Electronic Data Capture and Study Management

William Mattingly
Contents

List of Figures 5

Preface 9

1 Project Creation 11

1 Creating Your Study 13
   1.1 Setting Up Your REDCap Project ........................................... 13
   1.2 Navigating Around Your Project ............................................. 16
   1.3 Setting Up Project Features .................................................. 17

2 Designing Your eCRF 19
   2.1 Using the Online Designer Tool ............................................... 19
   2.2 Creating Your Data Instruments ............................................. 20
   2.3 Choosing Data Fields .......................................................... 21
   2.4 Using Surveys in Your Study ................................................ 24
   2.5 Creating a Longitudinal Study ................................................. 30

3 Managing Your Study Team 33
   3.1 Who Can Access Your Study .................................................. 33
   3.2 Assigning Study Roles ......................................................... 36
   3.3 Using Data Access Groups ..................................................... 36

4 Customizing Your Project 39
   4.1 Enabling Optional Modules ................................................... 39
   4.2 Making Additional Customizations .......................................... 40
   4.3 Moving Project to Production ............................................... 42
II  Project Management  

5 Improving Study Quality  
5.1 Exporting Data and Generating Reports  
5.2 Importing Study Data  
5.3 Comparing Study Records  
5.4 Viewing Access Logs for Your Study  
5.5 Using the Field Comment Log  
5.6 Storing Files Securely  
5.7 Validating and Locking Records  
5.8 Creating Data Quality Rules  

6 Application Programmer Interface  
6.1 What is an API?  
6.2 Requesting a Token  
6.3 Using the API Playground  
6.4 Writing Your Script  

7 REDCap Mobile App  
7.1 Accessing the App Stores  
7.2 Setting Up Your App  
7.3 Setting Up Your Mobile REDCap Project  
7.4 Collecting Your Study Data on the App  
7.5 Using Your Device Camera to Collect Data  

A Setting Up a REDCap Installation  
A.1 Obtaining a Copy  
A.2 Example Install  

Bibliography
List of Figures

1.1 REDCap NavBar .................................................. 13
1.2 Project Creation Dialog ........................................ 14
1.3 Research Project Metadata .................................... 15
1.4 REDCap Sidebar .................................................. 16
1.5 Project Setup Page .............................................. 17
1.6 Project Home Page ................................................ 18

2.1 Data Collection Instruments Panel .................................. 19
2.2 Online Designer Page .............................................. 20
2.3 Sample Data Instrument Page .................................. 20
2.4 Add Field Dialog ................................................... 21
2.5 Text Box Field ....................................................... 21
2.6 Calculated Field Equation Box .................................. 22
2.7 Multiple Choice Selections Box .................................. 22
2.8 Visual Slider Label Fields ....................................... 23
2.9 File Attachment Dialog .......................................... 23
2.10 Sidebar: Data Collection .......................................... 24
2.11 Sidebar: Data Collection w/ Surveys .............................. 25
2.12 Data Collection Instrument Panel w/ Surveys .................... 25
2.13 Basic Survey Options .............................................. 26
2.14 Survey Design Options .......................................... 26
2.15 Survey Customizations Panel .................................. 27
2.16 Survey Access Panel .............................................. 28
2.17 Survey Termination Options .................................... 29
2.18 Project Setup Longitudinal Panel ................................. 30
2.19 Define Events Page ................................................ 30
2.20 Add New Events Panel .......................................... 31
2.21 Designate Instruments Page ..................................... 31
### LIST OF FIGURES

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>User Rights Navbar</td>
<td>34</td>
</tr>
<tr>
<td>3.2</td>
<td>Add New Users Panel</td>
<td>34</td>
</tr>
<tr>
<td>3.3</td>
<td>Basic Rights Panel</td>
<td>35</td>
</tr>
<tr>
<td>3.4</td>
<td>Mobile and Locking Privileges</td>
<td>36</td>
</tr>
<tr>
<td>3.5</td>
<td>Other Privileges Section</td>
<td>36</td>
</tr>
<tr>
<td>3.6</td>
<td>User Role Table</td>
<td>37</td>
</tr>
<tr>
<td>3.7</td>
<td>Create New Groups Panel</td>
<td>37</td>
</tr>
<tr>
<td>3.8</td>
<td>Data Access Groups Table</td>
<td>37</td>
</tr>
<tr>
<td>4.1</td>
<td>Optional Modules Panel</td>
<td>39</td>
</tr>
<tr>
<td>4.2</td>
<td>Additional Customizations Dialog</td>
<td>41</td>
</tr>
<tr>
<td>4.3</td>
<td>Project Setup Bookmarks Panel</td>
<td>43</td>
</tr>
<tr>
<td>4.4</td>
<td>Project Setup Production Panel</td>
<td>43</td>
</tr>
<tr>
<td>5.1</td>
<td>Data Exports Page</td>
<td>48</td>
</tr>
<tr>
<td>5.2</td>
<td>Report Name Panel</td>
<td>48</td>
</tr>
<tr>
<td>5.3</td>
<td>Reports Access Panel</td>
<td>49</td>
</tr>
<tr>
<td>5.4</td>
<td>Fields to Include Panel</td>
<td>49</td>
</tr>
<tr>
<td>5.5</td>
<td>Report Filters Panel</td>
<td>50</td>
</tr>
<tr>
<td>5.6</td>
<td>Report Order By Panel</td>
<td>50</td>
</tr>
<tr>
<td>5.7</td>
<td>Other Export Options Panel</td>
<td>51</td>
</tr>
<tr>
<td>5.8</td>
<td>Sidebar: Reports Section</td>
<td>51</td>
</tr>
<tr>
<td>5.9</td>
<td>Data Imports Page</td>
<td>52</td>
</tr>
<tr>
<td>5.10</td>
<td>Data Comparison Page</td>
<td>52</td>
</tr>
<tr>
<td>5.11</td>
<td>Logging Page</td>
<td>52</td>
</tr>
<tr>
<td>5.12</td>
<td>Optional Modules Page</td>
<td>53</td>
</tr>
<tr>
<td>5.13</td>
<td>File Repository Page</td>
<td>53</td>
</tr>
<tr>
<td>5.14</td>
<td>E-signature Page</td>
<td>54</td>
</tr>
<tr>
<td>5.15</td>
<td>Data Quality Page</td>
<td>55</td>
</tr>
<tr>
<td>6.1</td>
<td>API Page</td>
<td>58</td>
</tr>
<tr>
<td>6.2</td>
<td>API Token Panel</td>
<td>58</td>
</tr>
<tr>
<td>6.3</td>
<td>API Playground Page</td>
<td>59</td>
</tr>
<tr>
<td>6.4</td>
<td>Sample API Request</td>
<td>59</td>
</tr>
<tr>
<td>6.5</td>
<td>Sample API Response</td>
<td>59</td>
</tr>
<tr>
<td>6.6</td>
<td>API Languages Panel</td>
<td>60</td>
</tr>
<tr>
<td>7.1</td>
<td>Mobile App Device Menu</td>
<td>62</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
<td>Page</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
<td>------</td>
</tr>
<tr>
<td>7.2</td>
<td>Mobile App Page</td>
<td>62</td>
</tr>
<tr>
<td>7.3</td>
<td>App Download Links</td>
<td>62</td>
</tr>
<tr>
<td>7.4</td>
<td>Set up Mobile Project on Device Panel</td>
<td>63</td>
</tr>
<tr>
<td>7.5</td>
<td>Sync Progress Screen</td>
<td>64</td>
</tr>
<tr>
<td>7.6</td>
<td>Mobile App Capture Screen</td>
<td>64</td>
</tr>
<tr>
<td>7.7</td>
<td>Mobile App Barcode Reader</td>
<td>65</td>
</tr>
<tr>
<td>A.1</td>
<td>CentOS Startup Screen</td>
<td>68</td>
</tr>
<tr>
<td>A.2</td>
<td>CentOS Installation Summary</td>
<td>68</td>
</tr>
<tr>
<td>A.3</td>
<td>CentOS User Password Setup</td>
<td>69</td>
</tr>
<tr>
<td>A.4</td>
<td>CentOS Install Complete Screen</td>
<td>70</td>
</tr>
<tr>
<td>A.5</td>
<td>Configuration Check Results</td>
<td>72</td>
</tr>
</tbody>
</table>
Preface

This book is intended for potential and current users of the REDCap electronic data capture software developed and maintained by Vanderbilt University.[1] While project creators are usually interested in performing either a prospective or retrospective clinical study, this software has much to offer as a general purpose web-based database. It has commonly been used in applications including biological sample tracking, personnel management, and form submission systems. In addition to covering its standard use case of electronic data capture this book will also examine the use of REDCap for these different application domains.

The most important question to ask when considering REDCap as a data management tool is whether a suitable server is available to you. The software is available to the project’s member consortium, and users representing academic or non-profit institutions can apply for membership and download REDCap at no cost. However, since it is web-based, it must be hosted on some type of physical hardware in order to be securely accessed by its users. The installation is not a 1-click process, and it requires some knowledge of the host operating system and computer networking.

Due to REDCap’s growing popularity, many academic institutions have already worked with their information technology department to establish a REDCap server for their faculty and staff. Users coming from this space would only need to request an account through their institution in order to get started creating their own project. Some organizations will have a specific on-boarding policy for new users, possibly including a signed agreement to use the system responsibly and conform with all necessary regulatory requirements involving the use of human subjects.

