ICOR

International CardioCel Outcomes Registry

Database User's Guide
& Reference Manual

Contents

Welcome to ICOR!

ICOR (International CardioCel Outcomes Registry) is a secure, free web-based database developed using the REDCap application which is specifically designed for building and managing online database projects and surveys. The purpose of the ICOR database is to manage CardioCel clinical and follow-up data.

ICOR will collect and store clinical data on the perioperative outcomes of patients receiving CardioCel for repair of congenital heart disease worldwide and will enable us to report regional patient demographics, risk factors, mortality and morbidity. This in turn will contribute to the consent process and help to inform parents' decisions with the available treatment options.

ICOR structure and terminology

Structure

There are two components to the data collection:

Operative Data

Completion of **Operative Data** is compulsory and ALL data fields are to be completed where applicable to ensure the completeness and integrity of the data.

Follow Up Data

Completion of **Follow Up** data is optional and will be completed periodically for research. Data collection will be performed by a dedicated ICOR Steering Committee member at a time to be determined by the Steering Committee.

Terminology

- **Branching logic** – branching logic has been employed when fields/questions need to be hidden for data entry under certain conditions.
- **Calendar** – project calendar to help organize scheduling and keep track of any upcoming events.
- **Data Access Group** – *Data Access Groups* restrict viewing of data within a database. A typical use of *Data Access Groups* is a multi-site study where users at each site should only be able to view data from their site but not any other sites. Users at each site are assigned to a *group*, and will only be able to see records created by users within your group/site.
- **Data Dictionary** – An Excel file containing the list of all data entry fields and their associated attributes.
- **Field** – represents unique items of data to be collected and analysed.

- **File repository** – repository that stores and retrieves files and documents used for a project. Whenever a data export is performed, the resulting data and syntax files are also stores in the file repository.
- **Logging** – module that lists all changes made to the project, including data exports, data changes, and the creation or deletion of users (audit trail).
- **User Rights** – the customized privileges that research team members have in terms of data form modification, data entry, and data access.

Section 1: Getting Started

1. Participating centres will receive an email granting access to the ICOR Database. Follow the instructions in the email.

2. Click on the email link to login for the first time. You will be prompted to change your password *(Figure 1).* Follow the instructions to set up a new password. For data security, please ensure that ONLY you have access to these login details. Please also set a security question so you are able to quickly recover your account if you forget your password.

> This message was automatically generated by REDCap]
>
> A REDCap account has been created for you in which your REDCap username is "**accs_test1**". Click the link below to set your new password and log in.
>
> Set your new REDCap password

Figure 1

3. Completing the password reset will lead you to the Project Homepage (Figure2.) All subsequent logins will lead you to this page. From this screen select ***ICOR International CardioCel Outcomes Registry*** from the **My Projects** tab*.*

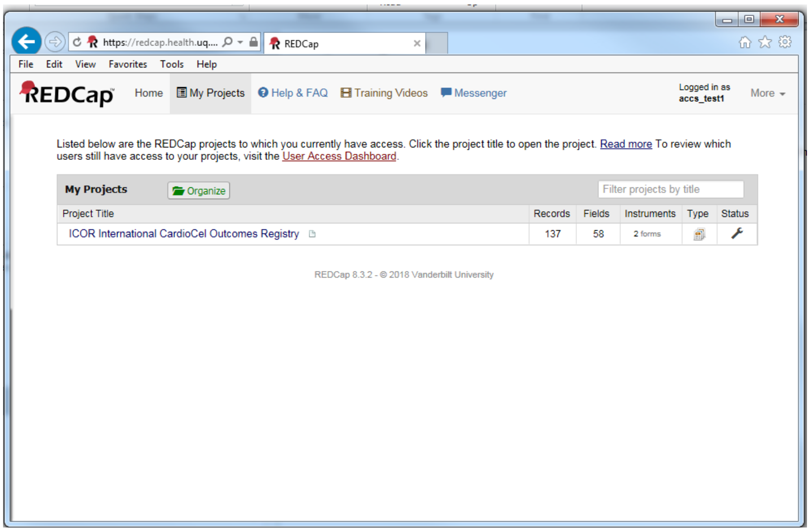

Figure 2

4. This will lead you to the ICOR homepage *(Figure 3).* This page will give you access to the following:

   - Data Collection – adding and editing records
   - Applications – data reporting, exporting, stats and graphs
   - Reports

