



effort trial

**The Effect of Higher Protein Dosing in Critically Ill Patients: A  
Multicenter Registry-based Randomized Trial  
The EFFORT Trial**

*Clinical trials.gov ID #NCT03160547*

## Patient CRF Worksheets and Instructions



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Complete ( <input checked="" type="checkbox"/> )	These Patient CRF Worksheets have been developed to assist your site in collecting data for the trial. The following table can be used by the site to track the completion of data collection for the patient.	Page
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# REDCap Entry Checklist

Study ID # \_\_\_\_\_

**This checklist may be used by the site to keep track of the data that is entered into REDCap. Place a  in the box once the data has been entered.**

FORM	Date:	Rando	Day 1 (ICU Adm)	2	3	4	5	6	7	8	9	10	11	12	13 → 28	Outcomes
Inclusion		<input type="checkbox"/>														
Exclusion		<input type="checkbox"/>														
Pre-Randomization		<input type="checkbox"/>														
Randomization		<input type="checkbox"/>														
Patient Information			<input type="checkbox"/>													
Conditions at Enrollment			<input type="checkbox"/>													
SOFA Score			<input type="checkbox"/>													
Nutrition Assessment			<input type="checkbox"/>													
Nutrition Goals			<input type="checkbox"/>													
Daily Nutrition Data			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Daily EN Data			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Daily IV Nutrition			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Daily Protein Data														<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Daily Nutritional Adequacy <i>(automatically calculated)</i>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vasopressors/Inotropes			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mechanical Ventilation																<input type="checkbox"/>
Renal Replacement Therapy (RRT)			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hospital Outcomes																<input type="checkbox"/>



## General Instructions

The following data collection worksheets (i.e. CRFs) have been developed to assist you with data collection and entry into REDCap™.

The instructions in this document should be reviewed and followed closely to ensure appropriate collection of data for the EFFORT Study.

1. To help you keep track, we recommend documenting the unique patient **Study ID #** on each worksheet. (Note: this number is assigned by REDCap™).
2. The date format that must be used when entering data into REDCap™ is year-month-day, entered as yyyy-mm-dd. For example, September 8th 2015 would be entered as: 2015-09-08 .
3. All times should be recorded using the 24-hour (calendar day) clock. Midnight is to be entered as 00:00 hrs.
4. Anywhere that 'Other (specify)' is selected, there must be an entry in REDCap™™ (in the space provided) describing what 'Other' means.
5. Study days are defined as follows and data **must** be collected according to study days:

**Study Day 1 = ICU admit date (not randomization) and time until 23:59 the same day.**

**Study Day 2 = the subsequent day starting at 00:00 to 23:59 that day**

**Example:** A patient is admitted to the ICU on Sept 8th, 2015 at 4:00 PM (16:00). The study days would be:

Study Day 1 = 2015-09-08 from 16:00 to 23:59 the same date (2015-09-08)

Study Day 2 = 2015-09-09 from 00:00 to 23:59 on 2015-09-09 (same date)

6. There may be occasions when data is unavailable, not applicable or not known. The measurement may not have been taken, the test not done, or the data may be missing from the medical record. Example: T-Bilirubin was not done on a particular study day. If the data is '**Not Available**' for any reason, indicate by selecting 'Not Available'.
6. The timeline for data entry for each patient into REDCap™ is **90 days from the date of ICU admission**. To complete a patient chart in REDCap™ you will need to complete all of the data entry and address all data queries.





## Screening/Randomization: Patient Eligibility (1)

<b>General Instructions</b>	Complete all of the information by selecting the appropriate box and entering the required data for each field as indicated. These data are to be collected once, at the time of screening.
<b>STEP 1: Confirm Subject Eligibility</b>	If eligible, the patient must be randomized to the trial <u>within 96h of admission to your ICU</u> .
<b>Inclusion Criteria</b>	<p><b>1. <math>\geq 18</math> years old.</b></p> <p><b>2. Have <u>one or more</u> of the following risk factors that make them a high nutritional risk.</b>  Each patient will need to be assessed for the presence of 2. a-e of these nutritional risk criteria however, it may be difficult to make contact with a proxy to perform some of these assessments during screening (e.g. SARC-F). If you are unable to complete some of the assessments listed below, that is okay! Please answer to the best of your ability at the time of screening. As long as the patient meets at least one of these criteria, say for example BMI, they qualify for inclusion #2.</p> <p><b><i>NOTE: Once the patient is randomized you will have more time to collect the malnutrition, CFS and SARC-F assessments (which are recorded on the Baseline Nutrition Assessment, see pg. 30-32).</i></b></p> <ul style="list-style-type: none"> <li>(a) Low (<math>\leq 25</math>) or high BMI (<math>\geq 35</math>)</li> <li>(b) Moderate to severe malnutrition (as defined by local assessments). (Refer to page 30, for information that will be collected).</li> <li>(c) Frailty (Clinical Frailty Scale of 5 or more from proxy). (Refer to page 32, for information that will be collected).</li> <li>(d) Sarcopenia (SARC-F score of 4 or more from proxy). (Refer to page 34, for information that will be collected).</li> <li>(e) From point of screening, projected duration of mechanical ventilation <math>&gt;4</math> days.</li> </ul> <p><b>3. Requiring mechanical ventilation with actual or expected total duration <math>&gt; 48</math> hours from time of screening.</b>  This includes any positive inspiratory pressure (excluding PEEP only) delivered via an endotracheal tube or a tracheostomy. Non-invasive methods of ventilation, such as high flow oxygen nasal cannula (OPTIFLOW), BI-PAP or mask-CPAP, are not permitted.</p> <p>The 48h window should be measured from the time of initiation of mechanical ventilation (i.e. intubation). A patient should either have already achieved at least 48h of mechanical ventilation or they are expected to achieve at least 48h from point of screening.</p> <p>Also, if the patient received <math>\geq 48</math>h of mechanical ventilation, but is extubated at the time of screening or been actively weaned, please do not enroll the patient. We want patients that will remain in ICU requiring artificial nutrition for another 3-4 days minimum from the point of screening.</p> <p>If the patient was intubated outside of the hospital setting (e.g. by paramedics in the field or at another hospital), use the precise time of intubation from the medical notes. However, if such a time is not available, use the time of admission to your hospital to determine this criterion.</p>



## Screening/Randomization: Patient Eligibility (2)

<p><b>Exclusion Criteria</b></p>	<p><b>1. &gt; 96 continuous hours of mechanical ventilation before screening.</b>            We want the study intervention to begin as early as possible and if more than 96 hours have transpired from the time of ICU admission, they likely have received significant amount of nutrition already. If the patient was intubated outside of the hospital setting (e.g. by paramedics in the field or at another hospital), use the precise time in the notes. However, if such a time is not available, use the time of your hospital’s admission to determine this criterion.</p> <p><b>2. Expected death or withdrawal of life-sustaining treatments within 7 days from screening.</b>            Patients who die or receive palliative therapy (have nutrition stopped) within days of randomization are not good study patients. They won’t help us answer the study question. By this criterion, we mean a <u>very high</u> likelihood of death or withdrawal of life-sustaining treatments (If the patient has an isolated DNR, they can still be included). It may be difficult for some clinicians to make this judgment. Therefore, only patients with a ‘high’ probability (&gt;50%) of not surviving the next 7 days should be excluded.</p> <p><b>3. Pregnant.</b>            We don’t know the safety of high protein on the fetus. Post-partum and lactating patients <u>are</u> permitted.</p> <p><b>4. The responsible clinician feels that the patient either needs low or high protein</b>            If this is the case, we require an understanding of the clinician’s reasons. From the options on the form, check all that apply.</p> <p><b>5. Patient requires parenteral nutrition only and site does not have products to reach the high protein dose group.</b></p>
<p><b>STEP 2: Is the subject eligible for the study?</b></p>	<p>Confirm the eligibility of the patient with one of the study leaders. Document this confirmation in the form.</p>



## Screening/Randomization: Patient Eligibility (1)

Study ID # \_\_\_\_\_

### STEP 1: Confirm Subject Eligibility

ALL INCLUSION CRITERIA must be marked as YES for subject to be eligible for the study:

YES	NO	1. $\geq 18$ years old	
YES	NO	2. Requiring mechanical ventilation with actual or expected total duration of mechanical ventilation >48 hours	
YES	NO	3. Nutritionally "high-risk", meeting one or more of the below criteria (check all that apply):	
		a) Low ( $\leq 25$ ) or High BMI ( $\geq 35$ )	Yes No
		b) Moderate to severe malnutrition (as defined by local assessments). We will document the means by which sites are making this determination and capture the elements of the assessment (history of weight loss, history of reduced oral intake, etc.).	Yes No
		c) Frailty (Clinical Frailty Scale 5 or more from proxy)	Yes No / Not Done
		d) Sarcopenia - (SARC-F score of 4 or more from proxy)	Yes No / Not Done
		e) From point of screening, projected duration of mechanical ventilation > 4 days	Yes No

ALL EXCLUSION CRITERIA must be marked as NO for subject to be eligible for the study:

YES	NO	1. > 96 continuous hours of mechanical ventilation before screening (i.e. ICU admission)
YES	NO	2. Expected death or withdrawal of life-sustaining treatments within 7 days from screening
YES	NO	3. Pregnant (Note: Post-partum and lactating patients are not excluded from the trial)
YES	NO	4. The responsible clinical feels that the patient either needs low or high protein  If no, specify all that apply: No longer critically ill, New onset of ARDS, Worsening renal function, Improved renal function, Starting dialysis, New wound (non-surgical), New surgical wound, Negative nitrogen balance, Increased protein losses, BMI $\geq 30$ , Improving hepatic failure, Worsening hepatic failure, Other, please specify: _____.
YES	NO	5. Patient requires parenteral nutrition only and site does not have products to reach the high protein dose group





## Screening/Randomization: Study Group Assignment

**Print a copy of the REDCap™ Randomization form and file it together with this CRF.**

<p>The participant has been randomized to a study treatment group. Record the assigned study treatment group on the CRF Worksheet.</p>													
<b>Nutrition Prescription</b>	<p>Protein and energy targets will be achieved through any combination of EN, protein supplements, and PN or amino acids. The only difference between the nutrition prescriptions between the 2 study groups is that the protein goals are set.</p>												
<b>Protein Target</b>	<table style="width: 100%; border: none;"> <tr> <td style="text-align: center; width: 30%;"><b><u>Lower Protein</u></b></td> <td style="width: 10%;"></td> <td style="text-align: center; width: 30%;"><b><u>Higher Protein</u></b></td> <td style="width: 30%;"></td> </tr> <tr> <td style="text-align: center;"><b><u>Dose</u></b></td> <td></td> <td style="text-align: center;"><b><u>Dose</u></b></td> <td></td> </tr> <tr> <td style="text-align: center;"><b>≤ 1.2 g/kg/day</b></td> <td style="text-align: center;">OR</td> <td style="text-align: center;"><b>≥ 2.2 g/kg/day</b></td> <td></td> </tr> </table> <p style="margin-top: 10px;">In both groups:</p> <ul style="list-style-type: none"> <li>Targets will be set using pre-ICU dry actual weight.</li> <li>For participants with BMI &gt;30, ideal body weight based on a BMI of 25 will be used.</li> </ul> <p style="margin-top: 10px;"><b>The protein target should be followed daily for each randomized patient until the first of:</b></p> <ul style="list-style-type: none"> <li>ICU Discharge*</li> <li>Death</li> <li>Transition to oral feeds</li> <li>Day 28</li> </ul> <div style="border: 1px solid black; padding: 5px; margin-top: 10px; width: fit-content;"> <p><i>*If a patient is discharged from the ICU and is then re-admitted to the ICU, the study protein target should be resumed. This should continue until the first of the following options listed to the left occurs.</i></p> </div>	<b><u>Lower Protein</u></b>		<b><u>Higher Protein</u></b>		<b><u>Dose</u></b>		<b><u>Dose</u></b>		<b>≤ 1.2 g/kg/day</b>	OR	<b>≥ 2.2 g/kg/day</b>	
<b><u>Lower Protein</u></b>		<b><u>Higher Protein</u></b>											
<b><u>Dose</u></b>		<b><u>Dose</u></b>											
<b>≤ 1.2 g/kg/day</b>	OR	<b>≥ 2.2 g/kg/day</b>											
<b>Calorie Target</b>	<p>Caloric goals should be the same in both groups and we recommend sites follow the SCCM/ASPEN clinical practice guidelines (McClave JPEN 2016).</p> <ul style="list-style-type: none"> <li>For non-obese participants, we suggest that their caloric prescription be around 20-25 kcal/kg/day.               <ul style="list-style-type: none"> <li>If the site chooses to use more sophisticated equations or indirect calorimetry, that is permissible.</li> </ul> </li> <li>For obese participants, if indirect calorimetry is used, the goal of the nutritional prescription should be to provide energy not to exceed 65%–70% of measured requirements.               <ul style="list-style-type: none"> <li>If indirect calorimetry is unavailable or not used, we suggest using the weight-based equation 11–14 kcal/kg actual body weight per day for participants with BMI in the range of 30–50 and 22–25 kcal/kg ideal body weight per day for participants with BMI &gt; 50.</li> </ul> </li> </ul>												
<p style="color: blue;"><b><i>The study team should make every effort to ensure that the patient receives at least 80% of their protein and calorie targets each day.</i></b></p> <p style="color: blue;"><b>**REDCap™ has a built-in Daily Nutritional Adequacy tool to help you monitor this. **</b></p>													

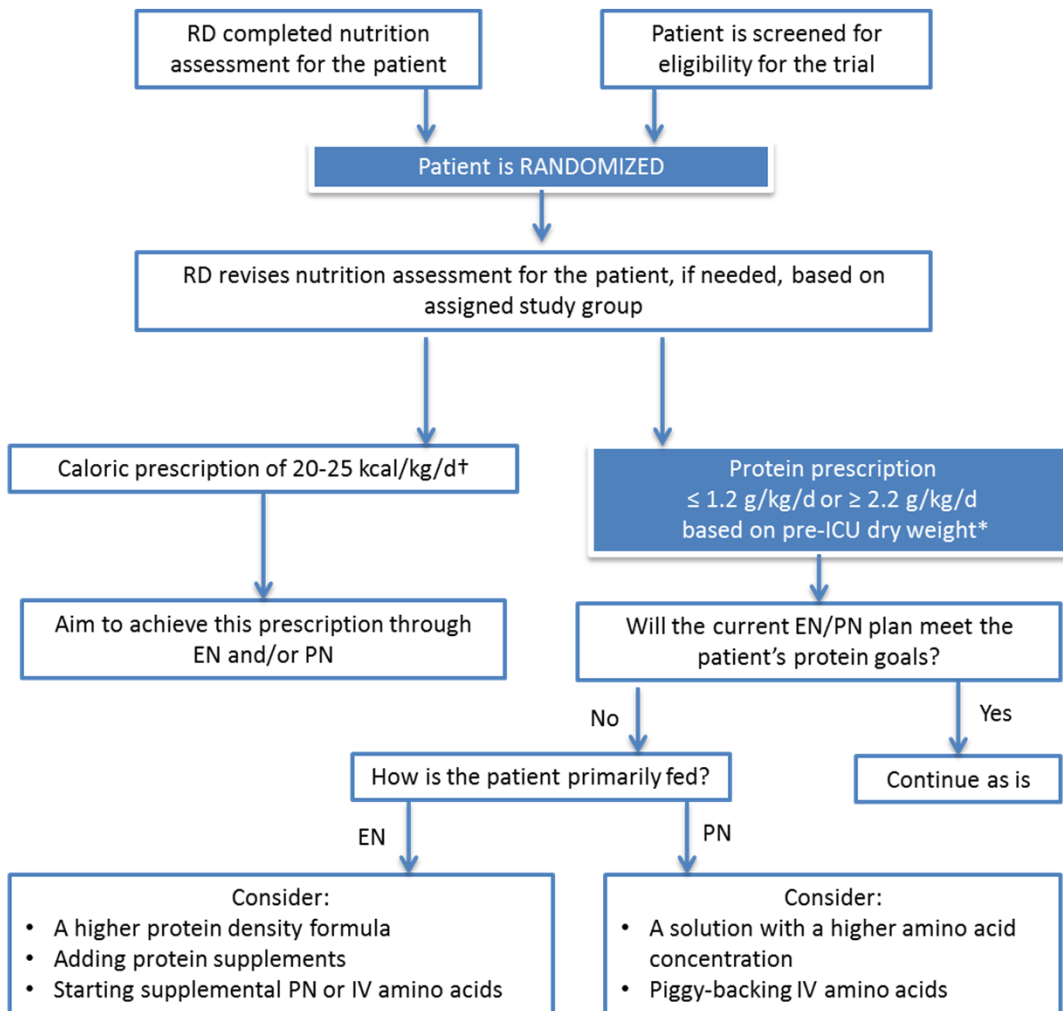
## Screening/Randomization: Study Group Assignment

This patient has been randomized to the following study treatment group:

Check the box for the study treatment group assigned by REDCap™.

Lower Protein Dose ( $\leq 1.2$  g/kg/day)
  Higher Protein Dose ( $\geq 2.2$  g/kg/day)

**\*\*Remember to use the Daily Nutritional Adequacy tool built into REDCap™ to monitor the participant's protein and caloric intake.\*\***



\*see SPM for details if BMI is >30

†see details in SPM if patient is obese or other questions/indirect calorimetry are used



## Baseline: Patient Information (1)

By baseline we are referring to data that is entered into REDCap™ on Day 1 only. **Day 1 is ICU admission day.**  
(We recognize this may be an incomplete day.)

Data for each study day should be collected following the calendar clock (midnight to midnight).