REDCap is a continually evolving software project with a very active user ecosystem. New versions are released on a regular schedule, and while this book will use the most recent version available at the time of writing, REDCap v 9.1.0, not all features will be covered. One of the goals of this book is to provide new users a concise resource for getting started with REDCap, and a comprehensive user manual would detract from that goal. REDCap does, however, have excellent contextual help provided within the software, and whenever there is more information on a topic, the reader will be directed to the relevant location.

Acknowledgements

I would like to thank the team at the Division of Infectious Diseases and the Center for Excellence in Infectious Disease Research at the University of Louisville’s School of Medicine for their help and support. Ideas for this book have arisen from their work with clinical studies. Thanks also to the many members of the REDCap consortium who contribute their knowledge to the Project REDCap community.
Part I

Project Creation
Chapter 1

Creating Your Study

The primary unit of organization in REDCap is the project. Depending on the application of REDCap, a project can be customized to support a public survey, a longitudinal study or even an inventory tracking system. The first step to creating and customizing a new project is to select New Project from the home screen.

1.1 Setting Up Your REDCap Project

After logging in to your REDCap instance, click the New Project button from the tabs at the top of the screen as seen in Figure 1.1. The project creation dialog shown in Figure 1.2 will display and you can enter specific metadata for the project.

Project title

This field will hold the title of the project. The title should be descriptive and concise. As you will likely be making more than one REDCap project, it will be helpful to have some sort of organizational scheme to your project titles. Since REDCap uses a unique number to refer to projects internally, you can rename your projects after they are created and even after data has been entered.

Purpose of this project

This field holds the type of project you will be creating. There are four primary types by which REDCap projects are organized: Practice, Operational Support, Research, and Quality Improvement. If the intended use of your project falls outside these categories, you can select Other and type in the purpose of your project. It’s important to note that these selections are for organization and reporting metrics only and will not affect the options and features available to your project once it is created.

- **Practice / Just for Fun** If you are interested in quickly looking through REDCap’s available features or experimenting with project creation and setup, this is the appropriate purpose selection.

- **Operational Support** As discussed previously, some of the many useful applications of REDCap involve taking advantage of its design as a secure web-based database. These can include inventory tracking, time management, file upload submissions and many others. If you are planning to use

Figure 1.1: REDCap’s NavBar at the top of the system home screen is used to navigate to the project creation dialog.
Figure 1.2: REDCap’s project creation dialog has the necessary fields for project metadata.

REDCap for this purpose, it is important to put some thought into the needs of your support project and consider REDCap’s limitations. It may be faster and less costly to adopt other software than to modify REDCap or use it in a way it was not intended.

- **Research** This is the primary type of project for which REDCap was designed. This can include observational studies, retrospective chart reviews, clinical trials, etc. When selecting the project type, REDCap will open a dialog for additional information.

- **Quality Improvement** Quality improvement projects will generally collect and analyze data in an ongoing effort to improve patient safety and clinical processes. Data collected for these projects must still be stored in HIPAA compliant environments, making REDCap an ideal choice for hosting this sort of project.

**Assign project to a Project Folder**

REDCap provides an organizational structure to help manage your projects. If you have already created project folders, you can select this checkbox and choose a folder to assign to your new project.

**Project notes**

Project notes is a free text field you may use to store information about your project that may help identify it to other members or provide a visual reminder about certain aspects of the project, such as the PI or clinical coordinator.

**Project Templates**

A new REDCap project can be blank, meaning it has no predefined structure, or it can take its structure from another project. Most projects will start with a blank slate, and have their structure created interactively through REDCap’s Online Designer.

New projects created by upload are XML files that follow the CDISC ODM format. Extensible Markup Language (XML) is a type of plain text file designed to contain arbitrary forms of structured data. The
Operational Data Model (ODM) is an XML specification designed by the Clinical Data Interchange Standards Consortium (CDISC) to facilitate easy communication and exchange of electronic clinical research tools like electronic case report forms (eCRFs) and clinical data sets. If you are planning to migrate a REDCap project from one REDCap system to another, you will need to export it in ODM-XML format from the source system first, before uploading it through the file upload dialog.

Project templates are projects that an administrator has designated may be used as a starting point for other projects. REDCap is distributed with some templates for common study types available (assuming they have not been disabled by institutional REDCap administrators).

**Types of Research Project**

If your project falls under the category of research, REDCap provides additional metadata fields to track relevant research information as shown in Figure 1.3. These fields are only used for tracking and project reporting statistics, and do not affect the type of features available in the project.

- **Name of P.I.** A research project is generally led by a single individual called the primary investigatory (PI). In research involving human or animal subjects it is this individual that ultimately maintains responsibility that the research is conducted in an ethical manner. REDCap has some features which can use the PI’s name to search the internet for publications related to a REDCap project.

- **Email of P.I.** This is the primary contact information for the PI of the project.

- **Name of P.I. as cited in publications** REDCap’s internal publication matching routine will use information from this field to search for PI publications if it is provided.

- **IRB number** If the project involves a study requiring approval from the institutional review board (IRB) of an organization, this field can contain that information.

- **Research Type** The checkboxes under *please specify* refer to the category of research your study would fall under.

  - **Basic or bench research** For a project holding data used to develop and test theories about physical and chemical phenomena
  - **Clinical Research study or trial** For a project holding patient clinical data related to an investigational or observational study or trial
  - **Translational Research 1** A project participating in the “Bench-to-Bedside” process of translating knowledge from the basic sciences into new treatments
  - **Translational Research 2** Translating the results of clinical trials into standard practice
– Behavioral or pyschosoical research study A project evaluating the behavior of human subjects as it effects their health or general well-being
– Epidemiology Projects aimed at discovering the relationship between diseases and the many factors which can cause them
– Repository A project serving as the look-up table for a bank of specimens
– Other If your project does not fall into one of the previous categories, you can specify Other and describe the purpose of your research project.

1.2 Navigating Around Your Project

After filling out the required information from the Create Project dialog, and clicking the Create Project button, you will be automatically navigated to the home page for your new project. If you navigate away from this page, you can get back to your project by navigating to the My Projects page and selecting it from the list of projects to which you have access. You are assigned access to all projects you create by default.

You may notice your project home page has changed the context of your REDCap session. When first logging in you were in the system context which shows the home page content and NavBar along the top. When in the project context the Navbar along the top is removed, and a sidebar with common project links and some useful contextual information is added to the left side of the screen as seen in Figure 1.4.

At the top of the sidebar, under the logo is the name of the current user and a link to log out of REDCap. Next are links to the My Projects page and REDCap Messenger, an instant messaging app allowing users to communicate directly or as a group. Next are four collapsible sections:

- Project Home and Design
- Data Collection
- Applications
- Help & Information

We will be going through the Data Collection and Applications sections in the following chapters, but for now we will focus on Project Home and Design.

The links in this section will allow you to navigate to the different subpages of your project and the project status indicator shows you whether your project is currently in development or production mode. The project subpages are
1.3. Setting Up Project Features

The first decision to make for a new project is whether or not it will be utilized as a survey or using a traditional data entry process. This is most often determined by the scientific domain of your project. Social sciences will often make use of surveys whereas observational clinical studies usually involve a clinical research coordinator entering data directly. If there is any part of your project that will need responses from the subject, you should enable surveys by clicking the Enable button next to Use surveys in this project.

The next decision is whether or not your project will be longitudinal. A longitudinal project is one which follows a group of subjects over an extended period of time, collecting the same data points at a set interval. This is usually done for prospective clinical trials, but could also be the case with a study involving surveys. This is why these two options are available independently, as projects can be survey-based, longitudinal, both, or neither.

You will need to navigate to the Main project settings panel if you ever decide to change the metadata of your project like the title, project notes, etc. Now that you’ve decided if your project uses surveys or is longitudinal, you can click the I’m done button in the Main project settings panel to track the completion of this step. The next checklist item is the Design your data collection instrument panel and this will be covered in the next chapter, Data Collection.
Before moving on in the project setup, click on Project Home. This page shown in Figure 1.6 becomes the landing page once your project design is complete and the project moves to production. In past versions of REDCap this is where several useful links were located, such as the link to the project codebook, a list of all the variables defined in your project, and a link to download your data dictionary. In the most recent version of REDCap these have been moved to the sidebar, making them much more accessible. However, there is still some useful information on the project home page including a list of the users that have access to your project, a list of upcoming events, when using REDCap’s calendar feature, and the number of records and most recent activity in your project.
Chapter 2

Designing Your eCRF

In the last chapter you created a new study project using the REDCap new project dialog. In this chapter we create the electronic case report form that will be used to collect survey or data fields.

2.1 Using the Online Designer Tool

Continuing with the Project Setup checklist from the previous chapter, the Design your data collection instruments panel shown in Figure 2.1 is the starting point for creating a new electronic case report form. There are several links of note in this panel. The Online Designer button will take you to the online_designer page and the Data Dictionary button leads to the data_dictionary_upload page. Links to these pages are also on the right sidebar as Designer and Dictionary. There is also the REDCap Shared Library button leading to a database of data collection instruments approved by REDLOC, the REDCap data collection working group. It’s a good idea to experiment with creating your own data collection instruments before moving on to downloading validated instruments from the shared library.

The online_designer page seen in Figure 2.2 has a tab bar that is the same as the tab bar present on the project_setup page, with a couple of exceptions. Instead of tabs for Other Functionality and Revision History there are now tab links to the Data Dictionary and Codebook. If you have trouble locating a tab button that was present before, it may be because the page you are currently on has changed. Many of REDCap’s layouts are contextual, meaning they can change in subtle ways when you navigate to a new page. Underneath the tab bar is a link to an instructional video for the Online Designer and a button called Create snapshot of instruments. REDCap’s online designer automatically saves any changes you make to your instruments as you develop them, but it does not implement any sort of undo feature. It’s a good idea to make regular snapshots of your instruments, in case you want to revert to a previous version.

