Study ID #

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

Version: 25-September-2019

effort study

Study ID #

Table of Contents

effort study

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	❑														
Exclusion	❑														
Pre-Randomization	❑														
Randomization	❑														
Patient Information		❑													
Conditions at Enrollment		❑													
SOFA Score		❑													
Nutrition Assessment		❑													
Nutrition Goals		❑													
Daily Nutrition Data		❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑		
Daily EN Data		❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑		
Daily IV Nutrition		❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑		
Daily Protein Data														❑	
Daily Nutritional Adequacy *(automatically calculated)*		❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	
Vasopressors/Inotropes		❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑		❑
Mechanical Ventilation															❑
Renal Replacement Therapy (RRT)		❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑		❑
Hospital Outcomes															❑

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'.

7. 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)

General Instructions	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.
STEP 1: Confirm Subject Eligibility	If eligible, the patient must be randomized to the trial within 96h of admission to your ICU.
Inclusion Criteria	**1. ≥ 18 years old.** **2. Have one or more of the following risk factors that make them a high nutritional risk.** 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. ***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. 32-35).*** (a) Low (≤25) or high BMI (≥35) (b) Moderate to severe malnutrition (as defined by local assessments). (Refer to pages 30-31, for information that will be collected). (c) Frailty (Clinical Frailty Scale of 5 or more from proxy). (Refer to pages 32-33, for information that will be collected). (d) Sarcopenia (SARC-F score of 4 or more from proxy). (Refer to pages 34-35, for information that will be collected). (e) From point of screening, projected duration of mechanical ventilation >4 days. **3. Requiring mechanical ventilation with actual or expected total duration > 48 hours from time of screening.** 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. 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. Also, if the patient received ≥ 48h 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. 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.

Screening/Randomization: Patient Eligibility (2)

Exclusion Criteria	**1. > 96 continuous hours of mechanical ventilation before screening.** 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. **2. Expected death or withdrawal of life-sustaining treatments within 7 days from screening.** 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 very high likelihood or 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 (>50%) of not surviving the next 7 days should be excluded. **3. Pregnant.** We don't know the safety of high protein on the fetus. Post-partum and lactating patients are permitted. **4. The responsible clinician feels that the patient either needs low or high protein** If this is the case, we require an understanding of the clinician's reasons. From the options on the form, check all that apply. **5. Patient requires parenteral nutrition only and site does not have products to reach the high protein dose group.**
STEP 2: Is the subject eligible for the study?	Confirm the eligibility of the patient with one of the study leaders. Document this confirmation in the form.

effort study

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. ≥ 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 (≤25) or High BMI (≥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 ≥ 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	

effort study

Screening/Randomization: Patient Eligibility (2)

Study ID #

STEP 2: Is the subject eligible for the study?	
Yes, the subject is eligible for the study. Engage the investigator for confirmation of eligibility and appropriateness to proceed with consent. Document dialogue with investigator. Enter name of investigator Proceed to next steps below.	No, the subject is not eligible for the study. Enter the subject into REDCap™, including the exclusion criteria that were present. STOP - No further action required.

To ensure it is medically appropriate for the patient to be enrolled in the study, it is necessary to review eligibility of the patient with a physician . This can be the site investigator or the attending physician responsible for the care of the patient.

Study eligibility was discussed with Dr. _____on _____ at _____.
physician name date time

❑ This patient meets all inclusion criteria and no exclusion criteria and is eligible to participate.

❑ This patient is NOT eligible to participate.

Screening/Randomization: Study Group Assignment

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

The participant has been randomized to a study treatment group. Record the assigned study treatment group on the CRF Worksheet.

Nutrition Prescription	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.
Protein Target	**Usual Protein Dose** ≤ 1.2 g/kg/day OR **Higher Protein Dose** ≥ 2.2 g/kg/day In both groups: • Targets will be set using pre-ICU dry actual weight. • For participants with BMI >30, ideal body weight based on a BMI of 25 will be used. **The protein target should be followed daily for each randomized patient until the first of:** • ICU Discharge* • Death • Transition to oral feeds • Day 28 **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.*

Calorie Target	Caloric goals should be the same in both groups and we recommend sites follow the SCCM/ASPEN clinical practice guidelines (McClave JPEN 2016).
	• For non-obese participants, we suggest that their caloric prescription be around 20-25 kcal/kg/day.
	  • If the site choses to use more sophisticated equations or indirect calorimetry, that is permissible.
	• 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.
	  • 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 > 50.

The study team should make every effort to ensure that the patient receives at least 80% of their protein and calorie targets each day.

**REDCap™ has a built-in Daily Nutritional Adequacy tool to help you monitor this. **

Screening/Randomization: Study Group Assignment

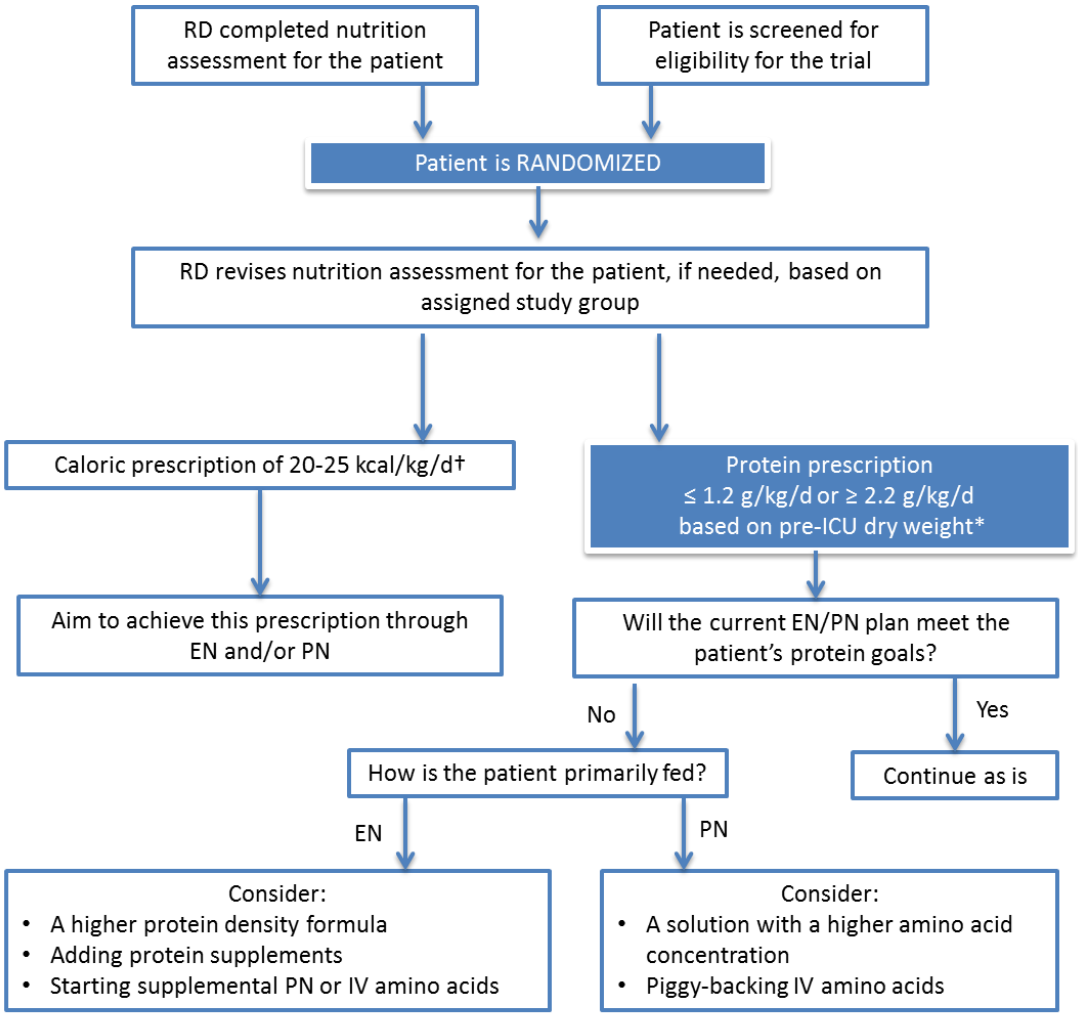
This patient has been randomized to the following study treatment group:

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

❑ Usual Protein Dose (≤ 1.2 g/kg/day)

❑ Higher Protein Dose (≥ 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).

Sex	Select the appropriate box (female or male).
Age	Enter the age of the patient in years at the time of admission to the ICU.
Hospital Admission Date/Time	• Enter the date and time the participant was admitted to the hospital. This is the formal time as noted in the medical record. • 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.
ICU Admission Date/Time	• Enter the date and time the participant was admitted to the ICU in your hospital. • If the participant has been admitted to your ICU multiple times, use the most recent admission. • 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.
Type of ICU Admission	Place a ☑ in only <u>one</u> of the following categories of ICU admission type: • <u>Medical</u>: 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). • <u>Surgical Elective</u>: 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). • <u>Surgical Emergency</u>: 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). 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.
Primary ICU Diagnosis	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). <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. 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. <u>Example:</u> If a participant is admitted with sepsis and pneumonia, select sepsis.

Instructions continued on next page.

