

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

Pati	ant CRE Worksheets	
I ath	ent etti worksneets	
	in a CDE Washe base base data land a secial successive in a lineating data for the	
mese rat	ent our worksneets nave been developed to assist your site in collecting data for the	trief.
The follow	ing table can be used by the site to track the completion of data collection for the pat	ient.
Complete	Form Name	Page
(~)		
Baseline (T	ese data are recorded on Day 1 only. Day 1 = ICU admission day)	
	Patient Information	
	Enrollment	
	Natrition Assessment	
	Malnutrition	
	Cinical Frailty Scale	
	SARC-F	
	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 12)	
	Deily Nutrition Data	
	Deliy Enteral Nutrition (EN) Data	
	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 (outomotically calculated by SEQCap)	
	Energy	
	Protein	
	Daily Vasopressors/inotropes	
Outcomer	Delity Kenal Keplacement Tinerapy	
outcomes	Vectore data are recorded at beach, or ico and Hospital discharge and bay so)	
	Mechanical Ventilation (Start and Stop Dates)	
	Renal Replacement Therapy (Start and Stop Dates)	
	Hospital Outcomes	
	ICU Stey	
	Hospital Discharge	
	60 Day Outcome	

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.

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.

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.

 All patient records sent to the coordinating centre, whether via fax, uploaded to REDCap or other method, will include the patient <u>study ID number ONLY</u>. 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.

Anna C Canala 🔄 Maati	Room Man-	Deadla	Fact C	chodul		KCUL	atranat		CEDIL	D (ontac	+11a C	and Dr			laborati	ue te	DA Con				A.,
Apps G Google Silveet	Ctudu ID 24		Edsy 5	chedui		KOHI	nuanei	-	CERU		Untaci	105-0	000 Ne		III - COI	liaborati	ven		IQAD	earning	- 1.	1
Study 10 2416-1	Study ID 24	10-1 -	1																	Enable flo	ating table	headers
plications	Collection Instrument	Randomization	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15	Day 16	Day 17	Day 18	Day 19	Day 20
Data Exports, Reports, and Stats	Inclusion	٢																				
Data Quality and Bresolve Issues	Exclusion	0																				
Help & Information	Pre- Randomization	۲																				
	Randomization																					
Video Tutorials	Patient Information		۲																			
ouggest a new reature	SOFA Score		۲																			
ntact your <u>REDCap administrator</u> .	Clinical Frailty Scale & SARC-F	railty																				
	Baseline Nutrition Assessment	(•)																		
	Daily Nutrition Data		۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲								
	Daily EN Nutrition Data		۲		۲		۲		۲		۲	۲	۲	۲								
	Daily PN Nutrition Data		۲	۲	۲		۲		۲	۲	۲	۲	۲	۲								
	Daily Nutritional Adequacy		۲	۲	۲		۲		۲	۲	۲	۲	۲	۲								
	Daily Protein Data															۲				۲	۲	
	Vasopressors And Inotropes																					
	Mechanical Ventilation																					
	Replacement Therapy (RRT)		۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲
	Hospital Outcomes																					
	Serious Adverse Event Report		۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲	۲
	Serious		0		0		0		0		0	0			0	0		0	0	0		0

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.

REDCap	Clinical Evaluation Research Unit	Kingston General Hospital									
Logged in as overveldeja Log out	EFFORT Test										
My Projects Project Home Project Setup Project status: Development	Actions: 🔊 Download PDF of instrument(s) 🗢										
Data Collection	Baseline Nutrition Assessment										
Add / Edit Records		Re-assign this record to another Data Access Group? Test 2	۲								
- Create new records or edit/view existing ones	Editing existing Study ID 2418-1										
E Study ID 2418-1 Select other record	Event Name: Day 1										
Event: Day 1	Study ID	2418-1									
Data Collection Instruments: Patient Information	Calculation of Nutrition Goal										
SOFA Score	Height	н									
Clinical Frailty Scale & SARC-F Baseline Nutrition Assessment	Treight	X.XX metres									
Classime Nutrition Xeassmont Daily Nutrition Data Daily EN Nutrition Data Daily EN Nutrition Data Daily PN Nutrition Data Daily Nutritional Adequacy Renal Replacement Therapy (RRT) Serious Adverse Event CERU	How was height determined?	H Catual									
	Dry Body Weight	⊕ ∽ xxx.x kg	res								
	How was weight determined?	 B O Actual O Estimated 									
Lock all forms	ВМІ	H View equation	res								
Data Exports, Reports, and Stats E-signature and Locking Mgmt	Was a nutrition assessment completed?	kg/m² ⊕ ® Yes ⊖ ◎ No	res								
Data Quality and Resolve Issues Help & Information	Date of Assessment	H Today Y-M-D									
Help & FAQ	Goal Calorie Requirement	H kcal/day									
 video i utorials Suggest a New Feature 	Goal Protein Requirement										

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

Incomplete (red dot)	No data has been entered on a form. Blanks forms will automatically be set to incomplete.
Unverified (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.
Complete (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.
Locked (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**

	Save and go to Grid
	Save and Stay
	Save and go to Next Form
	Save and go to Next Event
ſ	Cancel

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 ^{IJ} just left of the field (see below).

Editing existing Participant ID 1	
Event Name: Day 1	
Participant ID	1
Age	
	Range: 18 - 85
Sex	H Male
	rese

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.

lview (Assign record to a Data Acco	ess Group?
	Data History for varial	ble "sex" for r	ecord "1"	×
<u>Sele</u>	Listed below is the history of all sorted from earliest to most rec	data entered for the ent.	e variable "sex" for Participant ID "1". The data history re	sults are
	Date/Time of Change	User	Data Changes Made	
sess	2017-05-26 16:08:30	froesesh	Male (0)	
	2017-05-26 18:13:04	froesesh	Female (1)	
ons	2017-05-31 16:51:59 (most recent data change)	froesesh	Male (0)	
ntivi				
ition trop				Close
& RR	т			h or Other H

Data Conventions in REDCap[™]

- Dates should be entered using the <u>YYYY MM DD</u> format i.e. 2017 09 20. A date picker calendar is available to enter dates. Single 'click' on the ¹¹/₁₀ 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 <u>HH:MM</u> 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 <u>site responsibilities</u> at these various stages.