<b>Sex</b>	Select the appropriate box (female or male).
<b>Age</b>	Enter the age of the patient in years at the time of admission to the ICU.
<b>Hospital Admission Date/Time</b>	<ul style="list-style-type: none"> <li>Enter the date and time the participant was admitted to the hospital. This is the formal time as noted in the medical record.</li> <li>For participants transferred from another institution directly to the ICU, the ICU admission date/time is to be used for the hospital admission date/time. If the admit time is not available, enter the time of the first chart documentation.</li> </ul>
<b>ICU Admission Date/Time</b>	<ul style="list-style-type: none"> <li>Enter the date and time the participant was admitted to the ICU in your hospital.</li> <li>If the participant has been admitted to your ICU multiple times, use the most recent admission.</li> <li>If a participant is transferred from another ICU, enter the date of admission to your ICU. If the participant is admitted directly to your ICU, the ICU and hospital admission dates and times will be the same.</li> </ul>
<b>Type of ICU Admission</b>	<p>Place a <input checked="" type="checkbox"/> in only <u>one</u> of the following categories of ICU admission type:</p> <ul style="list-style-type: none"> <li><b>Medical:</b> defined as a participant admitted to the ICU for treatment of a medical problem (without any surgical intervention). This includes participants admitted from a cardiology/radiology intervention suite and burn participants. Proceed to Taxonomy A for Primary ICU Diagnosis Medical (Non-Operative Condition System).</li> <li><b>Surgical Elective:</b> defined as a participant admitted to the ICU from the operating room directly or a recovery unit following a planned surgical procedure. Proceed to Taxonomy B for Primary ICU Diagnosis (Operative Condition System).</li> <li><b>Surgical Emergency:</b> defined as a participant admitted to the ICU from the operating room directly or a recovery unit following an unplanned surgical procedure. Proceed to Taxonomy B for Primary ICU Diagnosis (Operative Condition System).</li> </ul> <p>Note: If a surgical participant develops a medical complication and is transferred to the ICU from the surgical ward, this would be a “medical” admission type.</p>
<b>Primary ICU Diagnosis</b>	<p>Choose the most pertinent diagnosis from the taxonomy provided (A or B) that resulted in the participant’s admission to ICU. Only one diagnosis can be chosen. Remember, symptoms are not an admission diagnosis (e.g. respiratory distress, hypotension, etc).</p> <p><u>Example:</u> A participant was admitted to hospital for an elective cholecystectomy. Post-operatively the participant experienced a cardiac arrest on the ward and was subsequently admitted to the ICU. This participant would be classified as medical admission type, and cardiac arrest as primary ICU diagnosis. If the admission diagnosis is not present in the taxonomy, under the correct admission type (Medical, Surgical Elective or Surgical Emergency) select “other” under the appropriate body system (Respiratory, Neurologic, etc) and specify the admission diagnosis.</p> <p>Note: We are specifically interested in reporting on participants with sepsis, pancreatitis, bariatric surgery, ARDS, and burns. If a suitable diagnosis for a participant includes one of these conditions, select this condition in preference to other diagnoses.</p> <p><u>Example:</u> If a participant is admitted with sepsis and pneumonia, select sepsis.</p>

Instructions continued on next page.



## Baseline: Patient Information (2)

If ICU Diagnosis = Burns complete the following section.			
<b>Date of burn injury</b>	Record the date of burn injury.		
<b>Total body surface area (%TBSA) burn:</b>	<ul style="list-style-type: none"> <li>Record the total burn size as percent Total Body Surface Area (%TBSA).</li> <li>This assessment is made by the attending surgeon/physician based on her/his clinical judgment.</li> <li>Record TBSA in the nearest whole number rounding up from 0.5 and down from 0.4; i.e. 26.5% is recorded as 27% and 26.4% is recorded as 26%.</li> </ul>		
<b>Type of burn:</b>	<p>Place a <input checked="" type="checkbox"/> in all the boxes that apply corresponding to the type of burn the participant has and if the type of burn is not listed, place a <input checked="" type="checkbox"/> in the "Other" box and specify the type of burn.</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <ul style="list-style-type: none"> <li>Scald</li> <li>Flash</li> <li>Flame</li> <li>Chemical</li> </ul> </td> <td style="width: 50%; vertical-align: top;"> <ul style="list-style-type: none"> <li>Radiation</li> <li>Electrical (high voltage contact)</li> <li>Unknown</li> <li>Other, specify:</li> </ul> </td> </tr> </table>	<ul style="list-style-type: none"> <li>Scald</li> <li>Flash</li> <li>Flame</li> <li>Chemical</li> </ul>	<ul style="list-style-type: none"> <li>Radiation</li> <li>Electrical (high voltage contact)</li> <li>Unknown</li> <li>Other, specify:</li> </ul>
<ul style="list-style-type: none"> <li>Scald</li> <li>Flash</li> <li>Flame</li> <li>Chemical</li> </ul>	<ul style="list-style-type: none"> <li>Radiation</li> <li>Electrical (high voltage contact)</li> <li>Unknown</li> <li>Other, specify:</li> </ul>		
<b>Is there presence of full thickness burn (3<sup>rd</sup> degree)?</b>	Full thickness burns destroy both layers of skin (epidermis and dermis) and may penetrate more deeply into underlying structures. These burns have a dense white, waxy or even charred appearance and the area is stiff. Often there is no pain, as sensory nerves in the dermis are destroyed.		
<b>Is Inhalation Injury Present?</b>  <b>If yes, specify Severity Score:</b>	<ul style="list-style-type: none"> <li>0 – No injury – Absence of carbonaceous deposits, erythema, edema, bronchorrhea, or obstruction</li> <li>1 – Mild injury – Minor or patchy areas of erythema, carbonaceous deposits, bronchorrhea, or bronchial obstruction</li> <li>2 – Moderate injury – Moderate degree of erythema, carbonaceous deposits, bronchorrhea, or bronchial obstruction</li> <li>3 – Severe injury – Severe inflammation with friability, copious carbonaceous deposits, bronchorrhea, or obstruction</li> <li>4 – Massive injury – Evidence of mucosal sloughing, necrosis, endoluminal obstruction</li> </ul>		
If ICU Diagnosis = Surgical, Vascular/Cardiovascular complete the following section			
<b>Date of cardiac surgery:</b>	Record the date of the cardiovascular/vascular surgery that resulted in the participant's admission to ICU.		
<b>The Canadian Cardiovascular Society (CCS) grading of angina pectoris</b>	<p>The CCS is a clinical tool used to assess the degree of severity of a participant's angina.</p> <ul style="list-style-type: none"> <li>No Angina</li> <li>Class 1 (I) – Angina only with strenuous exertion. (Presence of angina only during strenuous, rapid, or prolonged ordinary activity (walking or climbing) the stairs.</li> <li>Class 2 (II) – Angina with moderate exertion. Slight limitation of ordinary activities when they are performed rapidly, after meals, in cold, in wind, under emotional stress, during the first few hours after waking up, but also walking uphill, climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.</li> <li>Class 3 (III) – Angina with mild exertion. Having difficulties walking one or two stores or climbing one flight of stairs at normal pace and conditions.</li> <li>Class 4 (IV) – Angina at rest. No exertion needed to trigger angina.</li> <li>Not Done</li> </ul>		

Instructions continued on next page.





### Baseline: Patient Information (3)

<p><b>New York Heart Association (NYHA) Functional Classification</b></p>	<p>The NYHA Functional Classification provides a simple way of classifying the extent of heart failure.</p> <ul style="list-style-type: none"> <li>• <b>Class 1 (I)</b> – Cardiac disease, but no symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc.</li> <li>• <b>Class 2 (II)</b> – Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.</li> <li>• <b>Class 3 (III)</b> – Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g. walking short distances (20–100 m). Comfortable only at rest.</li> <li>• <b>Class 4 (IV)</b> – Severe limitations. Experiences symptoms even while at rest. Mostly bedbound participants.</li> <li>• <b>Not Done</b></li> </ul>
<p><b>Left Ventricular Ejection Fraction (LVEF):</b></p>	<p>LVEF is an important measurement in determining how well a participant’s heart is pumping out blood and in diagnosing and tracking heart failure. Record the most recent LVEF value measured, as a percentage, within 3 months of surgery.</p> <p>If the echo report includes descriptive results but no percent, document it as the following:</p> <ul style="list-style-type: none"> <li>• Normal = 51%</li> <li>• Moderate = 35%</li> <li>• Poor = 25%</li> <li>• Severe = 20%</li> </ul>
<p><b>Did the participant receive any of the following cardiac medications in the 4 weeks prior to day of surgery (select all):</b></p>	<ul style="list-style-type: none"> <li>• <b>ACE inhibitor</b> – a class of drugs used primarily for the treatment of hypertension and congestive heart failure. Examples include benazepril, zofenopril, perindopril, trandolapril, captopril, enalapril, lisinopril and ramipril.</li> <li>• <b>Acetylsalicylic acid (ASA)</b> – Aspirin is used long-term to help prevent heart attacks, ischemic stroke and blood clots in people at high risk.</li> <li>• <b>Beta Blockers</b> – is a class of drug that are used to manage cardiac arrhythmias and to protect the heart from a second heart attack, after a first heart attack. Examples include propranolol, labetalol, nadolol and oxprenolol.</li> <li>• <b>Statins</b> – a class of lipid-lowering drugs. Examples include atorvastatin (Lipitor), cerivastatin, lovastatin, and simvastatin.</li> </ul>
<p><b>Urgency of cardiac surgery:</b></p>	<ul style="list-style-type: none"> <li>• <b>Elective</b> – routine admission for operation.</li> <li>• <b>Urgent</b> – participants who have not been electively admitted for operation but who require intervention or surgery on the current admission for medical reasons. These participants cannot be sent home without a definitive procedure.</li> <li>• <b>Emergency</b> – Operation before the beginning of the next working day after decision to operate.</li> <li>• <b>Salvage</b> – Participants requiring cardiopulmonary resuscitation (external cardiac massage) en route to the operating theatre or prior to induction of anaesthesia. This does not include cardiopulmonary resuscitation following induction of anaesthesia.</li> </ul>
<p><b>Was the participant considered to be in a critical pre-operative state?</b></p>	<p>Check ‘yes’ if the participant experienced at least one of the following events before their surgery:</p> <ul style="list-style-type: none"> <li>• Ventricular tachycardia;</li> <li>• ventricular fibrillation;</li> <li>• aborted sudden death;</li> <li>• preoperative cardiac massage; preoperative ventilation before anaesthetic room;</li> <li>• preoperative inotropes;</li> <li>• IABP;</li> <li>• preoperative acute renal failure (anuria or oliguria &lt;10mL/h)</li> </ul>

Instructions continued on next page.



## Baseline: Patient Information (4)

<b>Weight of the surgical intervention</b>	<p>This measures the extent or size of the surgical intervention. All <u>major</u> interventions on the heart such as: CABG, valve repair or replacement, replacement of part of the aorta, repair of a structural defect, maze procedure, and/or resection of a cardiac tumour.</p> <p>Considering the extent of the participant’s surgical procedure, please select one option from the list below that most appropriately describes the weight of the surgical intervention:</p> <ul style="list-style-type: none"> <li>• <b>Isolated CABG procedure</b></li> <li>• <b>Isolated (single) non-CABG procedure</b> (e.g. single valve procedure, replacement of ascending aorta, correction of septal defect, etc.);</li> <li>• <b>Two (2) procedures</b> (e.g. CABG + aortic valve replacement), or CABG + mitral valve repair, or aortic valve replacement + replacement of ascending aorta, or CABG + maze procedure, or aortic valve replacement + mitral valve repair, etc.);</li> <li>• <b>Three (3) major procedures or more</b> (e.g. aortic valve replacement + mitral valve repair + CABG, or mitral valve repair + CABG + tricuspid annuloplasty, etc.), or aortic root replacement when it includes aortic valve replacement or repair + coronary reimplantation + root and ascending replacement).</li> </ul> <p>NOTE: Only major cardiac procedures should be noted. Examples of procedures which are <u>not</u> to be included are: sternotomy, closure of sternum, myocardial biopsy, insertion of intra-aortic balloon, pacing wires, closure of aortotomy, closure of atriotomy; removal of atrial appendage, coronary endarterectomy as part of CABG, etc.</p>
<b>Did the surgery involve the thoracic aorta?</b>	Indicate whether the participant’s surgery involved the thoracic aorta.
<b>Was Cardiopulmonary Bypass (CPB) used?</b>	Indicate whether CPB was used during the participant’s cardiac surgical procedure.
<b>Comorbidities</b>	
<ul style="list-style-type: none"> <li>• Place a <input checked="" type="checkbox"/> beside all co-morbidities present using Taxonomy C provided.</li> <li>• Comorbidities are listed according to body-system. Only record co-morbidities found on the taxonomy listing.</li> <li>• If the a participant has a co-morbidity that is not found on the taxonomy, it does not need to be entered. Co-morbidity information collected will be used to calculate the Charlson Comorbidity Index and the Functional Comorbidity Index.</li> </ul> <p><u>Example:</u> A participant’s primary ICU diagnosis is cardiac arrest, and the participant is asthmatic, has type II diabetes, is obese, and is hearing impaired. Under co-morbidities, select:</p> <ul style="list-style-type: none"> <li>• Pulmonary: Asthma</li> <li>• Endocrine: Diabetes Type I or II</li> <li>• Endocrine: Obesity and/or BMI &gt;30</li> <li>• Miscellaneous: Hearing Impairment</li> </ul>	

Instructions continued on next page.



## Baseline: Patient Information (5)

<b><u>Myocardial</u></b>	<ul style="list-style-type: none"> <li>• Angina: chest pain caused by reduced blood flow to the heart muscle.</li> <li>• Arrythmia: heartbeat is irregular, too fast, or too slow.</li> <li>• Congestive heart failure: chronic condition that affects the chambers of your heart where the heart does not function as it should.</li> <li>• Recent MI: MI within past 90 days.</li> <li>• Previous MI: MI more than 90 days ago.</li> <li>• Moderate pulmonary hypertension: RVSP = 31-55 mmHg.</li> <li>• Severe pulmonary hypertension: RVSP &gt; 55 mmHg.</li> <li>• Valvular: Indicate if the participant currently has any uncorrected valvular heart disease.</li> <li>• Active endocarditis: Participant still on antibiotic treatment for endocarditis at time of surgery.</li> <li>• Previous Cardiac Surgery: Prior cardiothoracic surgery causes scar tissue to form and may increase difficulty and or risk in subsequent procedures. Capture (yes/no) both open and minimally invasive procedures.</li> </ul>
<b><u>Vascular</u></b>	<ul style="list-style-type: none"> <li>• Hypertension: Physician diagnosis of hypertension.</li> <li>• Extracardiac arteriopathy: One or more of the following: claudication, carotid occlusion or &gt;50% stenosis, amputation for arterial disease or previous or planned intervention on the abdominal aorta, limb arteries or carotid.</li> <li>• Cardiovascular Disease (Stroke or TIA): Any history of documented neurological symptoms consistent with stroke including, where possible, imaging evidence of ischemic or hemorrhagic damage.</li> </ul>
<b><u>Pulmonary</u></b>	<ul style="list-style-type: none"> <li>• Chronic Lung Disease (Other than COPD and Asthma): Interstitial lung disease, or ILD, is a common term that includes more than 200 chronic lung disorders interstitial lung diseases are named after the tissue between the air sacs of the lungs called the interstitium. This tissue can be affected by fibrosis (scarring) and lead to respiratory insufficiency.</li> <li>• COPD: Diagnosis is confirmed and severity is graded using pulmonary function testing (PFT). Bronchitis and emphysema are considered COPD, asthma is not. Severe obstructive or restrictive lung disease requiring supplemental O2 at rest (e.g. emphysema, chronic bronchitis).</li> </ul>
<b><u>Neurologic</u></b>	<ul style="list-style-type: none"> <li>• Dementia: Indicate if there is a diagnosis of dementia.</li> <li>• Hemiplegia: Paralysis of one side of the body.</li> <li>• Neurologic illness: Indicate if there is a diagnosis, such as MS or Parkinsons.</li> </ul>
<b><u>Endocrine</u></b>	<ul style="list-style-type: none"> <li>• Diabetes type 1 or 2 on insulin: Regardless of the duration of disease, select this option if the participant is prescribed insulin at baseline</li> <li>• Diabetes type II, not on insulin: select if the participant is on oral hypoglycemic agents or no diabetes medication</li> <li>• Diabetes with end organ damage: In addition to selecting one of the two options above, indicate if end organ damage is present due to the disease</li> <li>• Obesity: Select if the participant's BMI is &gt;30</li> </ul>
<b><u>Renal</u></b>	<ul style="list-style-type: none"> <li>• Moderate renal disease: Creatinine clearance 51-85 mL/min.</li> <li>• Severe renal disease: Creatinine clearance <math>\leq</math>50 mL/min and NOT on dialysis</li> <li>• Dialysis (regardless of serum creatinine level): This measure is related to hemodialysis, peritoneal dialysis or CRRT. Does not include ultrafiltration. Note: this would exclude the participant from the study if they were on dialysis when randomized.</li> </ul>

Instructions continued on next page.



## Baseline: Patient Information (6)

<b><u>Gastrointestinal</u></b>	<ul style="list-style-type: none"> <li>• Gastrointestinal disease: This includes hernias or reflux</li> <li>• GI Bleeding: Any history of hemorrhage anywhere in the gastrointestinal tract that was investigated and/or required blood transfusion within the past 6 months.</li> <li>• Inflammatory bowel: Indicate if the participant has received this diagnosis</li> <li>• Mild liver disease: Raised serum aminotransferase or alkaline phosphatase levels or both, but total serum bilirubin &lt;2.5 mg/dL and no coagulopathy (INR &lt;1.5)</li> <li>• Moderate or severe liver disease: liver disease beyond the above definition for mild liver disease</li> <li>• Peptic ulcer disease: Any history of ulcers (defined as mucosal erosions equal to or greater than 0.5 cm) on any area of the gastrointestinal tract.</li> </ul>
<b><u>Cancer/Immune</u></b>	Indicate if the participant has a diagnosis of any of the listed comorbidities (AIDS, tumor, leukemia, lymphoma, metastatic solid tumor).
<b><u>Psychological</u></b>	Indicate if the participant has a diagnosis of any of the listed comorbidities (anxiety, panic disorder, depression)
<b><u>Musculoskeletal</u></b>	<ul style="list-style-type: none"> <li>• Arthritis: Select if the participant has either rheumatoid or osteoarthritis</li> <li>• Connective Tissue Disease: Indicate if the participant has received this diagnosis</li> <li>• Degenerative Disc Disease: This includes back disease, spinal stenosis or severe chronic back pain</li> <li>• Osteoporosis: Indicate if the participant has received this diagnosis</li> </ul>
<b><u>Substance Use</u></b>	<ul style="list-style-type: none"> <li>• Heavy alcohol use: if the participant has a documented history of alcohol abuse in the medical chart, it should be recorded here. Heavy alcohol use or binge drinking is defined as &gt;7 drinks/week or &gt;3 drinks/occasion for women and &gt;14 drinks/week or &gt;4 drinks/occasion for men.</li> <li>• Current Smoker: "Current smoker" should be selected if the participant stopped smoking &lt; than 6 weeks prior to surgical procedure.</li> <li>• Drug abuse history: if the participant has a documented history of drug abuse in the medical chart, it should be recorded here.</li> </ul>
<b><u>Miscellaneous</u></b>	<ul style="list-style-type: none"> <li>• Hearing impairment: indicate if the participant is very hard of hearing, even with hearing aids.</li> <li>• Visual Impairment: Indicate if the participant has a diagnosis of cataracts, glaucoma or macular degeneration.</li> <li>• Severe mobility impairment: Severe impairment of mobility secondary to musculoskeletal or neurological dysfunction.</li> </ul>

Instructions continued on next page.