Baseline: Patient Information (2)

If ICU Diagnosis = Burns complete the following section.	
Date of burn injury	Record the date of burn injury.
Total body surface area (%TBSA) burn:	• Record the total burn size as percent Total Body Surface Area (%TBSA). • This assessment is made by the attending surgeon/physician based on her/his clinical judgment. • 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%.
Type of burn:	Place a ☑ 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 ☑ in the "Other" box and specify the type of burn. • Scald • Flash • Flame • Chemical • Radiation • Electrical (high voltage contact) • Unknown • Other, specify: _____
Is there presence of full thickness burn (3rd degree)?	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.
Is Inhalation Injury Present? **If yes, specify Severity Score:**	• 0 – No injury – Absence of carbonaceous deposits, erythema, edema, bronchorrhea, or obstruction • 1 – Mild injury – Minor or patchy areas of erythema, carbonaceous deposits, bronchorrhea, or bronchial obstruction • 2 – Moderate injury – Moderate degree of erythema, carbonaceous deposits, bronchorrhea, or bronchial obstruction • 3 – Severe injury – Severe inflammation with friability, copious carbonaceous deposits, bronchorrhea, or obstruction • 4 – Massive injury – Evidence of mucosal sloughing, necrosis, endoluminal obstruction
If ICU Diagnosis = Surgical, Vascular/Cardiovascular complete the following section	
Date of cardiac surgery:	Record the date of the cardiovascular/vascular surgery that resulted in the participant's admission to ICU.
The Canadian Cardiovascular Society (CCS) grading of angina pectoris	The CCS is a clinical tool used to assess the degree of severity of a participant's angina. • No Angina • Class 1 (I) – Angina only with strenuous exertion. (Presence of angina only during strenuous, rapid, or prolonged ordinary activity (walking or climbing) the stairs. • 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. • 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. • Class 4 (IV) – Angina at rest. No exertion needed to trigger angina. • Not Done

Instructions continued on next page.

Baseline: Patient Information (3)

New York Heart Association (NYHA) Functional Classification	The NYHA Functional Classification provides a simple way of classifying the extent of heart failure. • ***Class 1 (I)*** – Cardiac disease, but no symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc. • ***Class 2 (II)*** – Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity. • ***Class 3 (III)*** – 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. • ***Class 4 (IV)*** – Severe limitations. Experiences symptoms even while at rest. Mostly bedbound participants. • ***Not Done***
Left Ventricular Ejection Fraction (LVEF):	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. If the echo report includes descriptive results but no percent, document it as the following: • Normal = 51% • Moderate = 35% • Poor = 25% • Severe = 20%
Did the participant receive any of the following cardiac medications in the 4 weeks prior to day of surgery (select all):	• ***ACE inhibitor*** – a class of drugs used primarily for the treatment of hypertension and congestive heart failure. Examples include benazepril, zofenopril, perinodopril, trandolapril, captopril, enalapril, lisinopril and ramipril. • ***Acetylsalicyclic acid (ASA)*** – Aspirin is used long-term to help prevent heart attacks, ischemic stroke and blood clots in people at high risk. • ***Beta Blockers*** – 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. • ***Statins*** – a class of lipid-lowering drugs. Examples include atorvastatin (Lipitor), cerivastatin, lovastatin, and simvastatin.
Urgency of cardiac surgery:	• ***Elective*** – routine admission for operation. • ***Urgent*** – 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. • ***Emergency*** – Operation before the beginning of the next working day after decision to operate. • ***Salvage*** – 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.
Was the participant considered to be in a critical pre-operative state?	Check 'yes' if the participant experienced at least one of the following events before their surgery: • Ventricular tachycardia; • ventricular fibrillation; • aborted sudden death; • preoperative cardiac massage; preoperative ventilation before anaesthetic room; • preoperative inotropes; • IABP; • preoperative acute renal failure (anuria or oliguria <10mL/h)

Instructions continued on next page.

Baseline: Patient Information (4)

Weight of the surgical intervention	This measures the extent or size of the surgical intervention. All major 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. 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: • ***Isolated CABG procedure*** • ***Isolated (single) non-CABG procedure*** (e.g. single valve procedure, replacement of ascending aorta, correction of septal defect, etc.); • ***Two (2) procedures*** (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.); • ***Three (3) major procedures or more*** (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). NOTE: Only major cardiac procedures should be noted. Examples of procedures which are not 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.
Did the surgery involve the thoracic aorta?	Indicate whether the participant's surgery involved the thoracic aorta.
Was Cardiopulmonary Bypass (CPB) used?	Indicate whether CPB was used during the participant's cardiac surgical procedure.

Comorbidities

- Place a ☑ beside all co-morbidities present using Taxonomy C provided.
- Comorbidities are listed according to body-system. Only record co-morbidities found on the taxonomy listing.
- 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.

Example: 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:

- Pulmonary: Asthma
- Endocrine: Diabetes Type I or II
- Endocrine: Obesity and/or BMI >30
- Miscellaneous: Hearing Impairment

Instructions continued on next page.

Baseline: Patient Information (5)

Myocardial	• Angina: chest pain caused by reduced blood flow to the heart muscle. • Arrythmia: heartbeat is irregular, too fast, or too slow. • Congestive heart failure: chronic condition that affects the chambers of your heart where the heart does not function as it should. • Recent MI: MI within past 90 days. • Previous MI: MI more than 90 days ago. • Moderate pulmonary hypertension: RVSP = 31-55 mmHg. • Severe pulmonary hypertension: RVSP > 55 mmHg. • Valvular: Indicate if the participant currently has any uncorrected valvular heart disease. • Active endocarditis: Participant still on antibiotic treatment for endocarditis at time of surgery. • 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.
Vascular	• Hypertension: Physician diagnosis of hypertension. • Extracardiac arteriopathy: One or more of the following: claudication, carotid occlusion or >50% stenosis, amputation for arterial disease or previous or planned intervention on the abdominal aorta, limb arteries or carotid. • Cardiovascular Disease (Stroke or TIA): Any history of documented neurological symptoms consistent with stroke including, where possible, imaging evidence of ischemic or hemorrhagic damage.
Pulmonary	• 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. • 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).
Neurologic	• Dementia: Indicate if there is a diagnosis of dementia. • Hemiplegia: Paralysis of one side of the body. • Neurologic illness: Indicate if there is a diagnosis, such as MS or Parkinsons.
Endocrine	• Diabetes type 1 or 2 on insulin: Regardless of the duration of disease, select this option if the participant is prescribed insulin at baseline • Diabetes type II, not on insulin: select if the participant is on oral hypoglycemic agents or no diabetes medication • 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 • Obesity: Select if the participant's BMI is >30
Renal	• Moderate renal disease: Creatinine clearance 51-85 mL/min. • Severe renal disease: Creatinine clearance ≤50 mL/min and NOT on dialysis • Dialysis (regardless of serum creatinine level): This measure is related to hemodialysis, peritoneal dialysis or CRRT. Does not include ultrafiltration.

Instructions continued on next page.

Baseline: Patient Information (6)

Gastrointestinal	• Gastrointestinal disease: This includes hernias or reflux • GI Bleeding: Any history of hemorrhage anywhere in the gastrointestinal tract that was investigated and/or required blood transfusion within the past 6 months. • Inflammatory bowel: Indicate if the participant has received this diagnosis • Mild liver disease: Raised serum aminotransferase or alkaline phosphatase levels or both, but total serum bilirubin <2.5 mg/dL and no coagulopathy (INR <1.5) • Moderate or severe liver disease: liver disease beyond the above definition for mild liver disease • 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.
Cancer/Immune	Indicate if the participant has a diagnosis of any of the listed comorbidities (AIDS, tumor, leukemia, lymphoma, metastatic solid tumor).
Psychological	Indicate if the participant has a diagnosis of any of the listed comorbidities (anxiety, panic disorder, depression)
Musculoskeletal	• Arthritis: Select if the participant has either rheumatoid or osteoarthritis • Connective Tissue Disease: Indicate if the participant has received this diagnosis • Degenerative Disc Disease: This includes back disease, spinal stenosis or severe chronic back pain • Osteoporosis: Indicate if the participant has received this diagnosis
Substance Use	• 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 >7 drinks/week or >3 drinks/occasion for women and >14 drinks/week or >4 drinks/occasion for men. • Current Smoker: "Current smoker" should be selected if the participant stopped smoking < than 6 weeks prior to surgical procedure. • Drug abuse history: if the participant has a documented history of drug abuse in the medical chart, it should be recorded here.
Miscellaneous	• Hearing impairment: indicate if the participant is very hard of hearing, even with hearing aids. • Visual Impairment: Indicate if the participant has a diagnosis of cataracts, glaucoma or macular degeneration. • Severe mobility impairment: Severe impairment of mobility secondary to musculoskeletal or neurological dysfunction.

Instructions continued on next page.

Baseline: APACHE II Score

APACHE II Score	• If routinely calculated, directly enter the score recorded in the participant's chart. • To calculate the score, you may use any tool you wish. We recommend using the following website: http://www.sfar.org/scores2/apache22. php. Record the calculated score. • To manually calculate the score, use the worksheet included in the CRF. General Instructions • All measurements should be obtained from within the first 24h of ICU admission. • If there is only one measure within the 24h scoring window for a given physiologic variable, record the single value as both the lowest AND highest values. • 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. • If any of the variables are not available (i.e. no data available) assume a normal value normal (i.e. '0 points'). • 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). • 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'). • Do not include values from the operating room. If the calculated APACHE II score is ≤ 10 please indicate if the score was calculated using complete data or if partial data was used (i.e. CBC was never done). If the APACHE II Score is not available, please provide the reason why the APACHE II Score cannot be calculated • No bloodwork taken • Data cannot be found
How to manually calculate APACHE II Score	
	
Acute Physiology Score	Temperature 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. Mean Arterial Pressure (MAP) 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: • LOWEST SBP with associated DBP • LOWEST DBP with associated SBP • HIGHEST SBP with associated DBP • HIGHEST DBP with associated SBP Heart Rate (HR) The lowest and highest heart rates (ventricular response). Respiratory Rate (RR) 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.

Instructions continued on next page.

Acute Physiology Score

Oxygenation

LOWEST: Record the lowest PaO2 (mmHg) and corresponding SpO2 (%), with the associated FiO2 (%), and PaCO2.

HIGHEST: record the highest FiO2 (%) with associated PaO2, corresponding SpO2 (%), and PaCO2.

If FiO2 ≥ 0.5, and multiple ABGs are available, you will need to calculate the A•aD02 (alveolar arterial gradient) to manually obtain the lowest and highest scores. To calculate A•aD02 all values used must come from the same ABG.

A•aD02 = [FiO2 (713) - (PaCO2/0.8)] - PaO2

pH Arterial

Record the lowest and highest pH levels measured.

Serum Bicarbonate (No-ABGs available)

If there are no ABGs available Serum bicarbonate (HCO3 venous) should be used in place of the above oxygenation data.

