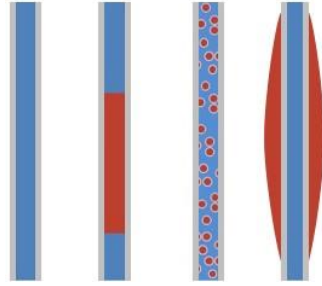


# PICC - CF



## Database User Reference

REDCap

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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**

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## REDCap application questions

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

**Deanna Williams**

*REDCap Database Manager*

Maine Medical Center

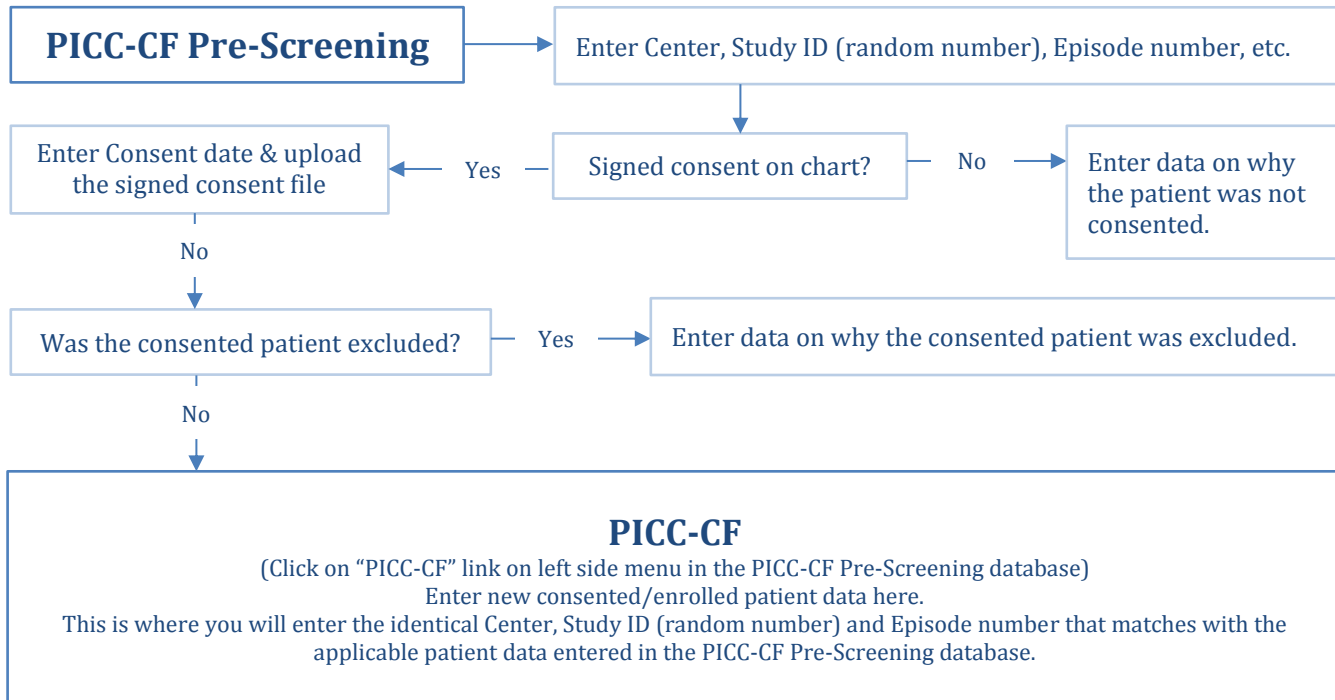
[willid6@mmc.org](mailto:willid6@mmc.org)

## 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.

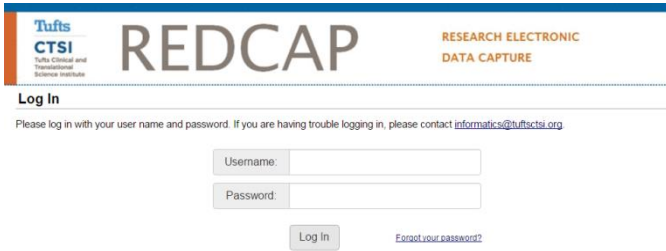
3. You will receive a confirmation email (usually within 10 days) from Tufts Medical Center with your username and instructions to set up your new password. *Note: once you've set up your password, you can login at any time and check your status.*