## Baseline: APACHE II Score

APACHE II Score	<ul style="list-style-type: none"> <li>If routinely calculated, directly enter the score recorded in the participant’s chart.</li> <li>To calculate the score, you may use any tool you wish. We recommend using the following website: <a href="http://www.sfar.org/scores2/apache22.php">http://www.sfar.org/scores2/apache22.php</a>. Record the calculated score.</li> <li>To manually calculate the score, use the worksheet included in the CRF.</li> </ul> <p><u>General Instructions</u></p> <ul style="list-style-type: none"> <li>All measurements should be obtained from within the first 24h of ICU admission.</li> <li>If there is only one measure within the 24h scoring window for a given physiologic variable, record the single value as <u>both</u> the lowest AND highest values.</li> <li>If variables are not available from the first 24 hours of ICU admission, go outside the 24 hour window and use data closest to the ICU admission.</li> <li>If any of the variables are not available (i.e. no data available) assume a normal value normal (i.e. ‘0 points’).</li> <li>If a patient has been transferred from another ICU or emergency department, refer to the data collected outside of the index ICU admission (but still within 24h window).</li> <li>For all measurements, choose the worst, most abnormal value. These values may be low or high, but will always be the most aberrant value with the highest point score (i.e. furthest away from a score of ‘0’).</li> <li>Do not include values from the operating room.</li> </ul> <p>If the calculated APACHE II score is <math>\leq 10</math> please indicate if the score was calculated using complete data or if partial data was used (i.e. CBC was never done).</p> <p>If the APACHE II Score is not available, please provide the reason why the APACHE II Score cannot be calculated</p> <ul style="list-style-type: none"> <li>No bloodwork taken</li> <li>Data cannot be found</li> </ul>
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### How to manually calculate APACHE II Score



Acute Physiology Score	<p><u>Temperature</u> Record lowest and highest ‘non-adjusted’ body temperatures in °C, including how they were measured: axilla, bladder, esophageal, oral, pulmonary artery, rectal or tympanic). In the event a patient is/has been cooled for therapeutic reasons, the temperature will be scored as normal.</p> <p><u>Mean Arterial Pressure (MAP)</u> If accurate MAPs are available, record the lowest and the highest MAP OR When MAPs are not available, record the following 4 sets of values:</p> <ul style="list-style-type: none"> <li>LOWEST SBP with associated DBP</li> <li>LOWEST DBP with associated SBP</li> <li>HIGHEST SBP with associated DBP</li> <li>HIGHEST DBP with associated SBP</li> </ul> <p><u>Heart Rate (HR)</u> The lowest and highest heart rates (ventricular response).</p> <p><u>Respiratory Rate (RR)</u> The lowest and highest respiratory rates should be recorded. For vented patients the RR should be a combined total of patient and ventilator breaths per minute. 17</p>
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Instructions continued on next page.

<p>Acute Physiology Score</p>	<p><u>Oxygenation</u>  LOWEST: Record the lowest PaO<sub>2</sub> (mmHg) and corresponding SpO<sub>2</sub> (%), with the associated FiO<sub>2</sub> (%), and PaCO<sub>2</sub>.  HIGHEST: record the highest FiO<sub>2</sub> (%) with associated PaO<sub>2</sub>, corresponding SpO<sub>2</sub> (%), and PaCO<sub>2</sub>.</p> <p>If FiO<sub>2</sub> ≥ 0.5, and multiple ABGs are available, you will need to calculate the A•aD0<sub>2</sub> (alveolar arterial gradient) to manually obtain the lowest and highest scores. To calculate A•aD0<sub>2</sub> all values used must come from the same ABG.  <math>A\bullet aD0_2 = [FiO_2 (713) - (PaCO_2/0.8)] - PaO_2</math></p> <p><u>pH Arterial</u>  Record the lowest and highest pH levels measured.  Serum Bicarbonate (No-ABGs available)  If there are no ABGs available Serum bicarbonate (HCO<sub>3</sub> venous) should be used in place of the above oxygenation data.</p> <p><u>WBC</u>  Record the lowest and highest white blood cell counts.</p> <p><u>Hematocrit</u>  Record the lowest and highest hematocrit measured.</p> <p><u>Platelets</u>  Record the lowest and highest platelet counts measured.</p> <p><u>Serum Sodium (Na<sup>+</sup>)</u>  Record the lowest and highest serum sodium levels measured within the first 24 hours following admission to the ICU. If there is no data; record NA (Not Applicable).</p> <p><u>Serum Potassium (K<sup>+</sup>)</u>  Record the lowest and highest serum potassium levels.</p> <p><u>Creatinine</u>  Record the lowest and highest serum creatinine levels.</p> <p><u>Acute Renal Failure (double points assigned)</u>  The patient fulfills the ‘acute renal failure’ criteria if any of the following definitions apply:</p> <ul style="list-style-type: none"> <li>• Creatinine &gt; 124 µmol/L and ≤ 177 µmol/L and subsequent creatinine values show a steady increase to &gt; 177 µmol/L; OR</li> <li>• Creatinine &gt; 177 µmol/L and <ul style="list-style-type: none"> <li>• Patient has documented pre-admission creatinine ≤ 124 µmol/L; OR</li> <li>• Creatinine decreases to &lt; 124 µmol/L while patient is hospitalized</li> </ul> </li> </ul> <p><u>GCS</u></p> <ul style="list-style-type: none"> <li>• GCS is assessed by summing the score in 3 domains: eye opening, verbal response and motor response. The highest (more alert) score, within 24h of the acute insult, should be recorded for each domain.</li> <li>• If the patient has multiple GCS recorded in the first 24 hours, lose the most lowest score for the purpose of calculating APACHE II.</li> <li>• If a patient is intubated, and therefore unable to verbalize but is following commands and communicating with gestures and mouthing words or writing where the ability to verbalize is restricted only by ETT, the verbal score may be amended to “5-Converse/Oriented.”</li> <li>• If data is not available within the 24h window, a ‘best estimate’ from before sedation/intubation is to be used. In this case, obtain information from the clinical staff in the ED and/or paramedics.</li> </ul>
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### Baseline: Patient Information

<b>Sex:</b> <input type="checkbox"/> Female <input type="checkbox"/> Male	<b>Age:</b> _____ years
<b>Hospital Admission</b> <b>Date:</b> (YYYY-MM-DD): _____ <b>Time</b> (HH:MM, 24h): _____	<b>ICU Admission</b> <b>Date:</b> (YYYY-MM-DD): _____ <b>Time</b> (HH:MM, 24h): _____
<b>Type of ICU Admission:</b> <input type="checkbox"/> Medical <span style="margin-left: 20px;"><i>(Check <u>one</u> option from taxonomy 'A' – page 20)</i></span> <input type="checkbox"/> Surgical Elective <span style="margin-left: 20px;"><i>(check <u>one</u> option from taxonomy 'B' – page 21)</i></span> <input type="checkbox"/> Surgical Emergency <span style="margin-left: 20px;"><i>(check <u>one</u> option from taxonomy 'B' – page 21)</i></span>	
<b>Does the patient have any comorbidities?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No ↓ <i>Check all that apply from taxonomy C – page 23)</i>	
<b>APACHE II Score:</b> _____	
Calculate the APACHE II score with the online calculator: <a href="http://www.sfar.org/scores2/apache22.php">http://www.sfar.org/scores2/apache22.php</a> <b>OR</b> Calculate the APACHE II manually on the provided form (see page 24-25).	
<i>If score ≤ 10, is the APACHE II Score based on:</i> <input type="checkbox"/> Partial data → → → provide reason(s) below. <input type="checkbox"/> Complete data	
<b>Please provide the reason for partial data:</b> <input type="checkbox"/> No bloodwork taken <input type="checkbox"/> Data cannot be found	



## Baseline: Patient Information ICU Admission Diagnosis Taxonomy

Study ID # \_\_\_\_\_

### TAXONOMY A - Primary ICU Diagnosis: Medical (Non-Operative Condition System)

Check only one.

#### **Cardiovascular/Vascular**

- Acute myocardial infarction
- Aortic aneurysm
- Cardiac arrest
- Cardiogenic shock
- Congestive heart failure
- Hypertension
- Peripheral vascular disease
- Rhythm disturbance
- Other CV disease (specify):  
\_\_\_\_\_

#### **Respiratory**

- Aspiration pneumonia
- Asthma
- Bacterial/ Viral pneumonia
- Chronic obstructive pulmonary disease
- Mechanical airway obstruction
- Parasitic pneumonia (i.e. pneumocystis carinii)
- Pulmonary edema (non-cardiogenic)
- Pulmonary embolism
- Respiratory arrest
- Respiratory neoplasm (including larynx and trachea)
- Other respiratory disease (specify):  
\_\_\_\_\_

#### **Gastrointestinal**

- GI bleeding due to diverticulosis
- GI bleeding due to ulcer/laceration
- GI bleeding due to varices
- GI inflammatory disease (ulcerative colitis, Crohn's disease)
- GI perforation/obstruction
- Cirrhosis/Acute-on-Chronic Liver Failure
- Acute Liver Failure/Fulminant Hepatic Failure
- Pancreatitis
- Other GI disease (specify):  
\_\_\_\_\_

#### **Neurologic**

- Intracerebral hemorrhage
- Neurologic infection
- Neurologic neoplasm
- Neuromuscular disease
- Seizure
- Stroke
- Subarachnoid hemorrhage
- Other neurologic disease (specify):  
\_\_\_\_\_

#### **Sepsis**

- Sepsis (other than urinary tract)
- Sepsis of urinary tract origin

#### **Trauma**

- Head trauma (with/without multiple trauma)
- Multiple trauma (excluding head trauma)

#### **Metabolic**

- Diabetic ketoacidosis
- Drug overdose
- Metabolic coma
- Other metabolic disease (specify):  
\_\_\_\_\_

#### **Hematologic**

- Coagulopathy/neutropenia thrombocytopenia
- Other hematologic condition (specify):  
\_\_\_\_\_

#### **Burns†**

- Burns

#### **Other**

- Renal disease (specify):  
\_\_\_\_\_
- Other medical disease (specify):  
\_\_\_\_\_

† Remember to complete the additional burn related data on page 22.





## Baseline: Patient Information ICU Admission Diagnosis Taxonomy

Study ID # \_\_\_\_\_

### TAXONOMY B - Primary ICU Diagnosis: Surgical Elective or Emergency (Operative Condition System)

Check only one

<p><b>Cardiovascular/Vascular*</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> CABG only</li> <li><input type="checkbox"/> Carotid endarterectomy</li> <li><input type="checkbox"/> Dissecting/ruptured aorta</li> <li><input type="checkbox"/> Elective abdominal aneurysm repair</li> <li><input type="checkbox"/> Peripheral artery bypass graft</li> <li><input type="checkbox"/> Peripheral vascular surgery (no bypass graft)</li> <li><input type="checkbox"/> Valvular heart surgery/CABG</li> <li><input type="checkbox"/> Valvular heart surgery only</li> <li><input type="checkbox"/> Other CV disease (specify): _____</li> </ul> <p><b>Respiratory</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Lung neoplasm</li> <li><input type="checkbox"/> Respiratory infection</li> <li><input type="checkbox"/> Respiratory neoplasm (mouth, sinus larynx, trachea)</li> <li><input type="checkbox"/> Other respiratory disease (specify): _____</li> </ul>	<p><b>Gastrointestinal</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> GI bleeding</li> <li><input type="checkbox"/> GI cholecystitis/ cholangitis</li> <li><input type="checkbox"/> GI inflammatory disease</li> <li><input type="checkbox"/> GI neoplasm</li> <li><input type="checkbox"/> GI obstruction</li> <li><input type="checkbox"/> GI perforation/rupture</li> <li><input type="checkbox"/> Liver transplant</li> <li><input type="checkbox"/> Pancreatitis</li> <li><input type="checkbox"/> Other GI disease (specify): _____</li> </ul> <p><b>Neurologic</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Craniotomy for neoplasm</li> <li><input type="checkbox"/> Intracerebral hemorrhage</li> <li><input type="checkbox"/> Laminectomy/other spinal cord surgery</li> <li><input type="checkbox"/> Subarachnoid hemorrhage</li> <li><input type="checkbox"/> Subdural/epidural hematoma</li> <li><input type="checkbox"/> Other neurologic disease (specify): _____</li> </ul>	<p><b>Trauma</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Head trauma (with/without multiple trauma)</li> <li><input type="checkbox"/> Multiple trauma (excluding head trauma)</li> </ul> <p><b>Renal</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Renal neoplasm</li> <li><input type="checkbox"/> Other renal disease (specify): _____</li> </ul> <p><b>Gynecologic</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Hysterectomy</li> </ul> <p><b>Orthopedic</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Hip or extremity fracture</li> </ul> <p><b>Bariatric Surgery</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Laproscopic Banding</li> <li><input type="checkbox"/> Laproscopic Gastric Bypass</li> <li><input type="checkbox"/> Open Gastric Bypass (Roux-en-Y)</li> <li><input type="checkbox"/> Vertical Banded Gastroplasty</li> </ul> <p><b>Burns†</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Burns</li> </ul> <p><b>Other</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Other surgical disease (specify): _____</li> </ul>
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\* Remember to complete the additional surgical cardiovascular/vascular related data on page 22.

† Remember to complete the additional burn related data on page 22.



# Baseline: Patient Information

## ICU Admission Diagnosis

### (If Burns or Surgical, Cardiovascular/Vascular)

Study ID # \_\_\_\_\_

†Only complete this section if the primary ICU diagnosis is Burns:

Date of burn injury (YYYY-MM-DD): \_\_\_\_\_

Total body surface area (%TBSA) burn: \_\_\_\_\_ %

Type of burn (check all that apply):

<input type="checkbox"/> Scald	<input type="checkbox"/> Radiation
<input type="checkbox"/> Flash	<input type="checkbox"/> Electrical
<input type="checkbox"/> Flame	<input type="checkbox"/> Unknown
<input type="checkbox"/> Chemical	<input type="checkbox"/> Other: _____

Is there presence of full thickness burn (3<sup>rd</sup> degree)?  Yes  No

Is inhalation injury present?  Yes  No



If yes, indicate the Inhalation Injury Severity Score:

(0) No injury  (1) Mild  (2) Moderate  (3) Severe  (4) Massive

\*Only complete this section if the primary ICU diagnosis is Surgical, Cardiovascular/Vascular:

Date of cardiac surgery (YYYY-MM-DD): \_\_\_\_\_

Urgency:  Elective  
 Urgent  
 Emergency  
 Salvage

Was the patient considered to be in a critical pre-operative state?

Yes  No

Weight of the intervention:  Isolated CABG  
 Single non-CABG  
 2 procedures  
 3 procedures

Did the surgery involve the thoracic aorta?

Yes  No

Was cardiopulmonary bypass (CPB) used?

Yes  No

Canadian Cardiovascular Society (CCS)

grading of angina pectoris:

No angina  Grade 1  Grade 2  
 Grade 3  Grade 4  Not Done

New York Heart Association (NYHA) Functional Classification:

Grade 1  Grade 2  Grade 3  
 Grade 4  Not Done

LVEF function:  >50% (normal)  31-50% (moderate)  21-30% (poor)  <20% (severe)

Did the patient receive any of the following cardiac medications in the 4 weeks prior to surgery: (select all given)  ACE Inhibitor  Aspirin  Beta blockers  Statins  None



# Baseline: Patient Information Comorbidity Taxonomy

Study ID # \_\_\_\_\_

## TAXONOMY C – Comorbidities (Check all that apply)

### Myocardial

- Angina
- Arrhythmia
- Congestive heart failure (or heart disease)
- Recent myocardial infarction ( $\leq 90$  days)
- Previous myocardial infarction ( $> 90$  days)
- Moderate pulmonary hypertension (PA systolic/RVSP 31-55 mmHg)
- Severe pulmonary hypertension (PA systolic/RVSP  $> 55$  mmHg)
- Valvular
- Active endocarditis
- Previous cardiac surgery

### Vascular

- Cerebrovascular disease (Stroke or TIA)
- Hypertension
- Extracardiac arteriopathy

### Pulmonary

- Asthma
- Chronic obstructive pulmonary disease (COPD, emphysema)

### Neurologic

- Dementia
- Hemiplegia (paraplegia)
- Neurologic illnesses (such as Multiple sclerosis or Parkinsons)

### Endocrine

- Diabetes Type I or II on insulin
- Diabetes type II not on insulin
- Diabetes with end organ damage
- Obesity and/or BMI  $> 30$  (weight in kg/(ht in meters)<sup>2</sup>)

### Renal

- Moderate renal disease (Creatinine clearance 51-85 mL/min)
- Severe renal disease (Creatinine clearance  $\leq 50$  mL/min off dialysis)
- Dialysis (regardless of serum creatinine)

### Gastrointestinal

- Gastrointestinal disease (hernia or reflux)
- GI bleeding
- Inflammatory bowel
- Mild liver disease
- Moderate or severe liver disease
- Peptic ulcer disease

### Cancer/Immune

- AIDS
- Any Tumor
- Leukemia
- Lymphoma
- Metastatic solid tumor

### Psychological

- Anxiety or Panic Disorders
- Depression

### Musculoskeletal

- Arthritis (Rheumatoid or Osteoarthritis)
- Connective Tissue disease
- Degenerative Disc disease (back disease or spinal stenosis or severe chronic back pain)
- Osteoporosis

### Substance Use

- Heavy alcohol use or binge drinking history
- Current smoker
- Drug abuse history

### Miscellaneous

- Hearing Impairment (very hard of hearing even with hearing aids)
- Visual Impairment (cataracts, glaucoma, macular degeneration)
- Severe mobility impairment

# Baseline: Patient Information APACHE II Score Sheet (1)

Study ID # \_\_\_\_\_

Use values from the first 24 hours from admission to ICU.