WBC

Record the lowest and highest white blood cell counts.

Hematocrit

Record the lowest and highest hematocrit measured.

Platelets

Record the lowest and highest platelet counts measured.

Serum Sodium (Na+)

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).

Serum Potassium (K+)

Record the lowest and highest serum potassium levels.

Creatinine

Record the lowest and highest serum creatinine levels.

Acute Renal Failure (double points assigned)

The patient fulfills the 'acute renal failure' criteria if any of the following definitions apply:

- Creatinine > 124 µmol/L and ≤ 177 µmol/L and subsequent creatinine values show a steady increase to > 177 µmol/L; OR
- Creatinine > 177 µmol/L and
  - Patient has documented pre-admission creatinine ≤ 124 µmol/L; OR
  - Creatinine decreases to < 124 µmol/L while patient is hospitalized

GCS

- GCS is assessed by summing the highest performance score in each of the 3 domains (eye opening, verbal response and motor response) within 24h of the ICU admission .
- If in the first 24 hours, you are using the GCS score documented in the flowsheet that has multiple GCS scores , then record the lowest calculated score for the purpose of calculating APACHE II.
- 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."
- 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.

effort study

Study ID # _____

Baseline: Patient Information

Sex: ❑ Female ❑ Male	**Age:** _____years ❑ Age ≥ 90 yrs
Hospital Admission **Date**:(YYYY-MM-DD): _____ **Time** (HH:MM, 24h): _____	**ICU Admission** **Date**:(YYYY-MM-DD): _____ **Time** (HH:MM, 24h): _____

Type of ICU Admission:
❑ Medical *(check one option from taxonomy 'A' – page 20)*
❑ Surgical Elective *(check one option from taxonomy 'B' – page 21)*
❑ Surgical Emergency *(check one option from taxonomy 'B' – page 21)*

Does the patient have any comorbidities?
❑ Yes ❑ No
↓
Check all that apply from taxonomy C – page 23)

APACHE II Score: _____

Calculate the APACHE II score with the online calculator: http://www.sfar.org/scores2/apache22.php
OR
Calculate the APACHE II manually on the provided form (see pages 24-25).

If score ≤ 10, is the APACHE II Score based on: ❑Partial data → → → provide reason(s) below.
❑Complete data

Please provide the reason for partial data: ❑ No bloodwork taken
❑ 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

Cardiovascular/Vascular*
- ❑ CABG only
- ❑ Carotid endarterectomy
- ❑ Dissecting/ruptured aorta
- ❑ Elective abdominal aneurysm repair
- ❑ Peripheral artery bypass graft
- ❑ Peripheral vascular surgery (no bypass graft)
- ❑ Valvular heart surgery/CABG
- ❑ Valvular heart surgery only
- ❑ Other CV disease (specify):

_____

Respiratory
- ❑ Lung neoplasm
- ❑ Respiratory infection
- ❑ Respiratory neoplasm (mouth, sinus larynx, trachea)
- ❑ Other respiratory disease (specify):

_____

Gastrointestinal
- ❑ GI bleeding
- ❑ GI cholecystitis/ cholangitis
- ❑ GI inflammatory disease
- ❑ GI neoplasm
- ❑ GI obstruction
- ❑ GI perforation/rupture
- ❑ Liver transplant
- ❑ Pancreatitis
- ❑ Other GI disease (specify):

_____

Neurologic
- ❑ Craniotomy for neoplasm
- ❑ Intracerebral hemorrhage
- ❑ Laminectomy/other spinal cord surgery
- ❑ Subarachnoid hemorrhage
- ❑ Subdural/epidural hematoma
- ❑ Other neurologic disease (specify):

_____

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

Renal
- ❑ Renal neoplasm
- ❑ Other renal disease (specify):

_____

Gynecologic
- ❑ Hysterectomy

Orthopedic
- ❑ Hip or extremity fracture

Bariatric Surgery
- ❑ Laproscopic Banding
- ❑ Laproscopic Gastric Bypass
- ❑ Open Gastric Bypass (Roux-en-Y)
- ❑ Vertical Banded Gastroplasty

Burns†
- ❑ Burns

Other
- ❑ Other surgical disease (specify):

_____

**** Remember to complete the additional surgical cardiovascular/vascular related data on page 22.***

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

effort study

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):

- ❑ Scald
- ❑ Flash
- ❑ Flame
- ❑ Chemical
- ❑ Radiation
- ❑ Electrical
- ❑ Unknown
- ❑ Other: _____

Is there presence of full thickness burn (3rd 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

effort study

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 (≤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)2)

Renal
- ❑ Moderate renal disease (Creatinine clearance 51-85 mL/min)
- ❑ Severe renal disease (Creatinine clearance ≤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)

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

Physiologic Variable		HIGH ABNORMAL RANGE (Check one range per variable and write the severity score in the column to the right. Note: use the worst possible score for all variables, except for the GCS score.)					LOW ABNORMAL RANGE				Severity Score
	Severity Points	+4	+3	+2	+1	0	+1	+2	+3	+4	
1	Temperature – rectal (°C) (add 0.5° to oral temp, add 1.0° to axillary temp)	☐ ≥41°	☐ 39-40.9°		☐ 38.5°-38.9°	☐ 36°-38.4°	☐ 34°-35.9°	☐ 32°-33.9°	☐ 30°-31.9°	☐ ≤29.9°	
2	Mean Arterial Pressure (mmHg)	☐ ≥160	☐ 130-159	☐ 110-129		☐ 70-109		☐ 50-69		☐ ≤49	
3	Heart Rate (Ventricular Response)	☐ ≥180	☐ 140-179	☐ 110-139		☐ 70-109		☐ 55-69	☐ 40-54	☐ ≤39	
4	Resp. Rate (non-ventilated or ventilated)	☐ ≥50	☐ 35-49		☐ 25-34	☐ 12-24	☐ 10-11	☐ 6-9		☐ ≤5	
5	Oxygenation: a. $FIO_2 \geq 0.5$ record $A\text{-}aDO_2$*	☐ ≥500	☐ 350-499	☐ 200-349		☐ <200					
	b. $FIO_2 < 0.5$ record only PaO_2					☐ PaO_2>70	☐ PaO_2 61-70		☐ PaO_2 55-60	☐ PaO_2 <55	
6	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	
7	Serum Sodium (mmol/L)	☐ ≥180	☐ 160-179	☐ 155-159	☐ 150-154	☐ 130-149		☐ 120-129	☐ 111-119	☐ ≤110	
8	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	
9	Serum Creatinine (µmol/L) (double point score for acute renal failure)	☐ ≥309.4	☐ ≥176.8≤309.3	☐ ≥132-176.7		☐ ≥53<132		☐ <53			
10	Hematocrit (%)	☐ ≥60		☐ 50-59.9	☐ 46-49.9	☐ 30-45.9		☐ 20-29.9		☐ <20	
11	White Blood Count (total/mm^3) (in 1000s)	☐ ≥40		☐ 20-39.9	☐ 15-19.9	☐ 3-14.9		☐ 1-2.9		☐ <1	
12	Glasgow Coma Score (GCS) Score=15 minus actual GCS				(Note: The best GCS used for the 1st 24 hours)						(15 - GCS Total)
		Eye	Verbal	Motor	GCS Total (= Eye + Verbal + Motor)						
A=Total ACUTE PHYSIOLOGY SCORE (APS): Total severity points indicated for Variables 1-12 in the column to the right.											
	Serum HCO_3 (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	

* $A\text{-}aDO_2 = [(FiO_2\ (713)-(PaCO_2/0.8)]-PaO_2$

Baseline: Patient Information
APACHE II Score Sheet (2)

Study ID #

A=	APS Points (see back)	
B=	Age Points (see back)	
C=	Chronic Health Points	
Total=	APACHE II Score	

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 hyposia, 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-suppresive treatment, chemotherapy, radiation, long term or recent high dose steroids, or has a disease that is sufficiently advanced to suppress resistance to infection (i.e., leukaemia, lymphoma, AIDS)

Baseline: Enrollment

Urine output at the time of randomization:	Indicate the urine output (UO) at the time of randomization. ❑ > 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 <u>before</u> onset of illness that brought patient to the hospital:	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.
Was a wound present at randomization?	If a wound was present, check all types that apply from the list below. • ***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 on 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.

Study ID #

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:**
❑ No

- ❑ Pressure ulcer
- ❑ Enterocutaneous fistula
- ❑ Open abdomen
- ❑ Wound dehiscence

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 on 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

