PICC - CF

Database User Reference

REDCap

Getting Started

Enter & Modify Patient Data

Data Quality

Other Features

11/15/2018

The PICC-CF study is using REDCap (Research Electronic Data Capture) for its data entry and management. REDCap is a web application for building and managing online surveys and databases. REDCap is HIPAA compliant. Data are stored on a secure server; data in REDCap are encrypted and access to the database requires authentication (a unique username and password); data are accessed based on the individual's role within the PICC-CF study. Every interaction with the data is logged, and an audit trail is created.

Clinical questions

(e.g., protocol, definitions)

Amanda Cass

Project Coordinator

Maine Medical Center

acass@mmc.org

REDCap application questions

(e.g., user account expiration, database navigation)

Deanna Williams

REDCap Database Manager

Maine Medical Center

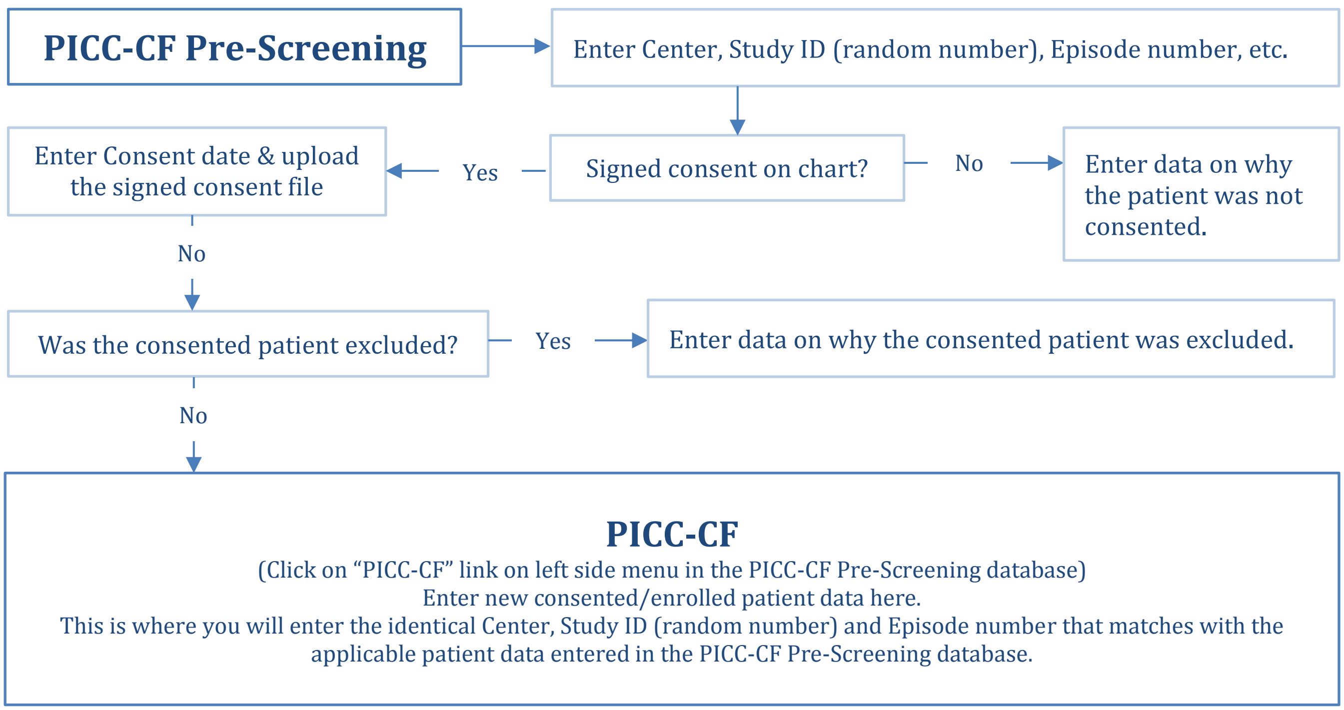
willid6@mmc.org

INITIAL DATA ENTRY FLOW

There are 2 databases that will require entry/maintenance of patient data (see steps below):

1) PICC-CF Pre-Screening is the database that you will enter all patients that have been pre-screened (consented or not consented). In addition to a few data points about the patient (e.g., exclusion criteria, consenting information if applicable); this is where you will first enter the patient's Center, Study ID (random number) and Episode Number. It is essential that these 3 data points are an **exact** match to the patient's Center, Study ID (random number) and Episode Number in the PICC-CF database. The Center, Study ID, and Episode Number will be used to link the PICC-CF Pre-Screening data to the PICC-CF study data for analysis.

2) PICC – CF database is where the enrolled/consented patient data is entered.



DATABASE USER ACCOUNT ACCESS

Please do not share user account/passwords. It is important that each individual has their own username and password. Once your center has received IRB approval; follow the steps below to obtain a database user account to access the databases.

