A Comprehensive Guide to REDCap

Composed by the Center for Health Insights University of Missouri - Kansas City Spring 2014









Overview of WorkflowWhy use REDCap?

<u>Secure</u> – Full user authentication (log-on/password), customizable user rights restrictions, real-time data validation, centralized & secure data storage, data de-identification options, and a full audit trail.

<u>Web-based</u> – Enter data or build your database from anywhere in the world over a secure web connection with authentication and data logging.

<u>Fast</u> – Quick project start-up. Clinical report forms can be implemented without the need for a programmer. Concept to production-level database is possible in <u>less than one day</u>.

<u>Easy</u> – Intuitive user interface and work flow, readily available online training materials, and assistance from the Center for Health Insights (CHI) make it easy to get started.

Fully customizable – You are in total control of shaping your database.

<u>Autonomous utilization</u> – Research groups have complete autonomy and control to add new users and set several levels of specific user rights.

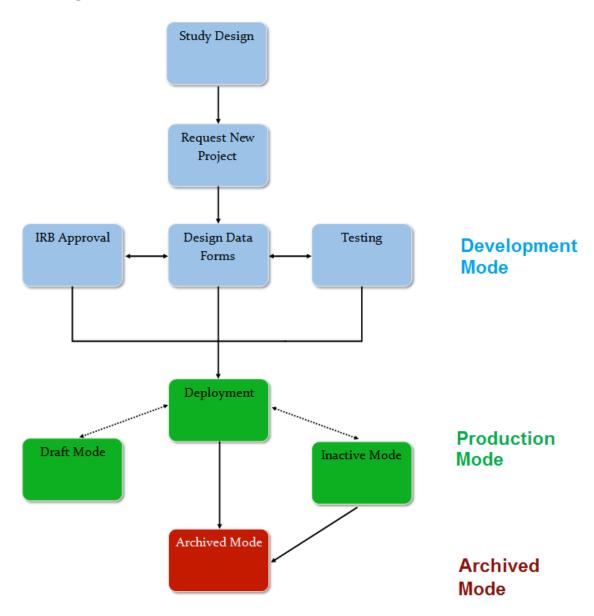
<u>Data export</u> – Seamless data downloads to common statistical packages (including SPSS, SAS, Stata, and R) and to the .csv (comma separated values) format, the most common import and export format for spreadsheets and databases.

Data import – Data import capability through Microsoft Excel

Advanced features - File uploading, auto-validation, branching logic, calculated fields, and more!



......Diagram



<u>Study Design</u>: Before beginning a REDCap project, you should formulate a general study design. Ex: Who or what are you planning to study? What kind of data are you measuring? Will your study be cross-sectional or longitudinal? Have you discussed your study design with a statistician?

<u>IRB Approval</u>: If your study is a research project with human subjects, you likely need the documented approval of your Institutional Review Board. For more information, see the <u>IRB-relevant</u> sections of our detailed REDCap guide.



<u>Request New Project</u>: In order to manage the volume of projects being hosted by our servers, you must submit a request to us via REDCap in order to begin a new project. The approval process generally takes less than 2 business days (48 hours).

<u>Design Data Forms</u>: In order to effectively collect and order your data, you must first design the data collection forms to do so. This step is the highlight feature of REDCap: immensely customizable, expandable, fluid data forms.

<u>Testing</u>: You should test data collection forms to verify all needed data are collected correctly before committing to production mode. If possible, designate one person to perform the build and another to perform the testing.

<u>Deployment</u>: Once your study enters Production Mode, you may enter, review, and analyze real data. In Production Mode, it is more difficult and risky to make major changes to your data entry forms, which is why thorough testing is strongly encouraged.

<u>Draft Mode</u>: If you enter production and find that you do need to modify an element of your data entry forms, you may enter Draft Mode and submit changes to be approved by a REDCap Administrator. Data activities can continue during this mode.

<u>Inactive Mode</u>: No data entry or update may take place in this mode, although you may view and analyze data. You can initiate this mode if you want to ensure that no new data entry will occur, but you would still like to access all of your data easily.

<u>Archived Mode</u>: If you have completed data analysis, moved your project to indefinite hiatus, or simply decided you no longer wish to use it, you may move the project to archived status as an alternative to full deletion. You can un-archive your project at any time.



REDCap Terminology

<u>Arms</u>: groups of events. You may want to employ multiple arms when using different treatment groups (control, experimental) or conducting a multi-site study, for instance.

<u>Branching Logic</u>: may be employed when fields/questions need to be hidden for data entry under certain conditions. For instance, you may want to hide the question "How many hours per week do you watch TV?" until a "Yes" answer is checked for a previous question, "Do you watch TV?"

<u>Data Access Groups</u>: restrict viewing of data within a database, for instance in a double-blind or multisite study.

<u>Data Collection Instrument</u>: a form created to capture data. This term is essentially interchangeable with "data entry form."

<u>Data Dictionary</u>: a specifically formatted .csv spreadsheet containing the metadata used to construct data collection instruments and fields.

<u>"Development" vs. "Production" Modes</u>: study status modes. In Development Mode, you are still working through the design of your data forms and testing them with mock data; you may make any changes to the forms at any time. In Production Mode, you have deployed your forms and you are collecting real data; changes to your forms are more difficult to implement once you have launched into Production Mode. (See also: Development vs Production Modes.)

<u>Event</u>: used in longitudinal designs. An event is a scheduled (or unscheduled) occurrence during which data is captured using your REDCap data instruments (forms).

Field: a singular data entry, such as age or height.

<u>Form Status</u>: status of the record's data form completeness, denoted with a color; red – incomplete; yellow – unverified; green – complete.

<u>Logging</u>: the audit trail of modification occurrences in the project.

<u>Record</u>: the set of information for a unique participant or subject. Each record is composed of a number of fields (pieces of data), which can be spread across multiple forms (instruments) per record.

<u>Record ID</u>: a unique key that can identify each record in the database. (You may label this differently in your project, but the ID must remain the first field in the first data form.)

<u>User Rights</u>: the customized privileges that research team members have in terms of data form modification, data entry, and data access. P.I.s may create "Roles" for groups of team members to ensure consistency in specified user rights.

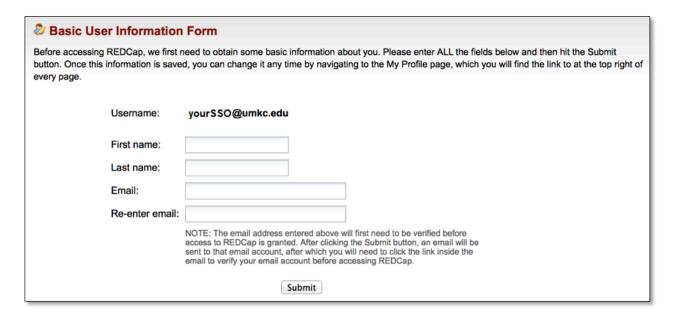


<u>Variable Name</u>: the name of the variable that is stored in the REDCap database (not visible during data entry).

Before Requesting a Project

......Signing in to REDCap for the first time

The first time you log in to REDCap.umkc.edu, it will prompt you for your basic information in order to verify your account.



Once you submit this information, an e-mail will be sent to your UMKC account.



CENTER FOR HEALTH INSIGHTS

Click the link included in that e-mail to verify your account, and you'll be all set to use REDCap!





......Things you should already know about your project

There are several things you should already know about your project before submitting a project creation request. The following items are intended to provide a starting ground for prior knowledge, but this will vary on a case-by-case basis. Some studies may have far more than this planned out already, while others may still be defining the basics.

☐ The end goals of your research
☐ The specific data you are going to be capturing
☐ The type of study you are going to be performing (longitudinal, cross-sectional, etc.)
☐ Who will comprise your research team



.....IRB status

When you meet with us for your consultation, one of the points we will discuss is your IRB protocol. We recommend designing your data forms in REDCap *before* submitting your final IRB protocol for approval, so that you may include PDF versions with your IRB submission. Whether you are in the beginning or ending stages of IRB approval, we will likely be able to assist and support your project. Notably, an IRB number will be required before we will be able to move your project to "Production" (official deployment) status.

.....Do I need IRB approval?

Note: The Center for Health Insights will not make this determination for you. If in doubt, we recommend consulting your IRB. The following information may help you prepare for that conversation.

The Institutional Review Board (IRB) is an independent, academically-based committee constituted of medical, scientific, and non-scientific members whose responsibility is to ensure the safety, well-being, and the protection of the rights of human subjects who take part in research studies. The IRB reviews research in accordance with the Department of Health and Human Services (DHHS) and the US Food and Drug Administration (FDA) regulations.

If your study involves research using human subjects, you likely need IRB approval before you will be able to conduct the study. The federal definitions are as follows:

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

<u>Human subject</u>: a living individual about whom an investigator (whether professional or student) conducting research obtains:

- 1. Data through intervention or interaction with the individual, or
- 2. Identifiable private information.

A research protocol may qualify for exemption if it meets certain criteria. View the <u>IRB exempt</u> research categories section for the detailed federal list.



.....IRB exempt research categories

The following describes human subjects research that qualifies for exemption from IRB review based on the Federal Register Title 45 § 46.101. IRB exemption status cannot be self-determined. All exemption determinations are made by the Research Compliance Office. If you believe that your protocol qualifies for exemption, please contact your institution's IRB for submission instructions and guidance.

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the



level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.



.....Obtaining IRB approval

If your research is based at UMKC or Truman, go here to learn how to apply: http://ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-review-board-(irb)

If your research is based at Children's Mercy Hospital, go here to learn how to apply: http://www.childrens-mercy.org/Unlinked_Content/Research/MARS/

If your research is based at St. Luke's Hospital, go here for relevant application documents: http://www.saintlukeshealthsystem.org/resources-investigators-forms-documents

What happens if I conduct human research without IRB approval?

Conducting human research without IRB approval will place the University out of compliance with Federal requirements that regulate research involving human subjects. This can result in Federal or IRB actions that will prevent you, your department/division, or the University from conducting research involving human subjects. It will also jeopardize the University's human research certification with the Office for Human Research Protections (the FWA).

Data collected without IRB approval cannot be used in class research, theses, or dissertations, which may ultimately prevent students from fulfilling graduation requirements.

Can I start collecting data before I receive official IRB approval?

No. You may enter practice data for the express purpose of testing your data forms, but **you** absolutely may <u>not</u> collect real data for research involving human subjects until you have explicit IRB approval.



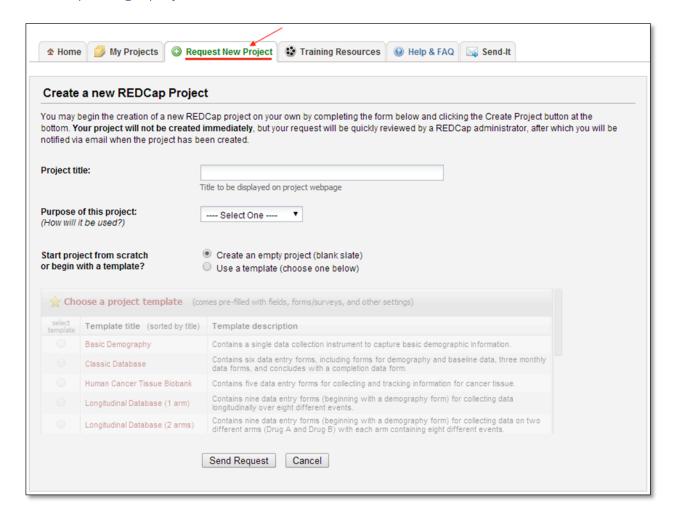
.....Citing REDCap in your IRB protocol

Below is the recommended REDCap documentation for the Data Management section of your IRB protocol:

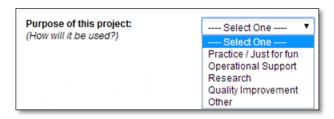
"The Center for Health Insights of the University of Missouri–Kansas City (UMKC) will be used as a central location for data processing and management. Vanderbilt University, with collaboration from a consortium of institutional partners, has developed a software toolset and workflow methodology for electronic collection and management of research and clinical trial data. REDCap (Research Electronic Data Capture) data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team with planning assistance from the Center for Health Insights. The iterative development and testing process results in a well-planned data collection strategy for individual studies. REDCap servers are housed in a local data center at the University of Missouri–Kansas City and all web-based information transmission is encrypted. REDCap was developed specifically around HIPAA-Security guidelines. REDCap has been disseminated for use locally at other institutions and currently supports over 1000 academic/non-profit consortium partners on six continents and over 100,000 research end-users (www.project-redcap.org)."