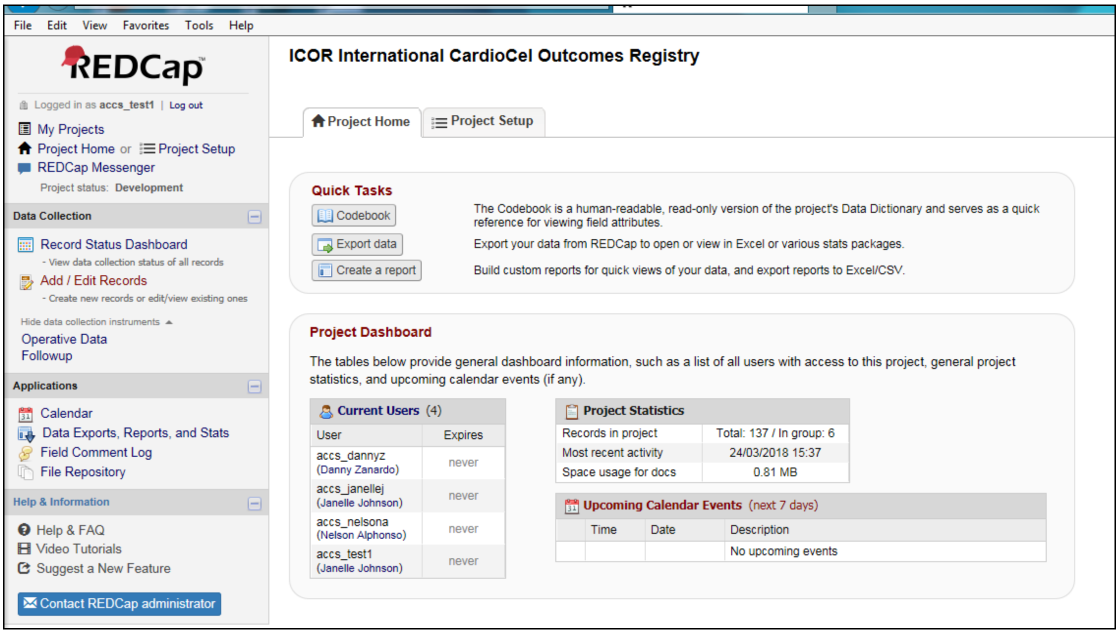

Figure 3

Section 2: Adding/Selecting/Editing a Record

Entering data for new patients

1. Each patient requires the creation of a new record.

2. On the left column of the ICOR Homepage, users can find the **Data Collection** section (Figure 4).

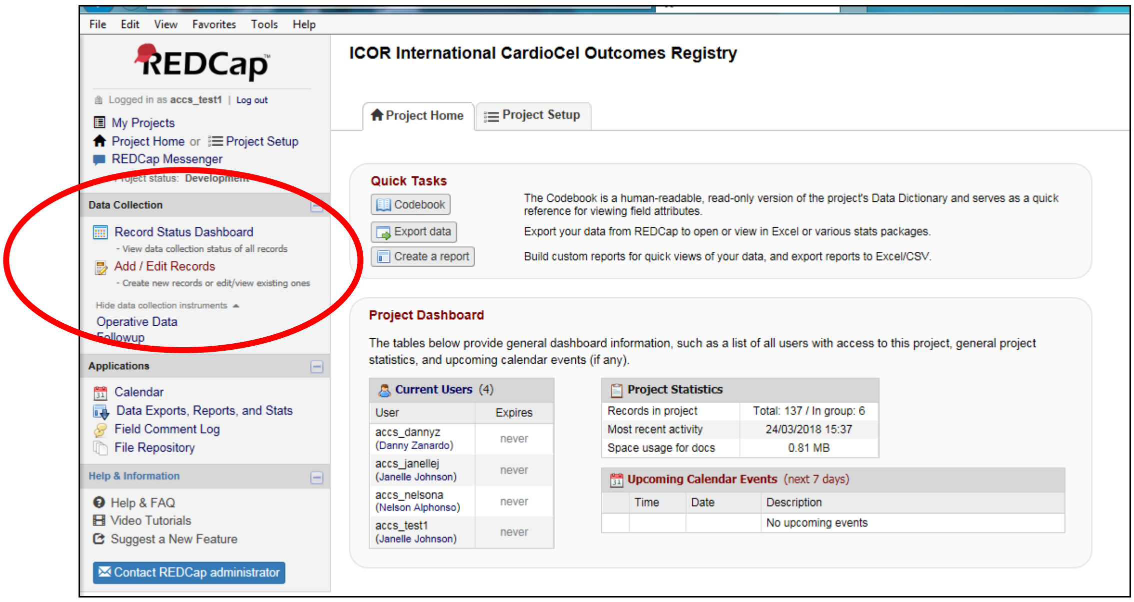

Figure 4

3. Click **Add/Edit Records.** This will lead you to the **Add/Edit Records** page as shown in Figure 5.

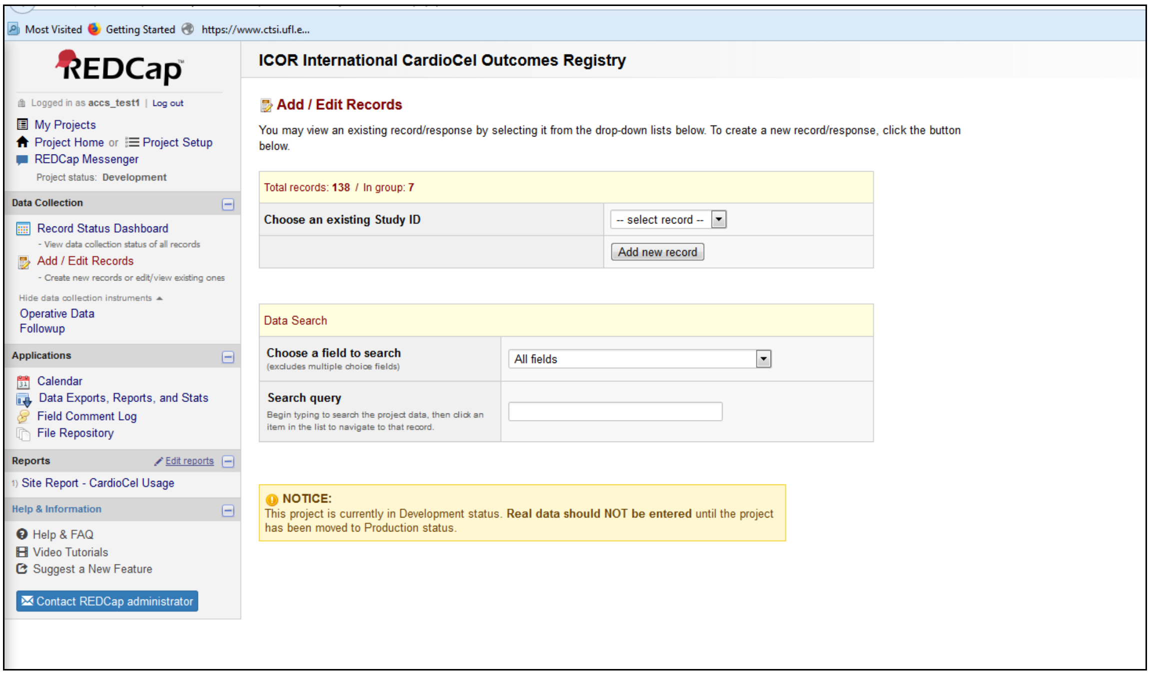

Figure 5

4. Select **Add new record** for each new patient record. A REDCap Study ID will be automatically generated for each new patient record entered.

5. This will open the **Record Home Page** which shows the **Data Collection Instruments** grid along with a **status icon** button which highlights the progress of each record (figure 6). On the top right of the screen you will see the **Legend for Status Icons**.