Physiologic Variable	HIGH ABNORMAL RANGE					LOW ABNORMAL RANGE				
	+4	+3	+2	+1	0	+1	+2	+3	+4	Severity Score
<b>1</b> Severity Points										
Temperature – rectal (°C) (add 0.5° to oral temp, add 1.0° to axillary temp)	≥41°	39-40.9°		36.5°-38.9°	36°-38.4°	34°-33.9°	32°-33.9°	30°-31.9°	≤29.9°	
Mean Arterial Pressure (mmHg)	≥160	130-159		110-129	70-109		50-69		≤49	
Heart Rate (Ventricular Response)	≥180	140-179		110-139	70-109		55-69	40-54	≤39	
Resp. Rate (non-ventilated or ventilated)	≥50	35-49		25-34	12-24	10-11	6-9		≤5	
Oxygenation:										
a. FIO <sub>2</sub> ≥ 0.5 record A-aDO <sub>2</sub> *	≥500	350-499	200-349		<200					
b. FIO <sub>2</sub> < 0.5 record only PaO <sub>2</sub>					PaO <sub>2</sub> ≥ 70	PaO <sub>2</sub> 61-70		PaO <sub>2</sub> 55-60	PaO <sub>2</sub> < 55	
Arterial pH	≥7.7	7.6-7.69		7.5-7.59	7.33-7.49		7.25-7.32	7.15-7.24	<7.15	
Serum Sodium (mmol/L)	≥180	160-179	155-159	150-154	130-149		120-129	111-119	≤110	
Serum Potassium (mmol/L)	≥7	6-6.9		5.5-5.9	3.5-5.4	3-3.4	2.5-2.9		<2.5	
Serum Creatinine (µmol/L) (double point score for acute renal failure)	≥309.4	≥176.8-309.3	≥132-176.7		≥53-132		<53			
Hematocrit (%)	≥60	50-59.9	46-49.9	30-45.9		20-29.9			<20	
White Blood Count (total/mm <sup>3</sup> ) (in 1000s)	≥40	20-39.9	15-19.9	3-14.9		1-2.9			<1	
Glasgow Coma Score (GCS) Score=15 minus actual GCS										(15 - GCS Total)
(Note: The best GCS used for the 1 <sup>st</sup> 24 hours)										
A=Total ACUTE PHYSIOLOGY SCORE (APS): Total severity points indicated for Variables 1-12 in the column to the right.										
Serum HCO <sub>3</sub> (venous-mmol/L) (Use in place of variable 6 if no ABGs)	≥52	41-51.9	32-40.9	22-31.9	18-21.9	15-17.9			<15	

\* A-aDO<sub>2</sub> = [(FIO<sub>2</sub> (713)-(PaCO<sub>2</sub>/0.8)]-PaO<sub>2</sub>

# Baseline: Patient Information APACHE II Score Sheet (2)

Study ID #

A=	APS Points (see back)	<input type="text"/>
B=	Age Points (see back)	<input type="text"/>
C=	Chronic Health Points	<input type="text"/>
Total= APACHE II Score		<input type="text"/>

### Glasgow Coma Scale:

#### Eye Opening

- 4- Spontaneous
- 3 - To speech
- 2 - To pain
- 1 - None

#### Best Motor Response

- 6 - Obeys commands
- 5 - Localizes to pain
- 4 - Withdraws from pain
- 3 - Abnormal flexion
- 2 - Extension
- 1 - None

#### Verbal Response

- 5 - Oriented
- 4 - Confused
- 3 - Inappropriate words
- 2 - Incomprehensible sounds
- 1 - None

### How to score age points (B):

Age (years)	Points
≤ 44	0
45-54	2
55-64	3
65-74	5
≥ 75	6

### How to score chronic health points (C):

If the patient has a history of severe organ system insufficiency (see below) or is immuno-compromised assign points as follows.

1. For non-operative or emergency postoperative patients → 5
2. For elective postoperative patients → 2
3. Patient does NOT have a history of severe organ system insufficiency and is NOT immuno-compromised: → 0

### CHRONIC HEALTH DEFINITIONS

Organ insufficiency or immuno-compromised state evident prior to this hospital admission and are consistent with the following criteria:  
**LIVER:** Biopsy-proven cirrhosis and documented portal hypertension; prior episodes of upper GI bleeding attributed to portal hypertension; or prior episodes of hepatic failure/encephalopathy/coma  
**CARDIOVASCULAR:** New York Heart Association Class IV  
**RESPIRATORY:** Chronic restrictive, obstructive, or vascular disease resulting in severe exercise restriction (i.e., unable to climb stairs or perform activities of daily living or household duties; or documented chronic hypoxia, hypercapnia, secondary polycythemia, severe pulmonary hypertension (>40 mmHg), or ventilator dependency  
**RENAL:** Receiving chronic dialysis  
**IMMUNO-COMPROMISED:** The patient has received therapy that suppresses resistance to infection (i.e., immuno-suppressive treatment, chemotherapy, radiation, long term or recent high dose steroid), or has a disease that is sufficiently advanced to suppress resistance to infection (i.e., leukaemia, lymphoma, AIDS)



## Baseline: Enrollment

<b>Urine output at the time of randomization:</b>	<p>Indicate the urine output (UO) at the time of randomization.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> &gt; 0.5 mL/kg/h for 6h, 12h or 24h</li> <li><input type="checkbox"/> &lt; 0.5 mL/kg/h for 6h</li> <li><input type="checkbox"/> &lt; 0.5 mL/kg/h for 12h</li> <li><input type="checkbox"/> &lt; 0.3 mL/kg/h for 24h</li> <li><input type="checkbox"/> anuria for 12 h</li> </ul>
<b>Creatinine <u>before</u> onset of illness that brought patient to the hospital:</b>	<p>Record the creatinine value from <u>before</u> the onset of illness that brought the patient to the hospital. Note: the units specified on Day 1 Daily Nutrition Data will be assumed to be the same for the creatinine value recorded here.</p>
<b>Was a wound present at randomization?</b>	<p>If a wound was present, check all types that apply from the list below.</p> <ul style="list-style-type: none"> <li>• <b>Pressure ulcer</b> – also called ‘bedsores’ or ‘decubitus ulcers’ are injuries to the skin and underlying tissue resulting from prolonged pressure on the skin. They most often develop on skin that covers bony areas, such as heels, ankles, hips and tailbone.</li> <li>• <b>Enterocutaneous fistula</b> – is an abnormal connection that develops between the intestinal tract or stomach and the skin. As a result, contents of the stomach or intestines leak through to the skin. Most enterocutaneous fistulas occur after bowel surgery.</li> <li>• <b>Open abdomen</b> – An abdominal wall defect created by intentionally leaving an abdominal incision open at the completion of intraabdominal surgery or by opening (or re-opening) the abdomen because of a concern for abdominal compartment syndrome.</li> <li>• <b>Wound dehiscence</b> – Is a surgical complication in which a wound ruptures along a surgical incision.</li> </ul>



## Baseline: Conditions at Enrollment

**Urine output at time of enrollment:**

- > 0.5 mL/kg/h for 6h, 12h or 24h
- < 0.5 mL/kg/h for 6h
- < 0.5 mL/kg/h for 12h
- < 0.3 mL/kg/h for 24h
- anuria for 12 h

**Creatinine before onset of illness that brought patient to the hospital:**

\_\_\_\_\_  mmol/L       Not available  
 mg/dL

**Was a wound present at randomization?**

- Yes → → → **Check all that apply:**
- Pressure ulcer
  - Enterocutaneous fistula
  - Open abdomen
  - Wound dehiscence
- No

**Pressure ulcer** – also called ‘bedsores’ or ‘decubitus ulcers’ are injuries to the skin and underlying tissue resulting from prolonged pressure on the skin. They most often develop on skin that covers bony areas, such as heels, ankles, hips and tailbone.

**Enterocutaneous fistula** – is an abnormal connection that develops between the intestinal tract or stomach and the skin. As a result, contents of the stomach or intestines leak through to the skin. Most enterocutaneous fistulas occur after bowel surgery.

**Open abdomen** – An abdominal wall defect created by intentionally leaving an abdominal incision open at the completion of intraabdominal surgery or by opening (or re-opening) the abdomen because of a concern for abdominal compartment syndrome.

**Wound dehiscence** – Is a surgical complication in which a wound ruptures along a surgical incision.



## Baseline: SOFA Score

<b>General Instructions</b>	<ul style="list-style-type: none"> <li>• These data are collected once at baseline for calculation of modified SOFA score. All data should be collected within the <b>first 24 hours after admission to ICU</b>.</li> <li>• If data is not available within the first 24 hours, go outside the 24 hour period and record data closest to admission.</li> </ul>	
<b>Lowest PaO<sub>2</sub>/FiO<sub>2</sub> (PF ratio)</b>	<p>Record the lowest PaO<sub>2</sub>/FiO<sub>2</sub> (PF ratio) observed on the study day by selecting from the options below. The PaO<sub>2</sub> and FiO<sub>2</sub> values should come from the same blood gas measurement.</p> <p> <input type="checkbox"/> ≥ 400 mmHg <b>or N/A</b>  <input type="checkbox"/> 300 – 399 mmHg  <input type="checkbox"/> 200 – 299 mmHg  <input type="checkbox"/> 100 – 199 mmHg with respiratory support  <input type="checkbox"/> &lt; 100 mmHg with respiratory support         </p> <p>If 'No' PF ratio, record <b>N/A by selecting the first option.</b></p>	
<b>Lowest Platelets</b>	<p>Record the lowest serum platelets observed on the study day by selecting from the options below.</p> <p> <input type="checkbox"/> ≥ 150 x 10<sup>3</sup>/mm<sup>3</sup> <b>or N/A</b>  <input type="checkbox"/> 100 - 149 x 10<sup>3</sup>/mm<sup>3</sup>  <input type="checkbox"/> 50 - 99 x10<sup>3</sup>/mm<sup>3</sup>  <input type="checkbox"/> 20 - 49 x10<sup>3</sup>/mm<sup>3</sup>  <input type="checkbox"/> &lt; 20 x10<sup>3</sup>/mm<sup>3</sup> </p> <p>If 'No' Platelet data, record <b>N/A by selecting the first option.</b></p>	
<b>Highest Bilirubin (total)</b>	<p>Record the highest total bilirubin observed on the study day by selecting from the options below.</p> <p> <input type="checkbox"/> &lt; 1.2 mg/dL (&lt; 20 μmol/L) <b>or N/A</b>  <input type="checkbox"/> 1.2 – 1.9 mg/dL (20-32 μmol/L)  <input type="checkbox"/> 2.0 – 5.9 mg/dL (33-101 μmol/L)  <input type="checkbox"/> 6.0 – 11.9 mg/dL (102-204 μmol/L)  <input type="checkbox"/> ≥ 12.0 mg/dL (&gt; 204 μmol/L)         </p> <p>If 'No' bilirubin data, record N/A by selecting <b>the first option.</b></p>	
<b>Vasopressors</b>  <b>Mean Arterial Pressure (MAP)</b>	<p>If 'Yes', select the highest dose received during the study day.</p> <p> <input type="checkbox"/> Dopamine ≤ 5μg/kg/min or Dobutamine (any dose)  <input type="checkbox"/> Dopamine 5 - 15 μg/kg/min or Epinephrine ≤ 0.1 μg/kg/min or Norepinephrine ≤ 0.1 μg/kg/min  <input type="checkbox"/> Dopamine &gt; 15 μg/kg/min or Epinephrine &gt; 0.1 μg/kg/min or Norepinephrine &gt; 0.1 μg/kg/min         </p>	<p>If no:</p> <p> <input type="checkbox"/> Mean Arterial Pressure (MAP) &lt; 70 mmHg  <input type="checkbox"/> Mean Arterial Pressure (MAP) ≥ 70 mmHg         </p>
<b>Highest Creatinine</b>	<p>Record the highest creatinine observed on the study day by selecting from the options below:</p> <p> <input type="checkbox"/> &lt; 1.2 mg/dL (&lt; 110 μmol/L) or N/A  <input type="checkbox"/> 1.2 - 1.9 mg/dL (110 - 170 μmol/L)  <input type="checkbox"/> 2.0 - 3.4 mg/dL (171 - 229 μmol/L)  <input type="checkbox"/> 3.5 - 4.9 mg/dL (300 - 440 μmol/L)  <input type="checkbox"/> ≥ 5 mg/dl (&gt; 440 μmol/L)         </p> <p>If 'No' creatinine data, record <b>N/A by selecting the first option.</b></p>	
<b>Urine output (mL)</b>	<p>Indicate the volume range of urine output for the study day by selecting from the list below:</p> <p> <input type="checkbox"/> ≥ 500 mL/day <b>or N/A</b>  <input type="checkbox"/> 200 - 499 mL/day  <input type="checkbox"/> &lt; 200 mL/day         </p> <p>If 'No' urine output data, record <b>N/A by selecting the first option.</b></p>	







## Baseline: Nutrition Assessment

<p><b>Did the patient have unintentional weight loss before admission to hospital?</b></p>	<p>Select from Yes, no and do not know.</p> <p>If yes, please respond to the following related questions:</p> <ul style="list-style-type: none"> <li>• What was the % weight loss?</li> <li>• Over how many months did the weight loss occur?             <ul style="list-style-type: none"> <li>• Select the most appropriate response (i.e. 1-12, &gt;12 months). If necessary, round to the nearest month and record the value.</li> </ul> </li> </ul>
<p><b>Did the patient have less than required food intake before admission to hospital?</b></p>	<p>Select from Yes, no and do not know.</p> <p>If yes, please respond to the following related questions:</p> <ul style="list-style-type: none"> <li>• Was the food intake &lt; 50% of needs?</li> <li>• Was the food intake reduced for: (1 week; 2 weeks; &gt;2 weeks; Do not know)</li> </ul>
<p><b>Does the patient have chronic malabsorption?</b></p>	<p>Selection from yes or no and do not know.</p> <p>Select 'yes' for example if the patient has a diagnosis of inflammatory bowel disease, short bowel syndrome, chronic dysmotility, etc.</p>
<p><b>Does the patient have moderate/severe fat and/or muscle wasting?</b></p>	<p>Select from Yes, no and do not know.</p> <p>If yes, please check the box(es) that apply for which evidence this assessment is based on:</p> <ul style="list-style-type: none"> <li>• Visual evidence of fat wasting</li> <li>• Visual evidence of muscle wasting</li> <li>• Physical exam</li> <li>• CT scan*             <ul style="list-style-type: none"> <li>• What findings lead you to conclude there is wasting?</li> </ul> </li> <li>• Ultrasound*             <ul style="list-style-type: none"> <li>• What findings lead you to conclude there is wasting?</li> </ul> </li> <li>• Other, specify: _____</li> </ul> <p>*If your site uses CT or ultrasound to assess muscle and/or fat wasting, please provide the qualitative or quantitative findings from the procedure that you used to determine wasting.</p>
<p><b>Is there other evidence of moderate to severe malnutrition not captured above?</b></p>	<p>Select from Yes and no.</p> <p>If yes, please check all that apply to support other evidence of moderate to severe malnutrition:</p> <ul style="list-style-type: none"> <li>• Refeeding syndrome</li> <li>• Moderate to severe edema</li> <li>• Other, (specify) : _____</li> </ul>
<p><b>Was a calf circumference measurement completed on the right leg?</b></p>	<p>Calf circumference is measured at the largest horizontal circumference of the right leg, with a non-stretchable tape measure. Do not complete the measure on the right leg if the patient has obvious edema or an amputation of the lower limb.</p> <p>If yes, enter the right leg measurement in centimeters (cm).</p> <p>If no, you were unable to measure the right leg, please measure the left leg using the same procedure as noted above and enter the left leg measurement in cm. Indicate reason why right calf not measured.</p>



### Baseline: Nutrition Assessment

<p><b>Did the patient have unintentional weight loss before admission to hospital?</b></p> <p><input type="checkbox"/> Yes → → →</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Do not know</p>	<p>→ If yes:</p> <p><b>What was the % weight loss?</b> _____ %</p> <p><b>Over how many months did the weigh loss occur?</b></p> <p><input type="checkbox"/> 1 month      <input type="checkbox"/> 7 months      <input type="checkbox"/> &gt; 12 months</p> <p><input type="checkbox"/> 2 months      <input type="checkbox"/> 8 months</p> <p><input type="checkbox"/> 3 months      <input type="checkbox"/> 9 months</p> <p><input type="checkbox"/> 4 months      <input type="checkbox"/> 10 months</p> <p><input type="checkbox"/> 5 months      <input type="checkbox"/> 11 months</p> <p><input type="checkbox"/> 6 months      <input type="checkbox"/> 12 months</p>
<p><b>Did the patient have less than required food intake before admission to hospital?</b></p> <p><input type="checkbox"/> Yes → → →</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Do not know</p>	<p>→If yes, was the food intake &lt; 50% of needs?</p> <p><input type="checkbox"/> Yes → <b>Was the food intake reduced for:</b></p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> 1 week</p> <p><input type="checkbox"/> 2 weeks</p> <p><input type="checkbox"/> &gt;2 weeks</p> <p><input type="checkbox"/> Do not know</p>
<p><b>Does the patient have chronic absorption?</b></p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Do not know</p>	
<p><b>Does the patient have moderate/severe fat and/or muscle wasting?</b></p> <p><input type="checkbox"/> Yes →If yes, please check the box(es) below for the evidence used to make this assessment.</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Do not know</p> <p><b>Moderate/severe fat and/or muscle wasting as evidenced by: (select all that apply)</b></p> <p><input type="checkbox"/> Visual evidence of fat wasting</p> <p><input type="checkbox"/> Visual evidence of muscle wasting</p> <p><input type="checkbox"/> Physical exam</p> <p><input type="checkbox"/> CT scan → → What findings lead you to conclude there is wasting? _____</p> <p><input type="checkbox"/> Ultrasound → → What findings lead you to conclude there is wasting? _____</p> <p><input type="checkbox"/> Other, specify findings: _____</p>	
<p><b>Is there other evidence of moderate to severe malnutrition not captured above?</b></p> <p><input type="checkbox"/> Yes →If yes, please check the box(es) below for the evidence used to make this assessment. (select all that apply)</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Refeeding syndrome</p> <p><input type="checkbox"/> Moderate to severe edema</p> <p><input type="checkbox"/> Other, specify: _____</p>	
<p><b>Was a calf circumference measurement completed on the right leg?</b></p> <p><input type="checkbox"/> Yes, Right leg: _____ cm</p> <p><input type="checkbox"/> No, specify reason: _____ (edema; lower leg amputation)</p> <p><b>Was a calf circumference measurement completed on the left leg?</b></p> <p><input type="checkbox"/> Yes, Left leg: _____ cm</p> <p><input type="checkbox"/> No, specify: _____ (edema; lower leg amputation)</p>	



## Baseline: Nutrition Assessment: Clinical Frailty Score (CFS) (inclusion criteria 2c)

This questionnaire will help us further understand the patient's level of fitness or frailty and will be an important subgroup analysis in this trial. The study team member screening the patient will complete this questionnaire with the closest family member or, if possible, by collecting the data directly from the patient later on after they recover.