1. Follow the link PICC-CF Database User Account Request
If the link above does not work, try copying the link below into your web browser:
https://collaborate.tuftsctsi.org/redcap/surveys/?s=THP9YLN8WX

2. Complete the survey, download the database tutorial (this document), and click Submit.

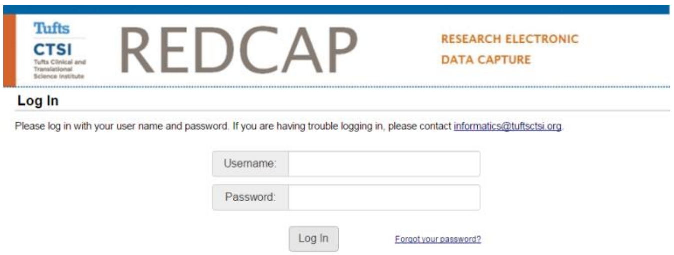
3. You will receive a confirmation email (usually within 10 days) from Tufts Medical Center with your username and instructions to set up your new password. *Note: once you've set up your password, you can login at any time and check your status.*

4. Review this PICC-CF Database Tutorial

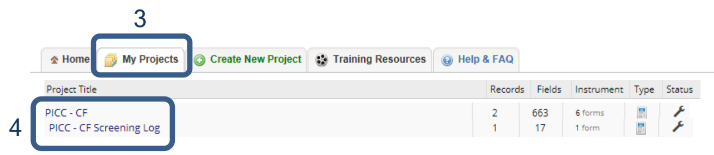
5. Start entering data!

PICC-CF LOG IN TO DATABASE

1. PICC-CF website   or use the direct link

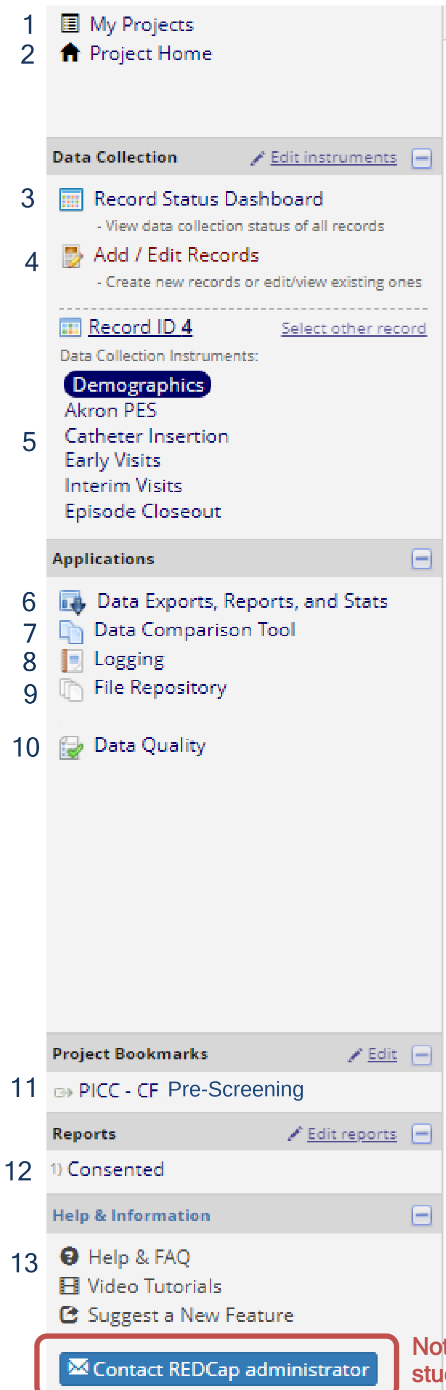


2. Enter Username and Password



3. Click on My Projects tab.
4. Click on PICC-CF or PICC-CF Pre-Screening

REGISTRY SIDE BAR NAVIGATION



1. My Projects: Returns to My Projects tab (initial view upon log in).

2. Project Home: PICC-CF homepage or PICC-CF Screening Log homepage.

3. Record Status Dashboard: Shows all of the exiting instruments/data by Center ID-Study ID-Episode number. This is where you will go to modify or enter data for Study IDs that already have some data entered. (PICC-CF Screening Log: patients that have not been enrolled will not have the Center ID-Study ID-Episode number displayed)

4. Add / Edit Records: Enter new patient that has not been entered. You can also search existing records using a specific data point already entered.

5. Data Collection Instruments: The Data Collection Instruments listed are the applicable data collection forms that will apply for each patient you enter.

6. Data Exports, Reports, and Stats:
- Data Exports: This is where you can export your center's data. You can export your data to the following files:
  - Microsoft Excel / CSV
  - SAS
  - Stata
  - R
  - SPSS
  - XML
- Reports: View/Create custom reports of your center's data using filters. Each report created, will show up under the "Reports" header on the left side bar.
- Stats: Inspect plots and descriptive statistics of your center's data.

