

A. Introduction

REDCap (Research Electronic Data Capture) is a secure web application for building and managing online surveys and databases. The University of New England has a license for REDCap for survey research. This guidance document provides researchers with essential steps and best practices for building, managing, and closing REDCap projects in compliance with IRB requirements. Following these guidelines ensures the proper handling of Personally identifiable information (PII), including Protected Health Information (PHI), and other sensitive data, maintaining participant confidentiality and data integrity throughout the research lifecycle.

B. Purpose

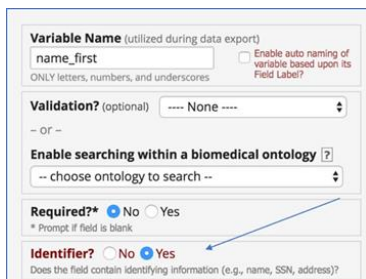
The purpose of this guidance is to assist researchers in the effective use of REDCap for data collection and management in their studies. It aims to ensure that all REDCap projects are designed, managed, and closed in a manner that complies with IRB protocols and data protection regulations. By following this guidance, researchers can minimize risks related to data security and enhance the quality and reliability of their research outcomes.

C. Scope

This document applies to all researchers using REDCap for studies involving human participants at UNE.

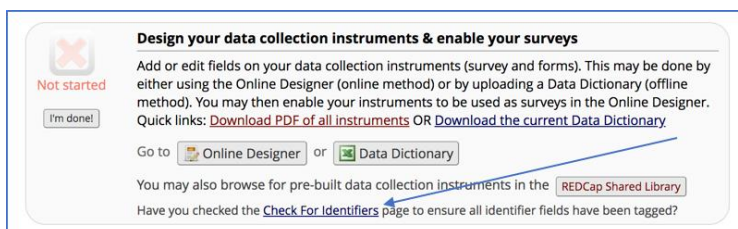
D. Build and Manage the REDCap Project


1. **Mark Identifiers:** When building your REDCap project, ensure any field holding Protected Health Information (PHI) is marked as an identifier. This makes it easy to limit access when exporting data.



Variable Name (utilized during data export)
 name_first Enable auto naming of variable based upon its Field Label?
ONLY letters, numbers, and underscores
 Validation? (optional) --- None ---
 -- Or --
 Enable searching within a biomedical ontology [?](#)
 -- choose ontology to search --
 Required?* No Yes
* Prompt if field is blank
 Identifier? No Yes
Does the field contain identifying information (e.g., name, SSN, address)?

2. **Check for Identifiers:** Use the "Check for Identifiers" feature in REDCap under Project Setup to ensure you've marked all PHI appropriately.