We stress that we need this scale recorded on all patients, not just those meeting this inclusion criteria. So it can be done prior to randomization (if part of the inclusion criteria) or after randomization if they are eligible using some other inclusion criteria.

The scale should be completed by considering the participant's overall condition from prior to getting sick and coming to hospital (within 2 weeks prior to the current hospitalization).









The interviewer should:

- Show the family member the pictures on the questionnaire. Read them the accompanying text for each category.
- The family member should then choose the one that most closely represents the patient's overall condition within two weeks prior to their current hospital admission.
  - If the family member is not sure if that is the best category for the participant, read them the text for the categories above and below it.
  - If they are cannot decide between 2 categories, select the category the represents the higher level of function.

## Baseline: Nutrition Assessment: Clinical Frailty Scale

Please consider the participant's overall condition 2 weeks *prior to this admission to hospital*.

How fit or frail was she/he at that time point? **Check one response only.** If you have trouble deciding between two options, choose the higher functioning level.

		Description
<input type="checkbox"/>		<p><b>Very Fit (category 1)</b></p> <p>People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.</p>
<input type="checkbox"/>		<p><b>Well (category 2)</b></p> <p>No active disease symptoms but less fit than people in category 1. Often, they exercise or are very active occasionally, e.g. seasonally.</p> <p>Well older adults share most attributes of the very fit, except for regular, vigorous exercise. Like them, some may complain of memory symptoms, but without objective deficits.</p>
<input type="checkbox"/>		<p><b>Managing Well (category 3)</b></p> <p>Medical problems are well controlled, but people in this category are not regularly active beyond routine walking.</p> <p>Those with treated medical problems who exercise are classed in categories 1 or 2.</p>
<input type="checkbox"/>		<p><b>Vulnerable (category 4)</b></p> <p>Not dependent on others for daily help, but often symptoms limit activities. A common complaint is being "slowed up" and/ or being tired during the day. Many people in this category rate their health as no better than "fair".</p> <p>Memory problems, if present, can begin to affect function (e.g. having to look up familiar recipes, misplacing documents) but usually do not meet dementia criteria. Families often note some withdrawal – e.g. needing encouragement to go to social activities.</p>
<input type="checkbox"/>		<p><b>Mildly Frail (category 5)</b></p> <p>More evident slowing and individuals help needed in "high" activities of daily living (finances, transportation, heavy housework, medications). Mildly frail people might have difficulty with shopping or walking outside alone, meal preparation, and housework. Often, they will have several illnesses and take multiple medications.</p> <p>This category includes people with mild dementia. Their common symptoms include forgetting the details of a recent event, even though they remember the event itself, asking the same question, or telling the same story several times a day and social withdrawal.</p>
<input type="checkbox"/>		<p><b>Moderately Frail (category 6)</b></p> <p>Individuals need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.</p> <p>If a memory problem causes the dependency, often recent memory will be very impaired, even though they seemingly can remember their past life events well.</p>
<input type="checkbox"/>		<p><b>Severely Frail (category 7)</b></p> <p>Completely dependent on others for all or most personal activities of daily living, such as dressing and feeding.</p>
<input type="checkbox"/>		<p><b>Very Severely Frail (category 8)</b></p> <p>Completely dependent, approaching the end of life. Typically, people in this category could not recover from even a minor illness.</p>



## Baseline: Nutrition Assessment: Sarcopenia SARC-F (inclusion criteria 2d)

The SARC-F has been developed as a possible rapid diagnostic test for sarcopenia. This questionnaire will help us further understand the patient's skeletal muscle mass and strength. The study team member screening the patient will complete this questionnaire with the closest family member or, if possible, by collecting the data directly from the patient later on after they recover.

We stress that we need this scale recorded on all patients, not just those meeting this inclusion criteria. So it can be done prior to randomization (if part of the inclusion criteria) or after randomization if they are eligible using some other inclusion criteria.

The scale should be completed by considering the participant's overall condition from prior to getting sick and coming to hospital (within 2 weeks prior to the current hospitalization).

The interviewer should:

- Ask the family member each of the 5 questions, first reading the question, then listing the response options.
- The family member should then choose the one that most closely represents the patient's overall condition within two weeks prior to their current hospital admission.



## Baseline: Nutrition Assessment: SARC-F (inclusion criteria 2c)

**How much difficulty did they have in lifting and carrying 10 pounds?**

- None – 0
- Some – 1
- A lot or unable – 2

**How much difficulty did they have walking across a room?**

- None – 0
- Some – 1
- A lot, use aids or unable – 2

**How much difficulty did they have transferring from a chair or bed?**

- None – 0
- Some – 1
- A lot or unable without help – 2

**How much difficulty did they have climbing a flight of 10 stairs?**

- None – 0
- Some – 1
- A lot or unable – 2

**How many times did they fall in the past year?**

- None – 0
- 1-3 falls – 1
- 4 or more falls – 2



## Baseline: Nutrition Goals (1)

<b>Height</b>	<p>Record height in meters.</p> <p>If unable to obtain “actual” value, use estimated height or height obtained from family member and check the box indicating the data was estimated.</p> <p>Indicate if the patient is a bi-lateral amputee by checking the appropriate box.</p>
<b>Dry Body Weight</b>	<p>Record participant’s dry weight based on pre-ICU actual weight in kilograms.</p> <p>If unable to obtain “actual” value, use estimated weight or weight obtained from family member and check the box indicating the data was estimated.</p>
<b>BMI</b>	<p>When entering data into REDCap™, this BMI value (kg/m<sup>2</sup>) will be calculated for you once height and dry weight are entered.</p>
<b>Post-Randomization Nutritional Goals</b>	
<b>Date of <u>post-randomization</u> nutrition goals assessment:</b>	<p>Enter the date the nutrition goals were determined following the randomization of the patient to a protein target.</p>
<b>Weight used to determine goal calorie requirement (kg)</b>	<p>Record the weight that was used to determine the energy goal calculations for the study (i.e. following the participant’s randomization to a study arm).</p> <p>NOTE: This weight may or may not be different from the dry body weight entered above. This weight will be used to determine energy adequacy (see Daily Nutritional Adequacy form).</p>
<b>Weight used to determine goal protein requirement (kg)</b>	<p>Record the weight that was used to determine the protein goal calculations for the study (i.e. following the participant’s randomization to a study arm).</p> <p>NOTE: This weight may or may not be different from the dry body weight entered above. This weight will be used to determine protein adequacy (see Daily Nutritional Adequacy form).</p>
<b>Goal Calorie Requirement (kcal/day)</b>	<p>Enter the goal kilocalories according to the nutrition assessment. If the requirement is a range, indicate one point in the range or take the midpoint of the range. If nutrition goals are initially reduced (eg. due to refeeding syndrome risk, post-op status, concern with feeding intolerance, etc) do not enter the reduced calorie requirements. Instead, enter the calories that the participant would ideally receive if these issues were not of concern.</p> <p>Eg. Mr.X is a 70 kg man and the RD used an equation of 25 kcal/kg/d to calculate calorie requirements and 1.2 g/kg/d to calculate protein requirements. This equates to 1750 kcal/d and 84 g protein/d. Enter 1750 for the goal calorie requirements.</p>
<b>Precise Goal Protein Requirement (within randomized protein group) (g/day)</b>	<p>Enter the goal for protein, in grams, according to the nutrition assessment. The goal protein requirements must fall within the range the participant was randomized to (<math>\leq 1.2</math> g/kg/d or <math>\geq 2.2</math> g/kg/d). If the requirement is a range, indicate a precise requirement or the midpoint of the range. If nutrition goals are initially reduced (eg. due to refeeding syndrome risk, post-op status, concern with feeding intolerance, etc) , do not enter the reduced protein requirements. Instead, enter the grams of protein the participant would ideally receive if these issues were not of concern.</p> <p>Eg. In the example above for Mr.X, the goal protein requirements would be entered as 84 g.</p>
<b>Was indirect calorimetry used to determine the goal calorie requirement?</b>	<p>If indirect calorimetry was used to determine the goal calorie requirement, indicate yes.</p> <p>Note: you will be prompted to enter the date(s) indirect calorimetry was performed on the Hospital Outcomes form (page 65.)</p>





## Baseline: Nutrition Goals (2)

Initiation of Nutrition Therapy	
For both enteral nutrition (EN) and parenteral nutrition (PN) enter the start and stop dates.	
When was [EN and/or PN] first initiated?	Indicate when EN and PN was first initiated, either before this ICU admission, during the first 28 days of ICU admission (include date and time) or not initiated during the first 28 days of this ICU admission.
When was [EN and/or PN] discontinued?	If EN or PN were started either prior to ICU admission or in ICU, indicate whether they stopped in ICU during first 28 days (include date and time), or indicate that the participant was still receiving EN or PN in ICU after study day 28.
What was the nutrition delivery technique recommended by physician or dietitian at initial assessment for enteral nutrition?	<p>Choose one option from the list which best describes the delivery technique recommended by the physician or dietitian at the initial order of nutrition. This means if an assessment was completed before randomization that is the one that should be used.</p> <p>Select <u>one</u> of the following:</p> <ul style="list-style-type: none"> <li>• <b>Initiate EN: start at low rate and progress to hourly goal rate</b> Eg. Start at 25 ml/hr and increase to 50 ml/hr then 75 ml/hr (hourly goal rate)</li> <li>• <b>Initiate EN: start at OR progress to 24 hr Volume Goal Based hourly rate</b> Hourly rate is determined by 24hr volume goal. This includes the following scenarios: <ul style="list-style-type: none"> <li>• Starting at lower rate on Day 1 and progressing to 24 hr volume based hourly rate. Eg. 24 hr volume goal = 1800 mls (75 ml/hr) and feeds start at 25 ml/hr Day 1 and then progress to full goal volume OR</li> <li>• Starting at full rate on Day 1 as determined by the 24 hr volume. Eg. 24 hr volume goal = 1800 ml (75ml/hr) and feeds start at 75 ml/hr</li> </ul> </li> <li>• <b>Initiate EN: start at hourly goal rate</b> Eg. Pt requires 75 ml/hr and feeding starts at 75 ml/hr</li> <li>• <b>Initiate EN: keep at low rate (trophic feed: no progression)</b> Eg. Start at 10 ml/hr and leave as is</li> <li>• <b>Initiate EN: bolus feeds</b> Eg. Pt requires 75 ml/hr and starts with boluses of 450 ml q 6 hours.</li> <li>• <b>Keep Nil Per Os or Nil By Mouth</b></li> <li>• <b>Oral nutrition</b></li> <li>• <b>Parenteral Nutrition</b></li> </ul>



## Baseline: Nutrition Goals (2)

<p><b>Height (meters):</b> _____</p> <p><b>How was height determined?</b> <input type="checkbox"/> Actual   <input type="checkbox"/> Estimated</p> <p><b>Is the patient a bi-lateral leg amputee?</b> <input type="checkbox"/> Yes</p>	<p><b>Dry Body Weight (kg):</b> _____</p> <p><b>How was weight determined?</b> <input type="checkbox"/> Actual   <input type="checkbox"/> Estimated</p>
<p>BMI (Automatically Calc'd): _____ kg/m<sup>2</sup></p>	

### Determining Nutrition Goals (Post-randomization)

<p><b>Date of post-randomization nutrition goal assessment ( YYYY-MM-DD):</b> _____</p>	
<p>Weight used to determine <b>goal calorie</b> requirement: _____ kg</p>	<p><b>Goal Calorie Requirement:</b> _____ kcal/day</p> <p><b>Was indirect calorimetry used to determine the goal calorie requirement?</b> <input type="checkbox"/> Yes → (Calorimetry data on the outcome form – page 65). <input type="checkbox"/> No</p>
<p>Weight used to determine <b>goal protein</b> requirement: _____ kg</p>	<p><b>Precise Goal Protein Requirement:</b> _____ g/day</p>



## Baseline: Nutrition Goals (2)

Initiation of Nutrition Therapy	
<u>Enteral Nutrition</u>	
<p><b>When was EN first initiated?</b></p> <p><input type="checkbox"/> EN initiated prior to ICU admission</p> <p><input type="checkbox"/> EN initiated during first 28 days in ICU:  <b>Date</b> (YYYY-MM-DD): _____  <b>Time</b> (HH:MM, 24h): _____</p> <p><input type="checkbox"/> EN not initiated during first 28 days in ICU</p>	<p><b>When was EN discontinued?</b></p> <p><input type="checkbox"/> EN discontinued during first 28 days in ICU:  <b>Date</b> (YYYY-MM-DD): _____  <b>Time</b> (HH:MM, 24h): _____</p> <p><input type="checkbox"/> Still receiving EN in ICU after study day 28</p>
<u>Parenteral Nutrition</u>	
<p><b>When was PN first initiated?</b></p> <p><input type="checkbox"/> PN initiated prior to ICU admission</p> <p><input type="checkbox"/> PN initiated during first 28 days in ICU:  <b>Date</b> (YYYY-MM-DD): _____  <b>Time</b> (HH:MM, 24h): _____</p> <p><input type="checkbox"/> PN not initiated during first 28 days in ICU</p>	<p><b>When was PN discontinued?</b></p> <p><input type="checkbox"/> PN discontinued during first 28 days in ICU:  <b>Date</b> (YYYY-MM-DD): _____  <b>Time</b> (HH:MM, 24h): _____</p> <p><input type="checkbox"/> Still receiving PN in ICU after study day 28</p>
<p>What was the delivery technique recommended by the physician or dietitian at the initial assessment for enteral nutrition? (check <u>one</u> of the following)</p> <p><input type="checkbox"/> Initiate EN: start at low rate and progress to hourly goal rate</p> <p><input type="checkbox"/> Initiate EN: start at or progress to 24hr volume goal based hourly rate</p> <p><input type="checkbox"/> Initiate EN: start at hourly goal rate</p> <p><input type="checkbox"/> Initiate EN: keep at low rate (trophic feeds: no progress)</p> <p><input type="checkbox"/> Initiate EN: bolus feed</p> <p><input type="checkbox"/> Keep Nil Per Os (NPO) or Nil By Mouth</p> <p><input type="checkbox"/> Oral nutrition</p> <p><input type="checkbox"/> Parenteral Nutrition</p>	



## Daily Data: Daily Nutrition Data (1)

<p><b>NPO because participant palliating or receiving comfort measures only today?</b></p>	<p>Day 1 only please see page 41 and follow instructions for indicating units of the biochemistry tests collected.</p> <p>Indicate, 'yes' if the participant is NPO because of palliation or comfort measures for the entire day (i.e. 24h). These are participants who may be undergoing a process of withdrawal of life-sustaining treatments, may be actively dying, or in whom nutrition therapy is not indicated and we don't need to capture the nutrition processes of care.</p> <p>If 'yes,' no further data is required to be entered on this form for this day.</p>
<p><b>Did the protein goal change to a target outside the range specified by the randomization group?</b></p>	<p>We are not asking about protein intake that does not meet the goal. We are asking about a change to the protein prescription since the participant was randomized to a protein group.</p> <p>For example, was there a clinical reason for why the participant could not remain on their randomized protein goal?</p> <p>If 'yes,' there is a change to the protein from the randomization group, specify the reason for this change from the list provided.</p> <p>(No longer critically ill; New onset of ARDS; Worsening renal function; Improved renal function; Starting dialysis; New wound (non-surgical); New surgical wound; Negative nitrogen balance; Increased protein losses (e.g. increased ostomy output; pleural fluid drainage, etc); Other, specify)</p>
<p><b>Was any nutrition received orally/by mouth?</b></p>	<p>Each study day, indicate whether or not the participant received any nutrition orally/by mouth.</p> <p>NOTE: Data on calories and protein from oral nutrition are not collected.</p>
<p><b>Was morning blood glucose measured?</b></p> <p>(closest to 8am)</p>	<p>If 'yes', record the blood sugar reading closest to 08:00 hrs. This can be either serum or capillary. If serum and capillary levels are completed at the same time or if 2 measurements are equidistant to 08:00 hrs, record the highest blood glucose reading.</p> <p>If no blood sugars were recorded that day, indicate 'no'.</p>
<p><b>Did the participant have a hypoglycemic event today?</b></p> <p>(&lt;3.5mmol/L or &lt;63 mg/dL)</p>	<p>A hypoglycemic event is defined as a glucose level of &lt;3.5mmol/L (&lt;63mg/dL).</p> <p>If 'yes', record the blood sugar value, including units. You may record up to 3 episodes per day. If there were more than 3 hypoglycemic events in one day, record the lowest 3 blood glucose values.</p> <p>If a glucose was treated and the hypoglycemic event was not &lt;63mg/dL then do not record this as an event.</p>