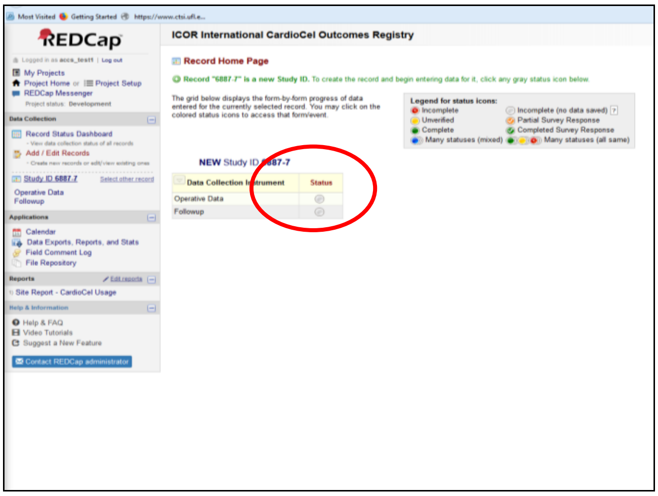

Figure 6

6. There are two data entry forms – **Operative Data** and **Follow Up** data. Completion of **Operative Data** is compulsory and ALL data fields are to be completed where applicable. Completion of **Follow Up** data is optional.

7. To start entering a new record click on the status icon alongside the data collection form to want to enter data into *(figure 6)*. You will be taken to the data entry form for a new record *(figure 7).*

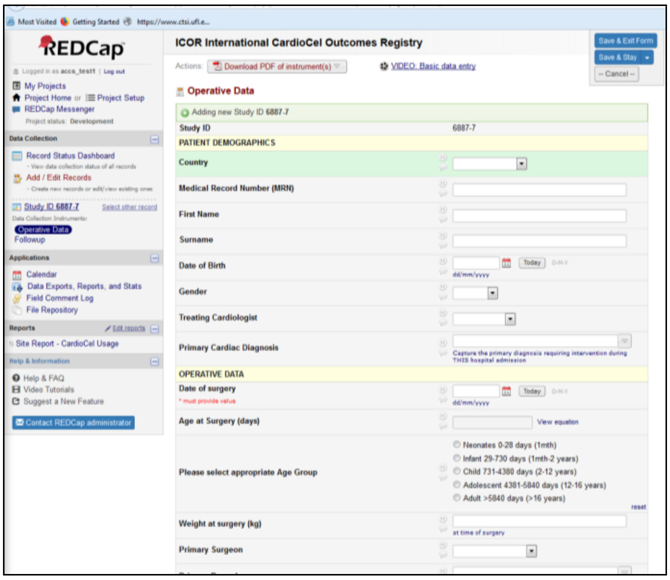

Figure 7

8. Once data has been completed, you **MUST** save the data by clicking one of the save option buttons on the bottom of the screen (*figure 8*).

