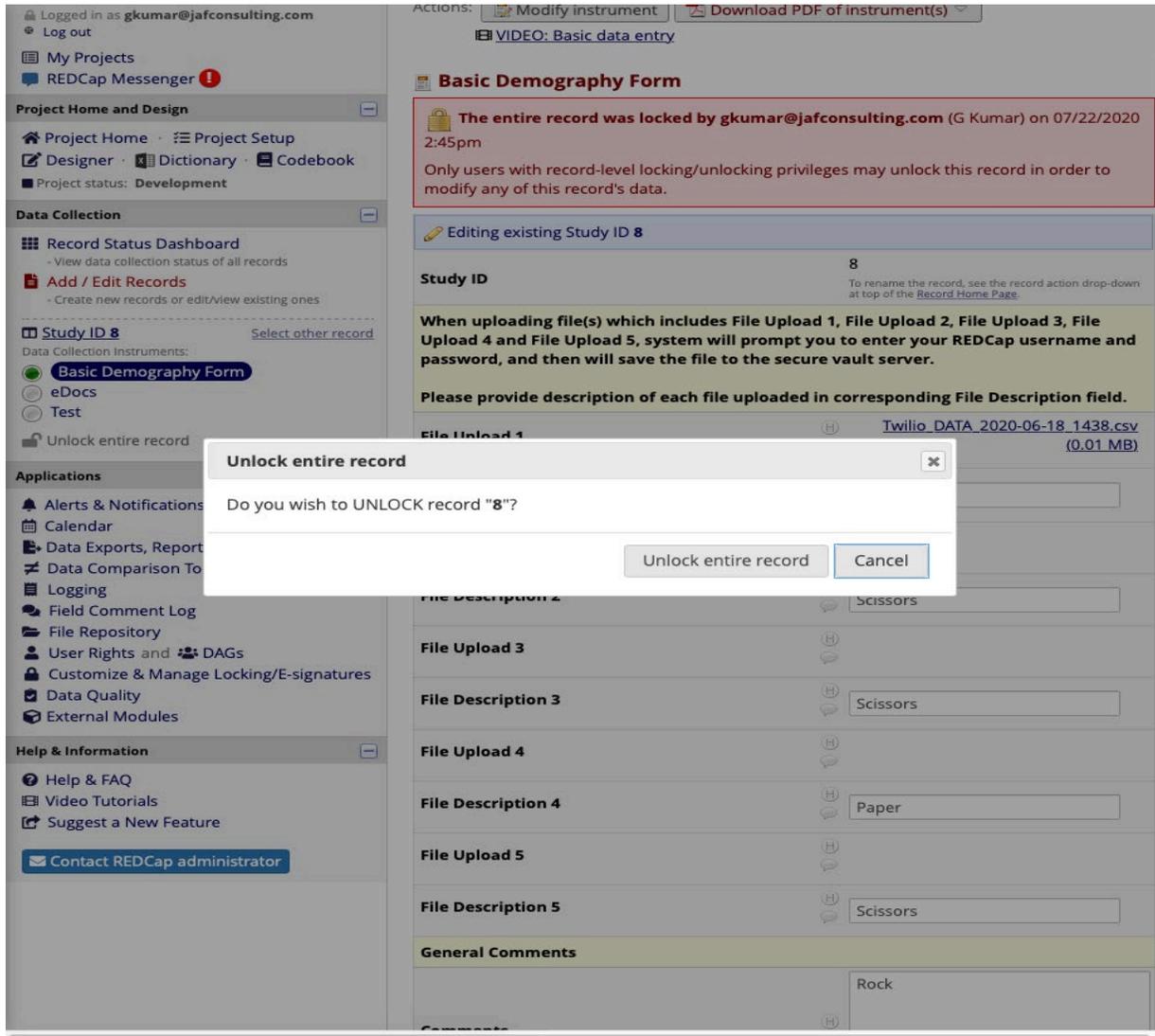
When uploading file(s) which includes File Upload 1, File Upload 2, File Upload 3, File Upload 4 and File Upload 5, system will prompt you to enter your REDCap username and password, and then will save the file to the secure vault server.

Please provide description of each file uploaded in corresponding File Description field.