## Daily Data: Daily Nutrition Data (2)

<p><b>Propofol</b> (continuous infusion ≥ 6 hours)</p>	<p>If the participant receives a <u>continuous</u> infusion of propofol ≥ 6 hours, record the total volume administered in millileters (mL). Select 'no' if propofol was NOT given, or if provided intermittently, or if continuous &lt; 6 hours.</p>
<p><b>Highest Creatinine</b></p>	<p>Record the highest creatinine measured this day. If not done on a particular day, use the 'Not Available' checkbox.</p> <p><b>On day 1 only</b>, indicate the units creatinine is measured in. The units you indicate on day 1 will represent the units creatinine is measured in for the duration of data collection.</p>
<p><b>Highest Urea/BUN</b></p>	<p>Record the highest urea/BUN measured this day. If not done on a particular day, use the 'Not Available' checkbox.</p> <p><b>On day 1 only</b>, indicate the units urea/BUN is measured in. The units you indicate on day 1 will represent the units urea is measured in for the duration of data collection.</p>
<p><b>Lowest Phosphate</b></p>	<p>Record the lowest serum phosphate (PO<sub>4</sub>) measured this day. If not done on a particular day, use the 'Not Available' checkbox.</p> <p><b>On day 1 only</b>, indicate the units PO<sub>4</sub> is measured in. The units you indicate on day 1 will represent the units PO<sub>4</sub> is measured in for the duration of data collection.</p>
<p><b>Location of Feeding Tube</b></p>	<p>Choose from the list (gastric, small bowel or none in place) to indicate the location of the feeding tube. This refers to any oro/nasogastric tube inserted for the purpose of enterally feeding the participant. If the position is not confirmed by x-ray or a few days have passed since location was confirmed, give us your guestimate of where the tube is located (best guess given the information you have).</p> <p>If the feeding tube is in 2 locations on a single day, indicate the location it was in for the most amount of time.</p>
<p><b>Did the participant receive any motility agents?</b></p>	<p>Select all motility agents that apply from the list provided.</p> <p>Alizapride, Lesuride, Cinitapride (Cintapro/Pemix), Methylnaltrexon, Domperidone, Metoclopramide, Erythromycin, Naloxone, Itopride (Ganaton), Other specify.</p> <p>You do not need to record the route or dose. If the participant has been prescribed combination therapy, select all motility agents the participant received on that day.</p>
<p><b>Definition of Motility Agent</b></p> <p>A drug which enhances gastric emptying and/or gastrointestinal motility by increasing the frequency and/or strength of contractions in the gastrointestinal tract.</p> <p><b>This does not include stool softeners or laxatives such as lactulose or herbal remedies.</b></p>	



effort study

## Daily Data: Daily Nutrition Data (1)

Study ID # \_\_\_\_\_

Study Day:	1	2	3	4	5	6	7	8	9	10	11	12
<b>ICU Admit</b>												
NPO because palliating or comfort measures?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
If you have indicated "Yes", no more data is needed to be entered today.												
Did the protein goals change from the randomization group?	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No
Enter all reasons why 'yes' using the taxonomy shaded in gray below:												
<b>If yes, use the taxonomy to indicate the reasons why the protein goal changed from the randomized group. Enter this information above.</b>												
(1) No longer critically ill; (2) New onset of ARDS; (3) Worse renal; (4) Improved renal; (5) start dialysis; (6) New wound; (7) New surgical wound; (8) Negative nitrogen balance; (9) Increased protein losses												
Was nutrition received orally/by mouth?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
Blood glucose (closest to 8am)	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
Hypoglycemic event? (<3.5mmol/L or <63 mg/dL)												
Record blood glucose values, up to 3.												



## Daily Data: Daily Nutrition Data (2)

Study ID # \_\_\_\_\_

Study Day:	1	2	3	4	5	6	7	8	9	10	11	12
<b>ICU Admit</b>												
<b>Propofol (≥ 6 hours)</b> If yes: Amount given (mL): _____	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
<b>Highest Creatinine</b> Units: <input type="checkbox"/> μmol/L <input type="checkbox"/> mg/dL	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A
<b>Highest Urea/BUN</b> Units: <input type="checkbox"/> mmol/L <input type="checkbox"/> mg/dL	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A
<b>Lowest Phosphate</b> Units: <input type="checkbox"/> mmol/L <input type="checkbox"/> mg/dL	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A
<b>Location of Feeding Tube: (Select one)</b> G = gastric; SB = small bowel; N = No tube	<input type="checkbox"/> G <input type="checkbox"/> SB <input type="checkbox"/> N	<input type="checkbox"/> G <input type="checkbox"/> SB <input type="checkbox"/> N	<input type="checkbox"/> G <input type="checkbox"/> SB <input type="checkbox"/> N	<input type="checkbox"/> G <input type="checkbox"/> SB <input type="checkbox"/> N	<input type="checkbox"/> G <input type="checkbox"/> SB <input type="checkbox"/> N	<input type="checkbox"/> G <input type="checkbox"/> SB <input type="checkbox"/> N	<input type="checkbox"/> G <input type="checkbox"/> SB <input type="checkbox"/> N	<input type="checkbox"/> G <input type="checkbox"/> SB <input type="checkbox"/> N	<input type="checkbox"/> G <input type="checkbox"/> SB <input type="checkbox"/> N	<input type="checkbox"/> G <input type="checkbox"/> SB <input type="checkbox"/> N	<input type="checkbox"/> G <input type="checkbox"/> SB <input type="checkbox"/> N	<input type="checkbox"/> G <input type="checkbox"/> SB <input type="checkbox"/> N
<b>Motility Agents</b>  If yes, enter <u>all</u> received using the taxonomy shaded in gray below.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
<b>If yes, use the taxonomy to indicate all motility agents received. Enter this information above.</b> (1) Alizapride; (2) Cinitapride; (3) Cisapride; (4) Domperidone; (5) Erythromycin; (6) Itopride; (7) Lesuride; (8) Methylnaltrexone; (9) Metoclopramide; (10) Mosapride; (11) Naloxone; (12) Other, specify: _____												



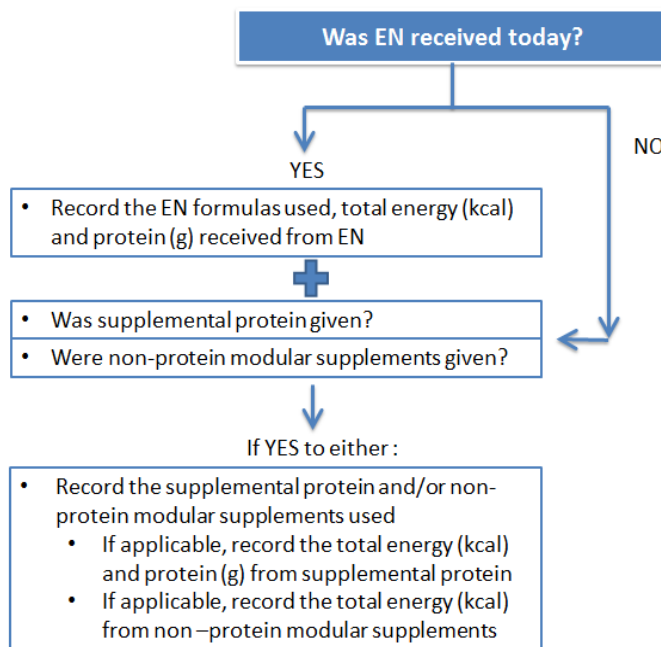
## Daily Data: Daily Enteral Nutrition Data (1)

**REMEMBER: If the participant is receiving a combination of EN and PN, only the calories/protein from EN are recorded on this form. The Daily IV Nutrition Data form will be used to record the data for PN.**

EXCEPTION: Protein received is the only daily data collection that extends past ICU day 12. Continue to collect this data until ICU day 28, ICU discharge or death, whichever comes first. Data to be collected on CRF *Daily Protein Data: Days 13-28* for data entry after day 12.

Note: record calories/protein from formulas, protein supplements, and other supplements **separately**.

The following diagram illustrates the data required depending on the whether the participant received EN or not on a given day. The instructions regarding each type of data field follow.



<p><b>Was enteral nutrition received?</b></p>	<p>Each study day, indicate whether or not the participant received EN. If 'yes', record the EN formula(s) used, total energy and protein received from EN.</p>
<p><b>EN Formula(s)</b></p>	<p>Refer to the taxonomy in REDCap™ to record enteral formula(s) received. You may specify up to 3 formulas per day. If the participant received more than 3 formulas in a day, select the 3 that provided the largest volumes but account for all calories and protein the participant received from EN. If, on any of the first 12 days in ICU, you indicate a formula which is not found in the EN formula taxonomy be sure to specify:</p> <ul style="list-style-type: none"> <li>• company and product name</li> <li>• If the product is polymeric</li> <li>• If the product contains supplemental glutamine (&gt; 10 g/L) in addition to the glutamine found naturally in the product</li> <li>• If the product contains supplemental arginine (&gt; 4.5 g/L) in addition to the arginine found naturally in the product</li> <li>• If the product contains fish oils</li> </ul> <p><i>Note:</i> If you cannot calculate the kcal and protein provided by a formula (e.g. congee, rather than a formula manufactured by a company) this would <b>not</b> be considered EN.</p>





## Daily Data: Daily Enteral Nutrition Data (2)

<b>Kilocalories received from EN</b>	<p>The total calories (kcal) from EN formula(s) will need to be calculated by the dietitian daily as follows:</p> <ul style="list-style-type: none"> <li>• Include calories from protein</li> <li>• <b>Do NOT</b> include calories from other supplements</li> <li>• <b>Do NOT</b> include calories from propofol or other IV solutions <ul style="list-style-type: none"> <li>○ Calories from propofol are to be recorded on the Daily Nutrition Data form.</li> </ul> </li> </ul> <p>Include calories from all EN formulas, even if the participant received nutrition from &gt;3 formulas/day</p>
<b>Protein received from EN</b>	<p>Total protein (g) will need to be calculated by the dietitian daily as follows:</p> <ul style="list-style-type: none"> <li>• <b>Do NOT</b> include protein from additional non-protein supplements</li> <li>• <b>Do NOT</b> include protein from glutamine supplements</li> <li>• Include protein from all EN formulas, even if the participant received nutrition from &gt;3 formulas/day</li> </ul>
<b>Protein Supplements</b>	
<p><b><i>Definition of Modular Protein Supplement</i></b></p> <p>A concentrated protein source. This does not include high-protein enteral formulas. High-protein formulas (that also have lipid, carbohydrate and micronutrient components) should be specified under the EN Formula section.</p>	
<b>Was supplemental protein given?</b>	<p>Indicate yes or no for whether or not a modular protein supplement was given. If yes, refer to the taxonomy in REDCap™ to record what supplement was given. If more than one supplement was given, select the one that provided the largest amount of protein.</p> <ul style="list-style-type: none"> <li>• Do not record glutamine supplements here.</li> </ul>
<b>Kilocalories received from Supplemental Protein</b>	<p>If the participant received a modular protein supplement, indicate total calories received (kcal) from the modular protein supplement (i.e. include calories from protein).</p> <ul style="list-style-type: none"> <li>• Include calories from all modular protein supplements</li> </ul>
<b>Protein received from Supplemental Protein</b>	<p>If the participant received a modular protein supplement, indicate the protein received (g) from the modular protein supplement.</p> <ul style="list-style-type: none"> <li>• Include protein from all modular protein supplements</li> <li>• Do NOT include protein from glutamine supplements</li> </ul>
<p><b><i>Definition of Non-Protein Modular Supplement</i></b></p> <p>Single macronutrients used in addition to enteral formulas. This includes glucose polymers, and fat emulsions. Typically modular supplements do not provide a source of micronutrients.</p>	
<b>Were non-protein modular supplements given?</b>	<p>Indicate yes or no for whether or not non-protein modular supplements were given. If yes, refer to the taxonomy in REDCap™ to record supplement(s) provided. If more than two supplements were given, select the two that provided the largest volumes.</p>
<b>Kilocalories from Other Non-protein Supplements</b>	<p>If the participant received a non-protein modular supplement, indicate calories received (kcal) from the non-protein modular supplement.</p>



## Daily Data: Daily Enteral Nutrition Data (3)

EN Interruption	
<p><b>Definition of EN interruption</b></p>	<p>EN being stopped at any point after it was initiated, with the intent that EN be restarted again. This does not include:</p> <ul style="list-style-type: none"> <li>• Brief or transient (i.e. less than one hour) interruptions for short bedside procedures</li> <li>• For cyclic or bolus feeding, time the participant was never intended to be fed according to the prescribed feeding schedule</li> <li>• Reduction in rate of feeds</li> <li>• Stopping the feeds permanently and transitioning to oral feeds</li> </ul>
<p><b>Was EN Interrupted today?</b></p>	<p>This question is to be answered if the participant received EN at some point during the day but it was stopped for a reason as seen in the definition below. If the participant did NOT receive any feed for the entire day (i.e. 24h), then this question does not need to be answered.</p> <p>Choose “yes” or “no” for whether or not EN was interrupted today.</p> <p>If yes, indicate the total duration of time the EN was interruption. Record in total number of hours and minutes.</p> <p><u>Example 1:</u> EN was initiated at 08:30 on study day 1. EN was stopped at 14:30 for a bedside procedure. EN was started again at 18:30. The time from 00:00 until 08:30 does not constitute an interruption. EN was interrupted from 14:30 until 18:30, which equals 4 hours (240 minutes).</p> <p><u>Example 2:</u> EN was initiated at 08:30 on study day 1. EN was stopped at 14:30. EN was not started again until study day 3 at 04:30, and then there were no further interruptions. EN was interrupted from 14:30 until the end of day 1 (midnight), which equals 9 hours and 30 minutes. On day 2, daily EN data is not completed because the participant did not receive EN. On day 3, midnight until 04:30 does not constitute an interruption, so no interruptions are recorded for day 3.</p> <p>If EN was interrupted, specify all reason(s) that EN was interrupted, by selecting <u>all</u> that apply from the list provided.</p>



# Daily Data: Daily Enteral Nutrition (EN) Data (1)

Study ID # \_\_\_\_\_

Study Day:	1	2	3	4	5	6	7	8	9	10	11	12
<b>ICU Admit</b>												
Was enteral nutrition (EN) received today?	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B
<b>Part A - If yes, EN was received today:</b>												
Record EN formula(s) received:												
Total kilocalories received from EN today:												
Total protein received from EN today: <i>Record in grams (g)</i>												
<b>Part B If no, EN was not received today:</b>												
Supplemental protein? <i>Specify supplement used.</i>	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
Kilocalories received from protein supplement today:												
Protein received from supplements today: <i>(Record in grams (g))</i>												
Non-protein modular supplements? <i>Specify (up to 2):</i>	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
Kilocalories received from other non-protein modular supplements: <i>(Record in grams (g))</i>												



## Daily Data: Daily Enteral Nutrition (EN) Data (2)

Study ID # \_\_\_\_\_

Study Day: **1**   **2**   **3**   **4**   **5**   **6**   **7**   **8**   **9**   **10**   **11**   **12**

ICU Admit

	1	2	3	4	5	6	7	8	9	10	11	12
<b>Was EN interrupted today?</b> If yes, enter the <b>total duration of time</b> interrupted (hours and minutes)	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
<b>If yes, EN was interrupted today:</b>	_____											
<b>Do you know the reason why EN was interrupted today?</b> If yes, select all that apply from the list of reasons for EN interruptions (from list below):	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
<b>Fasting for:</b>	_____											
(1) Endotracheal extubation /intubation /trach procedure;												
(2) Other bedside procedure;												
(3) Operating room procedure;												
(4) Radiology suite procedure;												
(5) Administration of medications;												
<b>Intolerance to enteral feeding:</b>	_____											
(6) high gastric residuals;												
(7) Increased abdominal girth or abdominal distension;												
(8) Vomiting /emesis;												
(9) diarrhea;												
(10) Subjective discomfort;												
(11) Necrotic bowel /gut ischemia;												
(12) No enteral access available /enteral access lost;												
(13) Inotropes, vasopressor requirement;												
(14) Subject deemed too sick to continue enteral feeding;												
(15) Enteral feeding formula not available;												
(16) New contraindication to EN;												
(17) Trial of oral intake;												
(18) NPO b/c subject palliating or receiving comfort measures only												
(19) Other: specify _____												

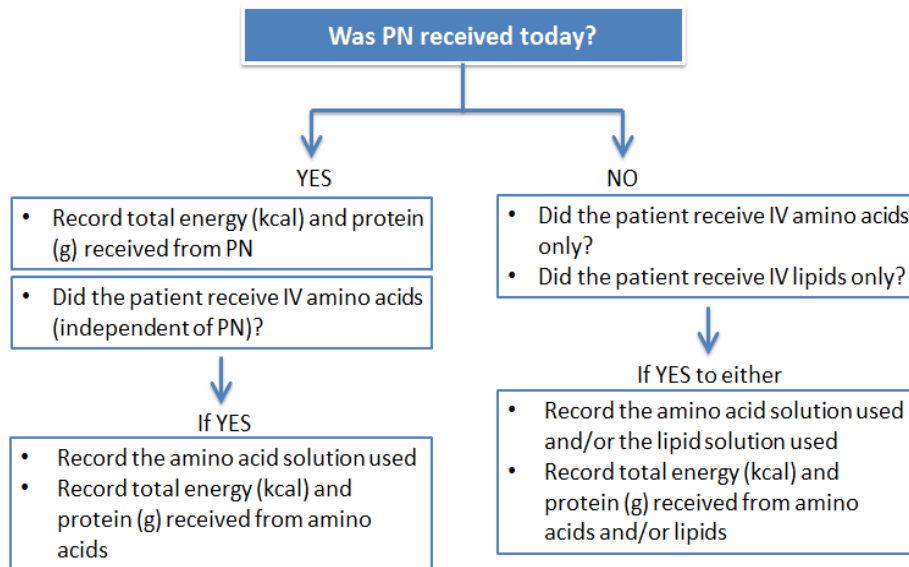


## Daily Data: Daily IV Nutrition Data (1)

**REMEMBER:** If the participant is receiving a combination of EN and PN, only the calories/protein from PN are recorded on this form. The Daily EN Data form will be used to record the data for EN.

