



# SECTION 5: DATA COLLECTION & ENTRY

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## Data Collection

Data collection should be conducted using the Patient CRF Worksheet. Comprehensive instructions on how to collect each data point is found in the Patient CRF Instructions. The Patient CRF Worksheet is formatted to match how you will enter your data (see REDCap information below). Each Patient CRF Worksheet organizes the data you will collect for each enrolled patient. The screen shot of the Patient CRF cover page, to the right, illustrates how the data is organized.



**Patient CRF Worksheet and Instructions** can be downloaded from the website.

NOTE: The information found in the “Data Entry” section of this procedure describes the electronic data capture system (REDCap) that you will use to enter the data you have collected. The procedures will also include instruction on how to navigate REDCap, general rules and data conventions (e.g. what format to use to enter dates), how the data you enter is checked and reviewed and how to organize your study documents.

Complete	Form Name	Page
(-)		
Baseline (These data are recorded on Day 1 only... Day 1 = ICU admission day)		
	Patient Information	
	Enrollment	
	Baseline SOFA Score	
	Nutrition Assessment	
	• Malnutrition	
	• Clinical Frailty Scale	
	• SARC	
	Nutrition Goals	
	• Determining Nutrition Goals	
	• Initiation of Nutrition Therapy	
Daily Data (These data are recorded daily until the first of ICU discharge, death or Day 28)		
	Daily Nutrition Data	
	Daily Enteral Nutrition (EN) Data	
	• Protein Supplements	
	• Non-Protein Modular Supplements	
	• EN Interruption	
	Daily Parenteral Nutrition (PN) Data	
	Daily Protein Data (Day 13-28)	
	(NOTE: these data are collected until the first of ICU discharge, death or Day 28)	
	Daily Nutritional Adequacy (automatically calculated by REDCap)	
	• Energy	
	• Protein	
	Daily Vasopressors/Inotropes	
	Daily Renal Replacement Therapy	
Outcomes (These data are recorded at the time of ICU and hospital discharge and Day 90)		
	Vasopressors/Inotropes (Start and Stop Dates)	
	Mechanical Ventilation (Start and Stop Dates)	
	Renal Replacement Therapy (Start and Stop Dates)	
	Hospital Outcomes	
	• ICU Stay	
	• Hospital Discharge	
	• 90 Day Outcome	

## Safeguarding Subject Privacy and Confidentiality

The site research team as well as the coordinating centre has the responsibility of safeguarding the privacy and confidentiality of the patients enrolled in the EFFORT study by safeguarding personally identifiable information (PII). Local, provincial/state and national privacy regulations must be followed.

**Personally identifiable information (PII)** - Is any data that could potentially identify a specific individual, when used alone or combined with other available information. Examples include, but are not limited to: name, initials, medical record/chart number, lab accession number, date of birth.

All participating sites must observe the following practices to safeguard the confidentiality of each research patient enrolled in the EFFORT study.

1. No patient record shall be removed from the participating site before it is de-identified. This includes any copies of patient records being faxed to the coordinating centre to data verification.

**De-identification** - Refers to the practice of obliterating PII from medical records and other study source documents to prevent an individual's identify from being connected with information.

2. All patient records sent to the coordinating centre, whether via fax, uploaded to REDCap or other method, will include the patient **study ID number ONLY**. This will be the number assigned to the patient at the time of randomization (via REDCap).

## Data Entry

### REDCap

REDCap™ is a web-based electronic data capture system that will be used as the EFFORT Trial electronic Case Report Forms (eCRFs). REDCap™ may be accessed directly at:

<https://ceru.hpcvl.queensu.ca/EDC/redcap/>.



You will be collecting data on each enrolled participant from the time of ICU admission until the Day 60 follow-up assessment. Refer to Table 2: Schedule of Events for the detailed timelines for the various types of data collection.