4. Review this PICC-CF Database Tutorial

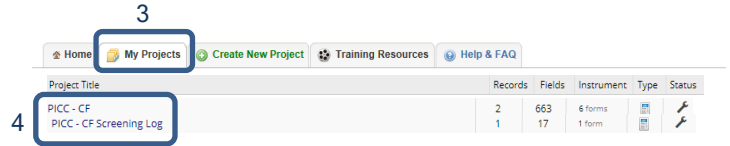
5. Start entering data!

# PICC-CF LOG IN TO DATABASE

1. PICC-CF website or use the direct link

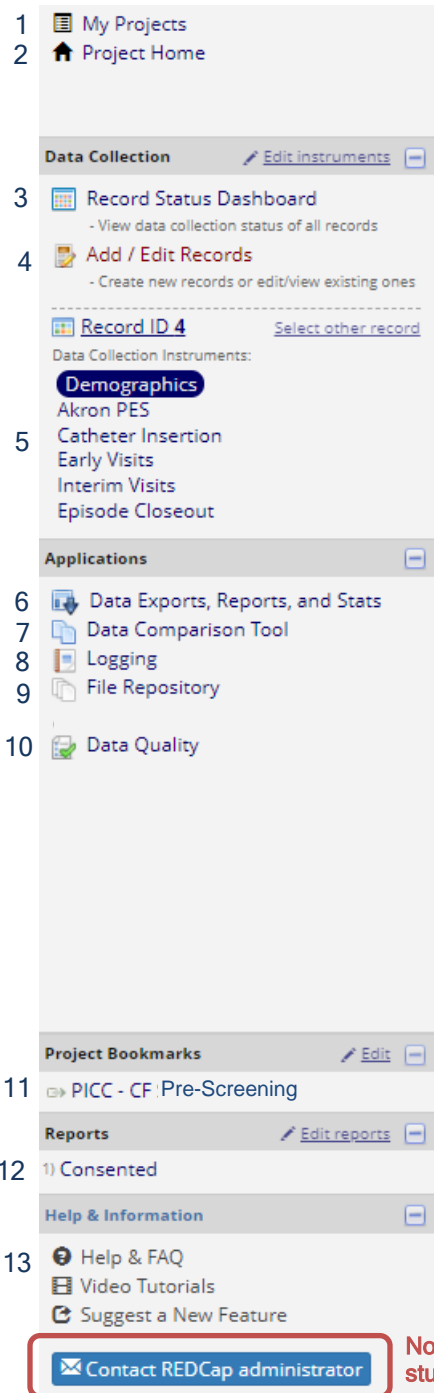


2. Enter Username and Password



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.


### Quick Tasks

 Codebook


The Codebook is a human-readable, read-only version of the project's Data Dictionary and serves as a quick reference for viewing field attributes.

 Export data

Export your data from REDCap to open or view in Excel or various stats packages.

 Create a report


Build custom reports for quick views of your data, and export reports to Excel/CSV.



 Check data quality

Build or execute data quality rules to find discrepancies and errors in your project data.



### Project Dashboard

The tables below provide general dashboard information, such as a list of all users with access to this project, general project statistics, and upcoming calendar events (if any).

 Current Users	
User	Expires
dwilliams (Deanna Williams)	never
dwilliams_test (Deanna Williams)	never



 Project Statistics	
Records in project	Total: 3 / In group: 1
Most recent activity	01/16/2017 1:46pm
Space usage for docs	1.25 MB
Project status	 Development

## ENTER A NEW PATIENT RECORD / MODIFY AN EXISTING PATIENT RECORD


Actions:  Download PDF of instrument(s) **2**  VIDEO: Basic data entry **3**



### Demographics **1**

You may view an existing record/response by selecting it from one of the drop-down lists below. The records are separated into each drop-down list according to their status for this particular data collection instrument. To create a new record/response, click the button below.