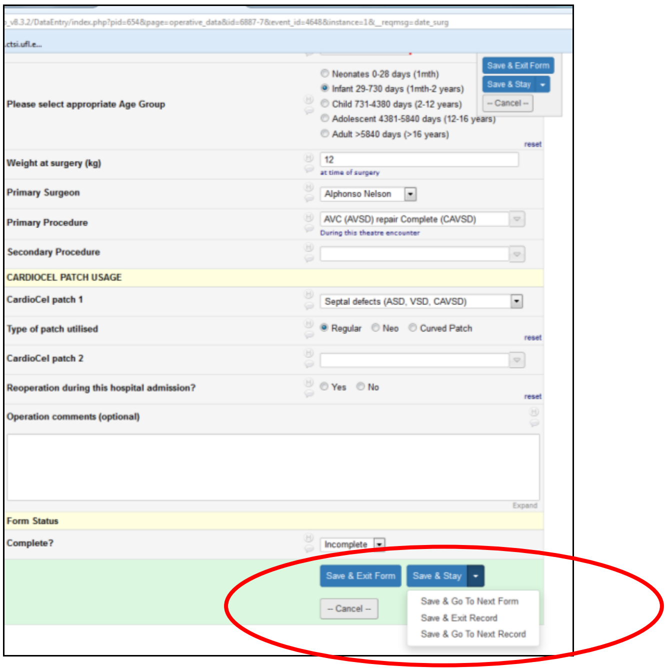

Figure 8

9. The Form Status section of the form also allows you to identify if the record is Incomplete, Unverified or Complete. If you have locking rights you may choose to lock the form.

10. There are a few options for saving your data.

- **Save & Exit Form** saves all the data entered so far and returns you to the **Record Home Page.**
- **Save and Stay** saves the data entered so far, refreshes the page and allows the user to continue data input but also includes a drop down box for further options:
    - **Save and Go to Next Form**
    - **Save & Exit Record**
    - **Save & Go to Next Record**

*Please note REDCap does not automatically save any entered data until you have selected a **SAVE** option.*

11. Once **"Complete"** is selected you will see on the **Record Status Dashboard** that the **Status Icon** for the data collection forms indicates the completeness of that record and will be **green** *(figure 9)*. Red indicates that the record is still **"Incomplete".**

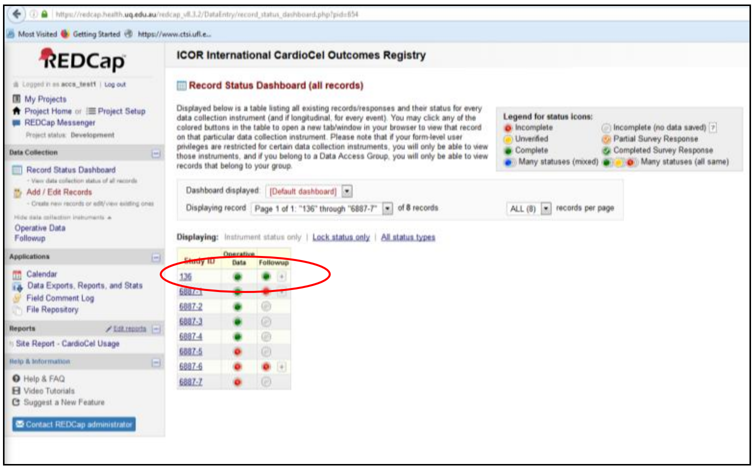

Figure 9

12. Data entry for **Follow Up** will be completed in the same format as above.

Returning to Pre-Existing Patients

1. You may want to return to a patient at a later time to complete their forms. Select **Add/Edit Records** under the **Data Collection** tab. Each saved patient can be reviewed on the drop-down menu (Incomplete and Complete Records). To open the forms, click on the relevant record ID listed in the dropdown menu (figure 10).

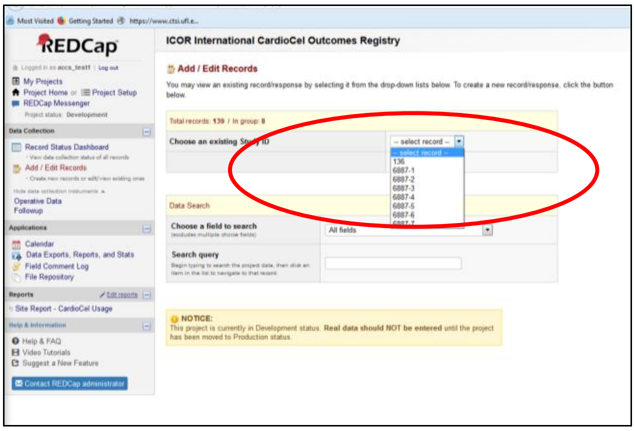

Figure 10

Section 3: Verifying and Finalising Data

1. You must ensure that for all patients, all fields are complete where applicable.

2. When all the data fields are complete within the data collection form, mark your form as complete by selecting COMPLETE in the **Form Status** field (figure 11).