General Instructions	• These data are collected once at baseline for calculation of modified SOFA score. All data should be collected within the **first 24 hours after admission to ICU**. • If data is not available within the first 24 hours, go outside the 24 hour period and record data closest to admission.
Lowest PaO_2/FiO_2 (PF ratio)	Record the lowest PaO_2/FiO_2 (PF ratio) observed on the study day by selecting from the options below. The PaO_2 and FiO_2 values should come from the same blood gas measurement. ❑ ≥ 400 mmHg **or N/A** ❑ 300 – 399 mmHg ❑ 200 – 299 mmHg ❑ 100 – 199 mmHg with respiratory support ❑ < 100 mmHg with respiratory support If 'No' PF ratio, record **N/A by selecting the first option**.
Lowest Platelets	Record the lowest serum platelets observed on the study day by selecting from the options below. ❑ ≥ 150 x $10^3/mm^3$ **or N/A** ❑ 100 - 149 x $10^3/mm^3$ ❑ 50 - 99 x$10^3/mm^3$ ❑ 20 - 49 x$10^3/mm^3$ ❑ < 20 x$10^3/mm^3$ If 'No' Platelet data, record **N/A by selecting the first option**.
Highest Bilirubin (total)	Record the highest total bilirubin observed on the study day by selecting from the options below. ❑ < 1.2 mg/dL (< 20 µmol/L) **or N/A** ❑ 1.2 – 1.9 mg/dL (20-32 µmol/L) ❑ 2.0 – 5.9 mg/dL (33-101 µmol/L) ❑ 6.0 – 11.9 mg/dL (102-204 µmol/L) ❑ ≥ 12.0 mg/dL (> 204 µmol/L) If 'No' bilirubin data, record N/A by selecting **the first option**.
Vasopressors **Mean Arterial Pressure (MAP)**	If 'Yes', select the highest dose received during the study day. ❑ Dopamine ≤ 5µg/kg/min or Dobutamine (any dose) ❑ Dopamine 5 - 15 µg/kg/min or Epinephrine ≤ 0.1 µg/kg/min or Norepinephrine ≤ 0.1 µg/kg/min ❑ Dopamine > 15 µg/kg/min or Epinephrine > 0.1 µg/kg/min or Norepinephrine > 0.1 µg/kg/min If no: ❑Mean Arterial Pressure (MAP) < 70 mmHg ❑Mean Arterial Pressure (MAP) ≥ 70 mmHg
What is the patient's state of consciousness?	GCS is assessed by summing the highest performance score in each of the 3 domains (eye opening, verbal response and motor response). • If in the first 24 hours, you are using the GCS score documented in the flowsheet that has multiple GCS scores , then record the lowest calculated GCS score.
Highest Creatinine	Record the highest creatinine observed on the study day by selecting from the options below: ❑ < 1.2 mg/dL (< 110 µmol/L) or N/A ❑ 1.2 - 1.9 mg/dL (110 - 170 µmol/L) ❑ 2.0 - 3.4 mg/dL (171 - 229 µmol/L) ❑ 3.5 - 4.9 mg/dL (300 - 440 µmol/L) ❑ ≥ 5 mg/dl (> 440 µmol/L) If 'No' creatinine data, record **N/A by selecting the first option**.
Urine output (mL)	Indicate the volume range of urine output for the study day by selecting from the list below: ❑ ≥ 500 mL/day **or N/A** ❑ 200 - 499 mL/day ❑ < 200 mL/day If 'No' urine output data, record **N/A by selecting the first option**.

effort study

Study ID #

Baseline: SOFA Score

NOTE: All values should be collected within the first 24h after ICU admission.

Is a computed SOFA Score available? ❑ Yes → *If yes*, SOFA Score: _____
❑ No → *If no, enter the following data:* ↓

Lowest PaO2/FiO2 (PF ratio)	❑ ≥ 400 mmHg **or N/A** ❑ 300 – 399 mmHg ❑ 200 – 299 mmHg ❑ 100 – 199 mmHg with respiratory support ❑ < 100 mmHg with respiratory support
Lowest Platelets	❑ ≥ 150 x 10^3 /mm^3 **or N/A** ❑ 100 - 149 x 10^3 /mm^3 ❑ 50 - 99 x 10^3 /mm^3 ❑ 20 - 49 x 10^3 /mm^3 ❑ < 20 x 10^3 /mm^3
Highest Bilirubin (total):	❑ < 1.2 mg/dL (< 20 µmol/L) **or N/A** ❑ 1.2 - 1.9 mg/dL (20 - 32 µmol/L) ❑ 2.0 - 5.9 mg/dL (33 - 101 µmol/L) ❑ 6.0 - 11.9 mg/dL (102 - 204 µmol/L) ❑ ≥ 12 mg/dL (> 204 µmol/L)

Did the patient receive vasopressors today?

❑ Yes ↓

If Yes, select the highest dose received during the study day:

❑ Dopamine ≤ 5µg/kg/min or Dobutamine (any dose)
❑ Dopamine 5 - 15 µg/kg/min or Epinephrine ≤ 0.1 µg/kg/min or Norepinephrine ≤ 0.1 µg/kg/min
❑ Dopamine > 15 µg/kg/min or Epinephrine > 0.1 µg/kg/min or Norepinephrine > 0.1 µg/kg/min

❑ No ↓

If no:

❑ Mean Arterial Pressure (MAP) < 70 mmHg
❑ Mean Arterial Pressure (MAP) ≥ 70 mmHg

What is the patient's state of consciousness? (Choose the options that give the highest performance score in each domain).

Eye Opening	**Verbal Response**	**Best Motor Response**
❑ 1- None	❑ 1- None	❑ 1- None
❑ 2- To pain	❑ 2- Incomprehensible words	❑ 2- Extension
❑ 3- To speech	❑ 3- Inappropriate words	❑ 3- Abdominal flexion
❑ 4- Spontaneous	❑ 4- Confused	❑ 4- Withdraws from pain
	❑ 5- Oriented	❑ 5- Localizes to pain
		❑ 6- Obeys commands

Highest Creatinine: ❑ < 1.2 mg/dL (< 110 µmol/L) **or N/A** ❑ 1.2 - 1.9 mg/dL (110 - 170 µmol/L) ❑ 2.0 - 3.4 mg/dL (171 - 229 µmol/L) ❑ 3.5 - 4.9 mg/dL (300 - 440 µmol/L) ❑ ≥ 5 mg/dl (> 440 µmol/L)	**Total urine output:** ❑ ≥ 500 mL/day **or N/A** ❑ 200 - 499 mL/day ❑ < 200 mL/day

Baseline: Nutrition Assessment

Did the patient have unintentional weight loss before admission to hospital?	Select from Yes, no and do not know. If yes, please respond to the following related questions: • What was the % weight loss? • Over how many months did the weight loss occur? • Select the most appropriate response (i.e. 1-12, >12 months). If necessary, round to the nearest month and record the value.
Did the patient have less than required food intake before admission to hospital?	Select from Yes, no and do not know. If yes, please respond to the following related questions: • Was the food intake < 50% of needs? • Was the food intake reduced for: (1 week; 2 weeks; >2 weeks; Do not know)
Does the patient have chronic malabsorption?	Selection from yes or no and do not know. Select 'yes' for example if the patient has a diagnosis of inflammatory bowel disease, short bowel syndrome, chronic dysmotility, etc.

Does the patient have moderate/severe fat and/or muscle wasting?	Select from Yes, no and do not know.
	
	If yes, please check the box(es) that apply for which evidence this assessment is based on:
	
	• Visual evidence of fat wasting
	• Visual evidence of muscle wasting
	• Physical exam
	• CT scan*
	  • What findings lead you to conclude there is wasting?
	• Ultrasound*
	  • What findings lead you to conclude there is wasting?
	• Other, specify: _____
	
	*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.

Is there other evidence of moderate to severe malnutrition not captured above?	Select from Yes and no. If yes, please check all that apply to support other evidence of moderate to severe malnutrition: • Refeeding syndrome • Moderate to severe edema • Other, (specify) : _____
Was a calf circumference measurement completed on the right leg?	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. If yes, enter the right leg measurement in centimeters (cm). 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.

effort study

Study ID #

Baseline: Nutrition Assessment

Did the patient have unintentional weight loss before admission to hospital?

❑ Yes → → →
❑ No
❑ Do not know

→ If yes:

What was the % weight loss? _____%

Over how many months did the weigh loss occur?

❑ 1 month
❑ 2 months
❑ 3 months
❑ 4 months
❑ 5 months
❑ 6 months
❑ 7 months
❑ 8 months
❑ 9 months
❑ 10 months
❑ 11 months
❑ 12 months
❑ > 12 months

Did the patient have less than required food intake before admission to hospital?

❑ Yes → → →
❑ No
❑ Do not know

→ If yes, was the food intake < 50% of needs?

❑ Yes → **Was the food intake reduced for:**
❑ No

❑ 1 week
❑ 2 weeks
❑ >2 weeks
❑ Do not know

Does the patient have chronic absorption?

❑ Yes
❑ No
❑ Do not know

Does the patient have moderate/severe fat and/or muscle wasting?

❑ Yes **→ If yes, please check the box(es) below for the evidence used to make this assessment.**
❑ No
❑ Do not know

Moderate/severe fat and/or muscle wasting as evidenced by: *(select all that apply)*

❑ Visual evidence of fat wasting
❑ Visual evidence of muscle wasting
❑ Physical exam
❑ CT scan → → What findings lead you to conclude there is wasting? _____
❑ Ultrasound → → What findings lead you to conclude there is wasting? _____
❑ Other, specify findings: _____

Is there other evidence of moderate to severe malnutrition not captured above?

❑ Yes **→ If yes, please check the box(es) below for the evidence used to make this assessment.** *(select all that apply)*

❑ No

❑ Refeeding syndrome
❑ Moderate to severe edema
❑ Other, specify: _____

Was a calf circumference measurement completed on the right leg?

❑ Yes, Right leg: _____cm
❑ No, specify reason: _____(edema; lower leg amputation)

Was a calf circumference measurement completed on the left leg?

❑ Yes, Left leg: _____cm
❑ No, specify: _____(edema; lower leg amputation)

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.

Study ID #

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
❑		***Very Fit (category 1)*** People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.
❑		***Well (category 2)*** No active disease symptoms but less fit than people in category 1. Often, they exercise or are very active occasionally, e.g. seasonally. 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.
❑		***Managing Well (category 3)*** Medical problems are well controlled, but people in this category are not regularly active beyond routine walking. Those with treated medical problems who exercise are classed in categories 1 or 2.
❑		***Vulnerable (category 4)*** 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". 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.
❑		***Mildly Frail (category 5)*** 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. 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.
❑		***Moderately Frail (category 6)*** 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. 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.
❑		***Severely Frail (category 7)*** Completely dependent on others for all or most personal activities of daily living, such as dressing and feeding.
❑		***Very Severely Frail (category 8)*** Completely dependent, approaching the end of life. Typically, people in this category could not recover from even a minor illness.