Total records: <b>3</b> / In group: <b>1</b>	
Incomplete Records (0)	-- select record --  <b>4</b>
Complete Records (1)	-- select record --  <b>5</b>
	Add new record <b>6</b>

[Show Unverified Records above](#)

Data Search	
Choose a field to search <small>(excludes multiple choice fields)</small>	-- select search field --  <b>7</b>
Search query <small>Begin typing to search the project data, then click an item in the list to navigate to that record.</small>	<input type="text"/> <b>8</b>

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.

### Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Record ID	Demographics	Akron PES	Catheter Insertion	Early Visits	Interim Visits	Episode Closeout
<u>2</u> 7-222222-1						
<u>3</u> 7-111111-1						

**Legend for status icons:**

Incomplete    Incomplete (no data saved) ?

Unverified

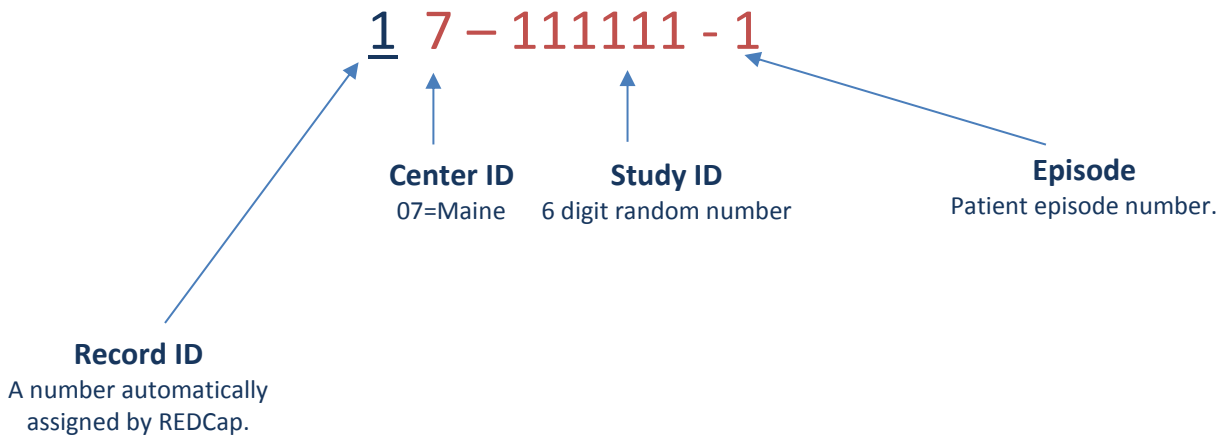
Complete

**Form Status**

Complete? (H) Complete ▾ **2**

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):



# DATA ENTRY

4

**PICC - CF**

Actions: Download PDF of instrument(s) [VIDEO: Basic data entry](#)

**1**  
**Demographics**

Data Access Group: **[No Assignment]**

Editing existing Record ID **1** 7-11111-1

<b>Record ID</b>	<b>5</b> <b>1</b>	To rename the record, see the record action drop-down at top of the <a href="#">Record Home Page</a> .
<b>Center</b> <small>* must provide value</small>	<b>6</b>	Maine Medical Center (7)
<b>Study ID</b> <small>* must provide value</small>		11111
<b>Episode number?</b> <small>* must provide value</small>		1 <small>HOVER CURSOR FOR DEFINITIONS</small>
<b>CF ID</b>		9999

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)

**Form Status**

Complete? (H) Complete ▾ 7

See #4 descriptions on page 5.

Save Record  
Save and Continue  
Save and go to Next Form

-- Cancel --

Deletes data from this form and other forms for the Patient ID indicated at the top (6). → Delete Record (All forms)

Additional delete options:  
Delete data for THIS FORM only

Deletes data from this form only for the Patient ID indicated at the top (6).