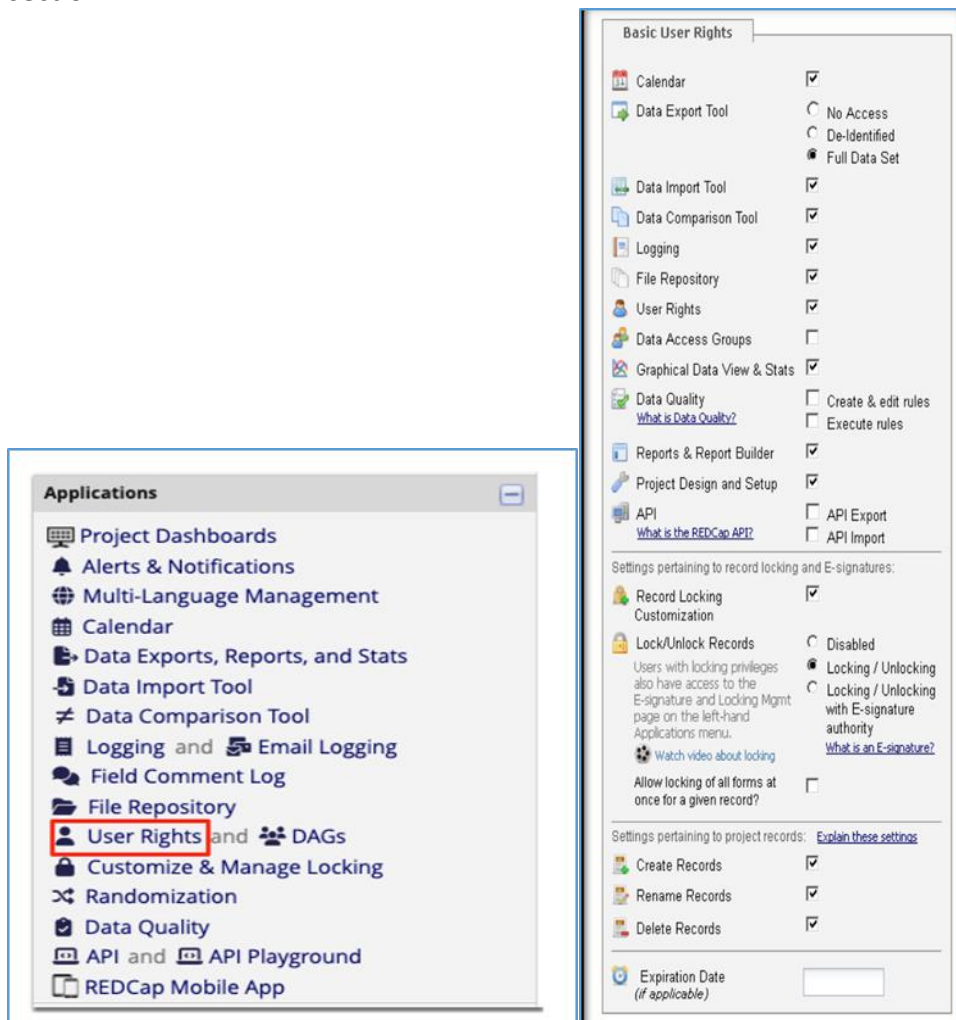


 **Design your data collection instruments & enable your surveys**
 Add or edit fields on your data collection instruments (survey and forms). This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method). You may then enable your instruments to be used as surveys in the Online Designer. Quick links: [Download PDF of all instruments](#) OR [Download the current Data Dictionary](#)
 I'm done!
 Go to [Online Designer](#) or [Data Dictionary](#)
 You may also browse for pre-built data collection instruments in the [REDCap Shared Library](#)
 Have you checked the [Check For Identifiers](#) page to ensure all identifier fields have been tagged?

Demographics PHI		
Variable Name	Field Label	Identifier?
name_first	First Name	<input checked="" type="checkbox"/>
name_last	Last Name	<input checked="" type="checkbox"/>
street	Street	<input checked="" type="checkbox"/>
state	State	<input checked="" type="checkbox"/>
city	City	<input checked="" type="checkbox"/>
zip	ZIP Code	<input checked="" type="checkbox"/>
phone	Phone number	<input checked="" type="checkbox"/>
birth_date	Date of Birth	<input checked="" type="checkbox"/>

Vital Signs		
Variable Name	Field Label	Identifier?
vs_date	Date vital signs taken	<input checked="" type="checkbox"/>

- Manage User Rights:** Assign user permissions through the “User Rights” and “Data Access Groups” (DAGs) section.



The image shows two screenshots from the REDCap interface. The left screenshot displays the 'Applications' menu with 'User Rights and DAGs' highlighted in a red box. The right screenshot shows the 'Basic User Rights' configuration page, which includes various tools and settings with checkboxes for enabling or disabling them.