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)

Height	Record height in meters. If unable to obtain "actual" value, use estimated height or height obtained from family member and check the box indicating the data was estimated. Indicate if the patient is a bi-lateral amputee by checking the appropriate box.
Dry Body Weight	Record participant's dry weight based on pre-ICU actual weight in kilograms. If unable to obtain "actual" value, use estimated weight or weight obtained from family member and check the box indicating the data was estimated.
BMI	When entering data into REDCap™, this BMI value (kg/m^2) will be calculated for you once height and dry weight are entered.
Post-Randomization Nutritional Goals	
Date of post-randomization nutrition goals assessment:	Enter the date the nutrition goals were determined following the randomization of the patient to a protein target.
Weight used to determine goal calorie requirement (kg)	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). 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).
Weight used to determine goal protein requirement (kg)	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). 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).
Goal Calorie Requirement (kcal/day)	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. 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.
Precise Goal Protein Requirement (within randomized protein group) (g/day)	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 (≤1.2 g/kg/d or ≥2.2 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. Eg. In the example above for Mr.X, the goal protein requirements would be entered as 84 g.
Was indirect calorimetry used to determine the goal calorie requirement?	If indirect calorimetry was used to determine the goal calorie requirement, indicate yes. Note: you will be prompted to enter the date(s) indirect calorimetry was performed on the Hospital Outcomes form (page 69).

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?	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.
	Select one of the following:
	• **Initiate EN: start at low rate and progress to hourly goal rate**
	Eg. Start at 25 ml/hr and increase to 50 ml/hr then 75 ml/hr (hourly goal rate)
	• **Initiate EN: start at OR progress to 24 hr Volume Goal Based hourly rate**
	Hourly rate is determined by 24hr volume goal. This includes the following scenarios:
	  • 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
	  • 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
	• **Initiate EN: start at hourly goal rate**
	Eg. Pt requires 75 ml/hr and feeding starts at 75 ml/hr
	• **Initiate EN: keep at low rate (trophic feed: no progression**)
	Eg. Start at 10 ml/hr and leave as is
	• **Initiate EN: bolus feeds**
	Eg. Pt requires 75 ml/hr and starts with boluses of 450 ml q 6 hours.
	• **Keep Nil Per Os or Nil By Mouth**
	• **Oral nutrition**
	• **Parenteral Nutrition**

effort study

Study ID #

Baseline: Nutrition Goals (2)

Height (meters):_____	**Dry Body Weight** (kg): _____
How was height determined? ❒ Actual ❒ Estimated	**How was weight determined?** ❒ Actual ❒ Estimated
Is the patient a bi-lateral leg amputee? ❒ Yes	
BMI (Automatically Calc'd): _____ kg/m^2	

Determining Nutrition Goals (Post-randomization)	
Date of post-randomization nutrition goal assessment (YYYY-MM-DD): _____	
Weight used to determine ***goal calorie*** requirement: _____kg	**Goal Calorie Requirement:** _____kcal/day **Was indirect calorimetry used to determine the goal calorie requirement?** ❒ Yes → (Calorimetry data on the outcome form – page **69**). ❒ No
Weight used to determine ***goal protein*** requirement: _____kg	**Precise Goal Protein Requirement:** _____ g/day

effort study

Study ID #

Baseline: Nutrition Goals (2)

Initiation of Nutrition Therapy	
Enteral Nutrition	
When was EN first initiated? ❑ EN initiated prior to ICU admission ❑ EN initiated during first 28 days in ICU: **Date** (YYYY-MM-DD):_____ **Time** (HH:MM, 24h):_____ ❑ EN not initiated during first 28 days in ICU	**When was EN discontinued?** ❑ EN discontinued during first 28 days in ICU: **Date** (YYYY-MM-DD):_____ **Time** (HH:MM, 24h):_____ ❑ Still receiving EN in ICU after study day 28
Parenteral Nutrition	
When was PN first initiated? ❑ PN initiated prior to ICU admission ❑ PN initiated during first 28 days in ICU: **Date** (YYYY-MM-DD):_____ **Time** (HH:MM, 24h):_____ ❑ PN not initiated during first 28 days in ICU	**When was PN discontinued?** ❑ PN discontinued during first 28 days in ICU: **Date** (YYYY-MM-DD):_____ **Time** (HH:MM, 24h):_____ ❑ Still receiving PN in ICU after study day 28

What was the delivery technique recommended by the physician or dietitian at the initial assessment for enteral nutrition? (check one of the following)

❑ Initiate EN: start at low rate and progress to hourly goal rate
❑ Initiate EN: start at or progress to 24hr volume goal based hourly rate
❑ Initiate EN: start at hourly goal rate
❑ Initiate EN: keep at low rate (trophic feeds: no progress)
❑ Initiate EN: bolus feed
❑ Keep Nil Per Os (NPO) or Nil By Mouth
❑ Oral nutrition
❑ Parenteral Nutrition

Daily Data: Daily Nutrition Data (1)

Please see and follow instructions for indicating units of the biochemistry tests collected (pages 40 -41). Note that you will need to indicate the units used at your site even if the measurement was not done on Day 1.	
NPO because participant palliating or receiving comfort measures only today?	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. If 'yes,' no further data is required to be entered on this form for this day.
Patient has fully transitioned to oral feeds	Indicate, 'yes' if the participant has permanently transitioned to oral feeds. These are participants who are recovering and receiving oral feeds and DO NOT receive EN and/or PN today and for the remainder of their ICU stay. If 'yes,' no further data is required to be entered on this form for this day.
Did the protein goal change to a target outside the range specified by the randomization group?	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. For example, was there a clinical reason for why the participant could not remain on their randomized protein goal? If 'yes,' there is a change to the protein from the randomization group, specify the reason for this change from the list provided. (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)
Was any nutrition received orally/by mouth?	Each study day, indicate whether or not the participant received any nutrition orally/by mouth. NOTE: Data on calories and protein from oral nutrition are not collected.
Highest and Lowest Blood Glucose	Record the highest and lowest blood glucose measured this day. If only one blood glucose measurement is done, record the same value for highest and lowest. If not done on a particular day, use the 'Not Available' checkbox. **On day 1 only**, indicate the units blood glucose is measured in at your site. The units you indicate on day 1 will represent the units blood glucose is measured in for the duration of data collection.
Did the participant have a hypoglycemic event today? (<3.5mmol/L or <63 mg/dL)	A hypoglycemic event is defined as a glucose level of <3.5mmol/L (<63mg/dL). 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. If a glucose was treated and the hypoglycemic event was not <63mg/dL then do not record this as an event.
Insulin	If the participant receives insulin, record the total number of units administered this day. Select 'no' if insulin was NOT given.

Daily Data: Daily Nutrition Data (2)

Propofol (continuous infusion ≥ 6 hours)	If the participant receives a <u>continuous</u> infusion of propofol ≥ 6 hours, record the total volume administered in milliliters (mL). Select 'no' if propofol was NOT given, or if provided intermittently, or if continuous < 6 hours.
Highest Creatinine	Record the highest creatinine measured this day. If not done on a particular day, use the 'Not Available' checkbox. **On day 1 only**, indicate the units creatinine is measured in at your site. The units you indicate on day 1 will represent the units creatinine is measured in for the duration of data collection.
Highest Urea/BUN	Record the highest urea/BUN measured this day. If not done on a particular day, use the 'Not Available' checkbox. **On day 1 only,** indicate the units urea/BUN is measured in at your site. The units you indicate on day 1 will represent the units urea/BUN is measured in for the duration of data collection.
Lowest Phosphate	Record the lowest serum phosphate (PO_4) measured this day. If not done on a particular day, use the 'Not Available' checkbox. **On day 1 only**, indicate the units PO_4 is measured in at your site. The units you indicate on day 1 will represent the units PO_4 is measured in for the duration of data collection.
Highest Triglycerides	Record the highest triglycerides measured this day. If not done on a particular day, use the 'Not Available' checkbox. **On day 1 only,** indicate the units triglycerides is measured in at your site. The units you indicate on day 1 will represent the units triglycerides is measured in for the duration of data collection.
Location of Feeding Tube	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). If the feeding tube is in 2 locations on a single day, indicate the location it was in for the most amount of time.
Did the participant receive any motility agents?	Select all motility agents that apply from the list provided. Alizapride, Lesuride, Cinitapride (Cintapro/Pemix), Methylnaltrexon, Domperidone, Metoclopramide, Erythromycin, Naloxone, Itopride (Ganaton), Other specify. 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.

Definition of Motility Agent

A drug which enhances gastric emptying and/or gastrointestinal motility by increasing the frequency and/or strength of contractions in the gastrointestinal tract.

This does not include stool softeners or laxatives such as lactulose or herbal remedies.

effort study

Daily Data: Daily Nutrition Data (1)

Study ID # _____

Study Day:	1 ICU Admit	2	3	4	5	6	7	8	9	10	11	12
NPO because palliating or comfort measures?	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No
Patient has fully transitioned to oral feeds	❑ Yes	❑ Yes	❑ Yes	❑ Yes	❑ Yes	❑ Yes	❑ Yes	❑ Yes	❑ Yes	❑ Yes	❑ Yes	❑ Yes
If you have indicated "Yes" to either of the above questions, no more data needs to be entered today.												
Did the protein goals change from the randomization group?		❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No
If yes, enter the primary reason why using the taxonomy below:		_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____
If yes, use the taxonomy to indicate the primary reason why the protein goal changed from the randomized group. Enter this information above. (1) No longer critically ill; (2) New onset of ARDS; (3) Worsening renal function; (4) Improved renal function; (5) Starting dialysis; (6) New wound (non surgical); (7) New surgical wound; (8) Negative nitrogen balance; (9) Increased protein losses; (0) Other, please specify: _____												
Was nutrition received orally/by mouth?	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N
Highest & Lowest Blood Glucose Units: ❑mmol/L ❑mg/dL	_____ _____ ❑ N/A	_____ _____ ❑ N/A	_____ _____ ❑ N/A	_____ _____ ❑ N/A	_____ _____ ❑ N/A	_____ _____ ❑ N/A	_____ _____ ❑ N/A	_____ _____ ❑ N/A	_____ _____ ❑ N/A	_____ _____ ❑ N/A	_____ _____ ❑ N/A	_____ _____ ❑ N/A
Hypoglycemic event? (<3.5mmol/L or <63 mg/dL) ***Record blood glucose values, up to 3.***	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____
Insulin If yes: **Total units/day:**	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____

effort study

Daily Data: Daily Nutrition Data (2)

Study ID # _____

Study Day:	1 ICU Admit	2	3	4	5	6	7	8	9	10	11	12
Propofol (≥ 6 hours) If yes: **Amount given** (mL):	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____
Highest Creatinine Units: ❑µmol/L ❑mg/dL	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A
Highest Urea/BUN Units: ❑mmol/L ❑mg/dL	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A
Lowest Phosphate Units: ❑mmol/L ❑mg/dL	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A
Highest Triglycerides Units: ❑mmol/L ❑mg/dL	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A	_____ ❑ N/A
Location of Feeding Tube: *(Select one)* *G = gastric;* *SB = small bowel;* *N = No tube*	❑ G ❑ SB ❑ N	❑ G ❑ SB ❑ N	❑ G ❑ SB ❑ N	❑ G ❑ SB ❑ N	❑ G ❑ SB ❑ N	❑ G ❑ SB ❑ N	❑ G ❑ SB ❑ N	❑ G ❑ SB ❑ N	❑ G ❑ SB ❑ N	❑ G ❑ SB ❑ N	❑ G ❑ SB ❑ N	❑ G ❑ SB ❑ N
Motility Agents ***If yes, enter <u>all</u> received using the taxonomy shaded in gray below.***	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____

If yes, use the taxonomy to indicate all motility agents received. Enter this information above.