Initial Project Set-UpRequesting a project



Submitting the project request is very simple. You will need to provide a project title and purpose. You have five options for project purpose:





If this is your first project in REDCap, we recommend selecting "Practice / Just for fun." This way, you can explore the various functionalities of REDCap and become acquainted with it before implementing a full project. See the <u>Project types</u> section for more details about the various project types. If you select the Practice option and later decide you would like to turn it into your official project, you may amend the project purpose on the main Project Setup page. Your project's title can be changed at any point in Development.

Notice the "Start project from scratch or being with a template?" option. 95% of the time, you will want to begin your project empty (blank slate) so that you can design it to your exact specifications. However, there are many templates available that have forms designed already, which can be added to and modified to fit your project's needs. This is not the only opportunity you will have to access these general forms: during the process of project design, you may also visit the Shared Library to add template forms to your project. See the Project templates and Shared Library sections for more details.

When your request is sent, this message will appear, and we will be able to approve your project so that you may begin. Project approvals will generally be granted within 1-2 business days (24-48 hours) of the request.

Request Sent!

Your request for a new REDCap project has been sent to a REDCap administrator. You will soon receive an email from them at your address (<u>@oumkc.edu</u>) confirming that your project has been created.

Once we approve your project, you will receive an e-mail similar to the one below confirming approval and providing a link to your new project. You can also access the project by simply logging into redcap.umkc.edu and clicking the "My Projects" tab.



Thu 3/20/2014 12:34 PM

UMKC RedCap

[REDCap] Approved: New Project Created

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[This message was automatically generated by REDCap]

The REDCap project that you requested has now been approved and created: Practice Project

Access your new project in REDCap

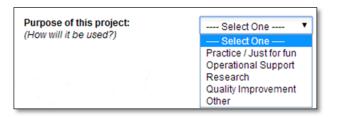
[TIPS AND TRICKS]:

1. If you've completed a consult with us about your study, we will be anticipating your project request, and it will get approved more quickly. In addition, any questions or concerns that we would have about your project will have already been discussed.



......Project types

When you first create your project, you will be asked to select a project purpose. You have five options: Practice / Just for fun, Operational Support, Research, Quality Improvement, and Other.



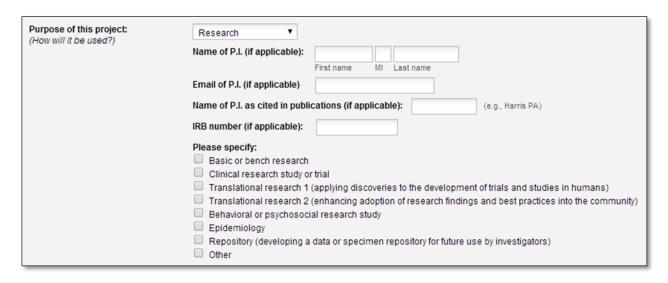
If you choose <u>Practice / Just for fun</u>, you will not be prompted for any additional information. This type is, as the title suggests, intended for practice purposes: to become familiar with the features and learn about REDCap.

<u>Operational Support</u> projects are generally intended for the management and monitoring of a system or technical environment issues. This can include management of an organization, bug report tracking, project tracking, and more.

<u>Quality Improvement</u> projects include projects such as evaluation surveys and suggestion forms. These projects can help channel organizational goals and facilitate performance improvement.

If you select <u>Other</u>, you will be prompted to briefly describe the intention of your project. If we have further questions about your project type, we will contact you before approving your project.

Selecting Research will prompt many new fields:



Fill out as much as you can before submitting your project request. If you do not have all of the information at the time of your project request, do not worry about it – you can add these details later, as long as they are all completed before launching into Production phase. In fact, we recommend that you wait until after designing your REDCap forms to submit your study to the IRB: this way, you can convert your forms to PDF documents and include them with your IRB submission.



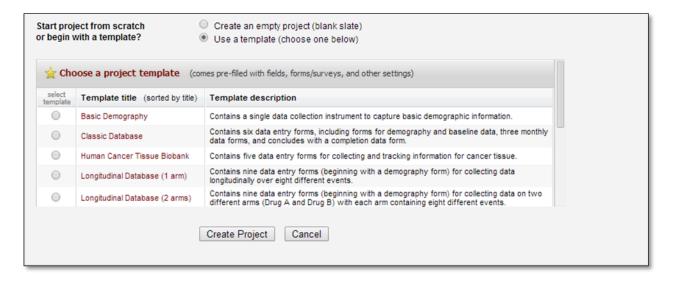
For other topics that might be considered "Project Types", see:

<u>Longitudinal studies</u> <u>Survey-based studies</u> <u>Multiple treatment groups (Arms)</u>



......Project templates

When requesting your project, you will generally want to select the "Create an empty project (blank slate)" option. This will allow you to customize your project to your exact specifications. However, if you would like to select a template to base your project upon, several are available.



The templates have varying numbers of data forms, each with a set of pre-specified fields. If you do decide to use a template, new forms/fields can still be added and existing forms/fields can be modified or deleted if you choose. The structure is still very flexible; this can just give you a base upon which to build your project.

If you create an empty project and later decide that you would like to use pre-designed forms, you may access the Shared Library to import forms that other REDCap users have uploaded. The Shared Library has many more options than the project templates. See the <u>Shared Library</u> section for more details.



......"Development" versus "Production" modes

You will begin your project in Development mode. This means that you are still in the process of designing and testing your data collection instruments. Everything can be modified freely in Development mode. If you are conducting a research study, your IRB number is not required until you move into Production mode.

Once you feel ready to deploy your project, you may request to have your project placed into Production mode. At this point, you should have fully tested the workflow, data validation and branching logic: you should be certain that your data forms are finalized and fully functional. You should also have your IRB approval number, if applicable. If this was not added to your project when you initially created it, you may add it under "Modify project title, purpose, etc." on your main project dashboard.

Moving your project to Production prior to collecting real study data ensures you are maintaining data accuracy and integrity. The post-production control process provides an additional check to ensure that data in your records is not modified, deleted, or overwritten unintentionally. In addition, it allows us to have a check point at which we require IRB numbers for validation; otherwise, we would have to require them at the time of project request.

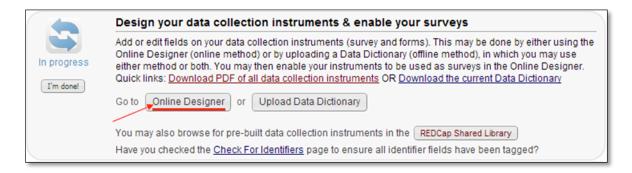
See the <u>Beyond Development Mode</u> sections for details about other project modes available *after* moving into Production mode.



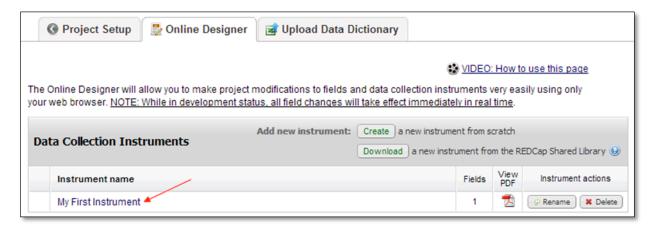
Designing Data Tools

.....Online designer

.....Overview

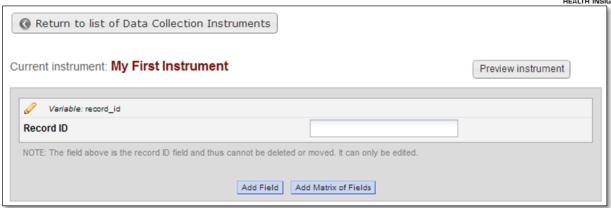


The Online Designer is the primary tool with which you will design your data forms. Assuming that you started with an empty project (started without using a template), you will see one default form already present in your Online Designer, entitled "My First Instrument." You may rename this form by clicking the "Rename" button on the right. To begin editing, click on the instrument name.



By default, your first form will have only one field, entitled "Record ID." This indicates the unique record/participant identifier, and must be preserved. You may change the name of the field by clicking the Edit icon (the yellow pencil). However, whatever you decide to call it ("Participant ID," "Study ID," etc.), its purpose as a unique identifier must remain the same. This field does not need to be repeated for any other data forms throughout the project; this is the only place you will need to be concerned with it.



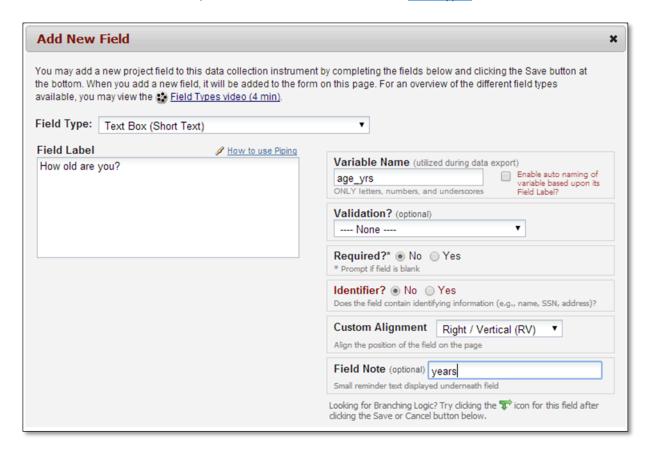


You may click the "Preview Instrument" button to preview what your form will look like during actual data entry. Calculated fields and branching logic will not work in this preview; practice data must be entered in records in order to test those particular functionalities.



.....Adding a new field

To create a new data field, click the "Add Field" button. There are twelve types of fields you may choose from. Our example in this section will use the "Text Box" field type (essentially a "short answer" field), one of the most common field types in REDCap data entry. The general "new field" addition process is very similar across field types – however, other types may have additional features or nuances associated with them, which is discussed in detail in the Field types section.



If you are designing a survey, the <u>Field Label</u> will generally be a question, such as "How old are you?" If you are designing a research data entry form, your Field Label may look more like a standard label, such as "Baseline heart rate:".

The <u>Variable Name</u> is used by REDCap to store the data. We strongly advise against enabling auto-naming for variables (the checkbox to the right of the Variable Name field). You generally want to keep variable names short but somewhat descriptive, so that if you need to export your data, you will be able to recognize key variables. For instance, "Q1" is *not* a very descriptive variable name, and is not advised for most situations. "Height" is a good variable name, but "height_in" or "height_cm" is even better, because you are reiterating your measurement unit within the variable name, which is a good practice.

Validation is an extended option which is discussed in detail in the Data validation section.



The <u>Required</u> option, by default, is set to "no." If changed to "yes," it will require an answer before a data form can be saved (or before a survey can be submitted, depending on your study set-up).

The <u>Identifier</u> option should be marked whenever a field asks for one of the 18 HIPAA identifiers. When you export or view deidentified data, the fields that were marked as identifiers will be omitted. A concise list of the 18 HIPAA identifiers is listed below, but for an official list and supporting details, see Box 2 on this page from the CDC website:

http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm

A brief reminder of the 18 HIPAA identifiers: 1.) names, 2.) geography more specific than state, 3.) any relevant dates more specific than year, 4.) phone numbers, 5.) fax numbers, 6.) e-mail addresses, 7.) SSNs, 8.) MRNs, 9.) health plan beneficiary numbers, 10.) account numbers, 11.) certificate/license numbers, 12.) vehicle identifiers, 13.) device identifiers, 14.) URLs, 15.) IP addresses, 16.) biometric identifiers, 17.) full-face photographic images, and 18.) any other unique identifying number, code, or characteristic.