7. Compare 2 Study ID records currently entered side-by-side.

8. Logging: Audit trail listing registry activity. You can download the log into a csv file.

9. File Repository: Used for storing and retrieving files and documents used for PICC-CF. All centers will have access to the files uploaded here. All data collection handbooks are available here with field definitions.

10. Data Quality: Execute data quality rules to check for discrepancies in your center's data.

11. Click to go directly to the PICC-CF Pre-Screening database.

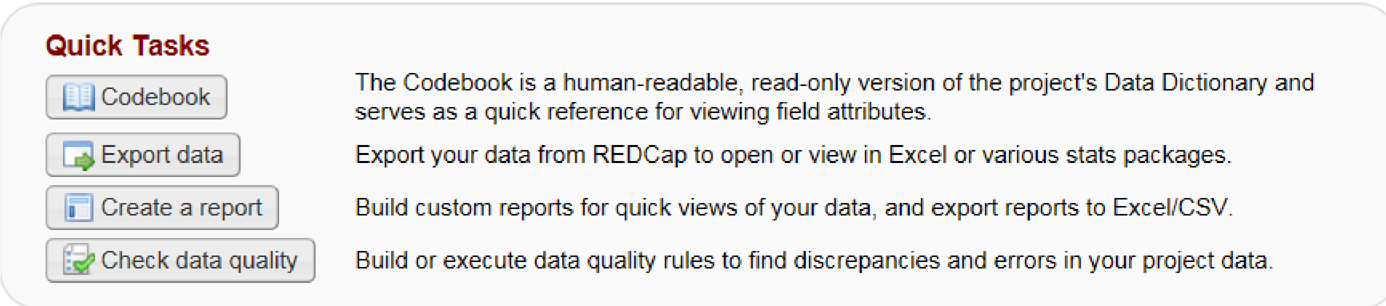
12. Reports: Within this section of the side bar, any custom reports you created will appear here.

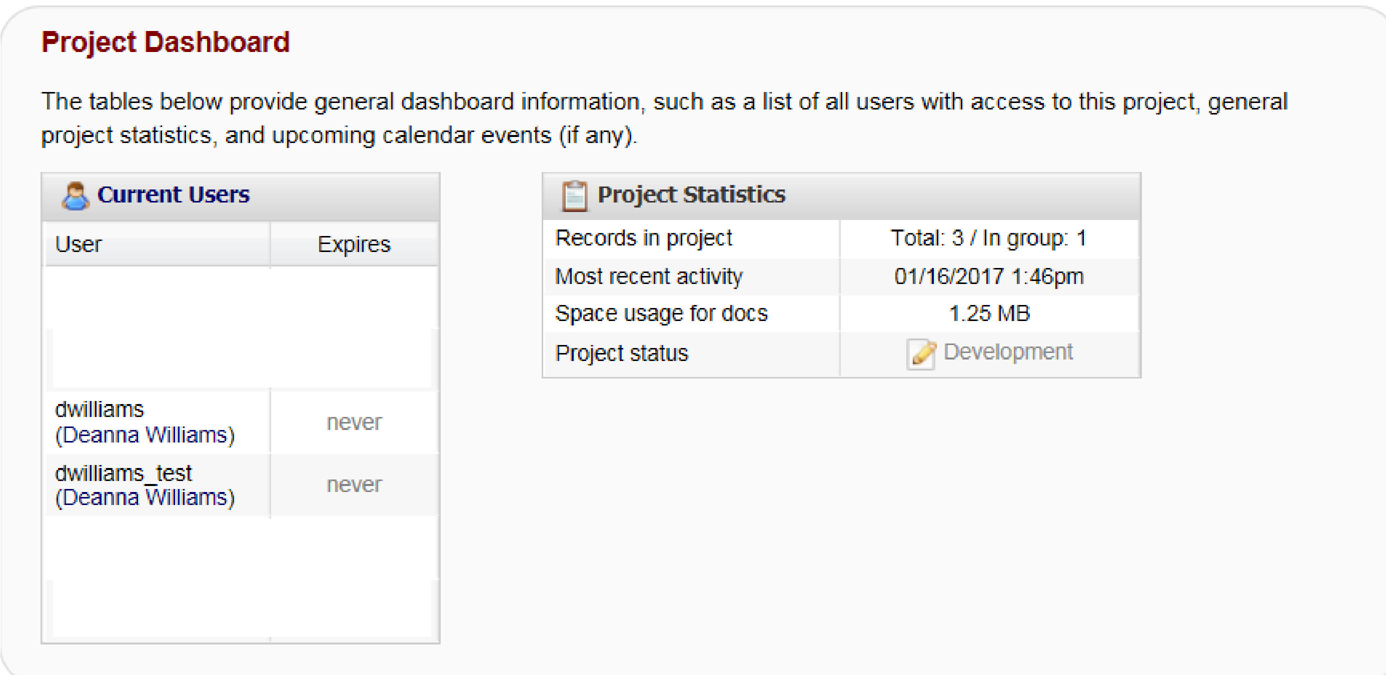
13. Help & Information: Help & FAQ and the Video tutorials for REDCap.