(1) Alizapride; (2) Cinitapride; (3) Cisapride; (4) Domperidone; (5) Erythromycin; (6) Itopride;

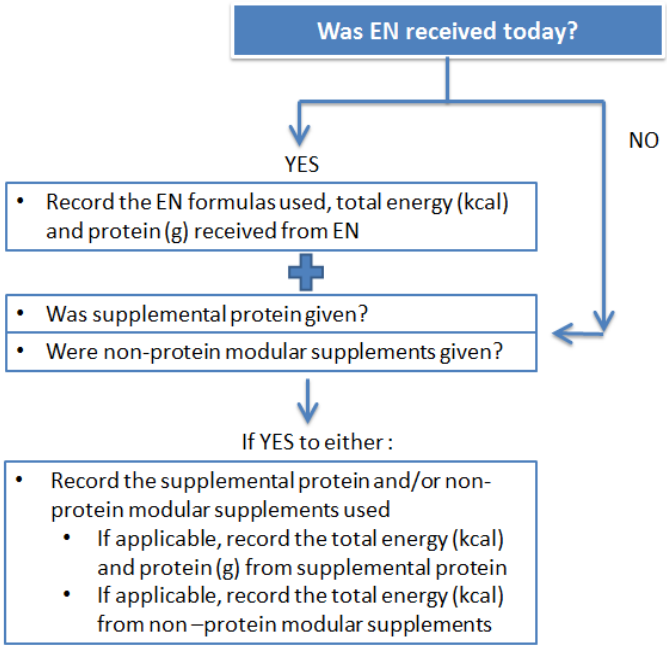
(7) Lesuride; (8) Methylnaltrexone; (9) Metoclopramide; (10) Mosapride; (11) Naloxone; (12) Other, specify: _____

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.



Was enteral nutrition received?	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.
EN Formula(s)	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: • company and product name • If the product is polymeric • If the product contains supplemental glutamine (> 10 g/L) in addition to the glutamine found naturally in the product • If the product contains supplemental arginine (> 4.5 g/L) in addition to the arginine found naturally in the product • If the product contains fish oils *Note:* 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 **not** be considered EN.

Daily Data: Daily Enteral Nutrition Data (2)

Kilocalories received from EN	The total calories (kcal) from EN formula(s) will need to be calculated by the dietitian daily as follows: • Include calories from protein • **Do NOT** include calories from other supplements • **Do NOT** include calories from propofol or other IV solutions ○ Calories from propofol are to be recorded on the Daily Nutrition Data form. Include calories from all EN formulas, even if the participant received nutrition from >3 formulas/day
Protein received from EN	Total protein (g) will need to be calculated by the dietitian daily as follows: • **Do NOT** include protein from additional non-protein supplements • **Do NOT** include protein from glutamine supplements • Include protein from all EN formulas, even if the participant received nutrition from >3 formulas/day
Protein Supplements	
Definition of Modular Protein Supplement 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.	
Was supplemental protein given?	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. • Do not record glutamine supplements here.
Kilocalories received from Supplemental Protein	If the participant received a modular protein supplement, indicate total calories received (kcal) from the modular protein supplement (i.e. include calories from protein). • Include calories from all modular protein supplements
Protein received from Supplemental Protein	If the participant received a modular protein supplement, indicate the protein received (g) from the modular protein supplement. • Include protein from all modular protein supplements • Do NOT include protein from glutamine supplements
Definition of Non-Protein Modular Supplement 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.	
Were non-protein modular supplements given?	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.
Kilocalories from Other Non-protein Supplements	If the participant received a non-protein modular supplement, indicate calories received (kcal) from the non-protein modular supplement.

Daily Data: Daily Enteral Nutrition Data (3)

EN Interruption	
Definition of EN interruption	EN being stopped at any point after it was initiated, with the intent that EN be restarted again. This does not include: • Brief or transient (i.e. less than one hour) interruptions for short bedside procedures • For cyclic or bolus feeding, time the participant was never intended to be fed according to the prescribed feeding schedule • Reduction in rate of feeds • Stopping the feeds permanently and transitioning to oral feeds
Was EN Interrupted today?	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. Choose "yes" or "no" for whether or not EN was interrupted today. If yes, indicate the total duration of time the EN was interruption. Record in total number of hours and minutes. Example 1: 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). Example 2: 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. If EN was interrupted, specify all reason(s) that EN was interrupted, by selecting all that apply from the list provided.

effort study

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

Study ID # _____

Study Day:	1 ICU Admit	2	3	4	5	6	7	8	9	10	11	12
Was enteral nutrition (EN) received today?	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No
Part A – Complete if EN was received today:												
Record EN formula(s) received:	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____
Total kilocalories received from EN today: *kcal*	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____
Total protein received from EN today: *grams (g)*	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____
Part B – Complete regardless of whether or not EN was received today:												
Supplemental protein? Specify (up to 3):	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____	❑ Y ❑ N _____ _____ _____
Kilocalories received from protein supplements:	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____
Protein (g) received from protein supplements:	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____
Non-protein modular supplements? Specify (up to 2):	❑ Y ❑ N _____ _____	❑ Y ❑ N _____ _____	❑ Y ❑ N _____ _____	❑ Y ❑ N _____ _____	❑ Y ❑ N _____ _____	❑ Y ❑ N _____ _____	❑ Y ❑ N _____ _____	❑ Y ❑ N _____ _____	❑ Y ❑ N _____ _____	❑ Y ❑ N _____ _____	❑ Y ❑ N _____ _____	❑ Y ❑ N _____ _____
Kilocalories received from non-protein modular supplements:	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____

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

Study ID # _____

Study Day:	1 ICU Admit	2	3	4	5	6	7	8	9	10	11	12
Was EN interrupted today? If yes, enter the ***total duration of time*** interrupted (hours and minutes)	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____
If yes, EN was interrupted today:												
Do you know the reason why EN was interrupted today?	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No
If yes, select all that apply from the list of reasons for EN interruptions (from list below):												
Fasting for: (1) Endotracheal extubation /intubation /trach procedure; (2) Other bedside procedure; (3) Operating room procedure; (4) Radiology suite procedure; (5) Administration of medications;												
Intolerance to enteral feeding: *(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_____*												

effort study

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

Study ID # _____

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

Company name: _____ Product name: _____

Is the formula polymeric? ❑ Yes ❑ No

If no, is the formula semi-elemental or elemental? ❑ Semi-elemental ❑ Elemental

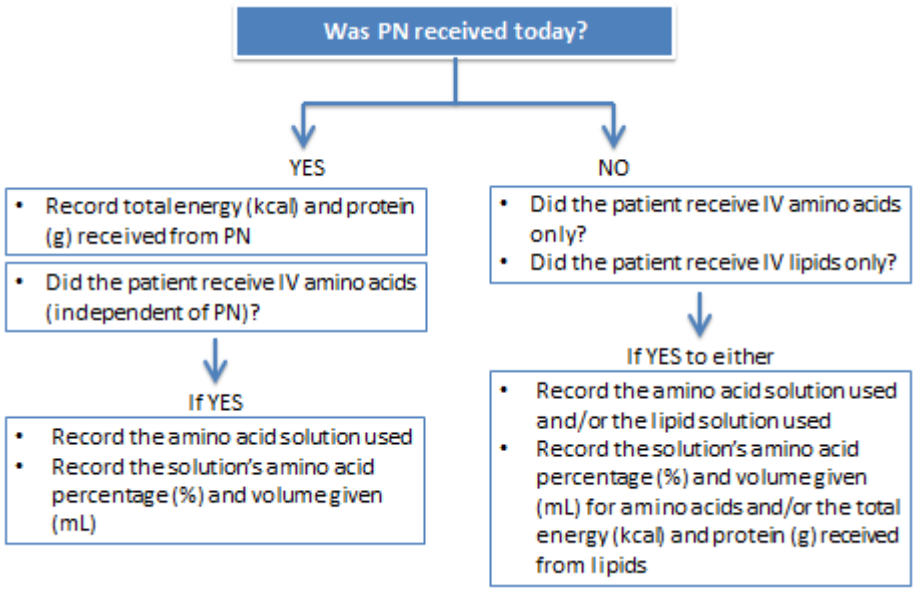
Does the formula contain: ❑ Fish oil ❑ Supplemental glutamine (>10g/L or powder) ❑ Supplemental arginine (>4.5 g/L)

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 the 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).