The <u>Custom Alignment</u> option changes how the question (and answers, if the field is a multiple choice option) appears in the data entry screen. We don't recommend adjusting this unless there is an aesthetic need to do so, but you may play around with the functionality as you explore REDCap's features.

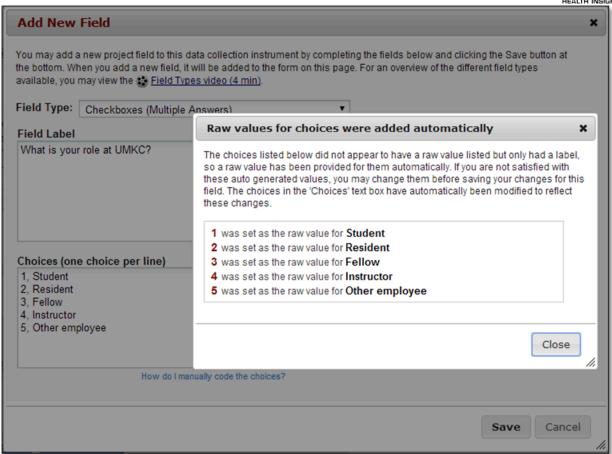
The <u>Field Note</u> option displays a side-note in small text beneath the text entry field (or multiple choice options) on the data entry screen. It is useful for designating units or clarifying a manner in which the question should be answered (e.g. "Mark all that apply").

The end result of the field creation in this example looks like this:



The <u>Choices</u> component of field creation is specifically for multiple choice field types (dropdown list, radio buttons, and checkboxes). It appears directly below the Field Label and serves as the place for you to list the various choices to select from, one choice per line. REDCap automatically "codes" these variables in increasing order beginning with "1." This is for data storage purposes, and will not affect the way the choices are viewed in data entry. Below is the screen that will be prompted if you have not provided manual codes for your choices:





[TIPS AND TRICKS]:

- 1. Generally, it is acceptable to have REDCap provide the automated coded values for your multiple choice options, but there may be instances in which you should manually enter or change the coded values. For instance, let's say you are writing a survey question inquiring about the frequency of a participant's consumption of fast food, and let's say you have decided your choices are "Never," "Once per month or less," "Two to five times per month," and "More than once a week." Since this is a scale with an absolute zero, coding "Never" as 0 and moving upward from there (rather than beginning at 1) is a wise decision.
- 2. If you have many forms, it can be helpful to add a prefix to your field variable names that indicates which form they are on. For instance, a variable representing age in years on your Demographics form might be labeled "dm_age_yrs."
- 3. We strongly advise against numbering your fields within the field label (e.g. "1. How old are you?"). Any branching logic or future decisions to move/delete fields will drop or mix numbers, causing unnecessary work later. The REDCap survey option features auto-numbering and custom numbering abilities, which should be used instead (toward the end of project design).



.....Field types

There are twelve types of fields you may choose from: Text Box, Notes Box, Calculated Field, Multiple Choice – Drop-down List, Multiple Choice – Radio Buttons, Checkboxes, Yes-No, True-False, Slider, File Upload, Descriptive Text, and Begin New Section.

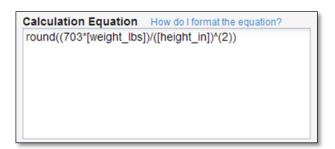
1.) <u>Text Box</u>: a single-line text box for text and numbers. The example in the <u>Adding a new field</u> section is a text box.



2.) <u>Notes Box</u>: a large text box for a large amount of text. This is convenient for long descriptions and "Additional Comments" boxes.



3.) <u>Calculated Field</u>: a field which performs real-time calculations based on the entries in other fields. The syntax for complicated calculations can be intricate, but REDCap will alert you to any syntax errors, and will refuse to attempt calculations until they are resolved, preventing data errors. Variable names are referred to in [brackets] in the written calculation equation.



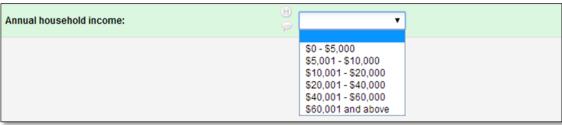
In this example, weight_lbs and height_in are two variables from previous questions being utilized to calculate Body Mass Index (BMI). Clicking the "How do I format the equation?" hyperlink will open a dialog box describing some of the nuances and specifications of the calculation syntax, such as the rounding function used in this example.



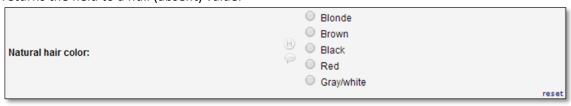


In data entry, it is impossible to directly edit the value of a calculated field (hence the red text). This ensures the integrity of the calculation procedure.

4.) <u>Multiple Choice – Drop-down List</u>: a drop-down menu with options. Only one option can be selected. This can help save space on a data form if there are many different choices to display.



5.) <u>Multiple Choice – Radio Buttons</u>: a set of radio buttons (round buttons), from which only one choice can be selected at a time. The "reset" button in the corner removes any current selection and returns the field to a null (absent) value.



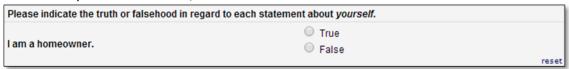
6.) Checkboxes: checkboxes which allow the selection of multiple options if desired.



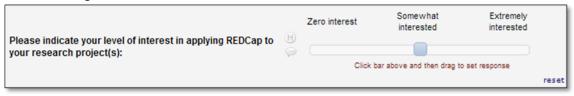
7.) Yes-No: radio buttons with the options "Yes" and "No." These values are automatically coded: "Yes" = 1, "No" = 0.



8.) <u>True-False</u>: radio buttons with the options "True" and "False." These values are automatically coded: "True" = 1, "False" = 0.



9.) <u>Slider</u>: visual analogue scale coded as values 0-100. You may provide labels above the left, middle, and right sides of the slider.



10.) <u>File Upload</u>: an uploading tool for any associated images or documents that may need to be attached to individual records.

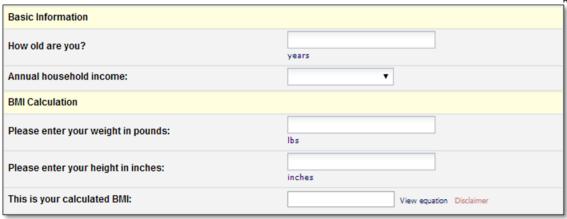


11.) <u>Descriptive Text</u>: text displayed with optional image/file attachment. The file may be displayed as a clickable (downloadable) link, or (if the file is an image) displayed in-line with the text.



12.) <u>Begin New Section</u>: a field composed of a single line appearing in different color from the rest of your form, indicating separation. This is largely for aesthetic/organization purposes. Adding text (to serve as a header) is optional. When deploying a survey, you have the option to break each section into separate pages, giving these headers a true separation functionality.





[TIPS AND TRICKS]:

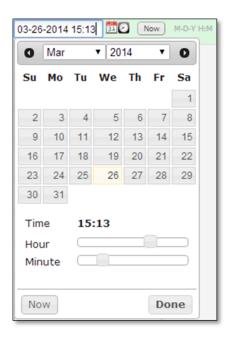
1. In your data entry screens (**not** including the survey submission screen), there is a small "H" and speech bubble appearing beside each field. The "H" tracks the history of all recorded data values for that particular variable. The speech bubble is the Field Comment Log, which allows users to make comments on particular fields, and lights up when a comment exists for a field.



.....Data validation

When using the Text Box method of entry, it is best to ensure that the data coming in is the type of data that you are expecting to see. One method of doing this is by employing the Validation option in the field creation screen. By utilizing this feature, REDCap will prompt an error when a field's entry does not meet certain expectations for data type. There are eleven basic data types that you can designate via the Validation option: date (3 formats), datetime (6 formats), e-mail, integer, letters only, MRN, number (5 formats), phone (U.S.), Social Security Number (U.S.), time (2 formats), and ZIP code (U.S.).

- 1.) <u>Date</u>: The three different formats you can specify for date are Day-Month-Year, Month-Day-Year, and Year-Month-Day. Regardless of which type you choose, a small calendar icon will be visible next to the field in data entry which you can utilize to easily specify a date in the appropriate format. You can also click the "Today" icon to automatically fill in the current date.
- 2.) <u>Datetime</u>: Datetime can be recorded with or without a "seconds" count. The three without seconds follow the same formats as the three Date formats (listed above), with an additional H:M to indicate time (Hours:Minutes). The three that do include seconds also follow the same three Date formats, with an additional H:M:S to indicate time (Hours:Minutes:Seconds). Like the Date option, a calendar icon appears next to the field, and in addition, a clock icon appears. You can also click the "Now" icon to automatically fill in the current date and time. An example of usage of the calendar/clock dialog box is below:



3.) <u>E-mail</u>: To validate an e-mail address entry, REDCap checks for a singular "@" symbol and an appropriate e-mail domain ending (such as ".com" or ".edu"). The inclusion of other special characters that would not be a part of valid e-mail addresses (such as "\$" or "#") will also prompt a data validation error. This is very widely applicable, however, if you are expecting e-mail addresses connected to new or uncommon domains, we do not recommend using this validation option.



- 4.) <u>Integer</u>: Integers include all of the negative and positive whole numbers, plus zero. This means that any decimal or fractional values will prompt a validation error, as well as any values outside the designated minimum-maximum range.
- 5.) <u>Letters only</u>: This validation type will only accept English alphabetical characters. It will not accept spaces, numbers, special characters, or accented letters.
- 6.) MRN: This validation type will only accept ten numerical digits, no longer and no shorter. No other non-numerical character is allowed.
- 7.) <u>Number</u>: This validation type accepts numbers, including decimal values. The five formats are derived from the number of decimal points you choose to allot: 1, 2, 3, 4, or unspecified. If you choose to specify a number of decimal points, an error will be prompted if that exact number of decimal points is not met. For instance, if you have specified two decimal points, an entry of "3" or "3.0" would not be accepted only "3.00" is considered a valid entry in this case.
- 8.) <u>Phone</u>: This validation type will only accept a ten-digit U.S. phone number. Not including a valid U.S. area code will prompt an error. It is fairly lenient regarding the input format (spaces, no spaces, hyphens, etc.), but it will change your entry to a standardized "(###) ###-####" format upon field completion.
- 9.) <u>Social Security Number</u>: This validation type will only accept nine numerical digits separated by hyphens in the appropriate U.S. SSN format. Example: 123-45-6789.
- 10.) <u>Time</u>: This validation type accepts only HH:MM time format. Like the Datetime type, the clock icon and/or the "Now" icon can be used to assist data entry.
- 11.) <u>ZIP code</u>: Only five- or nine-digit ZIP codes are accepted. Nine-digit ZIP codes must include a hyphen separating the first five from the final four, or an error will be prompted.

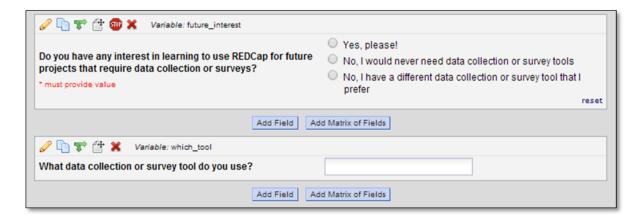
[TIPS AND TRICKS]:

1. Many of the data validation types include an option for setting minimum and maximum expected values. We strongly encourage users to employ this wherever applicable. For instance, if a field asks for the age of a participant, you may want to set the minimums and maximums around your study eligibility guidelines, such as 16 to 55. If you do not have study eligibility rules, it is still a good practice to set relatively reasonable limits, such as 4 to 120.