WARNING: *REDCap allows you to mark a form as complete even though your data fields are not all entered. Please ensure that all your applicable data fields are complete before marking it as complete.*

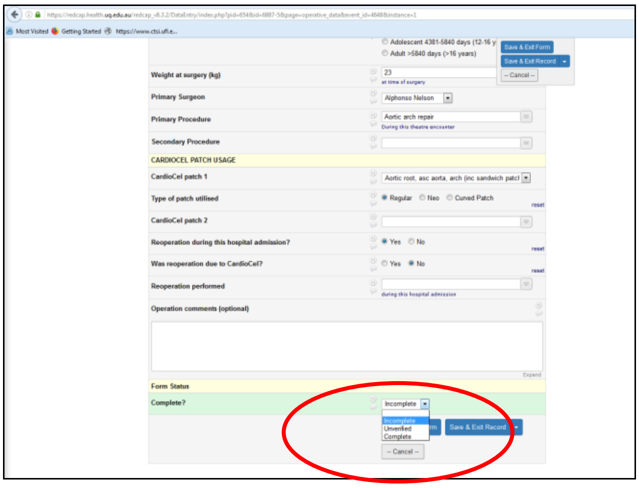

Figure 11

3. You may access the **Record Status Dashboard** under the Data Collection tab to provide an overview of incomplete and complete data forms for all patients (figure 12). When a data collection form has been marked as complete, the status button will be **green**.

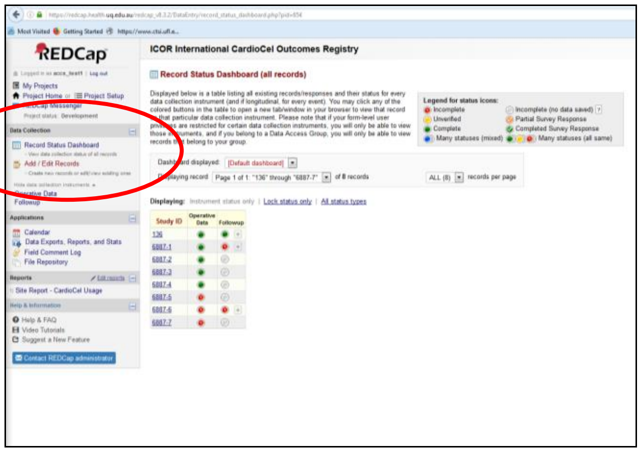

Figure 12

Section 3: Locking Data

1. Locking data indicates that the data from that particular patient is final and accurate. It is important to lock all data for patients before the data submission deadline.

2. Only records which are complete (ie. Having green status on the **Record Status Dashboard**) may be locked.

3. To lock data, click Lock Record on the relevant data collection form (*figure 13*).

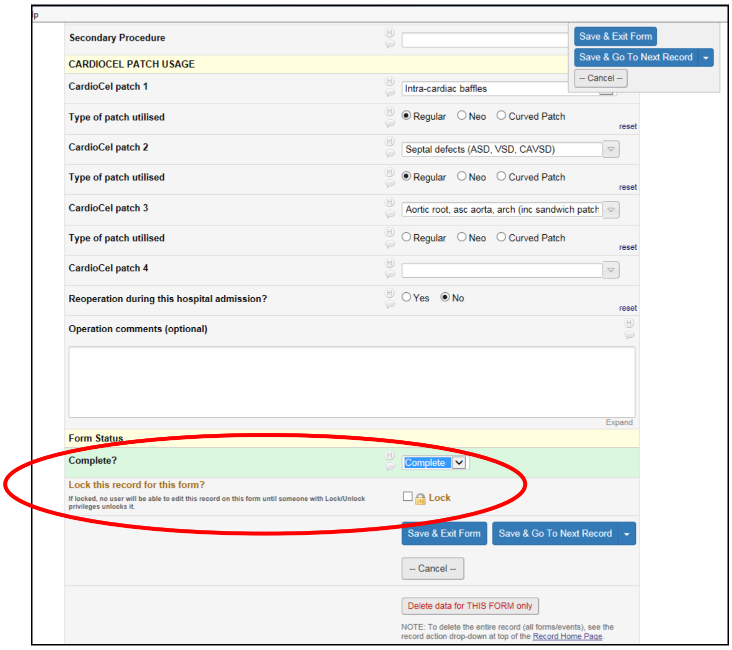

Figure 13

Section 4: Reports/Exporting Data

Report Builder

1. All reports are listed under the **Reports** tab on the left of the dashboard (figure 14). Clicking on any of the reports listed will open that report.