![Figure 2.1: The data collection instruments panel is the starting point for the initial setup of a project.](image-url)
2.2 Creating Your Data Instruments

If you examine the Data Collection Instruments panel, you should see several buttons under Add new instrument, Create, Import, and Upload. Import will take you to a page to pull an instrument from the REDCap shared library and Upload will open a dialog for uploading a Zip file containing a REDCap instrument. Create utilizes the online designer to develop a data instrument interactively. Below these buttons is a list of the instruments currently in your project. Every new blank REDCap project starts with the My New Instrument as its first instrument. Next to the instrument you will see cells describing the number of fields the instrument currently contains, a link to download a PDF of the current instrument, and button for performing miscellaneous instrument action. Clicking Choose Action will allow you to rename the instrument, copy it, delete it, or download it in Zip format to upload into another REDCap project. Notice you cannot delete an instrument if it is the only one in the project.

Mousing over the instrument name will show a pencil icon next to it which indicates that clicking will take you to the page for editing this instrument. Editing an instrument is how fields are added or removed interactively. Each instrument has its own page name, and editing it will take you to its page, as you can see in the URL of your browser window.

The page for editing an instrument is shown in Figure 2.3 and has a blue button that will return you to the Online Designer page, a button to allow previewing the way the instrument will look from a data entry screen, the label of the current instrument, and a list of the fields in the current instrument. Beneath each field will be two buttons Add field and Add Matrix of Fields. These buttons support the creating of new fields interactively within Online Designer.
2.3 Choosing Data Fields

Each field in the project has several metadata elements associated with it, the two most important of which are its label and variable name. Using the first field as an example, its label name is Record ID and its variable name is `record_id`. When looking at a survey or a data entry form, the field label will be displayed. When looking at a report or data export, it will be the variable name.

Clicking on the Add Field button will launch the Add New Field dialog shown in Figure 2.4 which starts with a drop-down list to select the type of the new field and a link to a short video tutorial. Each field type changes the layout of the Add New Field dialog to allow entry of additional data regarding the field.

**TextBox**

The first and most common type of field used in projects, is the Text Box. A text box field is meant to have input typed from a user’s keyboard, and is best for data that can not be known in advance like a physician’s notes or an open-ended survey response question.

In a live form or survey a text box will have it’s label and input field contained in a styled rectangle. The field input is on the right side and the field label is on the left with two icons. Clicking on the H icon will open the data history log for the field. Clicking the bubble icon will open either the field comment log or the data resolution workflow depending on which is enabled for the current project. These two features will be discussed in chapter Project Customizations. Survey input fields differ only in that they will not display these two icons.

**Notes Box**

The notes box input is similar to the text box, but is intended for larger amounts of text input. The box will appear larger on the screen for both survey and data entry forms. Unlike text box entry, there is no
CHAPTER 2. DESIGNING YOUR ECRF

![Calculation Equation](image)

Figure 2.6: Calculated fields require a calculation string specifying how the field value is derived.

![Multiple Choice](image)

Figure 2.7: Multiple choice fields require a list of possible values.

validation that can be defined for the notes box.

**Calculated Field**

A calculated field in REDCap is one which derives its value from other fields that have already been input into the form or survey. Its best use is for numerical calculations that would be tedious to perform upon each record. For example BMI is a common health metric used by clinicians and is based on a patients height and weight. Height and weight are commonly stored in electronic medical records, and use a calculated field, the field for BMI in REDCap would automatically populate once the corresponding fields for height and weight were filled. The calculated field can also perform more advanced manipulations such as calculating a follow-up date based on a date of service or an age based on a date of birth.

**Multiple Choice**

Multiple choice fields provide the means for a user to select the value for a field from a list of options. This is more convenient for a user, but also has advantages in terms of data quality. The form designer can determine the only values that will go into the final database by limiting the possible selections. Values can be selected by clicking on a drop-down menu, or by displaying the entire list of options at once using what’s called a radio button. For long lists, the drop-down option is necessary. Also useful for long lists is a selectable option for letting the user find the desired value from the list by typing into a search box.

**Checkboxes**

Checkboxes can be used when a field allows multiple different values to be associated with it, as in a “select all that apply” question. In the data dictionary, REDCap will number each checkbox item, and this number is used to refer to the response in reports and branching logic.

**Yes - No**

Yes-No and True-False fields are simply multiple choice type fields locked to two options. These come up frequently enough in survey and forms that it saves time to have a built-in type already set up.

**Signature**

REDCap supports digitized input from the mouse or a tablet screen which it will store in a field as an image file. This is intended for capturing signatures and other forms of consent.

**File Upload**

If a file needs to be uploaded in response to a survey or record, the file upload field can be used to provide a link to open a file attachment window. Once open the user can navigate to the file location in their operating
system and upload it through their browser. REDCap does not currently provide a convenient way to export all of the files for a given project. Doing so requires the help of a programming language and the REDCap API.

**Slider / Visual Analog Scale**

The visual slider field stores a response as a number, but unlike the standard text box entry it provides an on-screen slider to visually associate with the response.

**Descriptive Text**

Descriptive text is a selection that does not map to an entry in the data dictionary, but rather provides a place to present content to the survey respondent or data entry personnel. Content like text, images, download links to files, and even embedded videos can be placed on a form or survey using the descriptive text field type.

**Begin New Section**

The intention of the begin new section selection is to help organize the survey or form visually. Adding a new section provides a separator between groups of fields and can only be placed between two fields that have already been added. It can not be placed at the end or beginning of a form.

**Text Box Validation Rules**

One of REDCap’s most useful features is its input validation rules. These provide feedback to a user upon any input of data that is not of the expected type for a field or does not fit a pattern determined by the form designer. A list of the rules are shown in table

**Sidebar: Data Collection**

After creating the fields for a project it is useful to look at the project sidebar again and notice the Data Collection section. This section will appear differently depending on whether surveys have been enabled for the project in project setup.
Table 2.1: Supported REDCap Validation Rules

<table>
<thead>
<tr>
<th>Validation</th>
</tr>
</thead>
<tbody>
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<td>Letters only</td>
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<td>Email</td>
</tr>
<tr>
<td>Integer</td>
</tr>
<tr>
<td>MRN (10 digits)</td>
</tr>
<tr>
<td>MRN (generic)</td>
</tr>
<tr>
<td>Number</td>
</tr>
<tr>
<td>Number (1 decimal place)</td>
</tr>
<tr>
<td>Number (2 decimal places)</td>
</tr>
<tr>
<td>Phone (North America)</td>
</tr>
<tr>
<td>Social Security Number (U.S.)</td>
</tr>
<tr>
<td>Time (HH:MM)</td>
</tr>
<tr>
<td>Time (MM:SS)</td>
</tr>
<tr>
<td>Zipcode (U.S.)</td>
</tr>
</tbody>
</table>

Figure 2.10: Standard data collecton sidebar.

Without surveys, there are two links and an expandable list that are part of the data collection section. The first link is the Record Status Dashboard. This takes you to the record status dashboard page and shows a visual representation of all the instruments in the project and their states of completion.

The other link is the Add/Edit Records Link which takes you to the add record page. On this page a record from the current records can be selected, or a new record can be added. If auto numbering is enabled, the user only needs to click add record to be taken to the data entry field. Otherwise before adding a record, the user will have to assign the record some record ID.

The last link is a smaller one which reads show data collection instruments. This a newer feature in REDCap and clicking on it displays the full list of instruments in the project. Each instrument will be shown as a link and clicking an instrument link will first prompt the user to select a record if one is not selected. Otherwise it will navigate to the selected instrument for the current record.

The content of the data collection section of the sidebar includes one additional link when surveys are enabled, the survey distribution tools link. This links leads to a page which allows customization of how surveys will be made available to participants. This pages is covered in the next section on surveys.

### 2.4 Using Surveys in Your Study

Now that we are familiar with the way to structure form fields and instruments from the previous sections, we will look at the REDCap features aimed specifically at administering surveys. As discussed in the project
creation section, the first step to using surveys in REDCap is to make sure the surveys feature is set to enabled on the project setup page. Once it is, several new options are available in both the data collection sidebar and the online designer.

With surveys enabled, navigating to online designer page shows a new section called Survey Options. Within this section are the Survey Queue, Survey Login, Survey Notifications and Automated Survey Invitations Upload links. Additionally there is a new button on each instrument in the instrument list called Enable as survey, and a new section called survey related options. Enabling an instrument as a survey will show the Survey settings and Automated Invitations buttons to appear in the survey related options section. We’ll go over each section.

**Basic Survey Options**

The basic survey options include the Survey Title and the Survey Instructions. These will be placed at the top of the device on which the survey is being viewed. The survey instructions box can have text that is marked up with bold or italics, and can even include html like hyperlinks and tables.

Information can be piped from fields in a record to personalize the survey instructions. For example, if the survey is being sent to respondents that already have demographic data from a form in REDCap containing their name and email, these field values can be included in the survey instructions. For completely anonymous surveys where the record is blank at the time the survey is distributed, there will be no information stored to pipe from.

**Survey Design Options**

The survey design options panel includes several options to help customize survey presentation. A logo can be added to provide branding to a survey affiliated with a certain institution or organization. Enhanced radio buttons and checkboxes provide alternative mobile-friendly user interface elements for those fields, making it easier to complete the survey on a mobile device. Survey font and text size can be changed, as well as the survey theme. A preview window in the survey design options panel shows the effects of changes made to these settings.