Note: Suggest a New Feature and Contact REDCap administrator should not be used for study-specific updates/requests. Please contact the coordinating center for suggestions and questions.

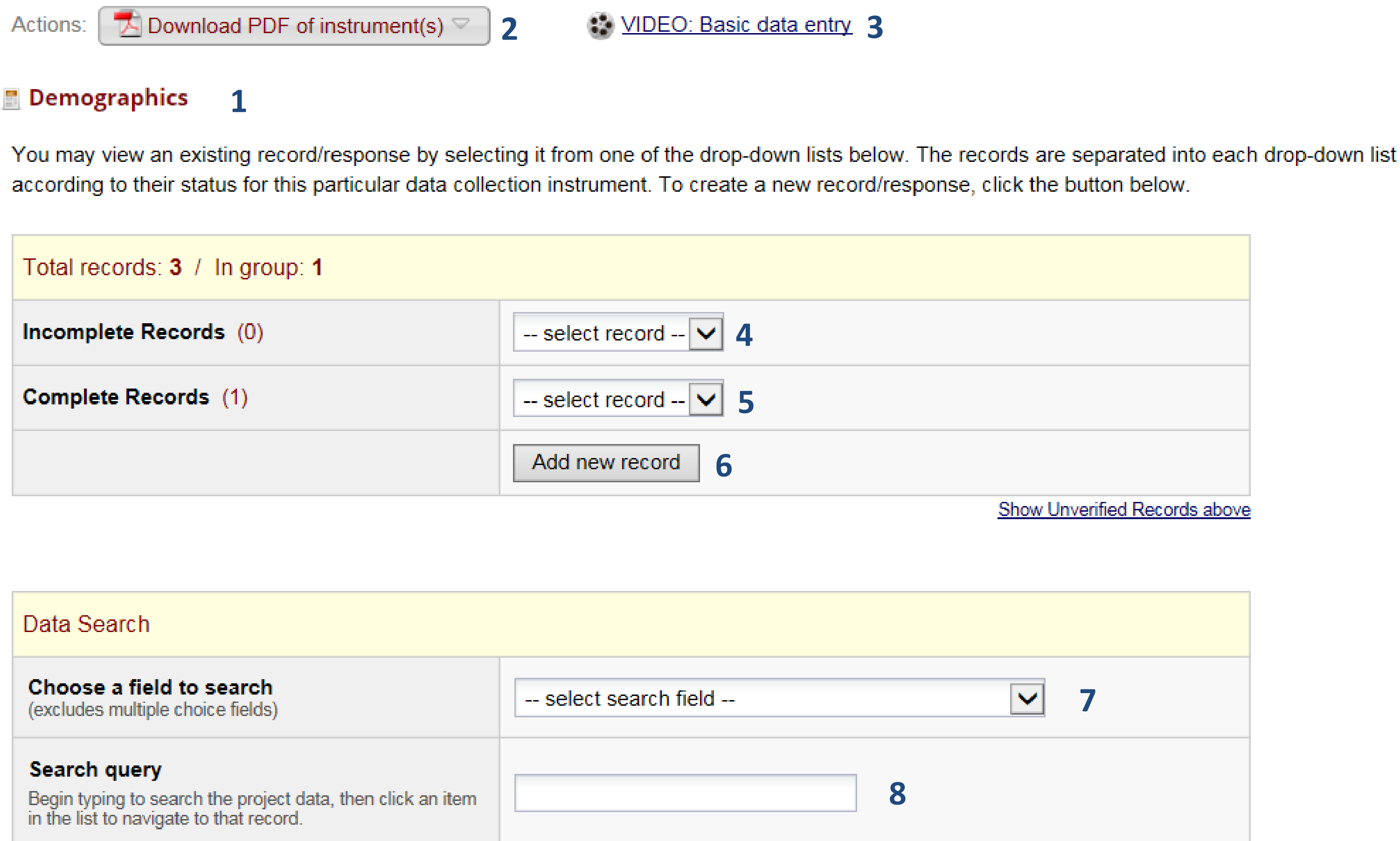
PROJECT HOME

Your homepage within the PICC-CF or PICC-CF Pre-Screening databases. It allows quick access to the Data Dictionary, exporting data, reports and data quality checks.