EXCEPTION: Protein received is the only daily data collection that extends past ICU day 12. Continue to collect this data until ICU day 28, ICU discharge or death, whichever comes first. Data to be collected on CRF *Daily Protein Data: Days 13-28* for data entry after day 12.

The following diagram illustrates the data required depending on whether the participant received PN or not on a given day. The instructions regarding each type of data field follow.



### Definition of PN

Provision of carbohydrates plus protein and/or lipid, with or without micronutrients, electrolytes or other additives, delivered directly into a vein. Infusion of dextrose alone does **not** constitute parenteral nutrition (ie. If a participant only received dextrose in the absence of amino acids, and lipids you should answer “no” for whether or not the participant received parenteral nutrition).

<b>Was parenteral nutrition (PN) received?</b>	Each study day, indicate whether or not the participant received PN.
<b>Kilocalories received from PN</b>	Total calories received (kcal) will need to be calculated by the dietitian daily as follows: <ul style="list-style-type: none"> <li>• Include calories from parenteral protein</li> <li>• Include calories from other parenteral supplements</li> <li>• Do <b>NOT</b> include calories from enteral formula or modular supplements</li> <li>• Do <b>NOT</b> include calories from propofol as this is to be recorded separately on the Daily Nutrition Data form.</li> <li>• Do <b>NOT</b> include calories from other IV solutions</li> </ul>
<b>Protein received from PN</b>	Total protein will need to be calculated by the dietitian daily as follows: <ul style="list-style-type: none"> <li>• Include protein from parenteral supplements, if applicable</li> <li>• Do <b>NOT</b> include calories from enteral formula or modular supplements</li> <li>• Do <b>NOT</b> include protein from glutamine supplements</li> </ul>



## Daily Data: Daily IV Nutrition Data (2)

<b>Did the participant receive IV amino acids (independent of PN)?</b>	If the participant received PN, indicate if IV amino acids were given in addition to their PN formula> Indicate the solution provided, and protein and kcals received from this solution.
<b>Did the participant receive IV amino acids only?</b>	If the participant received IV amino acids in the absence of dextrose, indicate the solution provided, and protein and kcal received from this solution.
<b>Did the participant receive IV lipids only?</b>	If the participant received IV lipids in the absence of dextrose, indicate the emulsion provided, and kcal received from this product.



## Daily Data: Daily IV Nutrition Data (1)

Study ID # \_\_\_\_\_

Study Day:	1	2	3	4	5	6	7	8	9	10	11	12
ICU Admit												
Was parenteral nutrition (PN) received today?	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B	<input type="checkbox"/> Y → A <input type="checkbox"/> N → B
<b>Part A - If yes, PN was received today:</b>												
Total kilocalories received from PN today:												
Total protein received from PN today: <i>Record in grams (g)</i>												
Did the patient receive IV amino acids (independent of PN)?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
<i>If yes, specify amino acid solution (See PN taxonomy):</i>												
Kilocalories (kcal) received from amino acids:												
Protein (g) received from amino acids:												
<b>Part B - If no, PN was not received today:</b>												
Did the patient receive IV amino acids only? <i>If yes, specify amino acid solution:</i>	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
Kilocalories received from amino acid solution today: (See PN taxonomy)												
Protein received from amino acid solution today: (Record in grams (g))												
Did the patient receive IV lipids only? <i>If yes, specify lipid solution: (See PN taxonomy)</i>	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
Kilocalories received from lipids today: (See PN taxonomy)												





## Daily Data: Daily IV Nutrition Data (2)

Study ID # \_\_\_\_\_

**If on any of the above days a parenteral nutrition formula(s) was/were provided which is/are not found in the provided REDCap taxonomy, specify:**

Company name: \_\_\_\_\_ Product name: \_\_\_\_\_

Lipid type:  olive oil  soybean oil  MCT/LCT physical mixture  MCT/LCT structured form  SMOF  
 fish oil  Other, specify: \_\_\_\_\_





## Daily Data: Daily Protein Data – Day 13-28 (1)

<p><b>NPO because participant palliating or receiving comfort measures only today?</b></p>	<p>Indicate, 'yes' if the participant is NPO because of palliation or comfort measures for the entire day (i.e. 24h). These are participants who may be undergoing a process of withdrawal of life-sustaining treatments, may be actively dying, or in whom nutrition therapy is not indicated and we don't need to capture the nutrition processes of care.</p> <p>If 'yes,' no further data is required to be entered on this form for this day.</p>
<p><b>Did the protein goal change to a target outside the range specified by the randomization group?</b></p>	<p>We are not asking about protein intake that does not meet the goal. We are asking about a change to the protein prescription since the participant was randomized to a protein group.</p> <p>For example, was there a clinical reason for why the participant could not remain on their randomized protein goal?</p> <p>If 'yes,' there is a change to the protein from the randomization group, specify the reason for this change from the list provided.</p> <p>(No longer critically ill; New onset of ARDS; Worsening renal function; Improved renal function; Starting dialysis; New wound (non-surgical); New surgical wound; Negative nitrogen balance; Increased protein losses (e.g. increased ostomy output; pleural fluid drainage, etc); Other, specify)</p>
<p><b>Was enteral nutrition received?</b></p>	<p>Each study day, indicate whether or not the participant received EN.</p> <p>If 'yes', record the EN formula(s) used, total energy and protein received from EN.</p>
<p><b>Protein received from EN</b></p>	<p>Total protein (g) will need to be calculated by the dietitian daily as follows:</p> <ul style="list-style-type: none"> <li>• Do NOT include protein from additional non-protein supplements</li> <li>• Do NOT include protein from glutamine supplements</li> <li>• Include protein from all EN formulas, even if the participant received nutrition from &gt;3 formulas/day</li> </ul>
<p><b>Was supplemental protein given?</b></p>	<p>Indicate yes or no for whether or not a modular protein supplement was given. If yes, refer to the taxonomy in REDCap™ to record what supplement was given. If more than one supplement was given, select the one that provided the largest amount of protein.</p> <ul style="list-style-type: none"> <li>• Do not record glutamine supplements here.</li> </ul>
<p><b>Protein received from Supplemental Protein</b></p>	<p>If the participant received a modular protein supplement, indicate the protein received (g) from the modular protein supplement.</p> <ul style="list-style-type: none"> <li>• Include protein from all modular protein supplements</li> <li>• Do NOT include protein from glutamine supplements</li> </ul>



## Daily Data: Daily Protein Data – Day 13-28 (2)

<b>Was parenteral nutrition (PN) received?</b>	Each study day, indicate whether or not the participant received PN.
<b>Protein received from PN</b>	Total protein will need to be calculated by the dietitian daily as follows: Include protein from parenteral supplements, if applicable Do <b>NOT</b> include calories from enteral formula or modular supplements Do <b>NOT</b> include protein from glutamine supplements
<b>Did the participant receive IV amino acids (independent of PN)?</b>	If the participant received IV amino acids in addition to their PN formula, indicate the solution provided, and protein and kcal received from this solution.
<b>Did the participant receive IV amino acids only?</b>	If the participant received IV amino acids in the absence of dextrose, indicate the solution provided, and protein and kcal received from this solution.



## Daily Data: Daily Protein Data (1)

Study ID # \_\_\_\_\_

Study Day:	13	14	15	16	17	18	19	20
NPO because subject palliating or receiving comfort measures only today?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
Did the protein goals change from the randomization group?	<input type="checkbox"/> Yes → <input type="checkbox"/> No	<input type="checkbox"/> Yes → <input type="checkbox"/> No	<input type="checkbox"/> Yes → <input type="checkbox"/> No	<input type="checkbox"/> Yes → <input type="checkbox"/> No	<input type="checkbox"/> Yes → <input type="checkbox"/> No	<input type="checkbox"/> Yes → <input type="checkbox"/> No	<input type="checkbox"/> Yes → <input type="checkbox"/> No	<input type="checkbox"/> Yes → <input type="checkbox"/> No
<i>Enter all reasons why 'yes' using the taxonomy shaded in gray below:</i>	_____	_____	_____	_____	_____	_____	_____	_____
Was enteral nutrition (EN) received today?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
If yes, protein received from EN: <i>(Record in grams (g))</i>	_____	_____	_____	_____	_____	_____	_____	_____
Supplemental protein received today?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
If yes, protein received from supplemental protein today: <i>(Record in grams (g))</i>	_____	_____	_____	_____	_____	_____	_____	_____
Was parenteral nutrition (PN) received today?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
If yes, protein received from PN today: <i>(Record in grams (g))</i>	_____	_____	_____	_____	_____	_____	_____	_____
Did the patient receive IV amino acids (independent of PN)?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
If yes, protein received from amino acids today: <i>(Record in grams (g))</i>	_____	_____	_____	_____	_____	_____	_____	_____



## Daily Data: Daily Protein Data (2)

Study ID # \_\_\_\_\_

Study Day:	21	22	23	24	25	26	27	28
NPO because subject palliating or receiving comfort measures only today?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
Did the protein goals change from the randomization group?	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No	<input type="checkbox"/> Yes→ <input type="checkbox"/> No
<i>Enter all reasons why 'yes' using the taxonomy shaded in gray below:</i>	_____	_____	_____	_____	_____	_____	_____	_____
Was enteral nutrition (EN) received today?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
If yes, protein received from EN: (Record in grams (g))	_____	_____	_____	_____	_____	_____	_____	_____
Supplemental protein received today?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
If yes, protein received from supplemental protein today: (Record in grams (g))	_____	_____	_____	_____	_____	_____	_____	_____
Was parenteral nutrition (PN) received today?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
If yes, protein received from PN today: (Record in grams (g))	_____	_____	_____	_____	_____	_____	_____	_____
Did the patient receive IV amino acids (independent of PN)?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
If yes, protein received from amino acids today: (Record in grams (g))	_____	_____	_____	_____	_____	_____	_____	_____



## Daily Data: Nutritional Adequacy (1)

Once you enter nutrition data in the following forms: Baseline Nutrition Assessment, Daily Nutrition, Daily EN Data and Daily PN Data, this form will automatically calculate daily nutritional adequacy. For information purposes the formulas to calculate each of these calculations is found below.

The table below outlines where each data element found within the formula is found within REDCap™.

### Energy

#### Table of Data Elements to Calculate Total Energy (kcal)

Energy Source (Data)	REDCap Name	REDCap Form Where Located
Weight for goal energy	Weight used to determine goal calorie requirement	Nutrition Goals
Goal energy	Goal Calorie Requirement	Nutrition Goals
Propofol	Propofol (continuous infusion ≥ 6h)	Daily Nutrition Form
EN	Total kilocalories received from all EN	Daily EN Data
Protein Supplements (PS)	Kilocalories received from supplemental protein	Daily EN Data
Non-Protein Modular Supplements (NPMS)	Kilocalories received from other non-protein modular supplements	Daily EN Data
PN	Total kilocalories received from PN	Daily IV Nutrition Data
Amino acids (independent)	Kilocalories received from amino acids	Daily IV Nutrition Data
Amino acids (AA) – no PN	Kilocalories received from amino acids	Daily IV Nutrition Data
Lipids – no PN	Kilocalories received from lipids	Daily IV Nutrition Data

### Energy Adequacy (%)

$$\text{ENERGY ADEQUACY (\%)} = \frac{\text{Energy from all nutritional sources (kcal)}}{\text{Energy Goal (kcal)}} \times 100$$

$$\text{ENERGY ADEQUACY (\%)} = \frac{\text{Propofol} + \text{EN} + \text{PS} + \text{NPMS} + \text{PN} + \text{AA} + \text{lipids (kcal)}}{\text{Energy Goal (kcal)}} \times 100$$

### Energy Adequacy (kcal/kg)

$$\text{ENERGY ADEQUACY (kcal/kg)} = \frac{\text{Energy from all nutritional sources (kcal)}}{\text{Weight used to determine goal calories requirement (kg)}}$$

$$\text{ENERGY ADEQUACY (kcal/kg)} = \frac{\text{Propofol} + \text{EN} + \text{PS} + \text{NPMS} + \text{PN} + \text{AA} + \text{lipids (kcal)}}{\text{Weight used to determine goal calories requirement (kg)}}$$



## Daily Data: Nutritional Adequacy (2)

### Protein

#### Table of Data Elements to Calculate Total Protein (g)

Protein Source (Data)	REDCap Name	REDCap Form Where Located
Weight for goal protein	Weight used to determine goal protein requirement	Nutrition Goals
Goal protein	Precise Goal Protein Requirement (within randomized protein group, enter the precise protein goal)	Nutrition Goals
EN	Total protein received from all EN	Daily EN Data
Protein Supplements (PS)	Protein (g) received from supplemental protein	Daily EN Data
PN	Total protein received from PN	Daily IV Nutrition Data
Amino acids (independent)	Protein received from amino acids	Daily IV Nutrition Data
Amino acids (AA) – no PN	Protein received from amino acids	Daily IV Nutrition Data

### Protein Adequacy (%)

$$\text{PROTEIN ADEQUACY (\%)} = \frac{\text{Protein from all nutritional sources (g)}}{\text{Goal Protein (g)}} \times 100$$

$$\text{PROTEIN ADEQUACY (\%)} = \frac{\text{EN + PS + PN + AA (g)}}{\text{Goal Protein (g)}} \times 100$$

### Protein Adequacy (g/kg)

$$\text{PROTEIN ADEQUACY (g/kg)} = \frac{\text{Protein from all nutritional sources (g)}}{\text{Weight used to determine goal protein requirement (kg)}}$$

$$\text{PROTEIN ADEQUACY (g/kg)} = \frac{\text{EN + PS + PN + AA (g)}}{\text{Weight used to determine goal protein requirement (kg)}}$$



## Daily Data: Nutritional Adequacy

Study ID # \_\_\_\_\_

*No data is to be collected on this form.  
This form is a tool you can use to transcribe the calculations found on the REDCap "Daily Nutritional Adequacy" form can be recorded here and used to ensure compliance with the study protocol.*

Study Day:	1	2	3	4	5	6	7	8	9	10	11	12
Energy Adequacy (%)												
Protein Adequacy (%)												
Energy Adequacy (kcal/kg)												
Energy Adequacy (g/kg)												

Study Day:	13	14	15	16	17	18	19	20	21	22	23	24
Energy Adequacy (%)												
Protein Adequacy (%)												
Energy Adequacy (kcal/kg)												
Energy Adequacy (g/kg)												

Study Day:	25	26	27	28
Energy Adequacy (%)				
Protein Adequacy (%)				
Energy Adequacy (kcal/kg)				
Energy Adequacy (g/kg)				



## Vasopressors/Inotropes - Outcomes

**Complete one separate form for each vasopressor/inotrope the patient received.**

Check the box at the top of the form to select the specific vasopressor/inotrope.

Only include continuous infusions of vasopressors, do not include single bolus injections.

**The following data are to be entered into REDCap™ on the Outcomes form.**

<b>Start Date/Time:</b>	Record the date and time the vasopressor or inotrope was initiated.
<b>Stop Date/Time:</b>	<ul style="list-style-type: none"> <li>• If the participant dies while receiving the vasopressor or inotrope, check the appropriate box. REDCap™ will automatically connect this to the date of death you enter.</li> <li>• If the participant was still receiving the vasopressor or inotrope at Day 60, check the appropriate box.</li> </ul>

**Separate Episodes**

The participant is considered free of the vasopressor or inotrope if they remain off the vasopressor or inotrope for **≥ 24 hours**. If the vasopressor or inotrope is re-instituted after 24 hours, this is considered a separate episode, corresponding start and stop dates should be recorded.

**The following data are to be entered into REDCap™ on the vasopressor/inotrope form from Day 1-12.**

<b>Did the participant receive a continuous infusion of vasopressors or inotropes today?</b>	If 'yes,' it was received on a particular day, record the highest hourly infusion rate for the vasopressor/inotrope selected.
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## Daily Data/Outcomes: Vasopressors/Inotropes

Study ID # \_\_\_\_\_

**Complete one form for each vasopressor/inotrope the patient received.**

### Select Vasopressor/Inotrope:

- Phenylephrine (>50µg/min)
- Dobutamine
- Dopamine (>5µg/kg/min)
- Epinephrine
- Vasopressin
- Norepinephrine
- Milrinone
- Levosimendan

	Episode 1	Episode 2	Episode 3	Episode 4	Episode 5
Start Date (YYYY-MM-DD)					
Start Time (HH:MM, 24h)					
Stop Date/Time:					
<input type="checkbox"/> Same as death date/time	<input type="checkbox"/> Death	<input type="checkbox"/> Death	<input type="checkbox"/> Death	<input type="checkbox"/> Death	<input type="checkbox"/> Death
<input type="checkbox"/> Still on vasopressor/inotrope at day 60	<input type="checkbox"/> Day 60	<input type="checkbox"/> Day 60	<input type="checkbox"/> Day 60	<input type="checkbox"/> Day 60	<input type="checkbox"/> Day 60
<input type="checkbox"/> Actual:	<input type="checkbox"/> Actual:	<input type="checkbox"/> Actual:	<input type="checkbox"/> Actual:	<input type="checkbox"/> Actual:	<input type="checkbox"/> Actual:
Stop date: (YYYY-MM-DD):					
Start Time (HH:MM, 24h):					
<b>Was the vasopressor/inotrope re-started ≥ 24 hours from the last stop date/time?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No					
Proceed to enter the details for the next episode. Enter up to 5 episodes, if applicable.					

Study Day:	ICU Admit											
	1	2	3	4	5	6	7	8	9	10	11	12
Did the participant receive a continuous infusion of vasopressors or inotropes today?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
If yes, record the highest hourly infusion rate for each day received.												



## Renal Replacement Therapy

Complete this form if the participant received renal replacement therapy during their hospitalization, until the first of day 60, ICU discharge or death.

The following data are to be entered into REDCap™ on the Outcomes form.

<b>RRT Start Date/Time:</b>	<ul style="list-style-type: none"> <li>If the participant was receiving RRT prior to admission indicate ‘yes.’</li> <li>If the participant did not start RRT until they were hospitalized, record the start date and time.</li> </ul>
<b>RRT Stop Date/Time:</b>	<ul style="list-style-type: none"> <li>Record the date and time RRT stopped.</li> <li>If the participant was still receiving RRT following hospital discharge or at Day 60, check the appropriate box.</li> </ul>

The following data are to be entered into REDCap™ on the renal replacement form from Day 1-12.