**Survey Customizations**

The survey customizations panel includes options for modifying how the survey is presented to different audiences. Questions are numbered by default but this can be disabled with the Question Numbering option. The entire survey form can be displayed on a single web page, or the survey can be split into multiple pages based on the sections of the REDCap survey form. This can be useful if you wish to avoid having a survey appear too long at the beginning, or when you don’t want survey respondents to be distracted by other
**Figure 2.13:** Basic survey options can be edited from this screen.

**Figure 2.14:** Survey design options control the appearance and theme of the survey.
text on the page when answering a question. You can allow users to navigate back to previous pages or not depending on your preference for the survey.

REDCap can allow survey participants to download a PDF of their responses after they have completed the survey but setting that field to yes in the customization panel. This PDF file is generated by REDCap after the survey is complete, and the link provided to the respondent will allow them to download it through their browser.

Survey-specific invitation fields can be set to allow different survey forms in a REDCap project to be sent to different email addresses. For simple surveys, one record will correspond to a single survey. However, REDCap supports projects with multiple surveys where responses are all stored in a single record. Using the survey-specific invitation field, different surveys could be sent to different email addresses, and therefore different respondents. For example a patient record could include surveys sent to different caregivers and physicians.

**Survey Access**

The survey access panel provides settings to limit when and how the survey can be accessed. Response Limit disables the survey after a certain number have been collected and Time Limit and Survey expiration limit the amount of time a respondent can spend on the survey and the date at which it can be accessed respectively.

Surveys can allow respondents to return later to complete a survey that has been previously started. REDCap will generate a return code for a respondent when they choose to save and return later, and upon entering this code they can complete their original survey. Return codes can be disabled for anonymous surveys, but should be left enabled for surveys with identifying information as all responses would be visible to returning respondents. Surveys also support allowing respondents to return and change their previous responses, but this is also disabled by default.

**Survey Termination Options**

The termination options panel controls the behavior following completion of a survey. If multiple surveys
Figure 2.16: The survey access panel controls how the survey is made available.

are in the project, the completed survey can be set to automatically move to the next one for the current respondent if this is the desired behavior. If not or if the project only has one survey for the current respondent, the survey can redirect the browser to a new web address or customized text can be entered similar to the survey instructions section.

If a survey will be functioning as a legal consent document, REDCap’s e-Consent Framework can be used to provide the necessary storage and documentation requirements. It’s important to check with your local institution to ensure your deployment of REDCap has been approved to manage electronic consents.

Finally, the survey can be configured to send a confirmation email to the respondent which includes their responses. This must be configured to come from a REDCap user or account associated with the project. At this point the settings can be saved and will be live once the survey is made available to potential respondents.

Now that the survey presentation has been established through the survey settings, we can take a look at the other survey features found on the designer pages.

Survey Queue

The survey queue provides a way to link multiple surveys in a project together and provide a convenient visualization to a respondent detailing which surveys they have completed, which are in progress, and which still need to be done. Clicking on this button brings up the survey queue dialog, which allows surveys to be added and ordered in the queue. The survey designer can also decide how the queue will handle the completion of surveys, i.e., whether a respondent is returned to the main page of the survey queue each time they complete a survey or they are automatically redirected to the next survey they should complete.

Survey Login

A survey login provides a secure way for users to authenticate to a survey before they provide information. The authentication can be a combination of up to three fields, for example first name, last name and date of birth. This provides a means to more securely track who is accessing a particular survey. This simplifies the process for returning to complete a survey later, as the user can use their authentication questions rather than a return code.

Survey Notifications

Each REDCap user associated with a project can receive email notifications when a survey is completed. The notification provides a link to the record for the completed survey, but cannot be customized to include different text or data piped in from the survey responses.

Automated Invitations
2.4. USING SURVEYS IN YOUR STUDY

Figure 2.17: The survey termination options determine survey behavior after completion.
Automated survey invitations provide a way to have REDCap automatically send survey invitations based on condition within the survey project. This can involve the completion of other surveys in the project or logic within the project itself. For example, if a record includes fields for names and other demographic information, and you only want to invite respondents with complete information to complete the survey, a condition for an automated invitation could be that certain fields cannot be empty. Once the condition evaluates to true, and those fields contain data, REDCap will schedule and send the invitation.

2.5 Creating a Longitudinal Study

After enabling longitudinal data collection forms on the project setup page, there will be a new panel on the project setup checklist. This panel contains the links to two new pages, Define my events and Designate instruments for my events.

Define Events

On the Define Events page you will be able to specify which events are part of your project. Each event will belong to an arm, and if you only wish to have a single group of events in your longitudinal study, all your events will belong to arm 1. On the Define Events page you are able to add new arms to your study and add new events to each arm.

REDCap will start new longitudinal projects with a single event named Event 1 in Arm 1, just as the first instrument in new projects is My First Instrument. You can change the name of Event 1 to something more descriptive by clicking on the pencil icon to edit the name.

Designate Instruments

Now that we have created events, we need to tell REDCap which instruments will be collected for each event. Although you could assign every instrument to each event, that would not be the best use of the longitudinal project. For example, if you wanted to collect patient lab data over 3 visits, your REDCap project would have a demographics form for patient information, a medical history form, and a lab values form. You could then divide your project into 4 discrete events. The first would be Enrollment or Project start. This event would have the Demographics and Medical history forms as its instruments. Then you would have Visit 1, Visit 2, and Visit 3. The Lab Values instrument would be in each of these events, but not in the Enrollment event. Likewise the Demographics and Medical History events would not be included in the Visit events.
2.5. CREATING A LONGITUDINAL STUDY

Figure 2.20: The add new events panel supports adding new arms and events by name.

Figure 2.21: Instruments can be designated as longitudinal from the designate instruments page.
Chapter 3

Managing Your Study Team

In the last chapter we continued the process of project creation with the design and implementation of the electronic case report form. In this chapter we will discuss the process of granting other REDCap users access to your project. By default the project creator will have access to all aspects of the project, and this may be sufficient for small projects. However, in most cases several project roles will be necessary for a successful study, including the primary investigator, co-investigators, data collection personnel, and biostatisticians. Since REDCap is web-based it can support collaboration on research projects between these individuals. It can also support the grouping of users based on specific records in the project to which they should have access, in the form of Data Access Groups (DAGs).

Sidebar: Applications

In Chapter 4 we looked at the Data Collection section of the sidebar and in this section we will look at the section titled Applications. The assignment of user rights to users in a project will affect which links are displayed in the applications section so we will start with a quick description of each of these links and discuss what types of users should have access to each. The applications themselves will be discussed more fully in subsequent chapters.

- Alerts & Notifications – send email alerts
- Calendar – schedule study events
- Data Exports, Reports, and Stats – export data
- Data Import Tool – import data
- Data Comparison Tool – compare records
- Logging – access project logs
- Field Comment Log – access field comments
- File Repository – access exports and uploaded files
- User Rights and DAGs – set user rights
- Customize & Manage Locking/E-signatures – set locking features
- Data Quality – set real-time data quality rules
- API and API Playground – set up API access
- REDCap Mobile App – set up mobile app access
- External Modules – assign external modules to project

3.1 Who Can Access Your Study

From the project setup page, we will move past the optional modules and project bookmarks panels to the User Rights and Permissions panel. Optional modules and project bookmarks will be covered later, as their
Figure 3.1: The nav bar of the user rights page includes the user rights and data access groups pages.

Figure 3.2: Users can create roles, assign users to created roles, or assign custom user rights to a user.

default values are usually sufficient for most projects. Within the user rights panel are links to the user rights and data access groups pages.

The first panel on the user rights page is the add new users panel. This is where a user in the REDCap system can be associated with the current project. Only users that have been given accounts in the REDCap instance are available to be assigned from this screen. If a user needs access to the system, a REDCap administrator will have to establish an account for them. Once this is done, their account will be accessible from the user rights page.

There are two ways to add a new user to a project. The first is to add them and manually assign their rights for the different project applications. The second is to assign them to a project role that has already had project rights for the role assigned. We will start with adding a user with custom rights.

For a small project with few users, adding with custom rights is a much faster way to get the project up and running. To add a user, start typing in their name or username in the field until their account information appears below the text entry box. If the account you are looking for does not appear you will want to verify you have the right information and that the desired account is currently in the REDCap system. Once you have selected the right account name, you can click the add with custom rights button to open the add new user dialog.

There are several panels in the adding new user dialog. On the left side are the panels for the types of project application access the user should have and on the right is the list for the types of data entry rights a user should have. The data entry rights are separated by REDCap instrument, and can be set to No Access, Read Only or View & Edit. If an instrument is set to No Access for a user, they will not be able to view or export any of the data associated with that instrument. Users with Read Only can read or export data for an instrument, but not change it. Users with View & Edit have full access to the instrument.

The project application access on the right has several sections starting with Basic Rights. The Expiration Date field allows setting an expiration date for the users access to this project. Next are the highest level privileges for the project, usually intended for the project designer and PI. Project Design and Setup allows adding new fields to the instruments and changing project settings in the project setup page. User rights allows adding new users to the project and editing their types of access. The user rights page is only accessible when this right is assigned. Creators of a project will have these rights set by default when the project is first created. Data Access Groups allows the Data Access Groups page to be accessed and those groups to
3.1. WHO CAN ACCESS YOUR STUDY

Figure 3.3: The basic rights panel determines the highest level privileges including project settings, adding users, and data export.

be changed. Next in basic rights are the privileges for all types of data exports. A user must have some type of export privilege assigned and the default is de-identified. This means no data field with the identifiable flag set during eCRF creation can be exported along with any date or free form text field. The other options are No Access, Remove all tagged Identifier fields, and Full Data Set. Remove all tagged Identifier Fields relaxes the date and free form text restrictions of de-Identified but still removes fields tagged with Identifier. Full Data Set provides no restrictions and No Access disables exports entirely.