.....Branching logic

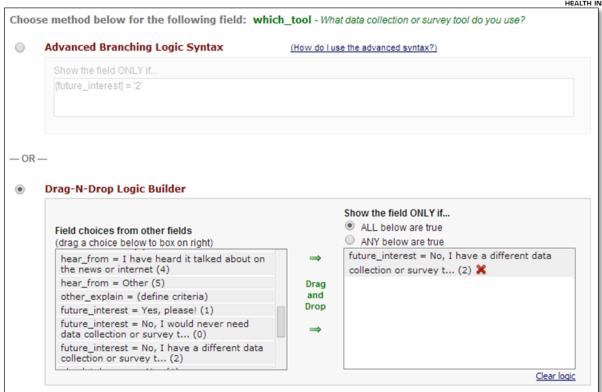
If you would like for certain questions to appear only under certain conditions, you may employ the REDCap technique "branching logic" to do so. The easiest way to demonstrate branching logic is by walking through an example. Let's say you are working in your Online Designer, and you are concerned with these two questions:



You only want that second question to appear if the participant selects "No, I have a different data collection or survey tool that I prefer." Otherwise, the question does not make much sense in context. Because the appearance of the second question (the variable "which_tool") is dependent on the answer to the first question (the variable "future_interest"), we call future_interest the *parent* (or *independent*) *question* and which tool the *child* (or *dependent*) *question*.

To begin defining your branching logic, click the branching logic icon (the green arrows) on the *child question*. The Branching Logic dialog box will appear. You may use either the Advanced Branching Logic Syntax box or the Drag-N-Drop Logic Builder box. For most branching logic uses, the Drag-N-Drop Logic Builder will be sufficient. We do not recommend using the Advanced Syntax box if you have no experience with computer science or programming syntax. If you have a question which you think may require the Advanced Syntax box, please feel free to contact us for assistance or review of the coding.





Simply drag and drop the appropriate conditions for appearance of the child question, being sure to specify whether you want ANY or ALL of the conditions to be true in order for the child question to appear.

Remember, branching logic is only employed on the child question. Since we want our first question to remain static regardless of any other values on the page, we leave it alone.

Implementation:

Survey appearance before choosing any option (or with a non-target option selected):

Do you have any interest in learning to use REDCap for future projects that require data collection or surveys? * must provide value	Yes, please! No, I would never need data collection or survey tools No, I have a different data collection or survey tool that I prefer reset
If you would like, you may enter your e-mail address here, and we can send you information about getting started with REDCap.	



Survey appearance **after** choosing the logic-dependent option:

Do you have any interest in learning to use REDCap for future projects that require data collection or surveys? * must provide value	Yes, please! No, I would never need data collection or survey tools No, I have a different data collection or survey tool that I prefer reset		
What data collection or survey tool do you use?			
If you would like, you may enter your e-mail address here, and we can send you information about getting started with REDCap.			

[TIPS AND TRICKS]:

- 1. Be sure to thoroughly test any use of branching logic with practice records to ensure that your fields/questions are being displayed exactly as you want them. Recall that the "Preview Instrument" function in the Online Designer will not test branching logic; only actual practice records can do this.
- 2. Try not to include too many conditions in your branching logic. Overuse of branching logic can lead to a higher chance of errors.



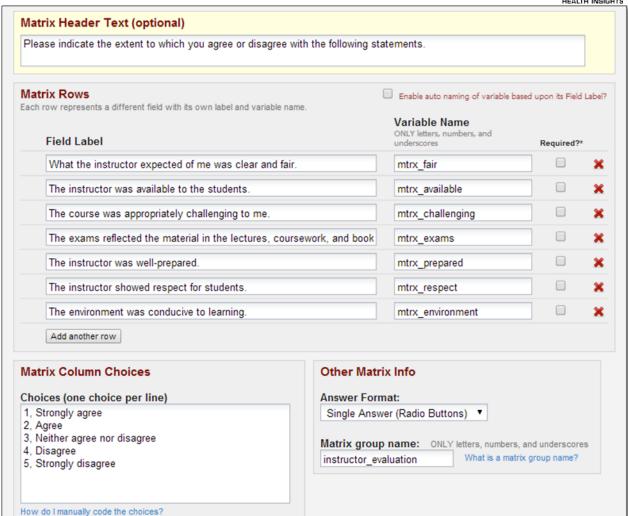
.....Adding a matrix of fields

For some data forms and surveys, the same set of answers may be used for many questions in a row, such as scales indicating frequency or agreement. To fully grasp the "matrix of fields" concept, it may be easier to view an example of a finished implementation before delving into the specifics of the set-up:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
What the instructor expected of me was clear and fair.				0	rese
The instructor was available to the students.	0	0	0	0	rese
The course was appropriately challenging to me.	0			\odot	rese
The exams reflected the material in the lectures, coursework, and books.	0	0	0	0	rese
The instructor was well-prepared.	0		0	0	rese
The instructor showed respect for students.	0	0	0	0	rese
The environment was conducive to learning.	0	0	0	0	rese

Setting up the matrix is essentially writing many questions at once, all of which use the same set of answers. As such, there is only one section to define column choices, but there are many field labels, each with their own variable names and requirement statuses. You may add as many rows as necessary for your matrix.





There are two answer formats for matrices of fields: Single Answer (Radio Buttons) and Multiple Answers (Checkboxes). For most matrices, Single Answer will be the preferred format.

A matrix group name must be provided. Its naming mechanism is similar to the general variable naming mechanism. The group name itself is basically a coded value which ensures that no matter what display platform the matrix goes through, all of the rows will be displayed together in a single matrix.

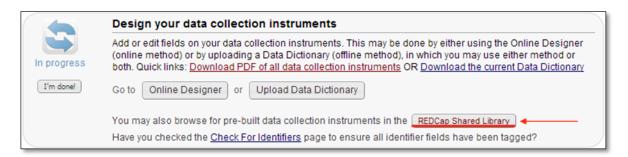
[TIPS AND TRICKS]:

1. When exporting data, it will be easier for your data manager to keep track of matrix fields by assigning each field's variable name the same short prefix, such as "mtrx_" or "eval_".



.....Shared Library

The Shared Library can be accessed from the home page of your Project Setup.



In the Shared Library, you can browse and search through a collection of data entry forms that have been uploaded by other users. Upon finding a form that sounds useful or interesting, you may view it as a web page or PDF and decide whether or not to incorporate it into your project as a new data form. Some forms may want you to agree to a "Terms of Use," which generally simply requests that you do not claim any of their forms as original works (which is usually rather easy to follow, given that you don't delete the descriptive text within the form giving details about intellectual property). Not all forms will ask this.

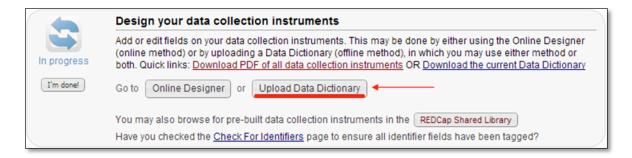
[TIPS AND TRICKS]:

1. If you don't find the results you want from your first search, be sure to search for synonymous and/or related keywords. For instance, if you search "education" and don't find any relevant results, try "academic" or "school."



......Data Dictionary

For large or repetitive projects, you may need to make large-scale changes to your forms that would be difficult or tedious to perform with the Online Designer. The Data Dictionary is a CSV file version of your project, and serves as an efficient way to make large-scale changes using (usually) Excel.



To begin making changes to your project using the Data Dictionary, click on "Upload Data Dictionary" on the home page of your Project Setup. It will prompt you to download the current Data Dictionary so that you can make changes to it. Here is a sample excerpt from a Data Dictionary (with the columns expanded for readability):

4	Α	В	С	D	E	F	G
1	Variable / Field Name	Form Name	Section Header	Field Type	Field Label	Choices, Calculations, OR Slider Labels	Field Note
2	record_id	form_1		text	Record ID		
3	date	form_1	Basic Informatio	text	What is today's date?		
4	datetime	form_1		text	What is the current datetime?		
5	email	form_1		text	What is your e-mail address?		
6	age_yrs	form_1		text	How old are you?		years
7	name	form_1		text	What is your name?		
8	mrn	form_1		text	MRN:		
9	price	form_1		text	Approximately what is the price of one gallon of gasoline in your area?		USD
10	phone	form_1		text	What is your phone number?		
11	ssn	form_1		text	SSN:		
12	time	form_1		text	What is the current time?		
13	zip	form_1		text	What is your zip code?		
14	weight_lbs	form_1	BMI Calculation	text	Please enter your weight in pounds:		lbs
15	height_in	form_1		text	Please enter your height in inches:		inches
16	bmi	form_1		calc	This is your calculated BMI:	(703*[weight_lbs])/([height_in])^(2)	
17	income	form_1		dropdown	Annual household income:	1, \$0 - \$5,000 2, \$5,001 - \$10,000 3,	\$10,001 - \$2

Large-scale changes made easier through the Data Dictionary may include copying many fields (rows) into another form. For instance, if you wanted to copy rows 3 through 13 into form_2, you would simply highlight rows 3 through 13 in Excel (the *entire* rows), copy, paste into the appropriate position (ensuring you did not paste *over* any other rows), and change the Form Name (column B) to "form 2" for the newly pasted rows.

To re-upload the modified Data Dictionary, save the CSV file and re-upload it back in the Upload Data Dictionary window. If REDCap notices any syntax errors it cannot read, it will prompt an error message alerting you to the issue. If there are no errors, it will ask for confirmation, ensuring that you know the new Data Dictionary will *replace* the old Data Dictionary (not append to it).



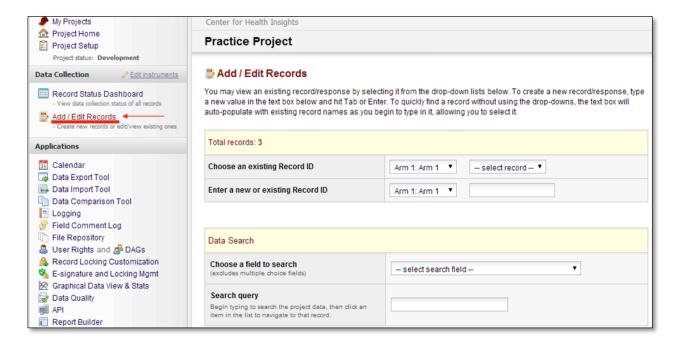
[TIPS AND TRICKS]:

- 1. Remember, the Data Dictionary does NOT contain any of the information from any of your practice records. Changing information in the Data Dictionary **can** sometimes affect information in the records (deleting fields, for instance), but it will not erase the records or corrupt the data.
- 2. If you are making large-scale changes using the Data Dictionary, it may be helpful to save separate copies of your old Data Dictionary in case you discover any errors later on after uploading it (for instance, if you mistakenly deleted several fields that you did not intend to delete).



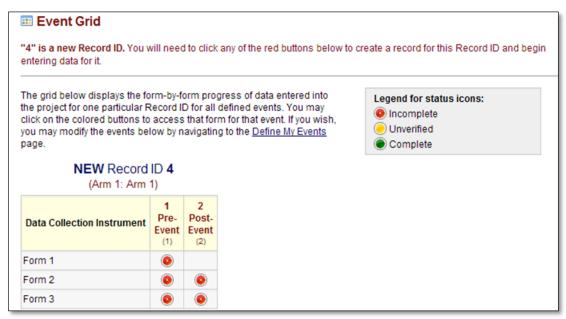
Practice Records

An important part of any project, big or small, is the testing phase. Whether you are using surveys or traditional data entry, REDCap allows you to create practice records to test the full functionalities of your forms. This is especially crucial for testing branching logic, calculated fields, and survey appearance (if applicable). For more information about practice records for **surveys**, see the Survey-based studies section.



Once you are in the main "Add/Edit Records" page, you may choose an existing record to edit, create a new record by typing in a new Record ID, or search for a particular record by a field value (for instance, using the search field "Name" and typing "Jane Doe" into the search query). If you are employing multiple Arms in your study, the first two options sort the records into groups by Arm. To search for a record whose Arm you are not certain of, using the Data Search option is best.