<b>Did the participant receive RRT today?</b>	<p>If ‘yes’, specify <u>all</u> modes received during the day (i.e. 24h period):</p> <ul style="list-style-type: none"> <li>Intermittent (IHD)</li> <li>Continuous (CRRT)</li> <li>Sustained low efficiency (SLED)</li> <li>Peritoneal (PD)</li> <li>Other (specify): _____</li> </ul>
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Study ID # \_\_\_\_\_

## Daily Data/Outcomes: Renal Replacement Therapy

	Episode 1	Episode 2	Episode 3	Episode 4	Episode 5
<b>Did the participant receive renal replacement therapy (RRT) during the study?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No					
<b>Start Date/Time:</b>					
<input type="checkbox"/> Started RRT prior to admission to ICU	<input type="checkbox"/> Prior to ICU	<input type="checkbox"/> Prior to ICU	<input type="checkbox"/> Prior to ICU	<input type="checkbox"/> Prior to ICU	<input type="checkbox"/> Prior to ICU
<input type="checkbox"/> Started in the ICU:	<input type="checkbox"/> In ICU:	<input type="checkbox"/> In ICU:	<input type="checkbox"/> In ICU:	<input type="checkbox"/> In ICU:	<input type="checkbox"/> In ICU:
Stop date: (YYYY-MM-DD): _____					
Start Time (HH:MM, 24h): _____					
<b>Stop Date/Time:</b>					
<input type="checkbox"/> Continued past hospital discharge	<input type="checkbox"/> Continued	<input type="checkbox"/> Continued	<input type="checkbox"/> Continued	<input type="checkbox"/> Continued	<input type="checkbox"/> Continued
<input type="checkbox"/> Still on RRT in hospital at day 60	<input type="checkbox"/> Day 60	<input type="checkbox"/> Day 60	<input type="checkbox"/> Day 60	<input type="checkbox"/> Day 60	<input type="checkbox"/> Day 60
<input type="checkbox"/> Actual:	<input type="checkbox"/> Actual:	<input type="checkbox"/> Actual:	<input type="checkbox"/> Actual:	<input type="checkbox"/> Actual:	<input type="checkbox"/> Actual:
Stop date: (YYYY-MM-DD): _____					
Start Time (HH:MM, 24h): _____					

Study Day:	1	2	3	4	5	6	7	8	9	10	11	12
<b>Did the participant receive a RRT today?</b>	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
<b>If yes, specify the mode:</b>	<input type="checkbox"/> IHD <input type="checkbox"/> CRRT <input type="checkbox"/> SLED <input type="checkbox"/> PD <input type="checkbox"/> Other: _____	<input type="checkbox"/> IHD <input type="checkbox"/> CRRT <input type="checkbox"/> SLED <input type="checkbox"/> PD <input type="checkbox"/> Other: _____	<input type="checkbox"/> IHD <input type="checkbox"/> CRRT <input type="checkbox"/> SLED <input type="checkbox"/> PD <input type="checkbox"/> Other: _____	<input type="checkbox"/> IHD <input type="checkbox"/> CRRT <input type="checkbox"/> SLED <input type="checkbox"/> PD <input type="checkbox"/> Other: _____	<input type="checkbox"/> IHD <input type="checkbox"/> CRRT <input type="checkbox"/> SLED <input type="checkbox"/> PD <input type="checkbox"/> Other: _____	<input type="checkbox"/> IHD <input type="checkbox"/> CRRT <input type="checkbox"/> SLED <input type="checkbox"/> PD <input type="checkbox"/> Other: _____	<input type="checkbox"/> IHD <input type="checkbox"/> CRRT <input type="checkbox"/> SLED <input type="checkbox"/> PD <input type="checkbox"/> Other: _____	<input type="checkbox"/> IHD <input type="checkbox"/> CRRT <input type="checkbox"/> SLED <input type="checkbox"/> PD <input type="checkbox"/> Other: _____	<input type="checkbox"/> IHD <input type="checkbox"/> CRRT <input type="checkbox"/> SLED <input type="checkbox"/> PD <input type="checkbox"/> Other: _____	<input type="checkbox"/> IHD <input type="checkbox"/> CRRT <input type="checkbox"/> SLED <input type="checkbox"/> PD <input type="checkbox"/> Other: _____	<input type="checkbox"/> IHD <input type="checkbox"/> CRRT <input type="checkbox"/> SLED <input type="checkbox"/> PD <input type="checkbox"/> Other: _____	<input type="checkbox"/> IHD <input type="checkbox"/> CRRT <input type="checkbox"/> SLED <input type="checkbox"/> PD <input type="checkbox"/> Other: _____



## Mechanical Ventilation

<p><b><i>Definition of Invasive mechanical ventilation</i></b></p> <p>We define invasive mechanical ventilation as any mode of intermittent positive pressure delivered via an oral/nasal tracheal tube or tracheostomy with or without positive end expiratory pressure and high frequency jet ventilation or oscillation.</p>	
<p><b>Ventilation Start Date/Time</b></p>	<p>Record the date and time invasive mechanical ventilation was initiated. If the time is not found in the medical record use the 'Not Available' checkbox in REDCap™.</p>
<p><b>Ventilation Stop Date/Time</b></p>	<p>Indicate when invasive mechanical ventilation was stopped or if still ongoing at day 60, check the 'still vented at day 60' option.</p> <p>Participants will be considered breathing without invasive mechanical ventilation if they are:</p> <ul style="list-style-type: none"> <li>• extubated and on face mask (nasal prong) OR</li> <li>• intubated or breathing through a t-tube OR</li> <li>• tracheostomy mask breathing OR</li> <li>• continuous positive airway pressure (CPAP) <math>\leq</math> 5cm H<sub>2</sub>O without pressure support or intermittent mandatory ventilation assistance.</li> </ul>
<p><b>Mechanical Ventilation Restarted?</b></p>	<p>If the participant is extubated and re-intubated within &lt;24 hours, we consider this the same ventilation event.</p> <p>If the participant is extubated and re-intubated <math>\geq</math> 24 hours, this is considered a new ventilation event and the new start date/time and stop date/time should be recorded. If applicable, up to 5 ventilation events may be entered for each participant.</p>



## Outcomes: Mechanical Ventilation

	Episode 1	Episode 2	Episode 3	Episode 4	Episode 5
<b>Start Date (YYYY-MM-DD):</b>					
<b>Start Time (HH:MM, 24h)</b>	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A
<b>Stop Date/Time:</b>	<input type="checkbox"/> Death <input type="checkbox"/> Day 60 <input type="checkbox"/> Actual:	<input type="checkbox"/> Death <input type="checkbox"/> Day 60 <input type="checkbox"/> Actual:	<input type="checkbox"/> Death <input type="checkbox"/> Day 60 <input type="checkbox"/> Actual:	<input type="checkbox"/> Death <input type="checkbox"/> Day 60 <input type="checkbox"/> Actual:	<input type="checkbox"/> Death <input type="checkbox"/> Day 60 <input type="checkbox"/> Actual:
<input type="checkbox"/> Same as death date/time <input type="checkbox"/> Still vented at day 60 <input type="checkbox"/> Actual:					
<b>Stop date: (YYYY-MM-DD):</b> <b>Start Time (HH:MM, 24h):</b>					
↑					
<p><b>Was the mechanical ventilation stopped then re-started ≥ 24 hours from the last stop date/time?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Proceed to enter the details for the next episode. Enter up to 5 episodes, if applicable.</p>					



## Hospital Outcomes (1)

<p>Complete this form after 60 days from the participant's initial ICU admission or after their death, whichever comes first.</p>	
<b>Was indirect calorimetry used to manage nutrition needs at any point?</b>	<p>If yes, indirect calorimetry was used during the patient's study participation, record the associated dates. Record up to 5 dates.</p>
<b>Was consent withdrawn during this ICU stay?</b>	<p>In the event that consent is withdrawn for the participant during their participation in the study, select 'yes.'</p>
<b>Date/time consent withdrawn:</b>	<p>Record the date and time the subject withdrew their consent to participate in the trial.</p>
<b>Type of withdrawal:</b>	<p>Specify whether the withdrawal of consent refers to the study intervention, data collection or both using the 3 options listed:</p> <ul style="list-style-type: none"> <li>• stop intervention, continue data collection</li> <li>• stop intervention, stop data collection (discard previous data)</li> <li>• stop intervention, stop data collection (keep previous data)</li> </ul>
<b>Reason consent was withdrawn</b>	<p>Indicate a brief reason why consent was withdrawn for this participant.</p>
<b>ICU Stay</b>	<p>Indicate if the participant died in the ICU on their initial admission.</p> <ul style="list-style-type: none"> <li>• If yes, indicate the date and time of death.</li> <li>• If no, they were discharged, indicate the date and time of discharge.</li> </ul> <p>If the participant was readmitted to the ICU.</p> <ul style="list-style-type: none"> <li>• We define readmission as <math>\geq 24</math> hours from ICU discharge. <ul style="list-style-type: none"> <li>• If less than this, consider it the same ICU admission</li> </ul> </li> <li>• If readmitted within 60 days from initial admission, complete the same information for each ICU readmission up to 5 readmissions.</li> </ul> <p>Alternatively, if <u>no</u> <u>and</u> they were still in ICU at day 60, check the appropriate box.</p>
<b>Hospital Discharge</b>	<p>If the participant was alive and discharged from ICU within 60 days, indicate if they died in hospital.</p> <ul style="list-style-type: none"> <li>• If yes, indicate the date and time of death.</li> <li>• If no, they were discharged, indicate the date and time of discharge and where they were discharged to.</li> <li>• Alternatively, if <u>no</u> <u>and</u> they were still in hospital at day 60, check the appropriate box.</li> </ul>
<b>Hospital Re-Admission</b>	<p>If the participant was ever readmitted to hospital within 60 days of their initial ICU admission:</p> <ul style="list-style-type: none"> <li>• We define a hospital readmission as <math>\geq 24</math> hours from hospital discharge <u>and</u> being admitted under an inpatient service. This does not include visits to the emergency room that do not result in the participant being under an inpatient service and in a ward bed.</li> <li>• If readmitted within 60 days from initial admission, complete the same information for each hospital readmission</li> </ul>



## Hospital Outcomes (2)

<p><b>60-day Outcomes</b> <b>**PRIMARY STUDY OUTCOME</b></p>	<p>This is our primary outcome and it is important that we record this accurately.</p> <p><b>On or after day 60 (this date is 60 days from the participant's initial ICU admit date),</b> please make an attempt (using the resources mentioned below) to confirm the participant's survival status:</p> <ul style="list-style-type: none"><li>• If the participant is <b>known to be alive:</b><ul style="list-style-type: none"><li>• Record the date the participant was last known to be alive. This date must be on or after day 60.</li></ul></li><li>• If the participant is <b>deceased:</b><ul style="list-style-type: none"><li>• Record the date of death if known. This date must be prior to day 60. If the date of death is unknown, record the date last known to be alive. This date must be before day 60.</li></ul></li><li>• If the survival status of the participant is <b>unknown:</b><ul style="list-style-type: none"><li>• Record the date the participant was last known to be alive. This date must be before day 60.</li></ul></li></ul> <p>For either response, where appropriate and permissible utilize the resources below to collect this information. Be sure to exhaust all resources in order to accurately capture this data.</p> <ul style="list-style-type: none"><li>• Medical Records – search electronic medical records for evidence of death or evidence is alive (eg. readmission, seen in clinic, procedure done, etc)</li><li>• Home care – if the participant had home care arranged at discharge, contact them to determine if the participant is alive</li><li>• Obituaries – search online obituaries for newspapers in the participant's local area for evidence of death</li><li>• Internet – Google search the participant for documented evidence of death</li><li>• Family Physician – contact the family physician's office to determine if the participant remains alive</li><li>• Facility participant was discharged to – if the participant was discharged to another health care or long term care facility, contact them to determine the participant's survival status.</li></ul>
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# Outcomes: Hospital Outcomes (1)

Study ID # \_\_\_\_\_

<p><b>Was indirect calorimetry used to manage nutrition needs at any point</b></p> <p><input type="checkbox"/> Yes →</p> <p><input type="checkbox"/> No</p>	<p>If yes, record the corresponding dates (up to 5):</p> <p>(1) _____; (2) _____; (3) _____</p> <p>(4) _____; (5) _____</p> <p><input type="checkbox"/> &gt; 5 (please check this box if calorimetry was used more than 5 times over the study period)</p>
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***If using waived consent, this section is not applicable.***

<p><b>Consent withdrawn during ICU stay?</b></p> <p><input type="checkbox"/> Yes →</p> <p><input type="checkbox"/> No</p> <p>↓</p>	<p><b>Date/time consent withdrawn/denied:</b> _____</p> <p><b>Type of withdrawal/denial of consent:</b> _____</p> <p><input type="checkbox"/> stop intervention, continue data collection</p> <p><input type="checkbox"/> stop intervention, stop data collection (discard previous data)</p> <p><input type="checkbox"/> stop intervention, stop data collection (keep previous data)</p>
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ICU Stay #1

Did the patient die during this ICU stay?		
<input type="checkbox"/> Yes ↓	<input type="checkbox"/> No, Patient Discharged ↓	<input type="checkbox"/> No, Patient Still in ICU at 60 days
Death Date/Time:	ICU Discharge Date/Time: →	Was the patient re-admitted to the ICU? <input type="checkbox"/> Yes ↓ <input type="checkbox"/> No

ICU Stay #2

Did the patient die during this ICU stay?		
<input type="checkbox"/> Yes ↓	<input type="checkbox"/> No, Patient Discharged ↓	<input type="checkbox"/> No, Patient Still in ICU at 60 days
Death Date/Time:	ICU Discharge Date/Time: →	Was the patient re-admitted to the ICU? <input type="checkbox"/> Yes ↓ <input type="checkbox"/> No

ICU Stay #3

Did the patient die during this ICU stay?		
<input type="checkbox"/> Yes ↓	<input type="checkbox"/> No, Patient Discharged ↓	<input type="checkbox"/> No, Patient Still in ICU at 60 days
Death Date/Time:	ICU Discharge Date/Time: →	Was the patient re-admitted to the ICU? <input type="checkbox"/> Yes ↓ <input type="checkbox"/> No

ICU Stay #4

Did the patient die during this ICU stay?		
<input type="checkbox"/> Yes ↓	<input type="checkbox"/> No, Patient Discharged ↓	<input type="checkbox"/> No, Patient Still in ICU at 60 days
Death Date/Time:	ICU Discharge Date/Time: →	Was the patient re-admitted to the ICU? <input type="checkbox"/> Yes ↓ <input type="checkbox"/> No

ICU Stay #5

Did the patient die during this ICU stay?		
<input type="checkbox"/> Yes ↓	<input type="checkbox"/> No, Patient Discharged ↓	<input type="checkbox"/> No, Patient Still in ICU at 60 days
Death Date/Time:	ICU Discharge Date/Time: →	Was the patient re-admitted to the ICU? <input type="checkbox"/> Yes ↓ <input type="checkbox"/> No





## Outcomes: Hospital Outcomes (2)

<b>Did the patient die during this Hospital stay?</b>		
<input type="checkbox"/> Yes ↓	<input type="checkbox"/> No, Patient Discharged ↓	<input type="checkbox"/> No, Patient still in Hospital at 60 days
<b>Death Date/Time:</b>	<b>Hospital Discharge Date/Time:</b> →	<b>Discharged to:</b> ↓ <input type="checkbox"/> Ward in another hospital <input type="checkbox"/> ICU in another hospital <input type="checkbox"/> Long term care facility <input type="checkbox"/> Rehabilitation Unit <input type="checkbox"/> Home with home care support <input type="checkbox"/> Home without home care <input type="checkbox"/> Other _____
<b>Was the patient re-admitted to hospital?</b> <input type="checkbox"/> Yes ↓ <input type="checkbox"/> No		

<b>Hospital Re-Admission #1 Date/Time:</b>		
<b>Did the patient die during this Hospital stay?</b>		
<input type="checkbox"/> Yes ↓	<input type="checkbox"/> No, Patient Discharged ↓	<input type="checkbox"/> No, Patient still in Hospital at 60 days
<b>Death Date/Time:</b>	<b>Hospital Discharge Date/Time:</b> →	<b>Discharged to:</b> ↓ <input type="checkbox"/> Ward in another hospital <input type="checkbox"/> ICU in another hospital <input type="checkbox"/> Long term care facility <input type="checkbox"/> Rehabilitation Unit <input type="checkbox"/> Home with home care support <input type="checkbox"/> Home without home care <input type="checkbox"/> Other _____
<b>Was the patient re-admitted to hospital?</b> <input type="checkbox"/> Yes ↓ <input type="checkbox"/> No		

<b>Hospital Re-Admission #2 Date/Time:</b>		
<b>Did the patient die during this Hospital stay?</b>		
<input type="checkbox"/> Yes ↓	<input type="checkbox"/> No, Patient Discharged ↓	<input type="checkbox"/> No, Patient still in Hospital at 60 days
<b>Death Date/Time:</b>	<b>Hospital Discharge Date/Time:</b> →	<b>Discharged to:</b> ↓ <input type="checkbox"/> Ward in another hospital <input type="checkbox"/> ICU in another hospital <input type="checkbox"/> Long term care facility <input type="checkbox"/> Rehabilitation Unit <input type="checkbox"/> Home with home care support <input type="checkbox"/> Home without home care <input type="checkbox"/> Other _____
<b>Was the patient re-admitted to hospital?</b> <input type="checkbox"/> Yes ↓ <input type="checkbox"/> No		



### Outcomes: Hospital Outcomes (3)

Study ID #

<b>What is the survival status of the patient on or after Day 60?</b>		
<input type="checkbox"/> Alive ↓	<input type="checkbox"/> Deceased ↓	<input type="checkbox"/> Unknown ↓
<b>Date last known to be alive:</b>	<b>Date of death known:</b> ↓ Yes <b>Date of death:</b>	↓ <b>Date last known to be alive:</b>
	↓ No <b>Date last known to be alive:</b>	

Data Collection for this patient is now complete.