The Add/Edit/Organize Reports allows the user to add and view reports, but may have certain data restricted at the report level. The stats are charts setting will allow the user to view the charting visualization for reports when they are viewed.

The next user rights panel focuses on the REDCap Mobile App access and project record access. If the REDCap Mobile App has been enabled for the project, assigning the REDCap Mobile App privilege will allow the user to interact with the project using the app from their mobile device. You can customize whether or not they are able to download data for all records to the app.

The next section involves Creating, Renaming and Deleting records. The default setting for a new user is to be able to create new records. If this is disabled, the user will only be able to interact with records already entered into the project. Renaming records allows a user to change the record ID for a record. This is not enabled by default as the record ID is the primary way REDCap organizes records, and changing the ID can create inconsistencies with previous data exports, data imports and logging. Deleting records is also not enabled by default as this setting allows a user to purge data from the system. Deleting a record cannot be undone.

Record locking privileges determine the user’s ability to lock and unlock records. Records are usually locked as a data quality action to prevent changes to a record once it has been reviewed by a project manager. E-signatures are intended to provide a higher level of validation than locking, as a user with e-signature privileges who locks a record with an e-signature is asked to input their REDCap login credentials to verify that the record should be locked and the time and date of the lock will be recorded in REDCap’s audit trail. Locked and e-signature locked records can be unlocked and changed any number of times by users with the relevant privileges.

Finally other privileges include the other project application pages discussed at the beginning of the chapter.
The privileges allow access to the project calendar, data import tool, Data Comparison Tool, Logging, File Repository, Data Quality and API pages.

3.2 Assigning Study Roles

As mentioned before, the privileges for a user can be assigned manually, but for larger projects with a large number of users and REDCap instruments, it is more efficient to use REDCap’s User Roles. A user role is a named template with all of the privileges on the user rights page already set. For example a user role for someone who will only be doing data entry for a project might have View & Edit access to all instruments, but no export or project design privileges. A biostatistician could have View Only access to all instruments and Full Export rights but not the create record privilege. Once these roles are established, adding new users to a project becomes very simple. In addition, it becomes much easier to track the different types of access users within an organization possess and roles in REDCap can be reconciled with roles in other management systems such as those used by an institutional review board.

3.3 Using Data Access Groups

Data Access Groups are a mechanism provided by REDCap to separate access to project records based on which user created the record. This is useful for studies which may be multi-site in nature. Data entry
3.3. **Using Data Access Groups**

Figure 3.6: The user role table provides a snapshot of the complete privileges of a user or role.

| Role name | Owner | Username | User rights | Data Access Groups | Data Users Tool | Data Environments and Data | Data Import tool | Data Extraction Tool | Data Log | Data Reporting Tool | Data Distribution Tool | Data Security Model | Data Quality Model | Data Access Groups | Data Access Groups | Data Access Groups | Data Access Groups | Data Access Groups |
|-----------|-------|----------|-------------|-------------------|----------------|---------------------------|------------------|---------------------|---------|--------------------|---------------------|-------------------|-----------------|-------------------|-------------------|-------------------|-------------------|
| [not assigned to a group] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] | [non-mentioned] |

Figure 3.7: Access groups can be created and users assigned from the create new groups panel.

personal at one site must have view and edit privileges for their own site data, but should not have it for other sites. Since user rights privileges only restrict access at the instrument level, there would be no way to achieve this in a single project without data access groups.

The data access groups page provides buttons to create new access groups and to assign users to a group. Users who are not assigned to any group will have no restrictions on the records they may interact with. Users assigned to a group, will only be able to interact with records created themselves or by other members of their data access group.

Figure 3.8: The data access groups table lists all the current data access groups in the project and shows which users are assigned to each.
Chapter 4

Customizing Your Project

In the last chapter we discussed setting up user management on the user rights and data access groups pages. In this chapter we will discuss some of the customizations and optional modules REDCap makes available.

4.1 Enabling Optional Modules

We return now to the third panel down on the project setup page, Enable optional modules and customizations. For many projects, the default settings on this panel are appropriate, but in some cases these additional features can be useful for a project or study.

Repeatable Instruments

The repeatable instruments setting allows instruments in REDCap to be designated as repeating, meaning they can have multiple groups of data per record for that instrument. REDCap’s data format is intended to closely resemble flat table formats like excel, where every field of data belong to the same row in the table. There are many instances when it would be more efficient to have multiple data fields linked to the same record. This was done similarly in REDCap with longitudinal projects. Unlike, longitudinal projects, a repeating form does not have to have each event created manually. A new repeating instance within a record can be created on an ad-hoc basis.

Auto-numbering

Auto-numbering for records is enabled by default on new projects. This setting tells REDCap to assign a unique record ID field to new records when a user adds a record from the Add/Edit Records page. This ensures that each record ID is unique, which is a requirement for all REDCap projects. If this is disabled, a user will need to enter a unique record ID every time a record is created or uploaded with the data import.

![Image](image.png)

Figure 4.1: The optional modules panel contains the most common project customizations. Auto-numbering is enabled by default on new projects.
tool. REDCap will scan the database when a user enters a new record ID, and if a record with that record ID already exists, the new record will not be created.

**Scheduling Module**

The scheduling module allows you to generate a schedule for visits or labs for the events in a longitudinal project. If this is enabled, a new link will be added to the data collection sidebar called Scheduling. The Define My Events page for longitudinal projects will also have a new field for each event called Days Offset. Days offset allows you to specify how many days an event is after or before the first defined event. Once this is set for the events, going to the Scheduling page will allow you to generate a schedule for events that will be stored on the Calendar page.

**Randomization module**

Randomization is a process used in clinical trials to vary which subjects are assigned to which control groups in an unbiased way. REDCap’s randomization feature allows a project designer to develop a randomization model for this purpose. Once this feature is enabled, a link to the randomization page will appear in the application sidebar.

The randomization page has tabs for setup and a dashboard. In randomization setup, there are settings for using a stratified randomization, randomizing by group or site, and selecting which field and event in the database will be used to store the randomized group assignment. The selected field will have a randomize button on the data collection form for users with the randomization user right. Randomization is also logged in the audit trail when it is performed.

**Designate an email field for sending survey invitations**

Designating an email field for survey invitations allows REDCap to pull all values from that field for sending survey invitations. Survey level invitations will override this field, and email invitations manually entered in the participant list will supersede both.

### 4.2 Making Additional Customizations

Another group of REDCap features are accessible from the Additional Customizations button on the optional modules and customizations panel. Clicking this button opens the additional customizations dialog. Each of these features are discussed below.

**Custom Record Labels**

REDCap can set custom record labels to display on the Add/Edit Records and Record status Dashboard pages. Any static text can be displayed along with piped data from a field, for example, to show a name beside a record ID, the custom record label might be `{last_name}`, `{first_name}` and would if record 1 was for John Doe, would show as 1 Doe, John on record status pages.

**Secondary Unique Field**

The record ID for each record in a REDCap project must be unique, but a secondary unique value can also be specified using this setting. REDCap will check all other values for a secondary unique field before allowing a record to be added, updated or imported. This is useful when auto-numbering is used for record IDs in REDCap but the study is using another identifier when communicating to other parties.

**Order records**

By default records are ordered by the record ID in the Add/Edit records drop down and record status dashboard, but this can be changed with this setting. The field can be used to order the records in ascending order by that fields contents.

**Field Comment Log and Data Resolution Workflow**

By default REDCap enables a feature called the Field Comment Log which stores plain text comments from users with every field. A small balloon icon next to a field in the data collection form allows a user to add
4.2. MAKING ADDITIONAL CUSTOMIZATIONS

![Additional customizations dialog](image)

You may use the options below to make customizations to the project. When done, click Save to save your changes.

- **Set a Custom Record Label**
  - You may append other data and/or static text to any record name (e.g., Study ID) as the record is displayed on your data collection instrument(s), such as inside the drop-down lists when choosing a record and at the top of the page after being selected. Simply provide the text you wish to display below, and place any variable names inside square brackets, after which the data collected for those variables for that record will replace the variable in the text.
  - **Custom Record Label:**
    - Example: If `[first_name] [last_name]` when ordered, then for record "123" it would display "123 (Joe, Lisa)"

- **Designate a Secondary Unique Field**
  - You may designate a field to serve as a unique constraint whose value cannot be duplicated or shared by any other record in the project. When a value is entered or imported for the secondary unique field, it will be checked in real time to ensure it is not shared by another record, and if so, it will ask the user to enter another value. Additional options exist below that dictate if and how the secondary unique field will be displayed in conjunction to a record name on various pages in the project.
  - **Display the value of the Secondary Unique Field next to each record name displayed?**
  - **Display the field label of the Secondary Unique Field when displaying the value?**

- **Order the records by another field**
  - The default setup is that all records are ordered by their record name (e.g., Study ID) when displayed in the drop-down lists on your data collection instrument(s), but you may alternatively order the drop-down lists by the values of another field in the project (e.g., last name), if desired. If you wish to order the records by another field, select the field below.