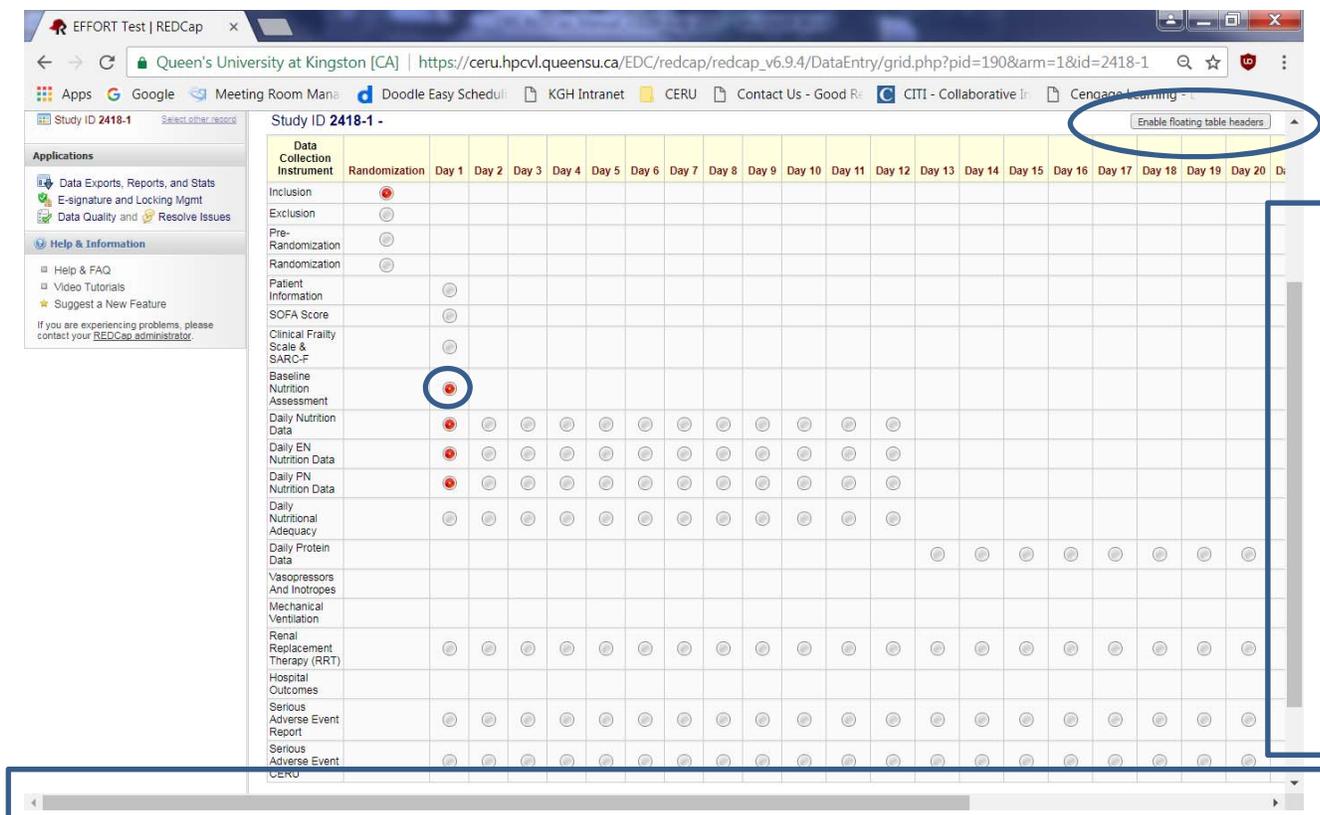
### REDCap Navigation

After you have selected a participant, you will be brought to the Event Grid. The Event Grid gives you a snap shot of the data entry forms for the participants.

Each type of data entry form (i.e. Data Collection Instrument) is the table row labels; each column of the table is labelled with the study day.

Each dot in the table represents an individual data entry form that is required for a particular participant.

Each individual entry form can be accessed by clicking on the dot. As you can see below, the circled dot is the Baseline Nutrition Assessment form for study day 1.



Select the Enable Floating table headers button circled, seen on the top right side of the event grid. This will allow the heading to follow as you scroll (i.e. similar to how you can 'freeze' cells in excel). Slide the horizontal navigation scroll bar outlined at the bottom to the right of the screen to reveal the rest of the Event Grid. You must select this button each time you return to the event grid.

You can navigate between forms on the same study day using the form links on the left side navigation menu by clicking on the desired data entry form.

At the end of each form, you will be asked to specify the form status. This legend is to be used to assist you in remembering what data is incomplete, unverified or complete. The status is indicated on the Event Grid Field using the following convention.

**Legend for status icons:**

- Incomplete
- Incomplete (no data saved) ?
- Unverified
- Complete

<b>Incomplete</b> (red dot)	No data has been entered on a form. Blanks forms will automatically be set to incomplete.
<b>Unverified</b> (yellow dot)	Data entry is partially completed on a form. The RC wants to double check data already entered on a form. Partially completed forms will automatically be set to unverified.
<b>Complete</b> (green dot)	Data entry is complete on a form. Further changes to the data are not anticipated. Only forms manually set to complete will have this status.
<b>Locked</b> (lock symbol)	Locked status will appear on all forms after all finalization checks are completed. Data on locked forms cannot be changed.

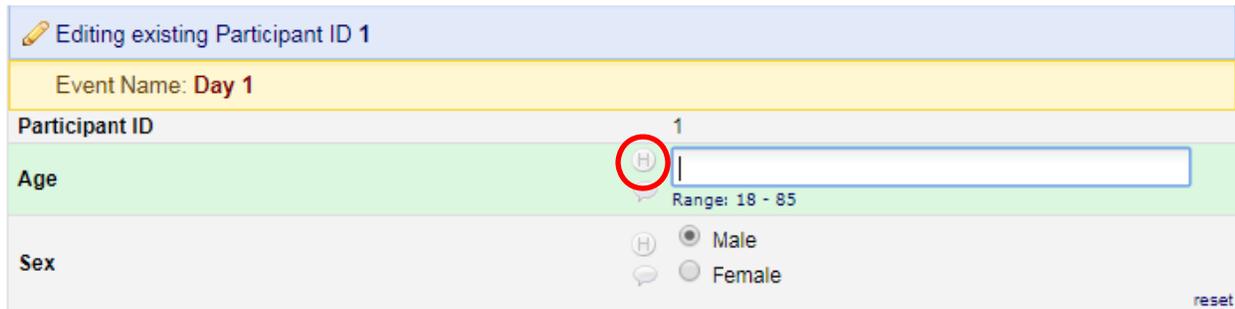
There may be up to 4 options at the end of each form to save your progress.