If your study is not employing multiple Events (i.e., if it is not a longitudinal study), your first data entry form will appear immediately, ready for data input. If your study *does* employ multiple Events, you will see a screen similar to the one above. Records are edited one Event at a time; clicking on the first form of an Event and filling it out will lead you through the forms assigned to that specific Event and then return you to this screen. To learn more about longitudinal studies and Events, see the Longitudinal studies section.



At the bottom of your data entry form, you have the option to mark the form as Incomplete, Unverified, or Complete. Incomplete forms will display a red icon, which is the default status for all forms in a new record; the yellow icon indicates Unverified, and green indicates Complete.

Clicking "Save and Continue" will save your progress and keep you on the current page. Clicking "Save and go to Next Form" will save all data and take you immediately to the next form for that record. Clicking "Save Record" will save all data and return you to the "Add/Edit Records" main page. You may also lock forms for a record to prevent other users from editing existing information.

The most important thing to remember about practice records is that they are intended for **practice**. This means that **no real data** should ever be entered into REDCap while your study is still in



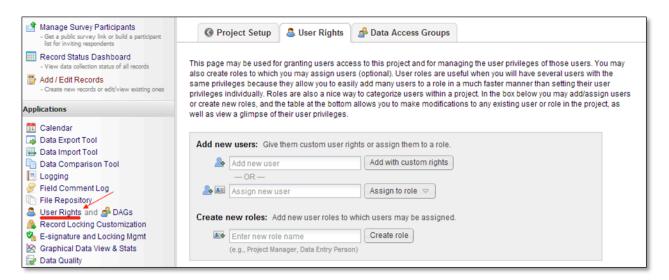
<u>Development mode</u>. Real data entry will occur once you deploy your project into Production mode, where your forms are finalized and data is more securely protected.

[TIPS AND TRICKS]:

1. In your data entry screens (not including the survey submission screen), there is a small "H" and speech bubble appearing beside each field. The "H" tracks the history of all recorded data values for that particular variable. The speech bubble is the Field Comment Log, which allows users to make comments on particular fields, and lights up when a comment exists for a field.

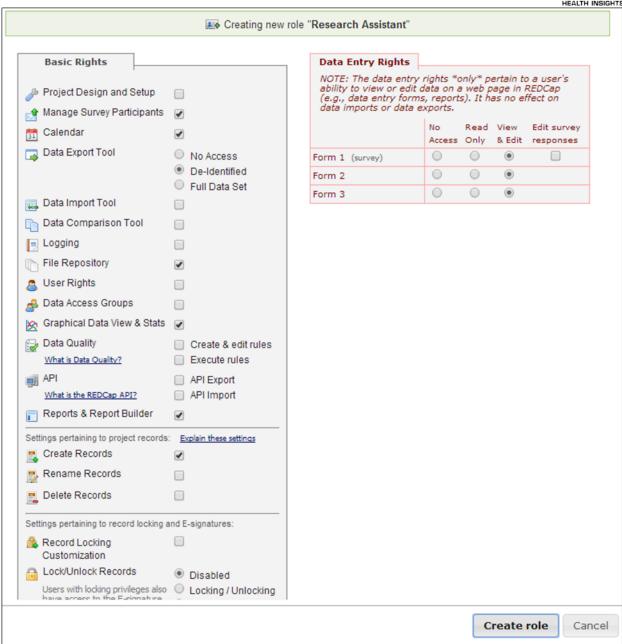


Data AccessUser Rights



Clicking on "User Rights" in the toolbar on the left will bring you to a screen displaying the current users on the project, and the rights to which they have access. You may also add new users to your project with customized rights, or create "roles" (such as P.I., Data Manager, or Statistician) with specific rights so that you may assign new users to a role right away. For research teams of 4 or more people, creating roles is recommended.





Being able to customize the access that individuals have to your project ensures that specific roles are going to be maintained, even if any breaches would be accidental.

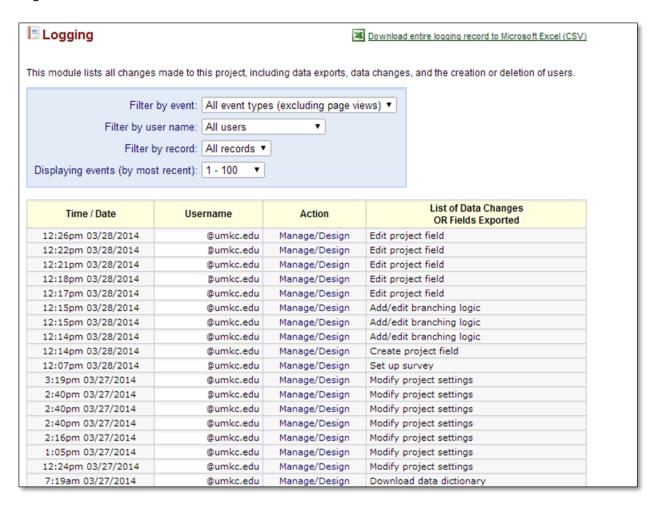
[TIPS AND TRICKS]:

1. For multi-site studies and other special situations, it may be advantageous to have entire groups of users blinded to entire sets of records. Utilizing the "Data Access Groups" (DAGs) tool is the easiest way to accomplish this. Once the DAGs are created, you may only see records that have been created by another member of your DAG. This tightens security and prevents data overlap.



.....Logging

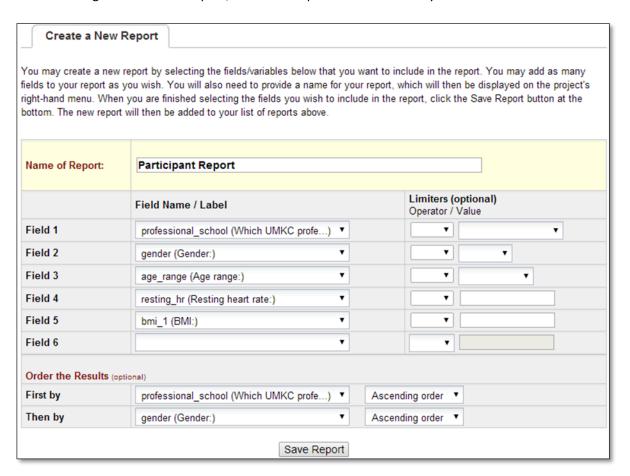
By clicking the "Logging" tool in the left-side toolbar, you can view the entire audit trail throughout the life of the project. Each event's category and specific change is listed along with the time/date and user's username. The logging box is easily filterable, and can even be downloaded to a singular CSV file if need be.





.....Report Builder

In the Report Builder application accessible from the left-side toolbar, you may view the results of a specific field or fields for all records in your project. The purpose of various reports can be to isolate records, identify groups, study certain demographics of your participant population, and more. Let's say I want to produce a general demographic report of my participants along with their resting heart rate and BMI. To generate a new report, click the "Report Builder" tool in your left-side menu.

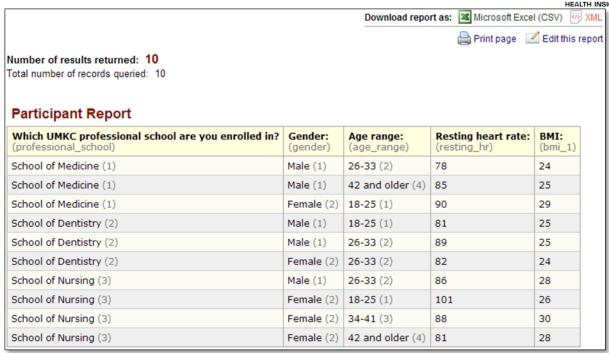


Name your report, and specify the variables you would like to the report to display. You may choose to order the results in a specific manner to make data viewing easier. In this example, I have sorted by professional school, and then within the groups of professional schools, I have sorted by gender. Once you are finished organizing the details, click "Save Report."

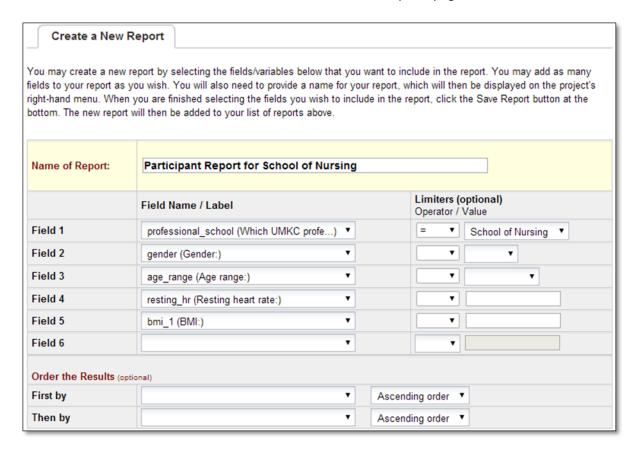
Clicking "View" next to the title of your report after you have saved it will present the current data report (see below). This is updated in real time as your data is collected. You may export your reports to .CSV or .XML format; you may also simply print your report.

NOTE: Please notice the number in parentheses next to certain variable names below. This number represents the encoded value of each multiple-choice variable option, and does **NOT** represent the number of records with that result.



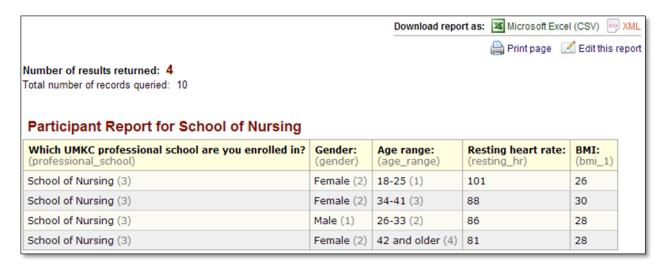


Let's say we only want to view records for those enrolled in the UMKC School of Nursing. To do this, we will utilize the "Limiters" in the initial "Create a New Report" page.





You will notice that this time, I have specifically indicated that I want to see only the records where [professional_school] = School of Nursing. Below is the result when viewing the report:



Notice that although 10 total records were queried, only 4 records matched our conditions, and thus only 4 are shown.

You may have multiple reports that you would like to generate for your project. This is easily tracked through REDCap. Each report is even given its own shortcut in the Reports Module (which will appear once you have created your first report).





[TIPS AND TRICKS]:

- 1. In the Report Builder, filtering/sorting by fields is easiest for fields that are single-answer multiple choice (drop-down, radio buttons, true/false, yes/no).
- 2. Each report changes in real time as new data records (or surveys) are created for the project. Once more records are completed, you can go back to the same report and it will update accordingly.



......Importing data

If you are conducting a study for which you already have some partial data, or if you are simply importing data from an additional source, using the Data Import Tool is one of the easiest ways to accomplish this task. First, you will be prompted to download one of two .CSV templates: one arranging separate records into rows, and another into columns. Whichever you choose may depend on how your other data is already arranged, and/or whichever you aesthetically prefer.

Once you have downloaded the template, use a program (generally Excel) to fill in the records, ensuring that the correct variables are slotted into the correct places. Then, on the same Data Import application page, you may re-upload the .CSV file and import your new data records.

NOTE: This section deals with importing data *records* into your project. For more information on importing your data dictionary (i.e. your data *forms*), see the <u>Data Dictionary</u> section.

[TIPS AND TRICKS]:

1. For ease of data transfer, ensure that the order of the variables is the same on both your external source and your REDCap data forms.