Was parenteral nutrition (PN) received?	Each study day, indicate whether or not the participant received PN.
Kilocalories received from PN	Total calories received (kcal) will need to be calculated by the dietitian daily as follows: • Include calories from parenteral protein • Include calories from other parenteral supplements • Do **NOT** include calories from enteral formula or modular supplements • Do **NOT** include calories from propofol as this is to be recorded separately on the Daily Nutrition Data form. • Do **NOT** include calories from other IV solutions
Protein received from PN	Total protein will need to be calculated by the dietitian daily as follows: Include protein from parenteral supplements, if applicable Do **NOT** include calories from enteral formula or modular supplements Do **NOT** include protein from glutamine supplements

Daily Data: Daily IV Nutrition Data (2)

Did the participant receive IV amino acids (independent of PN)?	If the participant received PN, indicate if IV amino acids were given in addition to their PN formula. Indicate the solution provided, the solution's amino acid percentage, and the volume given. The protein and kcals received from this solution will be calculated in REDCap.
Did the participant receive IV amino acids only?	If the participant received IV amino acids in the absence of dextrose, indicate the solution provided, the solution's amino acid percentage, and the volume given. The protein and kcals received from this solution will be calculated in REDCap.
Did the participant receive IV lipids only?	If the participant received IV lipids in the absence of dextrose, indicate the emulsion provided, and kcal received from this product.

effort study

Daily Data: Daily IV Nutrition Data (1)

Study ID # _____

Study Day:	1 ICU Admit	2	3	4	5	6	7	8	9	10	11	12
Was parenteral nutrition (PN) received today?	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No
Part A – If yes, PN was received today:												
Total kilocalories received from PN today:	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____
Total protein (g) received from PN today:	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____
Did the patient receive IV amino acids (independent of PN)? *If yes,* specify amino acid solution	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____
Solution's amino acid percentage (10% = 10 g amino acids/100 mL)	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____
Volume of amino acid given (mL):	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____
Part B – If no, PN was not received today:												
Did the patient receive IV amino acids only? *If yes,* specify amino acid solution	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____
Solution's amino acid percentage (10% = 10 g amino acids/100 mL)	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____
Volume of amino acid given (mL):	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____
Did the patient receive IV lipids only? *If yes,* specify lipid solution:	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____
Kilocalories received from lipids today:	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____

effort study

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)

NPO because participant palliating or receiving comfort measures only today?	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. If 'yes,' no further data is required to be entered on this form for this day.
Did the protein goal change to a target outside the range specified by the randomization group?	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. For example, was there a clinical reason for why the participant could not remain on their randomized protein goal? If 'yes,' there is a change to the protein from the randomization group, specify the reason for this change from the list provided. (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)
Was enteral nutrition received?	Each study day, indicate whether or not the participant received EN. If 'yes', record the EN formula(s) used and protein received from EN.
Protein received from EN	Total protein (g) will need to be calculated by the dietitian daily as follows: • Do NOT include protein from additional non-protein supplements • Do NOT include protein from glutamine supplements • Include protein from all EN formulas, even if the participant received nutrition from >3 formulas/day
Was supplemental protein given?	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. • Do not record glutamine supplements here.
Protein received from Supplemental Protein	If the participant received a modular protein supplement, indicate the protein received (g) from the modular protein supplement. • Include protein from all modular protein supplements • Do NOT include protein from glutamine supplements

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

Was parenteral nutrition (PN) received?	Each study day, indicate whether or not the participant received PN.
Protein received from PN	Total protein will need to be calculated by the dietitian daily as follows: Include protein from parenteral supplements, if applicable Do **NOT** include protein from enteral formulas or modular supplements Do **NOT** include protein from glutamine supplements
Did the participant receive IV amino acids (independent of PN)?	If the participant received IV amino acids in addition to their PN formula, indicate the solution provided, the solution's amino acid percentage, and the volume given. The protein received from this solution will be calculated in REDCap.
Did the participant receive IV amino acids only?	If the participant received IV amino acids in the absence of dextrose, indicate the solution provided, the solution's amino acid percentage, and the volume given. The protein received from this solution will be calculated in REDCap.

effort study

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? If you have indicated "Yes", no more data needs to be entered today.	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No
Did the protein goals change from the randomization group? ***If yes, enter the primary reason why using the taxonomy below:***	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____
If yes, use the taxonomy to indicate the primary reason why the protein goal changed from the randomized group. Enter this information above. (1) No longer critically ill; (2) New onset of ARDS; (3) Worsening renal function; (4) Improved renal function; (5) Starting dialysis; (6) New wound (non surgical); (7) New surgical wound; (8) Negative nitrogen balance; (9) Increased protein losses; (0) Other, please specify: _____								
Was enteral nutrition (EN) received today? **Protein received from EN:** (*Record in grams (g)*)	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____
Supplemental protein received today? **Protein received from supplemental protein:** (*Record in grams (g)*)	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____
Was parenteral nutrition (PN) received today? **Protein received from PN:** (*Record in grams (g)*)	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____
If yes to PN **Did the patient receive IV amino acids (independent of PN)?**	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N
If no to PN **Did the patient receive IV amino acids only?**	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N
Solution's amino acid percentage (10% = 10 g amino acids/100 mL)	_____	_____	_____	_____	_____	_____	_____	_____
Volume of amino acid given (mL)	_____	_____	_____	_____	_____	_____	_____	_____

effort study

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? If you have indicated "Yes", no more data needs to be entered today.	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No	❑ Yes ❑ No
Did the protein goals change from the randomization group? ***If yes, enter the primary reason why using the taxonomy below:***	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____	❑ Yes ❑ No _____
If yes, use the taxonomy to indicate the primary reason why the protein goal changed from the randomized group. Enter this information above. (1) No longer critically ill; (2) New onset of ARDS; (3) Worsening renal function; (4) Improved renal function; (5) Starting dialysis; (6) New wound (non surgical); (7) New surgical wound; (8) Negative nitrogen balance; (9) Increased protein losses; (0) Other, please specify: _____								
Was enteral nutrition (EN) received today? **Protein received from EN:** (*Record in grams (g)*)	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____
Supplemental protein received today? **Protein received from supplemental protein:** (*Record in grams (g)*)	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____
Was parenteral nutrition (PN) received today? **Protein received from PN:** (*Record in grams (g)*)	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____	❑ Y ❑ N _____
If yes to PN **Did the patient receive IV amino acids (independent of PN)?**	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N
If no to PN **Did the patient receive IV amino acids only?**	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N
Solution's amino acid percentage (10% = 10 g amino acids/100 mL)	_____	_____	_____	_____	_____	_____	_____	_____
Volume of amino acid given (mL)	_____	_____	_____	_____	_____	_____	_____	_____

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 – no PN	Kilocalories received from amino acids	Daily IV Nutrition Data
Lipids – no PN	Kilocalories received from lipids	Daily IV Nutrition Data

Energy Adequacy (%)

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

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

Energy Adequacy (kcal/kg)

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

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

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 (%)

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

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

Protein Adequacy (g/kg)

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

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

effort study

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 ICU Admit	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 <u>one</u> 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.	
Start Date/Time:	Record the date and time the vasopressor or inotrope was initiated.
Stop Date/Time:	• 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. • If the participant was still receiving the vasopressor or inotrope at Day 60, check the appropriate box.
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.	
Did the participant receive a continuous infusion of vasopressors or inotropes today?	If 'yes,' it was received on a particular day, record the highest hourly infusion rate for the vasopressor/inotrope selected.

effort study

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: ❑ Same as death date/time ❑ Still on vasopressor/inotrope at day 60 ❑ Actual: Stop date: (YYYY-MM-DD): Start Time (HH:MM, 24h):	❑ Death ❑ Day 60 ❑ Actual: _____ _____	❑ Death ❑ Day 60 ❑ Actual: _____ _____	❑ Death ❑ Day 60 ❑ Actual: _____ _____	❑ Death ❑ Day 60 ❑ Actual: _____ _____	❑ Death ❑ Day 60 ❑ Actual: _____ _____

Was the vasopressor/inotrope re-started ≥ 24 hours from the last stop date/time? ❑ Yes ❑ No

Proceed to enter the details for the next episode. Enter up to 5 episodes, if applicable.

Study Day:	1 ICU Admit	2	3	4	5	6	7	8	9	10	11	12
Did the participant receive a continuous infusion of vasopressors or inotropes today?	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ 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.	
RRT Start Date/Time:	• If the participant was receiving RRT prior to admission indicate 'yes.' • If the participant did not start RRT until they were hospitalized, record the start date and time.
RRT Stop Date/Time:	• Record the date and time RRT stopped. • If the participant was still receiving RRT following hospital discharge or at Day 60, check the appropriate box.
The following data are to be entered into REDCap™ on the renal replacement form from Day 1-12.	
Did the participant receive RRT today?	If 'yes', specify <u>all</u> modes received during the day (i.e. 24h period): • Intermittent (IHD) • Continuous (CRRT) • Sustained low efficiency (SLED) • Peritoneal (PD) • Other (specify): _____

Daily Data/Outcomes: Renal Replacement Therapy

____
Study ID #

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

Study Day:	1 ICU Admit	2	3	4	5	6	7	8	9	10	11	12
Did the participant receive a RRT today?	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N	❑ Y ❑ N
If yes, specify the mode: Intermittent (IHD) Continuous (CRRT) Sustained low efficiency (SLED) Peritoneal (PD) Other (specify)	❑ IHD ❑ CRRT ❑ SLED ❑ PD ❑ Other: ______	❑ IHD ❑ CRRT ❑ SLED ❑ PD ❑ Other: ______	❑ IHD ❑ CRRT ❑ SLED ❑ PD ❑ Other: ______	❑ IHD ❑ CRRT ❑ SLED ❑ PD ❑ Other: ______	❑ IHD ❑ CRRT ❑ SLED ❑ PD ❑ Other: ______	❑ IHD ❑ CRRT ❑ SLED ❑ PD ❑ Other: ______	❑ IHD ❑ CRRT ❑ SLED ❑ PD ❑ Other: ______	❑ IHD ❑ CRRT ❑ SLED ❑ PD ❑ Other: ______	❑ IHD ❑ CRRT ❑ SLED ❑ PD ❑ Other: ______	❑ IHD ❑ CRRT ❑ SLED ❑ PD ❑ Other: ______	❑ IHD ❑ CRRT ❑ SLED ❑ PD ❑ Other: ______	❑ IHD ❑ CRRT ❑ SLED ❑ PD ❑ Other: ______