Tool/Setting	Status
Calendar	<input checked="" type="checkbox"/>
Data Export Tool	<input type="radio"/> No Access <input type="radio"/> De-Identified <input checked="" type="radio"/> Full Data Set
Data Import Tool	<input checked="" type="checkbox"/>
Data Comparison Tool	<input checked="" type="checkbox"/>
Logging	<input checked="" type="checkbox"/>
File Repository	<input checked="" type="checkbox"/>
User Rights	<input checked="" type="checkbox"/>
Data Access Groups	<input type="checkbox"/>
Graphical Data View & Stats	<input checked="" type="checkbox"/>
Data Quality	<input type="checkbox"/> Create & edit rules <input type="checkbox"/> Execute rules
Reports & Report Builder	<input checked="" type="checkbox"/>
Project Design and Setup	<input checked="" type="checkbox"/>
API	<input type="checkbox"/> API Export <input type="checkbox"/> API Import

- Refer to your research protocol for guidance on who should have access to specific data. Typically, the Principal Investigator (PI) or designee manages user rights.

- Err on the side of being overly restrictive, granting permissions as needed to avoid protocol deviations. Ensure that the roles and access permissions granted align with the descriptions and responsibilities outlined in the IRB application:
 - Anyone who is accessing identifiable information must have been approved to do so by the IRB. If additional personnel need access to identifiable information, an amendment to the IRB application is required to add them to the study.

- 4. **Consent Form Statement:** Include a statement in the Participant Information Sheet (exempt research projects) or Consent Form (non-exempt research projects) that specifies what will happen to the data after the study is closed. This can detail whether data will be deleted, de-identified, or archived. If identifiable data is to be kept, participants must be fully informed and provide explicit consent for this retention. The consent process must clearly outline what identifiable data will be retained, the purpose of retaining this data, and the participants' rights to withdraw their consent at any time. This ensures compliance with ethical standards and respects participant autonomy.
 - **Example language for Data Deletion:**
 - *"After the study is concluded, all identifiers will be securely deleted from our systems to protect your privacy and confidentiality. No identifying information will be retained."*

 - **Example language for Data De-identification:**
 - *"After the study is concluded, all data will be de-identified. This means any information that could directly identify you will be removed, ensuring your anonymity in any future analysis or reporting."*

 - **Example language for Data Archiving:**
 - *"After the study is concluded, your data will be securely archived in a de-identified format. This archived data may be used for future research purposes, but it will not contain any information that could directly identify you."*

 - **Example language for Retention of Identifiable Data:**
 - *"As part of this study, you have the option to allow us to retain your contact information and basic health data. By consenting to this, you agree that we may keep your identifiable information in a secure database (REDCap) to contact you about future research studies. Your participation in this option is entirely voluntary, and you can withdraw your consent at any time by notifying the research team.*

Your data will be protected and used solely to identify potential participants for future research. We will not share your identifiable information with any third parties without your explicit consent. Your data will be kept indefinitely or until you request its removal. If you do not provide this consent, your data will be removed from the database after recruitment for the study has ended.

Please review the following options and indicate your preference by initialing the appropriate box:

- I agree to allow the research team to keep my contact information and basic health data in a secure online system (REDCap) so I can be contacted for future studies.
- I do not agree to allow the research team to keep my contact information and basic health data. I understand that my data will be removed from the database after recruitment for the study has ended.”

E. Close the REDCap Project After Study Completion

Options for Handling Data:

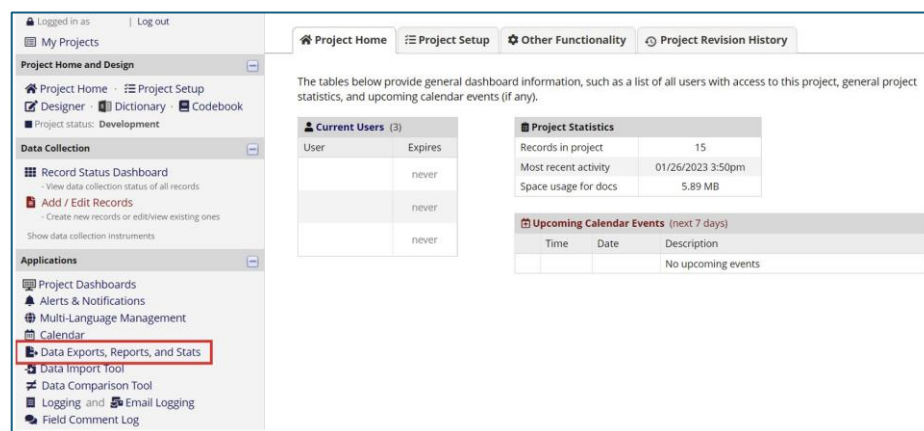
- ✓ **Delete Identifiers:** Go through your data and delete any identifiers. This can be done by editing the fields directly within REDCap.
- ✓ **Download De-identified Data:** Export a de-identified version of your data. Use REDCap’s de-identification options during the export process to remove PHI.
- ✓ **Delete the Study:** If data retention policies allow, you may choose to delete the entire REDCap project. This should be done only after ensuring all necessary data has been securely archived or exported.

1. Deleting Identifiers:

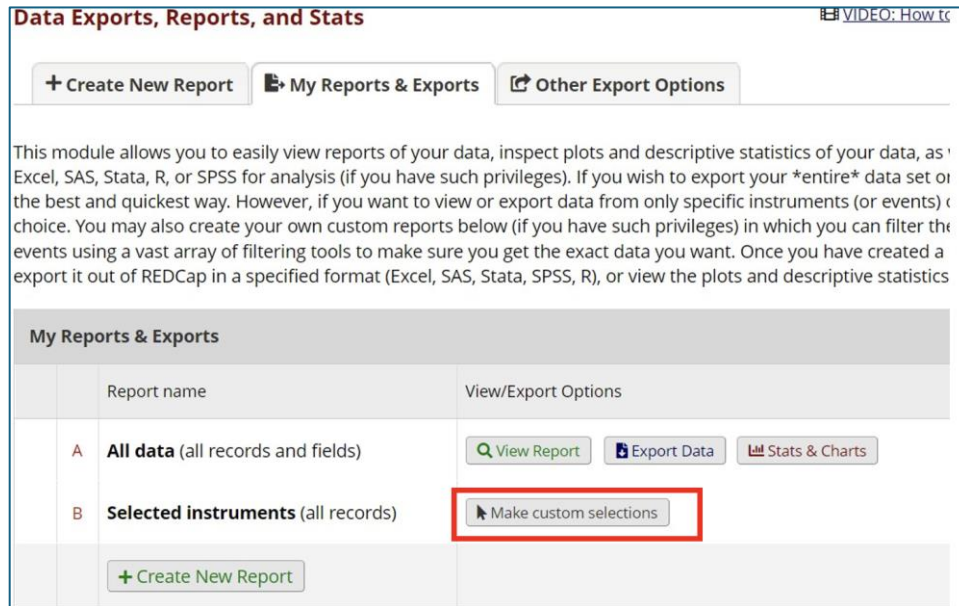
- Navigate to the field containing the identifier.
- Manually delete the data or remove the identifier attribute.

2. De-identified Export:

- Select “Data Exports, Reports, and Stats” from the menu column on the left-hand side.



- Select option B, “Selected Instruments (all records)”, by clicking on “Make custom selections”.



Data Exports, Reports, and Stats VIDEO: How to...