The following example is for: **Daily Nutrition – Study Day 1**

**NOTE: Always remember to “Save” before you navigate away from a form. Navigating from a form without saving will result in loss of data.**

### Data Entry History

REDCap™ has an option for users to see the data entry history for each data field. By clicking on the  just left of the field (see below).



Editing existing Participant ID 1

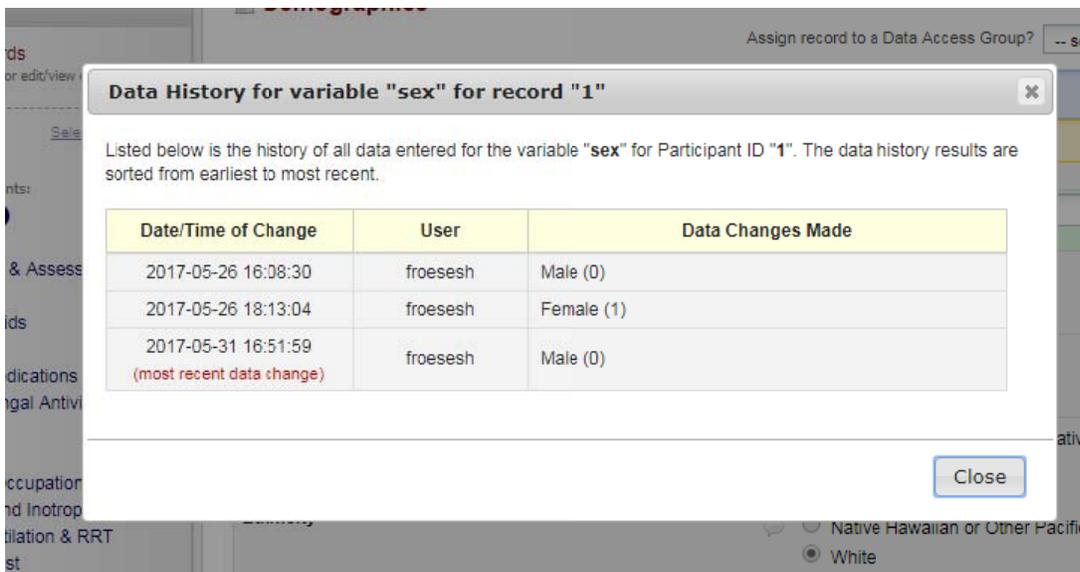
Event Name: Day 1

Participant ID 1

Age   Range: 18 - 85

Sex  Male  Female reset

A window will pop up listing the data entry history for that field showing the date and time, the date was entered, the user who entered the data and the data entered at that time.



Data History for variable "sex" for record "1"

Listed below is the history of all data entered for the variable "sex" for Participant ID "1". The data history results are sorted from earliest to most recent.

Date/Time of Change	User	Data Changes Made
2017-05-26 16:08:30	froesesh	Male (0)
2017-05-26 18:13:04	froesesh	Female (1)
2017-05-31 16:51:59 <i>(most recent data change)</i>	froesesh	Male (0)

Close

### Data Conventions in REDCap™

- Dates should be entered using the YYYY – MM – DD format i.e. 2017 – 09 – 20. A date picker calendar is available to enter dates. Single ‘click’ on the  icon and you can choose the appropriate month and year from the drop down boxes. Then ‘click’ the appropriate day.
- Enter all times using the HH:MM 24-hour period format i.e. 22:37. The colon ‘:’ must be entered. Use leading zeros where applicable i.e. 01:28
  - Midnight should be entered as 00:00

- To enter data directly into any text field, **single click** anywhere in the box and type the information.
- Do NOT press enter after entering data into a field. This will cause the form to automatically save and bring you to a new screen that will allow you to return to the Event Grid.
- There should be NO blanks. If data is NOT available use the **'Not Available'** option. This includes:
  - Data that is unavailable because the test was not done. *Example: Total-Bilirubin was not done on a particular study day.*
  - Data that is not known. This assumes every effort has been made to find the data but it is missing from source documents. *Example: A particular data point was NOT entered in the medical chart. Or an ICU flow sheet has gone missing.*
- A Study Day begins and ends at midnight, regardless of when your ICU flow chart begins and ends. If your participant records are computerized and the default start time is not midnight, you should be able to set the start time to midnight for the purposes of your data collection. If you do not use the calendar clock (00:00 – 23:59) to enter your data into REDCap™, you may receive errors indicating you have too much or too little data; you will be unable to finalize such participants until these errors are resolved.

### Data Flow

To help you determine the status of the patient data, we have designated different stages of data completion. Each stage marks the completion of a specific set of data. The diagram below summarizes the site responsibilities at these various stages.