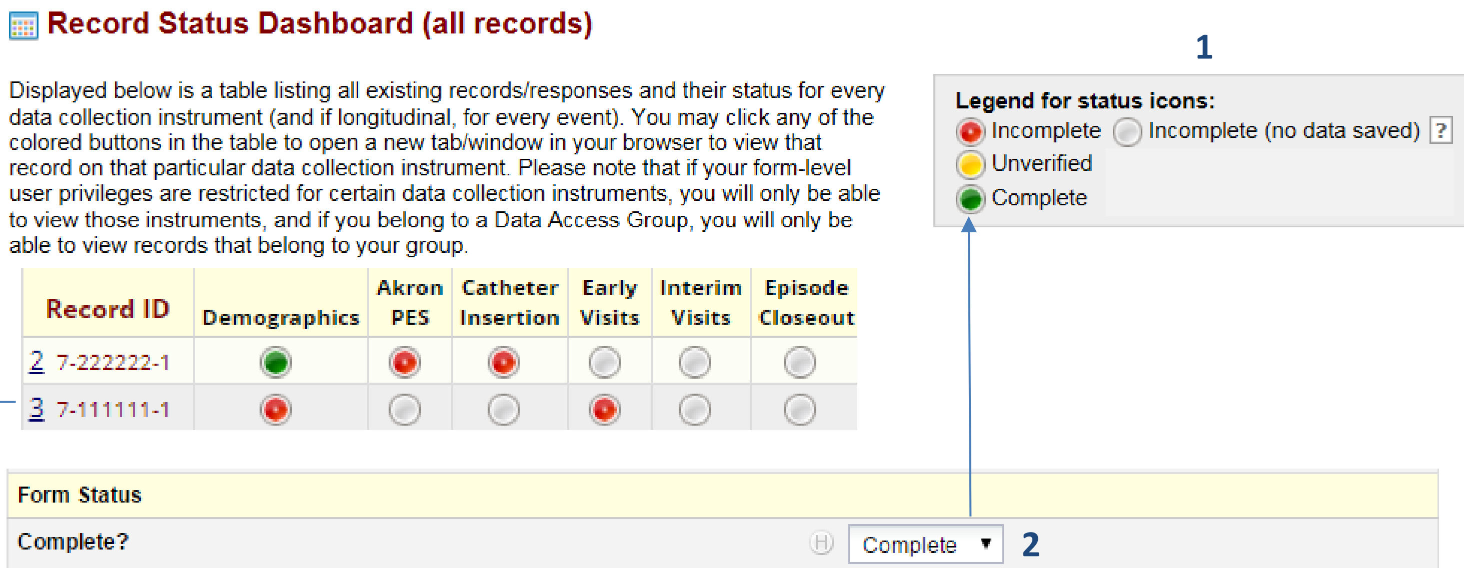
ENTER A NEW PATIENT RECORD / MODIFY AN EXISTING PATIENT RECORD



1. The name of the instrument that the dropdown lists are querying. You can change the instrument (e.g., Demographics) by clicking on the instrument name on the left side menu (Data Collection Instruments: section).
2. You can download a pdf of the current instrument (e.g., Demographics) or download pdfs of all instruments (without data).
3. Video (16:05 minutes) tutorial showing demonstrating data entry.
4. Incomplete Records: indicates the number of incomplete records in parenthesis. You can select a specific study id from this dropdown where the form status is “Incomplete”. This status is determined by the last field in each data entry form. This field is a dropdown to indicate the status of the data collection for the specific patient record and instrument. This is also notable in the Record Status Dashboard, where the incomplete status is indicated by a red bubble.
5. Complete Records: indicates the number of complete records in parenthesis. You can select a specific patient record from this dropdown where the form status is “Complete.” This status is determined by the last field in each data entry form. This field is a dropdown to indicate the status of the data collection for the specific patient record and instrument. This is also notable in the Record Status Dashboard, where the complete status is indicated by a green bubble.
6. Add a new patient record to the database (only for patients who do NOT have an existing record/data entered.
7. If you would like to open a patient record based on a field other than their Study ID, you can select the field from the dropdown and enter a value in the Search query field below (8).
8. After you have selected a field from the dropdown above (7), enter a value related to the field you selected. (e.g., if you selected “age” as a field from the dropdown, enter the value 52 here. It will return patient records where the age = 52.)

RECORD STATUS DASHBOARD

Click on the Record Status Dashboard on the left side menu to modify/add/review existing data.



1. These colors indicate the status of each of the Study ID's data collection instrument. The colors correspond with the table below the legend (3). Each of the status colors are determined by the last field (dropdown) on each data collection instrument. (e.g., Complete will show as a green bubble on the Record Status Dashboard, Incomplete will show as a red bubble, etc.)