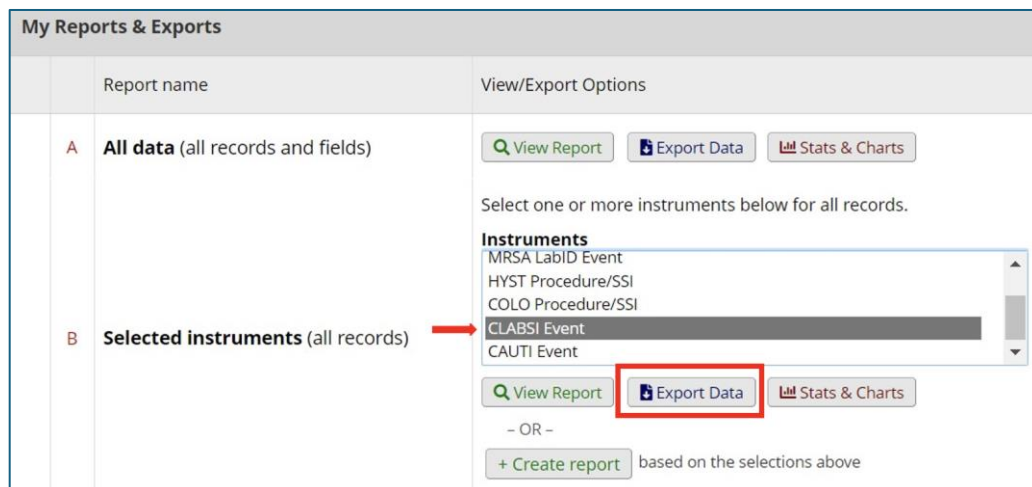
[+ Create New Report](#)
[My Reports & Exports](#)
[Other Export Options](#)

This module allows you to easily view reports of your data, inspect plots and descriptive statistics of your data, as well as export your data to Excel, SAS, Stata, R, or SPSS for analysis (if you have such privileges). If you wish to export your *entire* data set or only specific instruments (or events) (if you have such privileges), you can do so in the best and quickest way. However, if you want to view or export data from only specific instruments (or events) (if you have such privileges), you can do so by choice. You may also create your own custom reports below (if you have such privileges) in which you can filter the events using a vast array of filtering tools to make sure you get the exact data you want. Once you have created a report, you can view it or export it out of REDCap in a specified format (Excel, SAS, Stata, SPSS, R), or view the plots and descriptive statistics.

	Report name	View/Export Options
A	All data (all records and fields)	View Report Export Data Stats & Charts
B	Selected instruments (all records)	Make custom selections

[+ Create New Report](#)

- o Select the instrument you want to export data from and click the “Export Data” button.



My Reports & Exports

	Report name	View/Export Options
A	All data (all records and fields)	View Report Export Data Stats & Charts
B	Selected instruments (all records)	<p>Select one or more instruments below for all records.</p> <p>Instruments</p> <ul style="list-style-type: none"> MRSA LabID Event HYST Procedure/SSI COLO Procedure/SSI CLABSI Event CAUTI Event <p> View Report Export Data Stats & Charts </p> <p>- OR -</p> <p>+ Create report based on the selections above</p>

- o A window will pop up with various exporting options. Select “CSV/Microsoft Excel (raw data)” format and check the box “Remove all tagged Identifier fields” under Known Identifiers. This will remove all private health information. Leave all other options as the default selections and click the “Export” button at the bottom right corner.

3. Deleting or Archiving the Study

- **Project Deletion:** Under Project Management, select *“Delete the project”*. A pop-up window will display. Type *“DELETE”* in the text box and hit the *“Delete the project”* button. **Note:** This will permanently delete the project, and you will not be able to retrieve any data or forms from this project once it has been deleted.

- **Project archival:** Under Project Management, select *“Archive the project”*. **Note:** You can still access archived projects from the My Projects page by scrolling to the bottom of your projects list and selecting *“Show Archived Projects”*.

F. Conclusion

By adhering to this guidance, researchers can ensure their REDCap projects are compliant with IRB standards, thus safeguarding the integrity of their research and the confidentiality of their participants.

G. Contact

If you require assistance or have any questions about REDCap, please contact [Michael Lawrence](#) the UNE REDCap Administrator.

If you require assistance or have any questions about an IRB submission, please contact irb@une.edu.

H. Resources

- [UNE REDCap Training Resources](#)
- [UNE IRB Website](#)
- [UNE IRB FAQ Website](#)