- **Enable the Field Comment Log or Data Resolution Workflow (Data Queries)***
  - For this project, you may enable either the Field Comment Log or Data Resolution Workflow (also known as the Data Queries module). The Field Comment Log (enabled by default) allows users to leave comments for any given field on a data entry form by clicking the balloon icon next to the field. All comments can also be viewed, searched, and downloaded on the Field Comment Log page. Alternatively, if the Data Resolution Workflow is enabled, users will be allowed to open a workflow for documenting the process of resolving issues with data in the project (i.e., opening, responding to, and closing data queries). View more details.
  - **Enable Field Comment Log**
  - **Allow users to edit or delete Field Comments (excludes Data Resolution Workflow comments)?**

- **PDF Customizations**
  - Downloadable PDFs of data entry forms and surveys can be customized using the options below. Note: The options will be applied to ALL instruments in the project.
  1. [Set custom header text to appear at top left of every PDF page (it may be left blank, if desired). Note: Only static text can be entered; it's piping cannot be utilized here.]
     - **Confidential**
     - **Default text:** Confidential
  2. [Display or hide the REDCap logo and website URL at the bottom right of every PDF page?]
     - Display REDCap logo and website URL (default)
     - Hide REDCap logo/URL and instead display the following text: Powered by REDCap

![Save and Cancel buttons](image)

Figure 4.2: The additional customizations dialog contains settings for custom record labels and secondary unique fields. The field comment log is enabled by default on new projects.
a new comment to a field or read previous comment left by other users. Date, time and user name are all recorded with each comment. This feature can provide a data history for changes to a field’s values.

REDCap also supports a data quality procedure called the Data Resolution Workflow. Only one of the field comment log or data resolution workflow can be enabled at the same time. Enabling the data resolution workflow adds a link to the application sidebar next to Data Quality called Resolve issues. This link will take you to the resolve issues page where a list of current and previous queries can be viewed or exported. These queries can be opened from the data quality page as a result of the execution of a data quality rule or from the data collection form by clicking on the balloon previously used for the field comment log.

PDF Customizations
By default the text on a PDF has several features that are present on every page. Some of these features can be modified with this setting.

- Set custom header text to appear at top left of every PDF page
- Display or hide the REDCap logo and website URL at the bottom right of every PDF page?
- Display or hide the Secondary Unique Field value at the top right corner of the PDF

Data History widget
This setting is enabled by default and makes the data history of a field view-able by clicking the H icon displayed next to it.

Today/Now Button
This setting is enabled by default and displays a button which shows a popup window containing a calendar to make accurate date selection easier. A date/time field will likewise have the calendar and a slider for hour and minutes. Most modern browsers support these features, and there is little reason to ever disable them.

Require a Reason to Change Records
This setting can provide a more rigorous data quality process for a project, by requiring all changes to field values coming after initial data entry to be justified by the user. It should be carefully considered whether this is necessary to improve data quality and data entry workflow. If data must be changed too often, it is likely to encourage poor justifications for the sake of brevity, negating the usefulness of the feature.

Data Entry Triggers
Data entry triggers are an advanced feature that can allow notification of an external website whenever a record is changed in a project. Many systems like electronic medical records and patient registries will have features like these to support real time notification of any change. If this feature is enabled, an HTTP address can be entered into the text box here and the address will be sent an HTTP or HTTPS message containing record information. If your institution has agreed to share information with an external entity and that entity has the capability to set up an HTTP listener to receive data in a certain format from REDCap, this may be the most efficient way to facilitate the transfer.

4.3 Moving Project to Production

If your project has all of the features you need and you have tested that they work as expected, it’s time to click the last of the test checkboxes and move your project to production mode. The last box on the project checklist from Chapter 1 was project bookmarks. Project bookmarks provide a way to make links to other projects or even external websites more convenient. Any bookmarks added will appear in a new section on the sidebar. In cases where a link will be a REDCap project, you can specify in the bookmark settings that the link include a project and record ID.

Moving a project to production will sometimes require the approval of a REDCap administrator at your institution. Changes to your study will also be more time consuming after you move to production, as
4.3. MOVING PROJECT TO PRODUCTION

REDCap will keep a thorough history of new changes to the project setup. Requiring further changes to be approved by a REDCap administrator is a safeguard to protect a project from accidental loss of data due to modifying REDCap instruments. For example, removing a field from an instrument will result in the destruction of all data that was previously entered into the field. Given the time and costs needed for data collection, this could be a major loss. REDCap provides administrators some automated protections to inform them how much, if any, data loss would occur if proposed changes are made and production mode safeguards give them the chance to carefully check whether or not this is desired.

This concludes Part 1, project creation, and in the next part we examine project management starting with data quality and reports.
Part II

Project Management
Chapter 5

Improving Study Quality

Data quality in a study is similar to quality control in a manufacturing process. Goods produced without sophisticated quality control may seem to work initially, but usually have defects that become apparent after widespread use. In the same way, a study without data quality procedures can produce results that are inconsistent and inaccurate. These types of results make it hard to justify the time, effort, and cost involved in conducting the study and collecting data in the first place.

REDCap has many features that assist study investigators and coordinators in maintaining a high quality study. Some of these features were discussed in Chapter 3 CRF Design concerning data type validation. Placing restrictions on the type of data that can be entered into a field reduces the number of data entry mistakes that can be made on a project at virtually no cost. The designer need only specify that a field can only hold numbers or fields that match an email address, and the system will automatically prevent any other type of input. The features discussed in this chapter must be executed proactively by a project coordinator.

5.1 Exporting Data and Generating Reports

One of REDCap’s most useful and promoted features is its support for user created ad-hoc reports. These reports can provide customized views of the data currently in a project. Reports are accessed by clicking on the Data Exports, Reports, and Stats link in the applications section of the sidebar.

On the Data Exports page, a list of all reports in the project are shown following links at the top to simply display all data in the project in a flat table format. The links View Report, Export Data, and Stats & Charts next to All data will each show all data in the project without any filters. View report will show the data table within the web browser, and Export Data will format the data for download in Excel, CSV and other common statistical formats.

Often the data you are interested in may be contained only in specific instruments in which case the Selected instruments report will be more useful than All data. After clicking Make custom selection, you will be able to highlight the instruments that are of interest, and the report generated will only contain data from fields within the selected instruments.

Create New Report

To take full advantage of REDCap’s reporting functionality, a new report should be created. This link will be at the bottom of the list of reports. Create new report also has a tab link at the top of the exports page. After clicking either link you will be on the create report page for a new report.

Each report created for a project has a unique ID that is created by REDCap and stored internally. This ID will be in the URL of a report page and will not change once the report is created. The first step to creating
Figure 5.1: The data exports page includes a list of accessible reports and links to create new reports, export the entire data set, or export selected instruments only.

Figure 5.2: Naming new reports is required and providing a description is suggested.
5.1. EXPORTING DATA AND GENERATING REPORTS

Figure 5.3: New reports can be visible and editable by all users or specific users only.

Figure 5.4: The fields to include in a report can be added individually or as an entire instrument.

a new report is to give it a name. Since each report has an internal ID, you can feel free to change the name after the report is created. The name should be as descriptive as possible, as the number of reports in a project can grow to be very large. Reports can also have a description that will be displayed at the top of the report page when viewed. This is useful for storing information about the intended purpose of the report for either the report creator or other users of the report.

Redcap’s report creation page breaks down the process of creating an effective report into 4 steps, each with its own panel on the create report page. After providing a name and description for the report, the first step is to decide who will need access to it. Access to a report is divided into view access and edit access and these settings are shown in the user access section of the step 1 panel. By default a new report will be accessible to all users in the project for viewing and editing. By switching either to custom user access, you will be able to select the specific users, user roles or data access groups that the new report should be associated with.

In Step 2 of report creation, the fields the report will display need to be selected. By default the Record ID field will be included in the report. The Record ID field can be removed from the report, but at least one field must be in the report for it to be saved. New fields can be added to the report one at a time by typing the name into the text box next to the field number or by using the drop-down.

For large projects with a lot of fields REDCap includes some faster ways to add fields to the report. The Quick Add feature is at the top of the Step 2 panel and launches a dialog containing all fields in the project as checkboxes that can be checked off to quickly add those fields to the report. All fields in an entire instrument can also be added at once from this dialog. This makes it a little easier to fine tune the report to include only the fields that are necessary.

Checkbox fields in the project can be combined into a single column by checking the option under Additional report options. A report with this option selected will save some space by only showing checkboxes that were selected in a record, instead of showing the name of each checkbox with the checked or unchecked value.

The optioned displayed in Additional report options are related to the project features and will include an option to show survey identifiers for surveys and data access group names for each record if those respective project features are being used.

In Step 3 of report creation, filters for the report can be created and assigned. Filters are optional and if
none are used, the full data set of the selected report field will be shown. Since a report is intended to communicate some selective features of the data, a filter is usually part of an effective report. REDCap includes its own filtering logic that is similar to the branching logic used in data collection forms and surveys and the calculations used for calculated fields.

Filters can be created in two formats, basic and advanced. For a basic filter, you can use the drop down in the Filters section to select the field the filter will act on followed by the operator, such as “equals”, “not equals”, and the value. The operators can vary depending on the type of field and validation that is being used as a filter, i.e., text fields can have the “contains” operator and fields with date validation can have “less than” and “greater than” as operators.

As new filters are added using the drop-down, they need to be combined with either OR or AND logical connection. For example if you wanted only records with a last name of smith and first name of john, you would combine those two filters with the AND connection. Using an OR connection would have the report include anyone with a first name of john and anyone with a last name of smith.

Using the advanced logic removes the drop-downs from the panel and replaces them with a text box showing only the filter description using Redcap’s filter language. Using the preceding example, advanced logic for showing first name of john and last name of smith would be: “[first_name]="john" AND [last_name]="smith". REDCap includes a syntax validation tool that will provide feedback as to whether or not any syntax errors have been made, such as braces or quotations missing or in the wrong place.