2. You can click on any of the bubbles for a given record to review or enter data for a specific Study ID. Bubbles that do not have a color, indicates that the instrument has not been opened for that Study ID. **NOTE: "Complete" must be selected in the "Form Status Complete?" dropdown in order for the record to be included in the Data Quality Checks.**

Record ID is broken into 4 parts (see example below):

1 7 – 111111 - 1

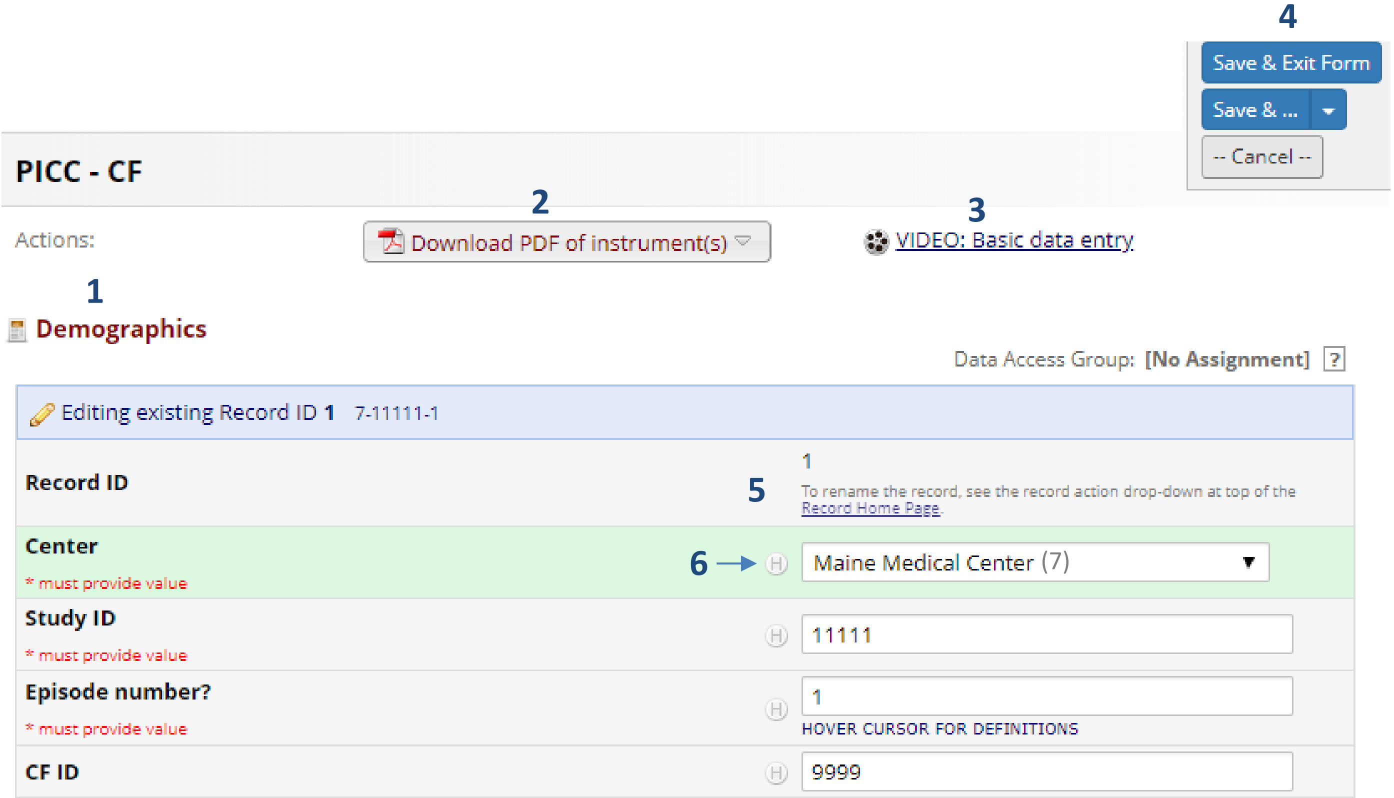
Center ID
07=Maine

Study ID
6 digit random number

Episode
Patient episode number.

Record ID
A number automatically assigned by REDCap.

DATA ENTRY



1. The name of the instrument you are currently in.
2. Download a pdf of this data entry form. There are 4 options:
    a. This data entry form (blank): This data entry form without data.
    b. This data entry form with saved data: This data entry form with data you've entered for a given Study ID.
    c. All forms/surveys (blank): This and all other data entry forms that where data is expected without data (e.g., Demographics, Akron PES, Catheter Insertion, Early Visits, Interim Visits, Episode Closeout)
    d. All forms/survey with saved data: Current form you are in as well as other forms data is expected for the given Study ID. With data entered.