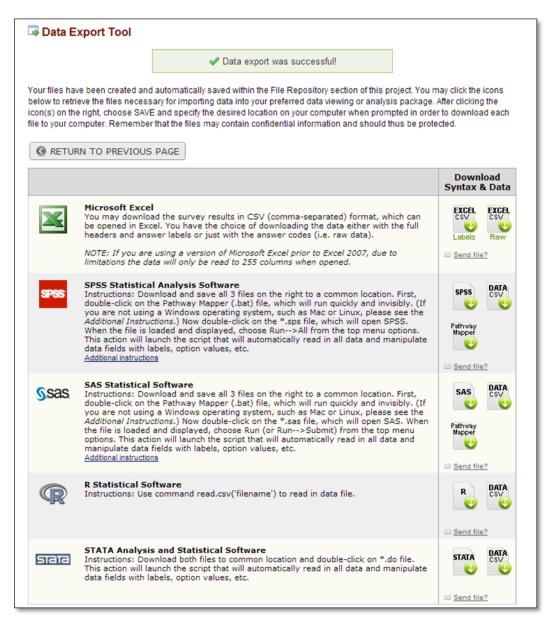
......Exporting data

When accessing the Data Export Tool, you can either choose the "Simple Data Export" or "Advanced Data Export" option. If you only want to export certain fields or forms, or if you want to deidentify the data before exporting, select "Advanced Data Export." If you wish to export all of the data you have access to, "Simple Data Export" is the best route.

Exporting your data "Raw" will export coded values. For instance, in a yes/no field type, data coded in that column will either be "1" or "0" – not "yes" or "no." In addition, field titles will be the coded versions of the variable names, rather than the field labels. The "Labeled" data option is precisely the opposite – exporting clear, labeled versions rather than coded values. For efficiency and compatibility with statistical analysis tools, we often recommend exporting raw values.

The Data Export Tool is compatible with many analysis programs: Excel, SPSS, SAS, R, and Stata.



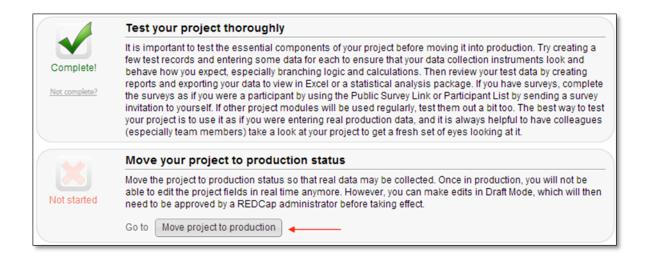


[TIPS AND TRICKS]:

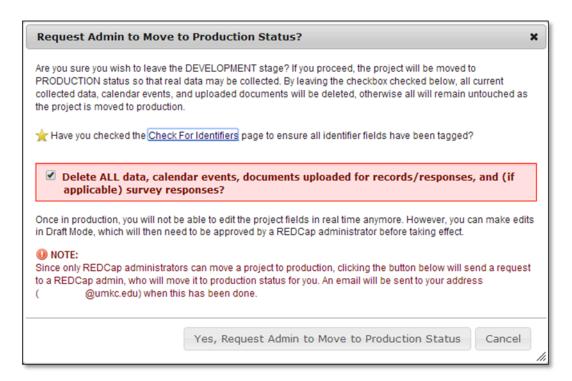
1. Exporting data to programs other than Excel produce syntax files, which are not always the easiest to deal with. Often, exporting to .CSV and then using your preferred statistical analysis program to import the .CSV is the ideal option. If you do choose this option, to ensure you are getting the data precisely the way you want it, be sure to download one of the .CSV files listed next to "Excel" rather than the one listed next to your program of choice.



Beyond Development ModeProduction Mode



Once your project has been created and tested adequately, you may be ready to move to Production mode and begin collecting real data. If your study requires IRB approval, your IRB number must be attached to your project before we will approve the project for Production status. For more information on what must be done in Development before moving to Production, see the <u>Development vs Production Modes</u> section.





By default, moving to Production erases all existing practice records, calendar events, and all other associated practice data. It is a very thorough way to flush all of the practice data out of your project before collecting real data, however, it *is* optional. Once your project is approved for Production, you will receive an e-mail alerting you to its new status. Now, your project is ready for real data to be collected.



Mon 3/31/2014 9:08 AM

UMKC RedCap

[REDCap] Approved: Project Moved to Production

To

[This message was automatically generated by REDCap]

The following REDCap project has now been moved to production status, as requested: Practice Project

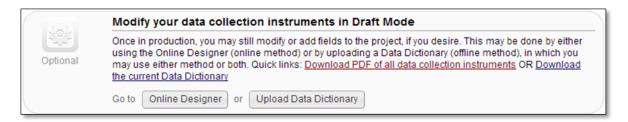
Access your REDCap project



......Draft Mode

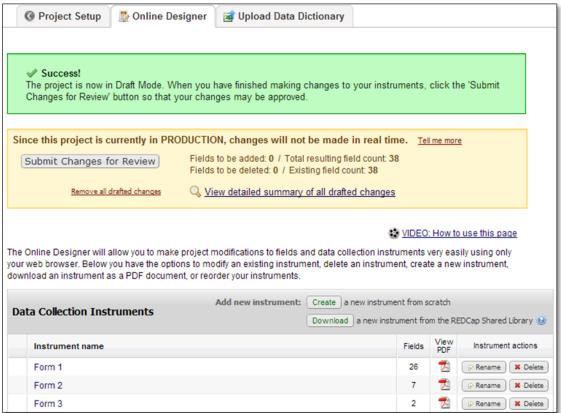
Once you move to Production, changes made to your project are still possible, but the rules are more stringent. There are a few things which you may modify post-Production without significant changes to the data integrity of your project. For instance, you may add new fields or add new choices to existing multiple choice fields. You may **not** make major changes to existing components (such as altering any existing fields or choices) without gaining approval from a REDCap administrator.

To make any changes, a new module will appear at the bottom of your main Project Setup page giving you the option of modifying your project in Draft Mode (NOTE: this make take several minutes to first appear in your project).



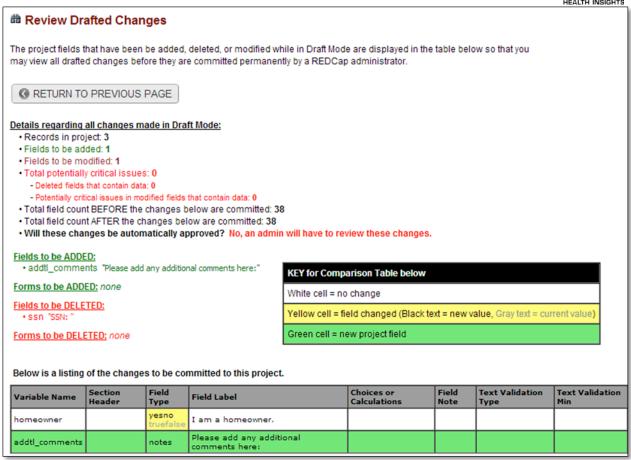
Once entered into the Online Designer, you will be prompted to ensure that entering Draft Mode is what you intend to do. Once you have clicked "Enable Draft Mode", you may make any necessary changes and submit them for review and approval.





Once you have made your change(s) to your data form(s), we strongly encourage you to click "View detailed summary of all drafted changes" before submitting your changes for review. In that screen, you will be able to view how many records will be affected by the changes, which modifications may take place immediately (versus which will need administrator approval), and other details about the drafted changes.





Any changes that need approval will be pending until your REDCap administrator verifies and approves them. You will be alerted to this approval (or rejection) by e-mail. Once the changes are approved (or rejected), your project will be back in full, official Production status and you have the option to enter Draft Mode again if necessary.

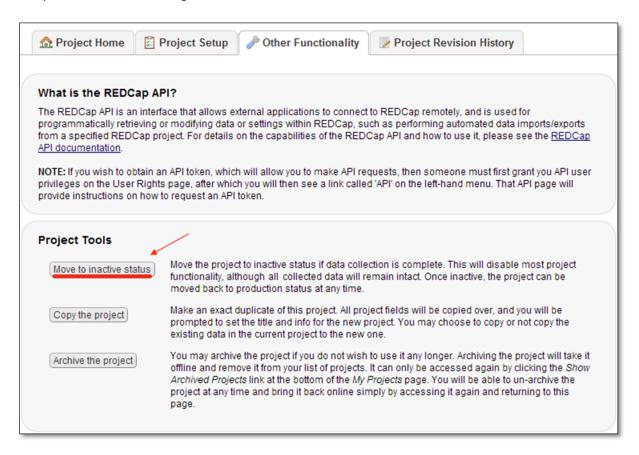
[TIPS AND TRICKS]:

1. Communication with your REDCap contact admin is key to ensuring your changes will be approved quickly. Sending a short e-mail describing the reasons behind your changes will help validate your modifications and get them implemented more swiftly.



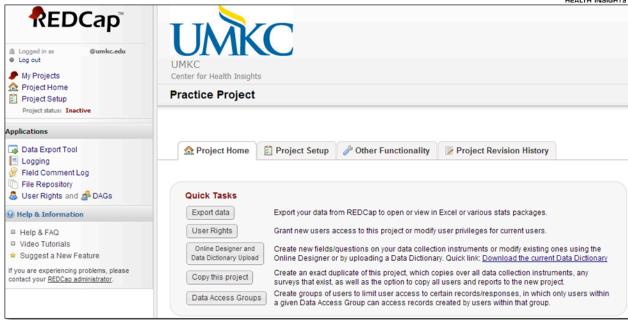
......Inactive Mode

Inactive Mode is only available once a project is already in Production Mode; it is not available in Development. Under the "Other Functionality" tab in your project's home page, you may move the project to an inactive status. This is ideal for a point in time where you would like to stop any incoming data entry, but you would still like to export and analyze the records you have collected. Accordingly, Inactive Mode will restrict data collection and any project setup changes, leaving record access and data analysis intact for all existing records.



Your project will still be accessible from your main "My Projects" page, but you will see a new red "Inactive" icon next to it. Once you enter the project, you will notice that there is now limited functionality. Not all of the modules from previous modes appear in your left-side menu, and your project status is explicitly listed as "Inactive."



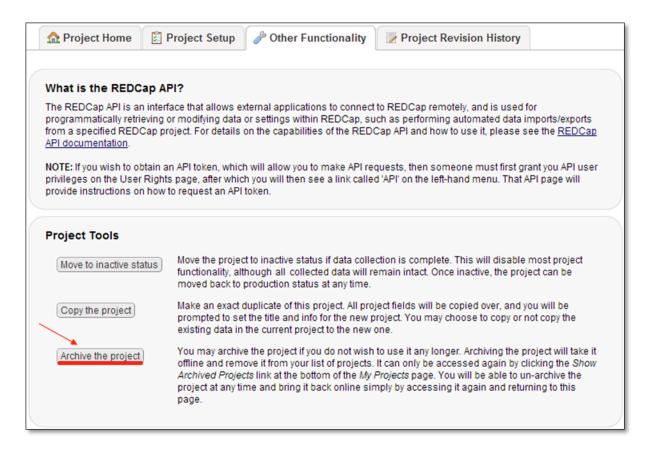


To move your project back into Production, simply click the "Other Functionality" tab and click "Move to production status." Since your project was already previously approved for Production, it does not need approval a second time; it will be immediately placed back into Production.



......Archived Mode

Once you are finished with a project, you may either delete it or archive it. We recommend archiving your projects rather than deleting them, in case you would like to perform any follow-up studies in the future. Unlike Inactive Mode, a project can be moved into Archived Mode whether it is in Development *or* Production status. You may even move a project into Archived Mode directly from Inactive Mode.



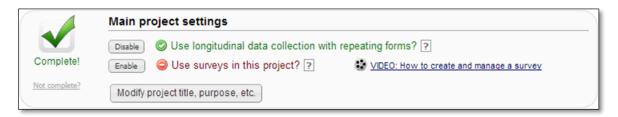
Once a project is moved to Archived Mode, a toggle will appear at the bottom of your projects listed in the main "My Projects" home page ("Show/Hide Archived Projects"). By default, archived projects will be hidden from your "My Projects" list, but toggling it to "Show" will enable you to access the project. Like Inactive Mode, limited data access abilities are still available. To move your project back into Production, simply click the "Other Functionality" tab and click "Move to production status."



Specific Study DesignsLongitudinal studies

Projects that use a longitudinal design may track records over a series of multiple events. Different data collection forms can be associated with different events; in addition, the same form can be utilized over multiple events. For instance, a Demographics form may only need to be completed at the very first event, while a Lab Results form may be required at each event.