Mechanical Ventilation

Definition of Invasive mechanical ventilation 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.	
Ventilation Start Date/Time	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™.
Ventilation Stop Date/Time	Indicate when invasive mechanical ventilation was stopped or if still ongoing at day 60, check the 'still vented at day 60 option. Participants will be considered breathing without invasive mechanical ventilation if they are: • extubated and on face mask (nasal prong) OR • intubated or breathing through a t-tube OR • tracheostomy mask breathing OR • continuous positive airway pressure (CPAP) ≤ 5cm H2O without pressure support or intermittent mandatory ventilation assistance.
Mechanical Ventilation Restarted?	If the participant is extubated and re-intubated within <24 hours, we consider this the same ventilation event. If the participant is extubated and re-intubated ≥ 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.

effort study

Outcomes: Mechanical Ventilation

Study ID # _____

	Episode 1	Episode 2	Episode 3	Episode 4	Episode 5
Start Date (YYYY-MM-DD):	_____	_____	_____	_____	_____
Start Time (HH:MM, 24h)	❑ N/A _____	❑ N/A _____	❑ N/A _____	❑ N/A _____	❑ N/A _____
Stop Date/Time: ❑ Same as death date/time ❑ Still vented at day 60 ❑ Actual: **Stop date: (YYYY-MM-DD):** **Start Time (HH:MM, 24h):**	❑ Death ❑ Day 60 ❑ Actual: _____ _____	❑ Death ❑ Day 60 ❑ Actual: _____ _____	❑ Death ❑ Day 60 ❑ Actual: _____ _____	❑ Death ❑ Day 60 ❑ Actual: _____ _____	❑ Death ❑ Day 60 ❑ Actual: _____ _____

Was the mechanical ventilation stopped then re-started ≥ 24 hours from the last stop date/time? ❑ Yes ❑ No

Proceed to enter the details for the next episode. Enter up to 5 episodes, if applicable.

Hospital Outcomes (1)

Complete this form after 60 days from the participant's initial ICU admission or after their death, whichever comes first.	
Was indirect calorimetry used to manage nutrition needs at any point?	If yes, indirect calorimetry was used during the patient's study participation, record the associated dates. Record up to 5 dates.
Was consent withdrawn during this ICU stay?	In the event that consent is withdrawn for the participant during their participation in the study, select 'yes.'
Date/time consent withdrawn:	Record the date and time the subject withdrew their consent to participate in the trial.
Type of withdrawal:	Specify whether the withdrawal of consent refers to the study intervention, data collection or both using the 3 options listed: • stop intervention, continue data collection • stop intervention, stop data collection (discard previous data) • stop intervention, stop data collection (keep previous data)
Reason consent was withdrawn	Indicate a brief reason why consent was withdrawn for this participant.
ICU Stay	Indicate if the participant died in the ICU on their initial admission. • If yes, indicate the date and time of death. • If no, they were discharged, indicate the date and time of discharge. If the participant was readmitted to the ICU. • We define readmission as ≥24 hours from ICU discharge. ◦ If less than this, consider it the same ICU admission • If readmitted within 60 days from initial admission, complete the same information for each ICU readmission up to 5 readmissions. Alternatively, if no and they were still in ICU at day 60, check the appropriate box.
Hospital Discharge	If the participant was alive and discharged from ICU within 60 days, indicate if they died in hospital. • If yes, indicate the date and time of death. • If no, they were discharged, indicate the date and time of discharge and where they were discharged to. • Alternatively, if no and they were still in hospital at day 60, check the appropriate box.
Hospital Re-Admission	If the participant was ever readmitted to hospital within 60 days of their initial ICU admission: • We define a hospital readmission as ≥24 hours from hospital discharge and 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. • If readmitted within 60 days from initial admission, complete the same information for each hospital readmission

Hospital Outcomes (2)

60-day Outcomes
****PRIMARY STUDY OUTCOME**
	This is our primary outcome and it is important that we record this accurately.
	
	On or after day 60 (this date is 60 days from the participant's initial ICU admit date), please make an attempt (using the resources mentioned below) to confirm the participant's survival status:
	
	• If the participant is **known to be alive**:
	  • Record the date the participant was last known to be alive. This date must be on or after day 60.
	
	• If the participant is **deceased**:
	  • 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.
	
	• If the survival status of the participant is **unknown:**
	  • Record the date the participant was last known to be alive. This date must be before day 60.
	
	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.
	
	• Medical Records – search electronic medical records for evidence of death or evidence is alive (eg. readmission, seen in clinic, procedure done, etc)
	
	• Home care – if the participant had home care arranged at discharge, contact them to determine if the participant is alive
	
	• Obituaries – search online obituaries for newspapers in the participant's local area for evidence of death
	
	• Internet – Google search the participant for documented evidence of death
	
	• Family Physician – contact the family physician's office to determine if the participant remains alive
	
	• 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.

effort study

Study ID #

Outcomes: Hospital Outcomes (1)

Was indirect calorimetry used to manage nutrition needs at any point ❒ Yes → ❒ No	If yes, record the corresponding dates (up to 5): (1) _____; (2) _____; (3) _____ (4) _____; (5) _____ ❑ > 5 *(please check this box of calorimetry was used more than 5 times over the study period)*

If using waived consent, this section is not applicable.	
Consent withdrawn during ICU stay? ❒ Yes → ❒ No ↓	**Date/time consent withdrawn/denied:** _____ **Type of withdrawal/denial of consent:** _____ ❒ stop intervention, continue data collection ❒ stop intervention, stop data collection (discard previous data) ❒ stop intervention, stop data collection (keep previous data)

ICU Stay #1

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

ICU Stay #2

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

ICU Stay #3

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

ICU Stay #4

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

ICU Stay #5

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

effort study

Study ID #

Outcomes: Hospital Outcomes (2)

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

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

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

effort study

Study ID #

Outcomes: Hospital Outcomes (3)

<table>
<tr><td colspan="3">What is the survival status of the patient on or after Day 60?</td></tr>
<tr><td>❑ Alive ↓</td><td>❑ Deceased ↓</td><td>❑ Unknown ↓</td></tr>
<tr><td rowspan="2">Date last known to be alive:</td><td>Date of death known:
↓Yes
Date of death:</td><td rowspan="2">↓Date last known to be alive:</td></tr>
<tr><td>↓No
Date last known to be alive:</td></tr>
</table>

effort study

Hand Grip ICU & Hospital Discharge

Hand Grip General instructions: Ensure the hand grip dynamometer is set with the moveable handle in the second setting/slot. Elbow flexed to 90 degrees, forearm in neutral position; wrist in 30 degrees dorsiflexion . Test the patient's right and left hands.

Read the following script to patient:

Please sit down and I am going to test the strength of your hands. Is there any reason why you think you cannot perform this test? (After participant agrees to participate) I will test both your hands. Bend your elbow and press your arm against your side. Grab the two pieces of metal together like this (DEMONSTRATE).

I will ask you to do the test three times with each hand. When I say "squeeze" squeeze as hard as you can. The two pieces of metal will not move, but I will be able to read the force of your grip on the dial.

When participant begins , say "squeeze, squeeze, squeeze!" (Do NOT provide any other encouragement aside from this specific phrase). Repeat the test 3 times with a rest interval of 1 minute between tests.

It is recommended that the tester alternate between hands to allow the 1 minute rest time and efficiently complete the test.

After the test, the Hand grip dynamometer should be cleaned after each participant by wiping it down with the appropriate disinfectant used at your site.

Was the hand grip test attempted?

❑ Yes ↓ Date Completed	❑ No, reason test was not performed ❑ Participant deceased ❑ Participant withdrew ❑ Not able to complete due to illness or physical limitation ❑ Participant refused ❑ Missed due to ICU/hospital discharge ❑ Missed due to RC unavailable ❑ Other (specify): _____

Which hand is dominant (i.e. used for hand writing)? ❒ Right ❒ Left

Which units are

Right Hand Test completion

Completed	Unable to Assess	Incomplete Test
Test 1 Test 2 Test 3		How many measurements obtained? ❒ 1 ❒ 2 Test 1 Test 2

Left Hand Test completion

Completed	Unable to Assess	Incomplete Test
Test 1 Test 2 Test 3		How many measurements obtained? ❒ 1 ❒ 2 Test 1 Test 2

Study ID #

Hand Grip ICU & Hospital Discharge

Time point: ❒ ICU Discharge ❒ Hospital Discharge

Was the hand grip test attempted? ❑ Yes (Indicate the date of completion) ⟶ ❑ No ❑ No, <72 hours between ICU and Hospital Discharge	**Date test was performed** **(YYYY-MM-DD)**
If you have indicated 'No', indicate the reason why the test was not done. ❑ Participant deceased ❑ Participant withdrew ❑ Not able to complete due to illness or physical limitation ❑ Participant refused ❑ Missed due to hospital discharge ❑ Missed due to RC unavailable ❑ Other (specify): _____	
Which hand is dominant (i.e. used for hand writing)?	❒ Right ❒ Left
<u>Right</u> Hand: Test completion: ❑ Completed ❑ Unable to Assess ❑ Incomplete Test (i.e. all 3 measurements cannot be obtained) *If you have indicated 'Incomplete Test (i.e. all 3 measurements cannot be obtained) see below:* **How many measurements were obtained?** ❑ 1 ❑ 2	**<u>Hand Testing Results:</u>** a) Test 1: _ _ b) Test 2: _ _ c) Test 3: _ _ * You may score odd numbers for lbs or kg although they do not appear on the dynamometer. Round down.
<u>Left</u> Hand: Test completion: ❑ Completed ❑ Unable to Assess ❑ Incomplete Test (i.e. all 3 measurements cannot be obtained) *If you have indicated 'Incomplete Test (i.e. all 3 measurements cannot be obtained) see below:* **How many measurements were obtained?** ❑ 1 ❑ 2	**<u>Hand Testing Results:</u>** a) Test 1: _ _ b) Test 2: _ _ c) Test 3: _ _ * You may score odd numbers for lbs or kg although they do not appear on the dynamometer. Round down.

Data Collection for this patient is now complete.