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 <span style="float: right;">✔ Processing Complete! Execute rules: <input type="button" value="All"/> <input type="button" value="All except A&amp;B"/> <input type="button" value="All custom"/> <input type="button" value="Clear"/></span>						
Apply to: <input type="text" value="-- All records --"/>						
Rule #	Rule Name	Rule Logic (Show discrepancy only if...)	Real-time execution <input type="checkbox"/>	Total Discrepancies	Delete rule?	
A	Missing values*	-		<input type="button" value="Execute"/>		
B	Missing values* (required fields only)	-		<input type="button" value="Execute"/>		
C	Field validation errors (incorrect data type)	-		<input type="button" value="Execute"/>		
D	Field validation errors (out of range)	-		<input type="button" value="Execute"/>		
E	Outliers for numerical fields (numbers, integers, sliders, calc fields)	-		<input type="button" value="Execute"/>		
F	Hidden fields that contain values**	-		<input type="button" value="Execute"/>		
G	Multiple choice fields with invalid values	-		<input type="button" value="Execute"/>		
H	Incorrect values for calculated fields	-		<input type="button" value="Execute"/>		
1	Missing screening date	[screendate]=""	<input type="checkbox"/>	1	<a href="#">view</a>	<input type="button" value="✕"/>

1. Click on “[view](#)” under Total Discrepancies column.

Rule #1: <b>Missing screening date</b>			
Discrepancies found: 1			
Record	Discrepant fields with their values	Status	Exclude <input type="checkbox"/>
1 07-11111-01 <b>2</b>	"Date screened" screendate: [no data] <b>3</b>	Issue exists	<a href="#">exclude</a>

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.  Data Exports, Reports, and Stats

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).

**Choose export format**

<input checked="" type="radio"/>		CSV / Microsoft Excel (raw data)
<input type="radio"/>		CSV / Microsoft Excel (labels)
<input type="radio"/>		SPSS Statistical Software
<input type="radio"/>		SAS Statistical Software
<input type="radio"/>		R Statistical Software
<input type="radio"/>		Stata Statistical Software
<input type="radio"/>		CDISC ODM (XML)

4. Click Export Data button on bottom right.

**Export Data**

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.

Record ID	
<input type="text" value="--- Choose a record ---"/>	<input type="text" value="--- Choose a record ---"/>
<input type="button" value="Compare"/>	

## 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.

 <b>User Files</b>	 <b>Data Export Files</b>	 <b>Upload New File</b>
<div style="border: 1px solid yellow; padding: 5px; display: inline-block;"> No files have been uploaded yet</div>		

# 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	<b>All data</b> (all records and fields)	View Report  Export Data  Stats & Charts	
B	<b>Selected instruments</b> (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.

- 1 **Name of Report:**
- 2 **STEP 1**  
**User Access:** Choose who sees this report on their left-hand project menu ?  
 All users - OR -  Custom user access (Choose specific users, roles, or data access groups who will have access)
- 3 **STEP 2**  
**Fields to include in report** Add all fields from selected instrument: ... choose instrument ...  
 Field 1 record\_id "Record ID" Instrument: Screening  
 Field 2 Type variable name or field label   
**Additional fields to include in report (optional)**  
 Include the Data Access Group name for each record (if record is in a group)?
- 4 **STEP 3**  
**Filters (optional)** **Operator / Value**  
 Filter Type variable name or field label =   
 1 Switch format: [Use advanced logic](#)  
**Additional Filters (optional)** (Records belonging only to ALL selections below will appear in the report)  
**Filter by DAG(s):** Cleveland Clinic, Columbia University Medical Center, Dartmouth-Hitchcock Medical Center, Hospital of the University of Pennsylvania, Johns Hopkins University Medical Center
- 5 **STEP 4**  
**Live Filters (optional)** Live Filters can be selected on the report page for dynamically filtering data in real time. Only multiple choice fields can be used as Live Filters (as well as Events, if longitudinal, and Data Access Groups, if any exist).  
 Live Filter 1 -- select a field --  
 Live Filter 2 -- select a field --  
 Live Filter 3 -- select a field --
- 6 **STEP 4**  
**Order the Results (optional)**  
**First by** record\_id "Record ID" Ascending order  
**Then by** Type variable name or field label Ascending order  
**Then by** Type variable name or field label Ascending order