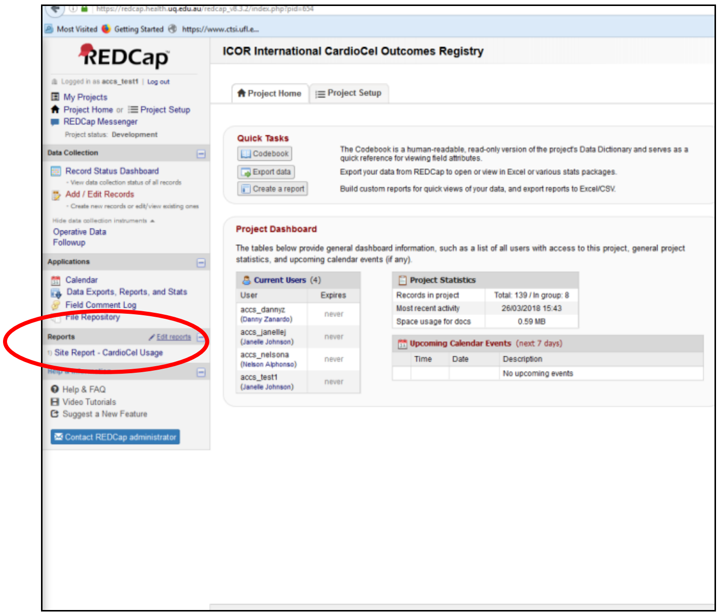

Figure 14

2. Clicking on **Edit Reports** will take you to the **Data Exports, Reports and Stats** screen (*figure 15*). Here you able to see all reports already created under **My Reports** and also able to create new reports under the **Create New Report** tab. You can also create a new report by clicking the green **Create New Report** under the list of **My Reports and Exports** (*figure 15*).

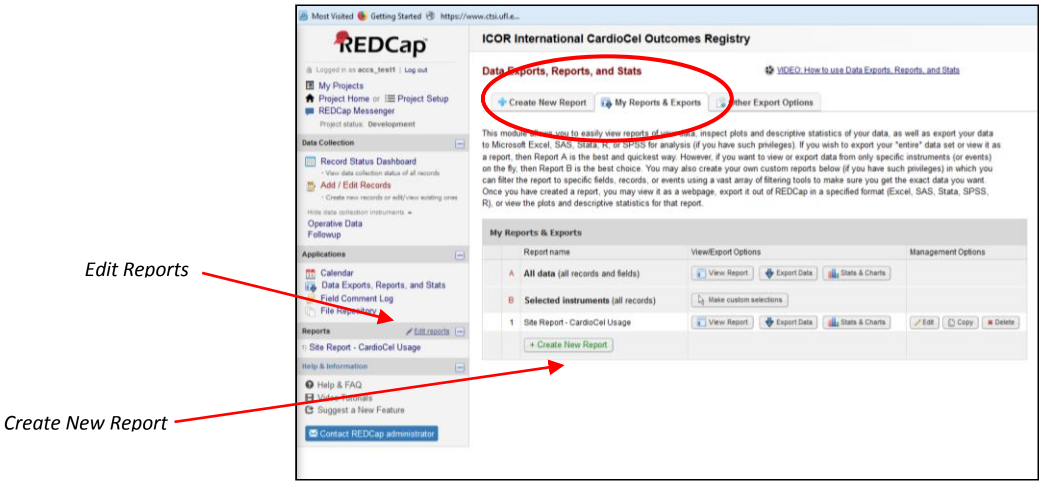

Figure 15

3. Clicking on **Create New Report** (as per above) will open up a new report design screen (*figure 16*). Firstly, name your report then follow the **steps** to create your customized report.

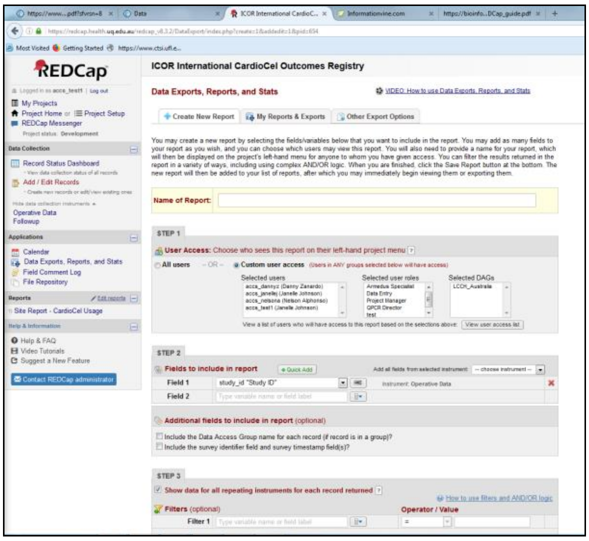

Figure 16

Step 1: *User Access* – here you can choose who sees the report in the reports menu on your dashboard – All Users or Custom User Access.

All Users – everyone will have access to your report. Users will only be able to their site data even though they may have access to this report.

Custom User Access – you can choose who sees this report. Selecting customer user will drop down the list of all users, their roles and Data Access Groups. Once again, selected users will only be able to see their own site data.

Step 2*: Fields to include in report*. Here is where you select all fields that you want to see in your report. You can choose which data collection form (instrument) you want to select your fields from or you can choose individual fields from the drop-down lists for each field.

You can also select as an 'option' to include the Data Access Group name for each record if required.

Step 3*: Filters*

Filters - Here you can choose to filter the data in your report by selecting a field and the type of filter you require. For example, you may want to only see all reoperations in your report, therefore you would select the reoperation field and the operator/value = yes (*figure 17*).