3. Video tutorial for basic data entry (16:05 minutes).

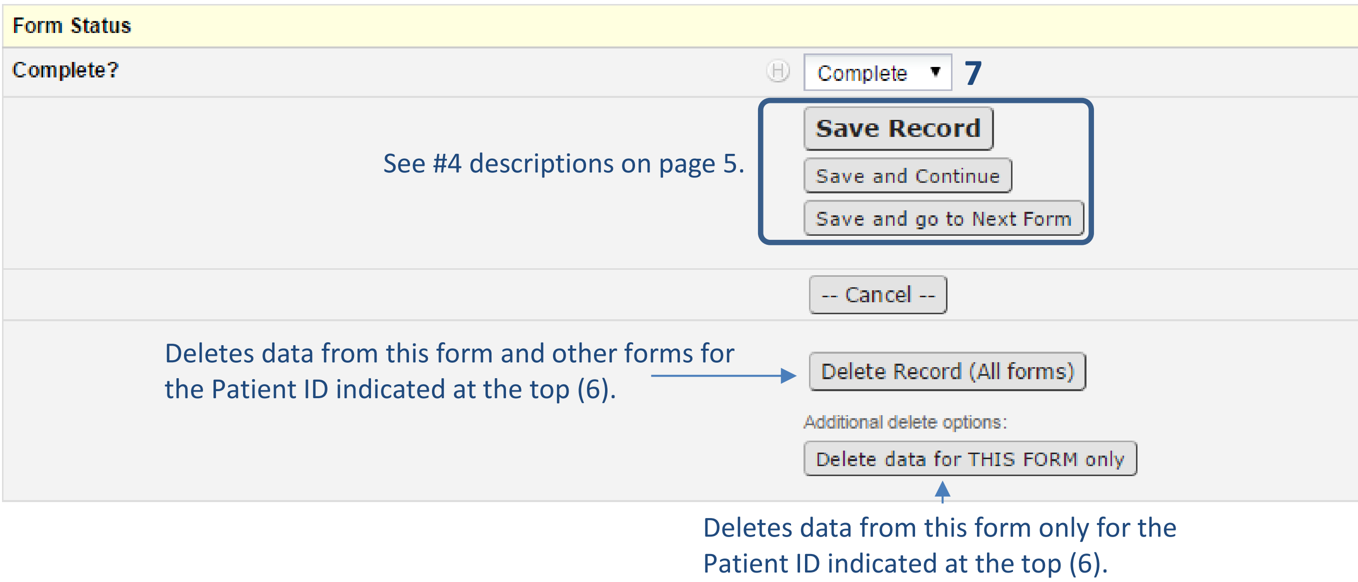
4. It is recommended that you "Save and Continue" throughout data entry. This will ensure you have saved the data in case of any power outage or if our internet shuts down.

    a. Save Record: save the data and take you to the "Add/Edit Records" view.
    b. Save and Continue: Save data and continue entering data in the current form.
    c. Save and go to Next Form: Save data and opens the next data entry form for the given Study ID

5. Unique REDCap record id (number).

6. This appears next to every field for each Study ID. Click this and you will see the history of data changes for the Study ID and that given field.

DATA ENTRY
(Continued)



7. At the end of every CRF is a status field for the given Study ID's data. What you select from the dropdown will show up on the Record Status Dashboard (left side menu) and be associated with a specific color.

   e. Incomplete
   f. Unverified
   g. Complete
   h. Instrument not opened

TIP: Some items have a description. Hover over the item prompt to view.

DATA QUALITY

Custom data quality checks can be executed here. The Rule Name indicates the description of the Data Check. To find discrepancies for a given rule, click the Execute button to the right of it, or click the Execute All Rules button to execute all rules at once. It will provide you with the total number of discrepancies found for each rule and will allow you to view the details of those discrepancies by clicking the View link next to each.

Data Quality Rules ✔ Processing Complete! **Execute rules:** All | All except A&B | All custom | Clear

Apply to: -- All records --

	Rule #	Rule Name	Rule Logic (Show discrepancy only if...)	Real-time execution ?	Total Discrepancies	Delete rule?
	A	Missing values*	-		Execute	
	B	Missing values* (required fields only)	-		Execute	
	C	Field validation errors (incorrect data type)	-		Execute	
	D	Field validation errors (out of range)	-		Execute	
	E	Outliers for numerical fields (numbers, integers, sliders, calc fields)	-		Execute	
	F	Hidden fields that contain values**	-		Execute	
	G	Multiple choice fields with invalid values	-		Execute	
	H	Incorrect values for calculated fields	-		Execute	
	1	Missing screening date	[screendate]=""		1 view	✖

1. Click on "view" under Total Discrepancies column.

Rule #1: **Missing screening date**
Discrepancies found: **1**

Record	Discrepant fields with their values	Status	Exclude
1 07-11111-01	*"Date screened"* screendate: [no data]	Issue exists	exclude

2 3

2. A window opens displaying the Record ID and Study ID.

3. If you would like to add data to the applicable Record, you can click on any of the data points to the right of the Record ID and it will take you directly to the data point for that Record ID.