The next section of the step 3 panel is for live filters. Live filters add a feature to a report that will change an active filter without needing to edit the report. A live filter can only use fields with a multiple choice type, and there are a maximum of three live filters that can be designated for a report.

Finally, in step 4 you set the default ordering for the report output. By default, reports will be sorted by Record ID in ascending order. You can choose up to three levels of ordering, each in ascending or descending order.

Other Export Options
The last tab on the export page is other export options. On this page you are presented with options to
export an entire project as an XML file or data in all data instruments as a PDF file. The XML file is formatted in the CDISC ODM format and will facilitate the transfer of a project to another REDCap server or to another CDISC compatible software system.

Sidebar: Reports

Once reports are added to a project, a new sidebar section is added called Reports. This section shows a list of all the reports in the project by name, and clicking on the report will run the report and take the user to the report page. Only reports that a user has been given access to during report creation will show up on the sidebar.

5.2 Importing Study Data

The data import tool can be an important part of study management, as it allows the direct upload of large volumes of data into a project. Patient data was previously stored in paper reports, and conducting a retrospective study would necessarily involve direct data entry into a system like REDCap. Many institutions now exclusively use electronic medical records and it is possible to get data into an exported table format. Using the data import tool, once data is converted to a flat table format that matches the REDCap header fields, it can be imported into a project in one step. REDCap performs basic type checking and field validation and will alert the user to problems in the import. Before final upload REDCap provides a preview as to which fields will added or changed once the upload is complete.
5.3 Comparing Study Records

The data comparison tool provides a side-by-side view of two records in a project. Two similar cases can be compared vertically this way rather than horizontally as they would be in a report.

5.4 Viewing Access Logs for Your Study

The logging page for a project provides a comprehensive history of all interactions and changes that have been made to it. Events can be filtered by user, date range, and type of change. A list of page views for each project is also available, but not shown by default.
5.5 Using the Field Comment Log

The field comment log and data resolution workflow are usually discussed together since only one or the other can be used in a project at the same time. The field comment log stores and associates user comments to fields in a project database. This is useful in discussing the history of a particular data field. The data resolution workflow provides a system of flagging and following up on potential errors with data entry and project coordinators. For most studies the field comment log provides sufficient reporting and has a smaller learning curve. Larger studies, especially multi-site studies, would benefit from the data resolution workflow, which mirrors the data query system all large clinical trial management systems employ.

5.6 Storing Files Securely

The file repository serves as a location to securely store any documents related to the project. A copy of all data and report exports are stored here, as well as data imports.

5.7 Validating and Locking Records

As mentioned before locking serves as a way to provide validation from a project coordinator that data for a record is complete and correct. Users have both locking and e-signature rights, and e-signatures serve as the highest level of validation for a record, as it requests authentication from the user performing the e-signing, and the signature contains the data, time and user name.
Figure 5.14: The e-signature and locking management page lists the name of forms from records that have been locked or e-signed.

5.8 Creating Data Quality Rules

The data quality section page includes a list of common checks that can be performed on data to improve its accuracy and usability. The most common of these is missing data. Missing data will always be the main limiting factor on the ability of a dataset to provide meaningful information. Next to each data quality rule is an Execute button that will perform the check on all records in the database, then provide the total number of occurrences that match the rule.

Rules can be set to run in real-time, that is whenever a case is saved in data-entry, the data quality rule will be executed, and the data quality page will be updated to include new occurrences as well as alerting the data entry user of the data quality event.
### 5.8. Creating Data Quality Rules

**Data Quality**

This module will allow you to execute data quality rules upon your project data to check for discrepancies in your data. Listed below are some pre-defined data rules that you may utilize and run. You may also create your own rules or edit, delete, or reorder the rules you have already created. To find discrepancies for a given rule, simply click the execute button next to it, or click the execute all rules button to find all the rules at once. It will provide you with a total number of discrepancies found for each rule and will allow you to view the details of those discrepancies by clicking the view link next to each. [Read more detailed instructions](#).

<table>
<thead>
<tr>
<th>Rule #</th>
<th>Rule Name</th>
<th>Rule Logic (Show discrepancy only if...)</th>
<th>Real-time execution</th>
<th>Total Discrepancies</th>
<th>Delete rule?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Missing values*</td>
<td>-</td>
<td>Execute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>Missing values* (required fields only)</td>
<td>-</td>
<td>Execute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>Field validation errors (incorrect data type)</td>
<td>-</td>
<td>Execute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>Field validation errors (out of range)</td>
<td>-</td>
<td>Execute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>Outliers for numerical fields (numbers, integers, sliders, calc fields)**</td>
<td>-</td>
<td>Execute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>Hidden fields that contain values***</td>
<td>-</td>
<td>Execute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>G</td>
<td>Multiple choice fields with invalid values</td>
<td>-</td>
<td>Execute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H</td>
<td>Incorrect values for calculated fields</td>
<td>-</td>
<td>Execute</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Add**

- Enter descriptive name for new rule (e.g., Participants below age 18)
- Enter logic for new rule (e.g., $(age\leq18)$)
- Execute in real time on data entry forms

Figure 5.15: The data quality page lists the default data quality rules followed by user-created rules. User created rules can be set to run manually or automatically when a record is saved.
Chapter 6

Application Programmer Interface

REDCap’s application programmer interface or API makes it possible to use REDCap data with a programming language in real time. This is most useful for performing data analysis without needing to go through the process of downloading a file from REDCap and opening in your statistics package every time a dataset changes.

6.1 What is an API

An application programmer interface is usually added to a software program when it would make it easier to perform large numbers of complex tasks. For example, if the software allowed a user to modify text documents and save them, an API could make it possible to modify hundreds or thousands of documents using a programming language and a single program, rather than spending hours and hours of modifications by hand. The API is the interface that connects a programming language to a software program and REDCap’s API supports connecting securely to several different programming languages, each with different strengths.

6.2 Requesting a Token

REDCap uses tokens to maintain secure access to the data through the API. A token is a unique string generated by the REDCap server to identify a user and a project. When a users writes a software program to interface with REDCap through the API, they need only include the project token in the script to gain access to the data they are authorized to view or edit. If the token were lost, it could be used to get data from REDCap, but would not expose the user name or the name of the project, as those are only stored in REDCap.

When navigating to the API page for a project, the page provides a brief description of how the API works and how to request an API token. REDCap tokens are managed by administrators and must be requested for each project. Once you have an API token, you will be able to access everything you could normally access through the user interface through a programming language instead.

6.3 Using the API Playground

The API playground is a web interface within REDCap to quickly test various API functionality. It provides helpful documentation all in the same web page, and once a function is working as expected in the playground,
My Project

API

The REDCap API is an interface that allows external applications to connect to REDCap remotely, and is used for programmatically retrieving or modifying data or settings within REDCap, such as performing automated data imports/exports from a specified REDCap project. For details on the capabilities of the REDCap API and how to use it, please see the REDCap API documentation.

API Security: Best Practices

It is important to remember that when making requests to the REDCap API, you should always validate the REDCap server’s SSL certificate to ensure the highest level of security during communication with the API. For details on what this means and how to do it, see the ‘API Security: Best Practices’ section in the REDCap API documentation.

Obtain API token for "My Project"

Use the button below to request an API token for this project from your REDCap administrator. You will need a different token for each project you would like to access. Please note that your REDCap administrator is emailed every time a token is requested.

- Request API token
- Create API token now (Administrators Only)

Your API token for project "My Project"

The API token below is ONLY for you and will work ONLY with this project. This token allows special access to REDCap data and should NOT be shared with others. If you think your token has been compromised, then please contact your REDCap administrator immediately and either delete or regenerate your token by using the buttons below.

API Token:
15D4FD2E72B60F3589E969753DCDA284

- Delete token
- Regenerate token

Finished using the API for this project? If so, please delete your token for security reasons. Think someone else knows your token? If so, please regenerate your token for security reasons.

The following user(s) have API tokens for this project: admin

Figure 6.1: API tokens can be requested from the API page.

Figure 6.2: An alphanumeric token generated by REDCap for secure API access.
6.4 Writing Your Script

Figure 6.5 below shows an example for connecting to the API using the scripting language REDCap uses to interact with its database server, PHP. The example demonstrates how to export the project metadata for a project. The data array takes the users token, the content field specifies that project metadata is being requested, and the sending and return formats are specified as json, JavaScript Object Notation. Once the query is constructed the following lines show how to send the query to a REDCap server using PHP’s CURL functionality.

Figure 6.5: The API response will be in a structured format and response data can be extracted using a programming language.
Figure 6.6: Users can browse examples of API requests each of the listed programming languages.
Chapter 7

REDCap Mobile App

Project REDCap has developed a mobile application that can link to a project on a REDCap server. This app is available on the apple store for iOS devices and the Google store for android devices. The app was developed to fulfill the need to enter data for a project in the absence of a connection to the internet. Since REDCap is web-based, it can only be accessed via a web browser and internet connection. For data collection that needs to be performed offline, the REDCap mobile app can be used.

The mobile app is not a stand alone instance of REDCap, it must be connected to an existing REDCap server in order to function. Once it has been paired with a REDCap project, it can store data for that project offline, then perform synchronization with the REDCap server when a data connection is available.

7.1 Accessing the App Stores

Depending on which device you want to use, you will need an account to access either the apple store for iOS or the Google play store for android. The REDCap mobile app is free of charge on both services, but an account is needed with the service to authenticate and download the app. A search for REDCap will likely return the official REDCap app as the first result. Make sure that the name of the app is REDCap Mobile App and the developer is Vanderbilt University Medical Center.