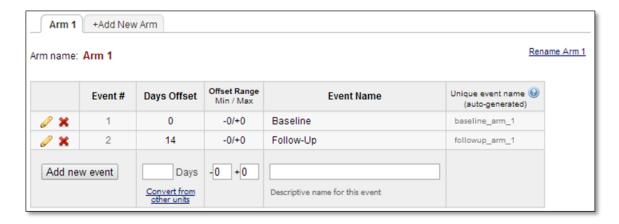
In order to utilize the longitudinal study features of REDCap, you must have enabled the use of longitudinal data collection in your "Main project settings" options on your Project Setup home page.



Once you have enabled the user of longitudinal data collection, a new module will appear in your main Project Setup page so that you may define your events.



When defining your events, be sure to title each event and specify the "Days Offset" from the initial event. You first event's "Days Offset" should be 0.

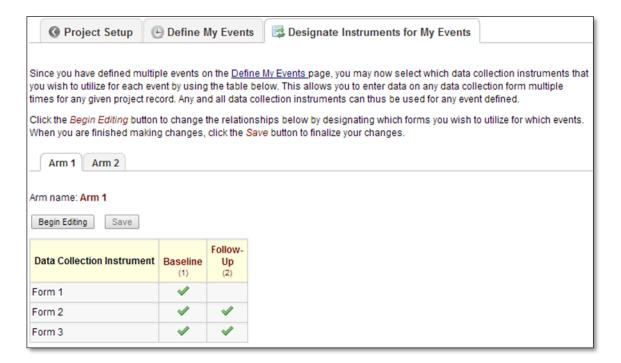


This page is also where you are able to define your study's Arms. If you have multiple treatment groups or multiple sample populations, you may want to utilize this feature. Arms can be custom-



named, and do not necessarily need to have the same forms/events as other Arms. This can allow you to easily group/block records. A single record may not belong to more than one Arm.

Once you have defined your events (and Arms, if applicable), you must now designate forms for your events. To do this, click the "Designate Instruments for My Events" tab and "Begin Editing" to assign forms to your defined events. In a longitudinal design, each form must be attached to at least one event. If there are data entry forms which have been created within your project but are not attached to any events whatsoever, your REDCap administrator will assume this is an error and will not approve the project for Production status until it is corrected.



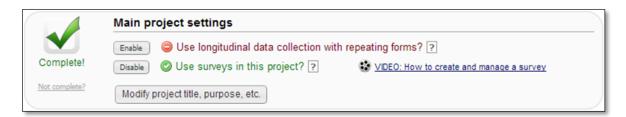
[TIPS AND TRICKS]:

1. See the <u>Calendar/Scheduling</u> section for information on how to automatically add scheduled Events to the Calendar module.



......Survey-based studies

In order to utilize the survey features of REDCap, you must have enabled the use of surveys in your "Main project settings" options on your Project Setup home page.



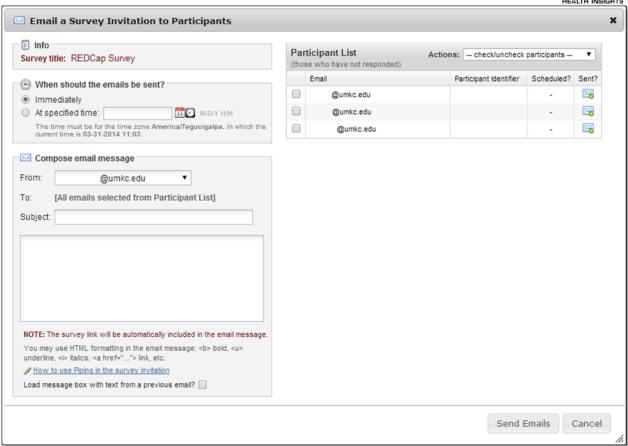
Once this is enabled, a new module in your left-side menu will be available: "Manage Survey Participants." Upon entering this module for the first time, you will be prompted to enable at least one of your existing data collection forms as a survey. There are many customizable survey settings that you will be prompted to confirm, which you may edit later by clicking the "Survey settings" option next to the form on the front page of your Online Designer.

Once you have enabled a data form as a survey and you have navigated to the Manage Survey Participants module, you will see three tabs: Public Survey Link, Participant List, and Survey Invitation Log.

The <u>Public Survey Link</u> is a singular URL to your survey, which does not track IP addresses, e-mail addresses, or any other identifying information. This means that any person with that survey link can take the survey multiple times if need be. While this is an optimal feature for some surveys, it is not the best option for projects in which we must ensure that no participant has taken the survey more than one time. New records that are created by survey submissions appear in your existing records in autonumbered order and are labeled only by the date/time of submission.

The <u>Participant List</u> tab will enable you to send out a pool of e-mails to participants from REDCap. Each e-mail will contain a unique URL that is only valid for one submission. To add the e-mail addresses of your participants to the participant list, click "Add participants" and type in the e-mail addresses, one per line. This will only create your pool of participant e-mail addresses; no e-mails have been sent out by the completion of this step. This is in case you would like to send the surveys out in batches rather than all at one time. To actually begin sending out the survey e-mails, click the "Compose Survey Invitations" button.

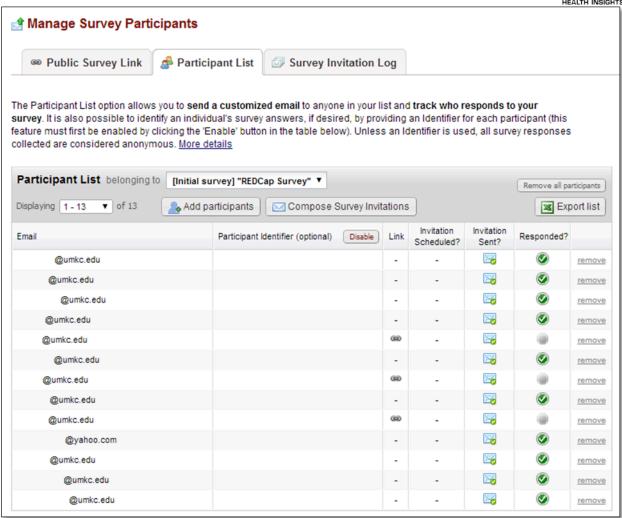




You may designate the time at which the e-mails are sent out, the subject of the e-mail, any additional content or comments of the e-mail invitation, and the checklist of participants to whom you would like to send the e-mail.

Later, once you return to the Manage Survey Participants module (seen below), you will see the list of participants along with a sent/unsent status regarding the e-mail invitation, and a status checking whether or not the participant has responded. If Participant Identifiers are not enabled, there is **no** way to link an individual's e-mail address to a particular record, maintaining survey anonymity. If necessary for your records, you may export the participant list as a .CSV file.





The <u>Survey Invitation Log</u> (not pictured) allows you to sort your participant list with various filters and view some finer details (such as the time at which a survey invitation was sent out to a participant). Individual times at which survey invitations should be sent out (if the invitation to a participant is not already sent) can be modified here.

[TIPS AND TRICKS]:

- 1. We do not recommend enabling multiple data collection forms as surveys if **all** surveys will be sent to **all** participants. If there is concern about survey length, the best solution is to divide groups of questions into sections with section headers (a field type) in the Online Designer and setting the Question Display Format as "One section per page" in your Survey Settings.
- 2. If you have a long list of e-mail addresses separated by some punctuation other than line breaks, using the "Replace" feature (Windows shortcut Ctrl-H) in a program such as Word or Notepad++ will easily fix this formatting so that you can paste the list into REDCap. For instance, if your e-mail addresses are separated by ";" (semicolon space),



in the Replace window of Microsoft Word, simply have the program find ";" and replace with " 1 " (carat lowercase-L). (In Notepad++, line breaks are specified with " 1 " rather than " 1 ".)

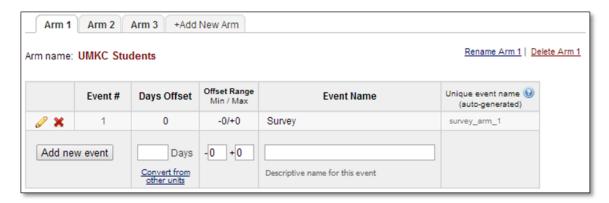
- 3. If there is another e-mail address you would like to have the survey e-mails come from (besides the main e-mail address associated with your account), you may click the "From:" drop-down box in the "Compose Survey Invitations" window and add an additional e-mail address to your account. This e-mail address must be verified via a verification e-mail before it can be utilized in this manner.
- 4. If a survey contains study-qualifying information in a multiple-choice field, you may choose to end a survey prematurely when certain qualifications are (or are not) met by using the Stop Action icon in the Online Designer (the red stop sign). This will prevent you from gathering unnecessary data, and save time for the survey-taker. For instance, if your question is "What is your role at UMKC?" and you want the survey to continue for everyone who *isn't* a student, you may click the Stop Actions icon and select to stop the survey at that point for the "Student" response.



......Multiple treatment groups (Arms)

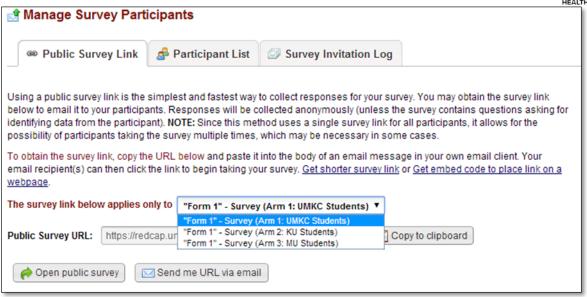
When you have multiple treatment groups in your study, there are two primary ways to handle this in REDCap:

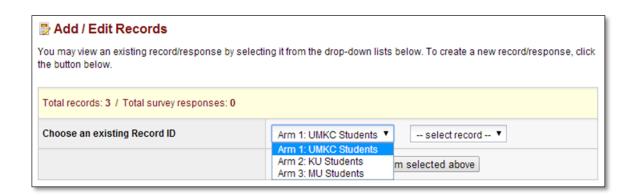
- 1. Create a field in your data form which identifies which treatment group the record belongs to and use the Report Builder to organize the data groups accordingly.
- 2. Enable longitudinal data collection methods, even if the study is not longitudinal, so that you may utilize the "Arms" feature. This specific use of the "Arms" feature is discussed below. See the Longitudinal studies section for more general information on Arms.



You can see in this example that we only have one event, meaning that in technical terms, this is not considered an actual longitudinal study. **However**, we are able to use the Arms feature of the longitudinal design to easily group records. Even in the Manage Survey Participants module, Arms are fully taken into consideration. View the screencaps below for examples of REDCap's Arm sorting and distinguishing.







Note that when exporting data, it is not possible to export each Arm's data separately, however, a record's Arm is listed as the second-column variable (immediately after Record ID), making it very easy to distinguish between the groups and separate the initial .CSV file into multiple files.



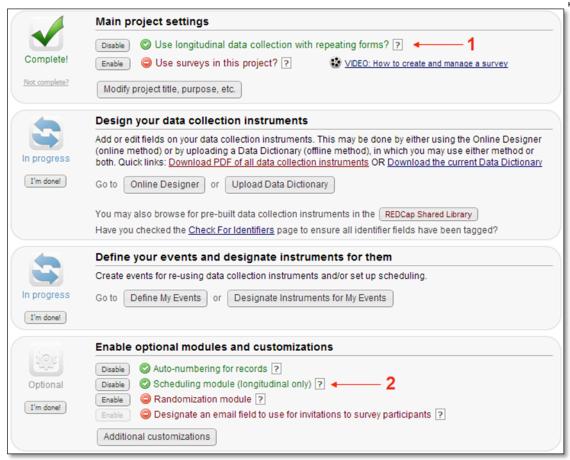
Additional Features of REDCapCalendar/Scheduling

March ▼ 2014 ▼										
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday				
						+ New				
New 2	+ New	+ New 4	+ New 5	+ New 6	+ New 7	+ New				
2		□ Design Meeting	- Hell			. 11611				
New 9	+ New 10	+ New 11	+ New 12	+ New 13	+ New 14	+ New 1				
	The state of the s	1100	0 1 - Initial Visit	13	14					
New 16	+ New 17	+ New 18	+ New 19	+ New 20	+ New 21	+ New 2				
10	0 1 - Follow-Up	10	13	2 - Initial Visit	21					

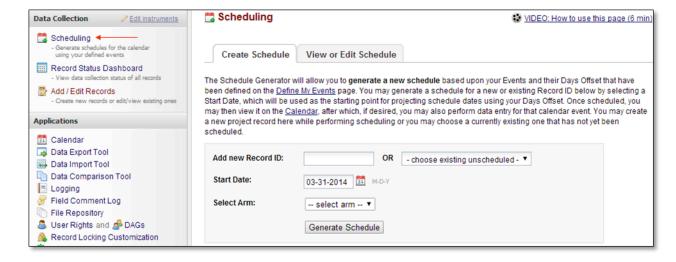
The calendar feature of REDCap allows you to keep track of events related to your project/study, with the option of associating each event with a record. In the above example, three of the events are attached to specific records, while the Design Meeting is not. Various viewing modes are available for the calendar, and you may print the calendar as well.