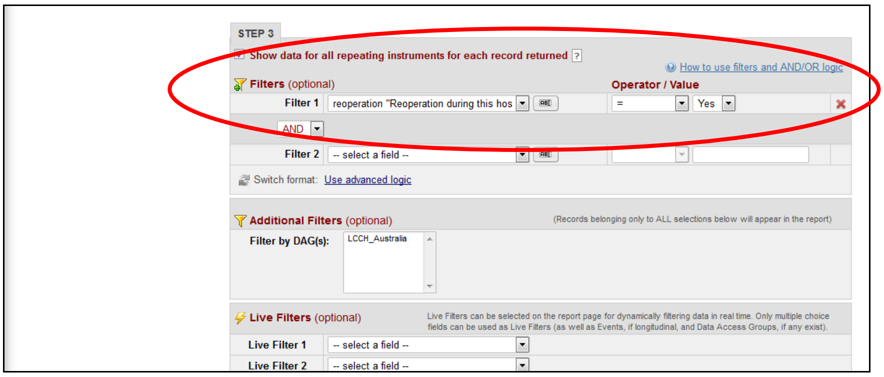

Figure 17

Additional Filter (optional) - Step 3 also has the option to filter DAG (data access groups). This will NOT apply to individual centres as you will ONLY be able to view your own data.

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, and only **three (3)** fields can be selected for filtering *(figure 18).*

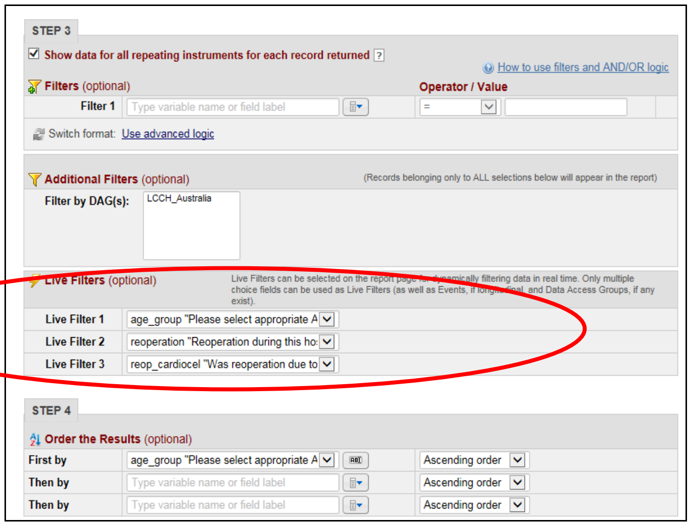

Figure 18

Step 4*: *Order the Results (optional) – here you can order the results of the report by selecting the required fields and the order required. There is an option of three (3) fields to order *(figure 19).*

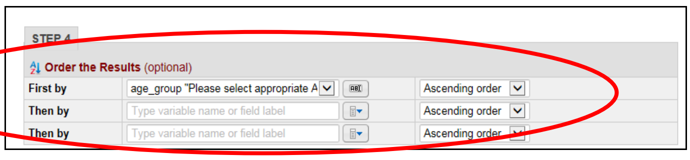

Figure 19

4. Save your report by select the **Save Report** button.

5. The new report will then be added to your list of reports, after which you may immediately begin viewing them or exporting them. Once you have created a report, you can export it out of REDCap in a specified format (Excel, SAS, Stata, SPSS, R), or view the plots and descriptive statistics for that report.

Report Viewer/Exporting Data

1. Once the report has been saved you are able to View Report, Export Data, view Stats & Graphs, Print Report or Edit Report *(figure 20):*

    a. **View Report** - click on View Report.

        i. You are now able to use the **Live Filters,** if formatted in your report, by selecting the appropriate filter from the top of the screen under **Live Filters**

        ii. You are also able to sort each column in your report by selecting the selection arrows in the right hand top corner of each column.

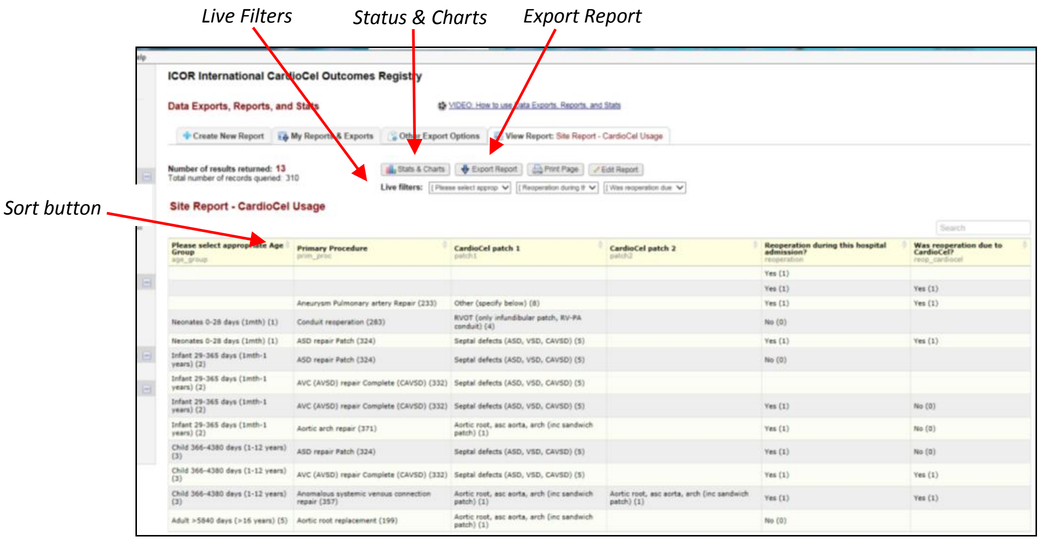

Figure 20

    b. **Export Data** (from the report)

        i. Selecting the **Export Data** tab will take you to the **Exporting Report** screen where you are able to select how you want the data in your report exported *(figure 21).* **ALL** data will be exported de-identified and you will **NOT** be able to change the options available for record identifiers.

        ii. Select your export settings from **Choose Export Format** on left hand side screen.