7.2 Setting Up Your App

Once you have installed the app on your device, you can open it and start the setup process. The app will ask you to setup a local user account and a PIN for security purposes. Once you have completed this step, you should see a screen like figure. Selecting Set Up Mobile Project will take you to the screen for pairing the device with a project on REDCap.

7.3 Setting Up Your Mobile REDCap Project

Within a REDCap project, a user with mobile app rights can navigate to the REDCap Mobile App page to set up the app with a mobile device. The user must also have an API key which can be requested from the Mobile App page as well. The index page will have a QR code that the mobile app can scan in order to store all the data of the project, such as instruments, field name and data. Once the project has been set up, data can be collected using the device.
Figure 7.1: The main menu for the REDCap mobile app.

Figure 7.2: The REDCap mobile app page.

Figure 7.3: REDCap can email a user links to the REDCap mobile app on the Apple Store and Google Play.
### 7.4 Collecting Your Study Data on the App

After the project has completed setup, you can navigate to the My Projects section of the app to see a list of the apps that have been set up on your device. Tapping the project you wish to collect data for will take you to the project’s mobile home screen. If you now tap Collect Data, you’ll be taken to a screen where you can select the instrument. After selecting the instrument, you will see a list of records with data in the current instrument as well as a button for creating a new record.

Just like the record status dashboard from REDCap’s data collection sidebar, icons next to each record ID are colored to indicate the status of the record, red for incomplete, green for complete, yellow for unverified, and grey for a record with no data entered. Tapping the record ID will take you to the record with that ID on the instrument you chose previously. Here you can add or edit information for the record and save. You could also have tapped Create New Record to enter data for a new record starting on the instrument chosen previously.

Once you have saved data for a record on the mobile device, it only exists locally until you synchronize your database with the REDCap server. The project mobile home screen will now have a button called Send Data to Server. Tapping this button will prompt you to send all locally saved records to the server or select a partial subset to send. After initiating the upload, you should see the following confirmation screen.

### 7.5 Using Your Device Camera to Collect Data

The mobile app has some useful features that can be used in projects beyond its ability to save data offline. One of these is to make use of the components that are commonly included on mobile devices like microphones and cameras. For forms which have the upload file type, the mobile app is presented with the following screen when choosing to add data. These options allow taking a phone and recording a video with the phone camera and uploading directly into a REDCap field. Likewise an audio-only file can be recorded using the phone’s microphone.

In addition to file upload fields, any text box field that has the @barcode action tag, can use the mobile app to record a barcode directly into the text field for upload into REDCap. On selecting to enter data for a barcode field, the mobile app will open the screen shown in Figure, and lining up the barcode and tapping anywhere on the screen will attempt to process the barcode and show the result in the text box in the app.
Figure 7.5: Progress when syncing the app to the server.

Figure 7.6: The REDCap capture screen.
Figure 7.7: The REDCap barcode reader.
Appendix A

Setting Up a REDCap Installation

If your organization does not have access to a REDCap instance, it is possible to set one up given the necessary hardware environments. Generally, the following things will be necessary to set up an installation of REDCap suitable for managing a clinical data set.

- A computing environment (physical or virtual) capable of running a modern version of Linux (Ubuntu, Debian, RHEL, CentOS) or Microsoft Windows
- A secure network accessible from the internet and capable of transmitting email

Given these two requirements, the REDCap software can be obtained electronically from Vanderbilt and installed at no cost. This section will detail the process of obtaining the software and setting it up on a Linux-based operating system.

A.1 Obtaining a Copy

The REDCap software can be download by consortium members who sign up at https://www.project-redcap.org/. Once memership has been approved, you will be able to log in to the REDCap community portal and download the latest and previous versions of REDCap. REDCap will come in a compressed .zip file and will need to be copied to your computing environment and decompressed in order to be used.

A.2 Example Install

**Environment** Our install environment will use CentOS, a Linux-based operating system. CentOS and Red Hat Enterprise Linux (RHEL), are commonly referred to as SELinux or Secure Linux because of several features that increase system security. These features can also make it more difficult to get software applications to work correctly, which is why versions of Linux like Debian and Ubuntu are more popular among users. REDCap will run well in either environment, but if you are intending to run REDCap in a HIPAA environment you should use a version of SELinux.

CentOS was developed by Amazon as an open source alternative to RHEL. It can be downloaded from . The install image is in an iso format typical for hardware sytems. The minimal iso version of CentOS is ideal for a stack running REDCap since a desktop user environment is not necessary.

The install process will prompt the user for several pieces of system information. At this stage the main decision is how much disk space to allocate. 20-30 GB would be sufficient for REDCap including storing incremental database backups on the disk.
Figure A.1: The startup screen for the CentOS operating system.

Figure A.2: This summary screen shows the different CentOS installation settings.
A root user password for the system will also need to be set. This is analogous with an admin user in other systems. In Linux systems, many structures are organized as a tree, including users. So the root user can be thought of as the primary user, or the root of the tree.

Once the CentOS installation completes and the system reboots, you will be at the system login screen. If you enter the user name and password you specified in the install process, you will be taken to the system prompt. Here you can setup and install system software necessary for hosting an instance of REDCap.

CentOS uses a package manager called yum. Package managers are programs which manage the dependencies of complex software systems. They maintain a centralized database of software programs, their versions, and the versions of all their dependencies in a large tree. When installing the software dependencies of REDCap, like the web server, the package manager will automatically install their dependencies as well.

There is not a REDCap package on any distributed package management systems because the package management system would be a distributor of REDCap at that point. As mentioned earlier, REDCap’s license prohibits redistribution of the source code. However, it is not difficult to install each of REDCap’s dependencies using a package manager and obtain the source code through the REDCap consortium.

The yum package manager will make changes to the underlying CentOS system, and for that reason, it needs to be run with elevated privileges. Linux systems accomplish this with the sudo command. The first thing needed after a fresh install is to update the package manager with the update command. This contacts the distributed package manager and updates the package listings.

```bash
sudo yum update
```

You should see a prompt that explains the sudo privilege of the system and asks you to re-enter your password.

Once the system finishes updating, you will be ready to install new software. Editing configuration files from the terminal will be necessary for the installation and a Linux based tools that makes that fairly easy is called nano.

```bash
sudo yum install nano
```

Apache
Since REDCap is web-based, it needs a program called a web server to be running in order to function. A simple and reliable web server that is packaged for almost all operating systems is known as Apache HTTP (Hyper Text Tranfer Protocol) Server. This program will answer all page requests for REDCap content.

```
sudo yum install httpd
```
Install Apache web server

```
sudo firewall-cmd --add-service=http --permanent && sudo firewall-cmd --add-service=https --permanent
```
Update Firwall to allow http traffic

```
Restart firewall sudo systemctl restart firewalld
```

**MariaDB**

REDCap stores all its data in a transactional database. Transactional databases are very reliable because they organize information updates into transactions that can be undone in the case of data corruption or mechanical failures. Data updates have little to no chance of compromising the data that is already being stored. The transactional database software used in this install will be MariaDB, the open source equivalent to the MySQL database server now owned by Oracle.

```
Install mysql (mariadb) sudo yum install mariadb-server
```

```
sudo systemctl start mariadb
```

```
sudo systemctl enable mariadb.service
```

```
sudo mysql_secure_installation
```
Input a root password and remove test database/disallow remote root access

Change mysql config to support Unicode characters (any Names or strings with non-ascii characters or accents will be stored and shown incorrectly in the software if this is not done first)

```
sudo nano /etc/my.cnf
```
A.2. EXAMPLE INSTALL

```bash
[client]
default-character-set = utf8mb4

[mysql]
default-character-set = utf8mb4

[mysqld]
skip-character-set-client-handshake
character-set-server = utf8mb4
collation-server = utf8mb4_unicode_ci

Create REDcap database Login to MySql

mysql -uroot -p

Add the redcap database

cREATE DATABASE redcap;

Add user for REDCap application

GRANT ALL ON redcap.* TO 'redcapuser'@'localhost' IDENTIFIED BY 'redcapuser-password';

exit

PHP

PHP is a general purpose programming language that can be interpreted by the Apache Server and is used as REDCap’s server side programming language. REDCap’s client side software is written mostly in HTML and JavaScript, but since those run entirely on a client’s browser, only PHP needs to be installed in the host environment.

```bash
sudo yum install epel-release
```bash
sudo yum install http://rpms.remirepo.net/enterprise/remi-release-7.rpm
```bash
sudo yum install php73 php73-php-mysql
```bash
sudo systemctl restart httpd

PostFix/Sendmail

```bash
sudo yum install sendmail sendmail-cf
```bash
sudo setsebool -P httpd_can_sendmail on

Unpacking the Software

Copy REDCap files to environment using sftp client
Move REDcap source to Apache default web root ’/var/www/html’
Unzip

```bash
sudo yum install unzip
```
unzip redcap.

Edit file database.php

# Change values below to match your mysql user created above
$hostname = 'localhost';
$db = 'redcap';
$username = 'root';
$password = 'root';

**Installation Steps** On the browser you can now navigate to localhost/redcap/install.php or the host name for your installation. The installation can be completed by following the web-based instructions and the steps will be specific to the installation environment.

Once installation is complete, REDCap will perform a configuration check, and any changes that need to be made to installation environment will be listed on screen. Changes can be made to the environment to address problems and returning to the configuration check screen will show their status. Often certain system services, such as the web server, will need to be restarted to update the output.
Bibliography