Another feature of the Calendar module is the Scheduling module, which is available for longitudinal studies only. The Scheduling module can be seen by enabling both the "Use longitudinal data collection with repeating forms?" option and the "Scheduling module (longitudinal only)" option.





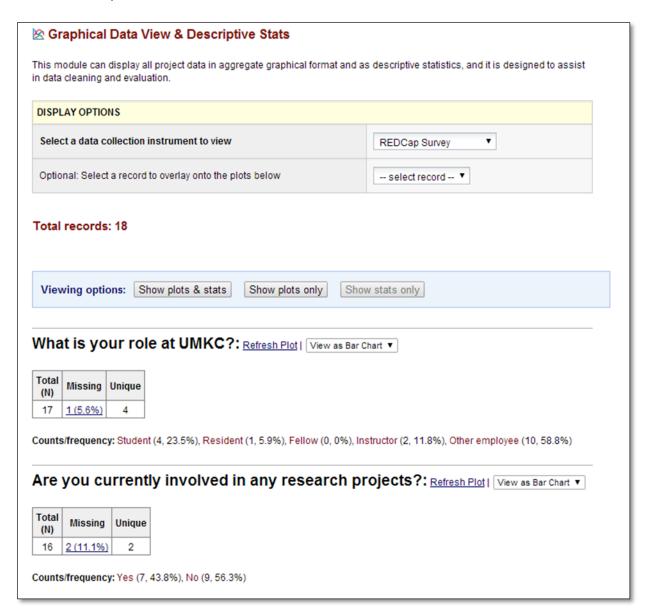
Once both of those options are enabled, a new "Scheduling" tool will appear in the left-side menu. Assuming that you have already set up your Events with the correct "days offset" specifications (see the Longitudinal studies section), adding new Record IDs will automatically generate a schedule to add to the calendar with all events accordingly booked for that record. You may also generate a schedule for the remaining events on any existing record.





......Graphical Data View & Stats

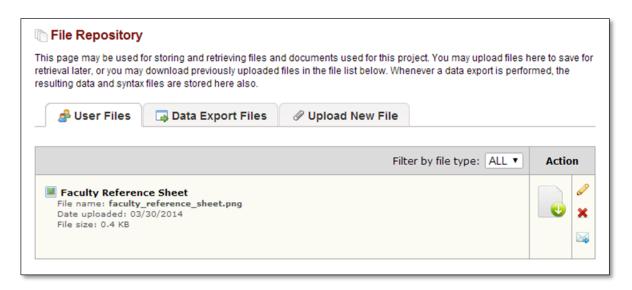
This module takes aggregate data from your data set (organized by data form) and automatically generates relevant plots and simple statistical analyses. It is a useful tool for data overview and evaluation. You can choose to view only the plots, only the statistics, or both. In the example below, I have chosen to view only the statistics. Total responses, missing values, and count frequencies for individual responses are listed. When viewing the plots, you may choose between viewing them either as bar charts or pie charts.





.....File Repository

The File Repository module contains all of the data exports that have been performed on your data set. In addition, users may upload relevant files for other users to download and/or utilize.



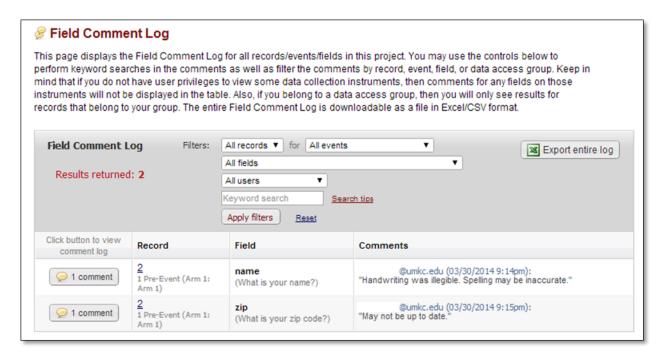


......Field Comment Log

When entering data into a data form, you may have comments or caveats concerning specific fields. If this is the case, you may utilize the Field Comment Log. To first create your comment, click the speech bubble next to the field in the record you are working on. Enter your comment and click "Save." You will notice that the speech bubble icon is now lit, indicating that a comment exists for that field.



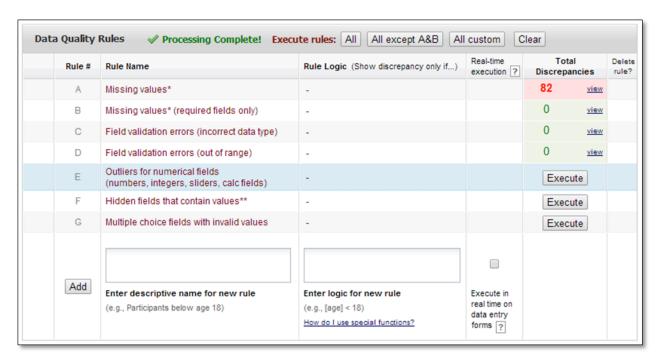
To view the collective comments for all records, click the Field Comment Log module in the left-side toolbar. Comments are linked to their corresponding records, along with the user who made the comment, and the date/time at which the comment was made. You may sort through the comments with various filters, as well as export the comment log to a .CSV file.





......Data Quality

Running a check in the Data Quality module can help you keep track of invalid or missing data across fields. You may execute each "rule" in the pre-made list (as well as create your own) and check for discrepancies such as missing values and data validation errors. I have run a few of them in the example below. As you can see, while I do not have any data validation errors, there are 82 total missing values among my records, which (depending on the fields that are missing) can cause problems in advanced data analysis.





FAQ

Note: Many of the FAQs below stem directly from the Vanderbilt REDCap "Help & FAQ" section. We chose to include only those that we felt were the most important and relevant to the general purposes of our clients. For Vanderbilt's full FAQ, see the "Help & FAQ" module inside redcap.umkc.edu.

Q: How much experience with programming, networking and/or database construction is required to use REDCap?

No programming, networking or database experience is needed to use REDCap. Simple design interfaces within REDCap handle all of these details automatically.

It is recommended that once designed, you have a statistician review your project. It is important to consider the planned statistical analysis before collecting any data. A statistician can help assure that you are collecting the appropriate fields, in the appropriate format necessary to perform the needed analysis.

Q: How should I cite REDCap for the Data Management section of my IRB submission?

We do have recommended documentation; see the <u>Citing REDCap in your IRB protocol</u> section of our REDCap Walkthrough.

Q: What is the Record Status Dashboard?

This is a table listing all existing records/responses and their status for every data collection instrument (and for a longitudinal project, for every event). When viewing this page, form-level privileges are utilized (i.e. a user cannot see a form's status if the user does not have access to that form), and if the user belongs to a Data Access Group, they will only be able to view the records that belong to their group.

Note: Since projects may now have many surveys, REDCap no longer displays the Survey Response Summary on the Project Home page.

Q: How do I enter / view my data?

To enter or view individual records, you can navigate to the "Data Collection" section on the left menu bar. Depending on your project type, you will see "Add or View Survey Responses", a listing of your form names, or a "Data Entry" icon. Use the drop down record lists so you can select or add a new record/response.

Use the Report Builder tool to view your data. The Report Builder tool serves as the search engine of a REDCap database. The Report Builder queries the database in real time and displays the resulting data in table format. Variables are listed in columns and individual records are displayed in rows

Use the Graphical View & Stats tool to view your data. The Plots tab displays graphical representations for all numerical and categorical variables and provides links for cleaning notable data (missing, highest, lowest values). The Descriptive Stats tab displays descriptive statistics for all variables.



Q: Can I upload files to attach to individual subject records?

Yes, you can upload documents for individual records. To create a new document upload field in the Data Dictionary for any given REDCap project, set the Field Type = 'file.' You may add as many 'file' fields as needed to your data collection instruments.

Documents can be uploaded and downloaded by navigating to the record's data entry page and clicking the file link. A document can be deleted at any time, and there is no limit to how many times the document can be replaced by uploading another file to that record's file upload field.

Q: Do I need to select the record number again each time I change data entry forms?

No. To navigate between forms within a given record, select the colored dots indicating form status (i.e. incomplete, unverified, and complete) which appear to the left of the form name when a record is open. Note that moving to a new form by selecting the form status indicator will close the current form without saving entries. In order to save entries, select the "Save and Continue" button located at the bottom of the form before using the form status indicators to move to a new form. Alternatively, you can select the "Save and go to Next Form" button if you wish to move to the next form for the current record.

Q: What are the risks of modifying a database that is already in Production?

Altering a database that is in Production can cause data loss. If a Production database must be modified, follow these rules to protect your data:

- Do not change existing variable names, or data stored for those variables will be lost. To restore data that has been lost in this way, revert to previous variable name(s).
- Do not change existing form names via a data dictionary upload, or form completeness data will be lost. Form names may be changed within the Online Designer without data loss.
- Do not modify the codes and answers for existing dropdown, radio, or checkbox variables; or existing data will be lost or confused. It is only acceptable to add choices to a dropdown, radio, or checkbox field.

Q: When exporting data from redcap into SPSS, will the variable codes that you've defined be automatically imported into SPSS (for ex 1, Female 2, Male)?

Yes. REDCap uses the metadata you have defined in your data dictionary to create syntax files for SPSS, SAS, R, and Stata. The Data Export tool includes instructions for linking the exported syntax and data files. Note that SPSS has several variable naming conventions:

- The name MUST begin with a letter. The remaining characters may be any later, digit, a period or the symbols #, @, _, or \$
- Variable names cannot end with a period
- The length of the name cannot exceed 64 bytes (64 characters)
- Spaces and special characters other than the symbols above cannot be used
- No duplicate names are acceptable; each character must be unique
- Reserved keywords cannot be used as variable names (ALL, AND, BY, EQ, GE, GT, LE, LT, NE, NOT, OR, TO, and WITH)



Q: How do I import data from another source?

Data from another source can be imported using the Data Import Tool (most commonly used) or the API (Application Programming Interface).

The Data Import Tool requires that data to be imported is in CSV (comma separated variables) format. The order of the fields or the number of fields being imported does not matter, except that the record identifier (e.g., Subject ID) must be the first field.

Q: How do I import longitudinal data?

The Data Import Tool requires you to use the "redcap_event_name" column when importing data. You must specify the event name in the file using the unique "redcap_event_name." You can upload multiple event data per subject.

The unique "redcap_event_name"s are listed on each project's Define My Events page.

You can insert this field after the unique identifier as the second column or you can add it to the end of your import spreadsheet (last column).



Additional Resources

Links:

Full REDCap FAQ: https://redcap.umkc.edu/index.php?action=help

REDCap Training Videos: https://redcap.vanderbilt.edu/consortium/videos.php \

Center for Health Insights website: http://chi.umkc.edu

Departmental Contacts:

REDCap Support Team

Mark Hoffman, CHI Director

Ronnie Blackburn, CHI Software Support Analyst