File Upload 1	Twilio_DATA_2020-06-18_1438.csv <small>(0.01 MB)</small>
File Description 1	<input type="text" value="Scissors"/>
File Upload 2	
File Description 2	<input type="text" value="Scissors"/>
File Upload 3	
File Description 3	<input type="text" value="Scissors"/>
File Upload 4	
File Description 4	<input type="text" value="Paper"/>
File Upload 5	
File Description 5	<input type="text" value="Scissors"/>

General Comments

Attachment 004



Attachment 004

Logged in as gkumar@jafconsulting.com
 Log out
 My Projects
 REDCap Messenger

Project Home and Design
 Project Home · Project Setup
 Designer · Dictionary · Codebook
 Project status: Development

Data Collection
 Record Status Dashboard
 Add / Edit Records
 Study ID 8
 Data Collection Instruments:
 Basic Demography Form
 eDocs
 Test
 Lock entire record

Applications
 Alerts & Notifications
 Calendar
 Data Exports, Reports, and Stats
 Data Comparison Tool
 Logging
 Field Comment Log
 File Repository
 User Rights and DAGs
 Customize & Manage Locking/E-signatures
 Data Quality
 External Modules

Help & Information
 Help & FAQ
 Video Tutorials
 Suggest a New Feature
 Contact REDCap administrator

ACTIONS: Modify instrument | Download PDF of instrument(s)
 VIDEO: Basic data entry

Basic Demography Form
 Editing existing Study ID 8
 Study ID: 8
 When uploading file(s) which includes File Upload 1, File Upload 2, File Upload 3, File Upload 4 and File Upload 5, system will prompt you to enter your REDCap username and password, and then will save the file to the secure vault server.
 Please provide description of each file uploaded in corresponding File Description field.

File Upload 1	Twilio_DATA_2020-06-18_1438.csv (0.01 MB)
File Description 1	Scissors
File Upload 2	Upload file
File Description 2	Scissors
File Upload 3	Upload file
File Description 3	Scissors
File Upload 4	Upload file
File Description 4	Paper
File Upload 5	Upload file
File Description 5	Scissors

General Comments
 Comments: Rock

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

Attachment 004

REDCap Record Lock Operation and Administration SOP v 1.0

Final Audit Report

2020-08-21

Created:	2020-08-21
By:	Gaurav Kumar (gkumar@jafconsulting.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAWI2f1WM8h-OV4Ry6udA3sq1dHXa4XzDF

"REDCap Record Lock Operation and Administration SOP v 1.0" History

-  Document created by Gaurav Kumar (gkumar@jafconsulting.com)
2020-08-21 - 3:55:54 PM GMT- IP address: 96.230.18.134
-  Document e-signed by Gaurav Kumar (gkumar@jafconsulting.com)
Signature Date: 2020-08-21 - 3:58:37 PM GMT - Time Source: server- IP address: 96.230.18.134
-  Document emailed to Rob Taylor (rob.taylor@vumc.org) for signature
2020-08-21 - 3:58:39 PM GMT
-  Email viewed by Rob Taylor (rob.taylor@vumc.org)
2020-08-21 - 4:05:59 PM GMT- IP address: 104.47.49.254
-  Document e-signed by Rob Taylor (rob.taylor@vumc.org)
Signature Date: 2020-08-21 - 4:06:41 PM GMT - Time Source: server- IP address: 160.129.251.127
-  Document emailed to Colleen E. Lawrence (colleen.lawrence@vumc.org) for signature
2020-08-21 - 4:06:43 PM GMT
-  Email viewed by Colleen E. Lawrence (colleen.lawrence@vumc.org)
2020-08-21 - 4:09:48 PM GMT- IP address: 104.47.48.254
-  Document e-signed by Colleen E. Lawrence (colleen.lawrence@vumc.org)
Signature Date: 2020-08-21 - 4:10:24 PM GMT - Time Source: server- IP address: 160.129.251.127
-  Document emailed to Joseph Franchetti (jfranchetti@jafconsulting.com) for signature
2020-08-21 - 4:10:26 PM GMT
-  Email viewed by Joseph Franchetti (jfranchetti@jafconsulting.com)
2020-08-21 - 4:20:57 PM GMT- IP address: 73.196.185.110

 Document e-signed by Joseph Franchetti (jfranchetti@jafconsulting.com)

Signature Date: 2020-08-21 - 4:21:12 PM GMT - Time Source: server- IP address: 73.196.185.110

 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