- CSV/Microsoft Excel (raw data) – will include the raw data for each field – any drop-down field will include the codes.

- CSV/Microsoft Excel (labels) – will include the drop-down fields as a description (label), not the code.

- There are also statistical software options including SAS, R, and Stata.

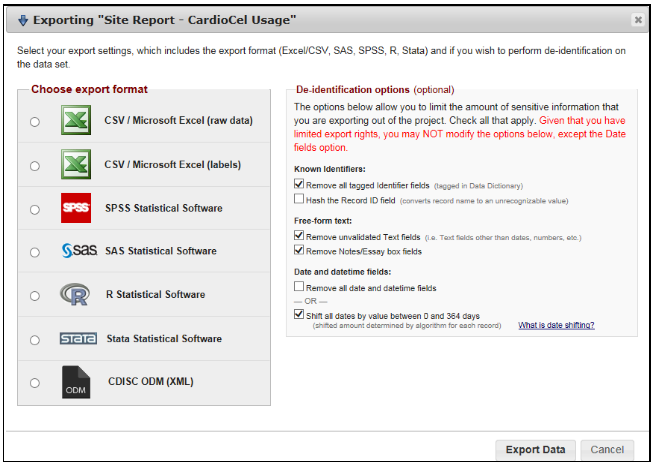

Figure 21

c. View **Stats & Charts –** select from the top of the viewed report. The Stats and Charts screen will show the data for the current report. In this screen you can also use the Live Filters as previous mentioned.

   i. Select from the Display Options;

      - Show plots & stats (the default)

      - Show plots only

      - Show stats only

   ii. You also have the option to view **Bar Chart** or **Pie Chart** by selecting from the drop-down box on the top right of the **Stats & Chart Report** screen (*Figure 22*).

   iii. You can also select a record to overlay onto the chosen plots. Record selection can be found on the top right drop down *record selector* on the Stats Report (*figure 22*).

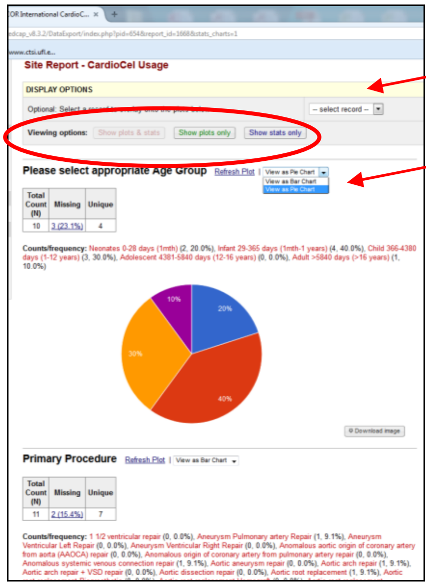

Figure 22

Exporting Data *(for analysis)*

1. To export **ALL** data for analysis:

   a. Select report **A** - **All Data** from the list of reports under the **My Reports and Exports** tab. This report shows all records and fields.

   b. Follow the same steps *as above* to export in the required format.

2. To export data from a specific report or data collection instrument:

   a. Select the report or instrument from the report list under the **My Reports and Exports** tab.

   b. Follow the same steps *as above* to export in the required format.

Section 5: File Repository

The **File Repository** can be found on the left-hand side tab under **Applications**. The file repository stores any uploaded documents to be accessed including data export files.

User Files

Files to be accessed by all users will be stored under **User Files**.

The current files available under **User Files** are:

- ICOR Database User Guide and Reference Manual
- ICOR Staff Participation Form

Data Export Files

Whenever a data export is performed, the resulting data and syntax files are stored here under **Data Export Files**.

Upload New File

This section is only to be used by the Registry for uploading documents to be accessed by all users. Please **DO NOT** up-load any of your own files.

Section 6: Adding Staff Members

To add new or additional staff members (Surgeon or Cardiologist) to be included in the Registry, a **Staff Participation Form** is available for download in the File Repository. Please complete and return via email to the ICOR Administrator.

ICOR Administrator: *Janelle Johnson*
janelle.johnson@health.qld.gov.au
(07) 3069 7824

Section 7: Requesting Access & Users Rights

To request user access to the ICOR database, please email the ICOR Administrator. Each individual user will be given access rights according to their allocated role.

ICOR Administrator: *Janelle Johnson*
Janelle.johnson@health.qld.gov.au
(07) 3069 7824

Section 8: Contacts

ICOR Administrator:

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