If you would like a Record ID to be excluded from the specific Data Quality Check in the future, you can select "exclude" to the right of the Record ID. You can go back and "remove exclusion" if you choose.

Note: For Patient data to be included in the Data Quality Checks, "Complete" must be selected in the Form Status for each Patient's instrument.

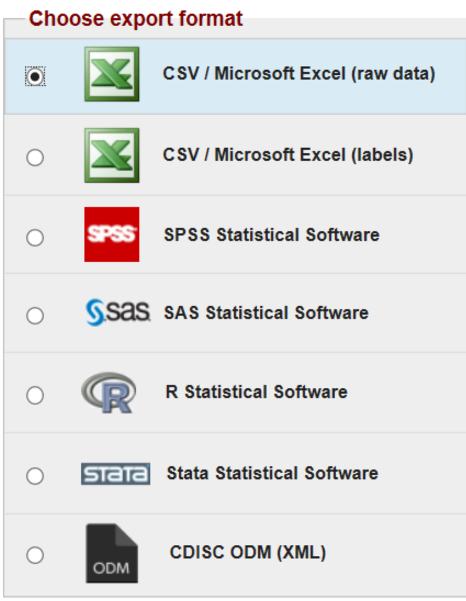
EXPORTING DATA

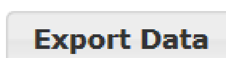
You can export your center's data at any time.

1. Select Data Exports, Reports, and Stats from the left side menu. 

2. Click the Export Data button 

3. Choose the file type you would like the data exported in (i.e., CSV / Microsoft Excel, SPSS, SAS, R, Stata, and XML).

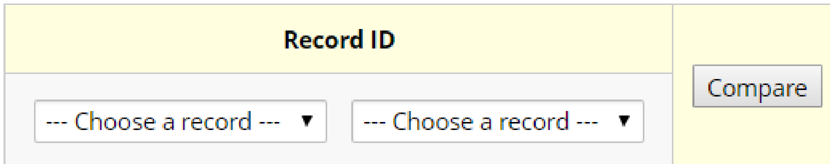


4. Click Export Data button on bottom right. 

5. Follow the exporting instructions.

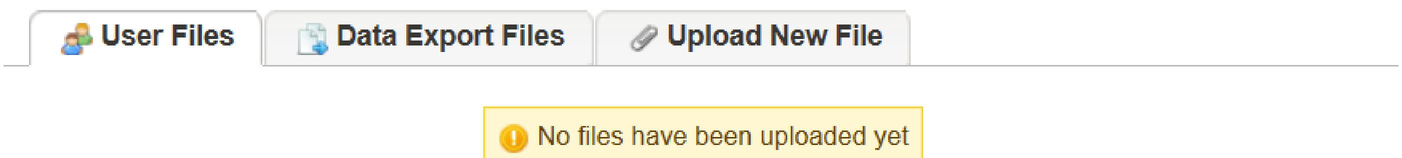
DATA COMPARISON TOOL

Compare 2 Record ID's data (side-by-side) currently entered in the registry. Select a record from each of the list below and click the "Compare" button. A comparison table will display showing the differences between the 2 patients.



FILE REPOSITORY

This may be used for storing and retrieving files and documents used for the PICC-CF databases. You can upload files here to save for retrieval later. Any files uploaded here will be accessible to all centers.



CUSTOM REPORTS

You can create custom on-demand reports with custom filters. You can have as many fields in your report as you choose as well as choose which users can view the report. Custom reports created appear in the left side menu with the name you have designated. You can filter the results in the report using and/or logic. You can also export the data within the report via .csv file.

1. Select Data Exports, Reports, and Stats from the left side menu. Data Exports, Reports, and Stats

My Reports & Exports

	Report name	View/Export Options	Management Options
A	**All data** (all records and fields)	View Report · Export Data · Stats & Charts	
B	**Selected instruments** (all records)	Make custom selections	
1	Consented	View Report · Export Data · Stats & Charts	Edit · Copy · Delete
	+ Create New Report		

Existing Custom Report:

1. View existing report.
2. Export data for that report (with applicable filters). This will export in a .csv file.
3. Stats & Charts (will run summary statistics for that report). It will also create histograms that you can export as a jpeg file for the fields included in that specific report.

Create New Report

If you want to create a new report that will show up in 2 places (left side menu under "Reports" header and within the "My Reports & Exports" window (see above).

1. Name of report. Once the report has been created and saved, the name will show up on the left side menu to execute.

2. Users you want to access the report.

3. Fields you want to include in report.

4. Filters (And/Or/Equal to/Not equal to) for report.

5. Live filters to be included at the top of the report for users to implement additional filters.

6. Ordering the results.