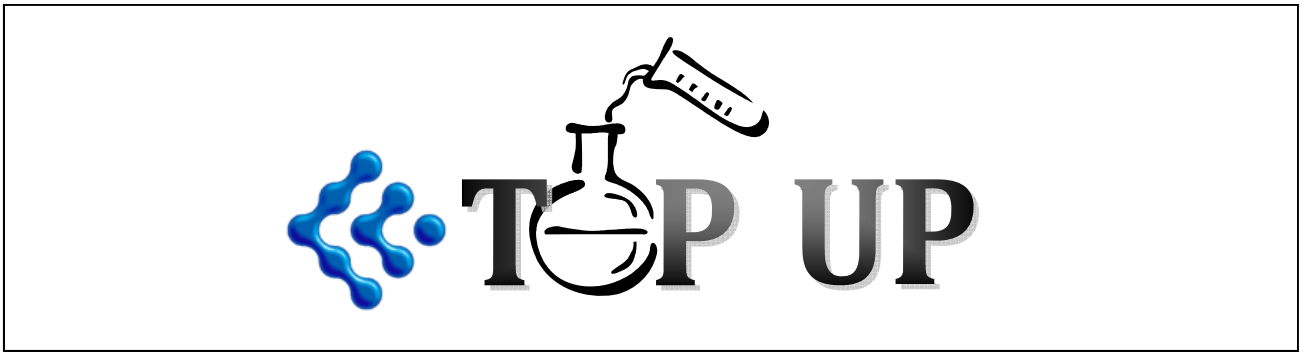
1	0			-				

Site Number Enrollment Number



Mock Electronic Case Report Forms (e-crfs) and Instructions

This study is registered at Clinicaltrials.gov.
Identification number NCT01206166

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General Instructions

The following mock case report forms have been developed to assist the Research Coordinator at the participating site with data collection. The Research Coordinator may choose to record the data from the patient's medical chart (source document) on these forms before entering the data on to the electronic data capture system i.e. REDCAP. Alternatively, she/he may choose to use their own worksheets or enter data directly from the medical chart. In any case, the instructions on each page that detail how and when the data is to be collected **must** be reviewed.

NOTE: the appearance of these mock CRFs and the order in which they appear will vary slightly from REDCAP. This is done to allow for more streamlined data collection. For example, the Barthel Index and SF-36/Nutritional Assessment appear earlier in these CRFs as this information must be obtained from the next of kin soon after consent.

1. To help you keep track, we recommend numbering the worksheets using both the site number & the patient enrollment number assigned by the Central Randomization System (CRS).

1	0			-	1			
Site Number					Enrollment Number			

2. Date format will be year-month-day, entered as YYYY-MM-DD. For example: 2011- 05- 15

3. All times should be recorded using the 24 hour (military) clock. Midnight is to be entered as 00:00 hrs.

4. Anywhere in the CRF worksheet that "Other, specify" is indicated and/or has been checked, there must be an entry on the line provided further describing what "other" means.

5. Record the dates for the corresponding study days according to **calendar day**:
   Study Day 1 date = ICU admit date and time until 23:59 that day, **regardless of when the patient was randomized.**
   Study Day 2 date = the subsequent day starting at 00:00 to 23:59.

   Example 1: Patient admitted to ICU Sept 9 @ 02:00
   Day 1= September 9 (02:00 until 23:59)
   Day 2 = September 10 (00:00 until 23:59)
   Day 3 = September 11 (00:00 until 23:59)

   Example 2: Patient admitted to ICU Sept 8 @ 12:00
   Day 1= September 8 (12:00 until 23:59)
   Day 2 = September 9 (00:00 until 23:59)
   Day 3 = September 10 (00:00until 23:59)

6. The duration of daily data collection and frequency will vary depending upon each data element/form and is as follows:
   - **Collected once:**
     Baseline Barthel ADL Index, Baseline SF-36, Nutritional Assessment, Baseline, Nutrition Timing, Ventilation/ Dialysis, Outcomes Barthel ADL Index, 6-minute Walk Test, Hospitalization Overview, 3-month SF-36 Follow-up and 6-month SF-36 Follow-up
   - **Daily from Study Day 1 until ICU discharge or death for a maximum of 28 days from ICU admission:**
     Daily Nutrition Monitoring, Daily Organ Dysfunction, Daily Laboratory and Intra Abdominal Pressure, Rehabilitation Practices and Concomitant Medications
   - **Daily from Study Day 1 until 3 days after ICU discharge or death for a maximum of 28 days**
     Antibiotic/Antiviral/Antifungal and Microbiology
   - **Weekly/Other specified intervals:** Weekly Laboratory Testing, Muscle Function Testing (Weekly study Femoral Ultrasounds) and Abdominal/Pelvis CT Scans/Femoral Ultrasounds, Hand Grip Strength (twice), i.e. once at ICU discharge and once at Hospital discharge

   Remember to refer to the instructions outlined for each CR form and the Implementation Manual for more details.

7. The duration of the study intervention is 7 days post randomization* or until death whichever comes first.
   Exceptions: If the patient is discharged from the ICU to your hospital ward **before** 7 days:
   - **Supplemental PN Group**: Continue PN intervention at 100% goal until 7 days post randomization* regardless of whether the patient is tolerating adequate amounts of oral nutrition
   - **Both groups**: Collect daily data from Study Day 1 until 7 days post randomization*
   - **Both groups:** Collect antibiotic and microbiology data from Study Day 1 until 10 days post randomization**

   ***7 days post randomization = day of randomization PLUS an additional 7 FULL days**

**Example :

Study Day 1 = Patient admitted to ICU	Sept 4 @ 02:00
Study Day 2 = Patient randomized to TOP-UP	Sept 5 @ 10:00
Study Day 5 = Patient discharged from ICU	Sept 9 @ 12:00
Study Day 9 = Last day of Daily Data Collection	Sep 12 @ 23:59
Study Day 12 = Last day of Antibiotic and Microbiology collection	Sep 15 @ 23:59

For special cases i.e. patient never received the study intervention and died, contact the Project Leader asap.

Screening - Inclusion Instructions

The following pages from page 4- 9 inclusive, refer to the data to be entered into the Central Randomization (CRS). When you are ready to screen and/or randomize a patient, you must access the CRS at the following link

https://ceru.hpcvl.queensu.ca/randomize/ Refer to Implementation Manual for further details regarding the CRS

Date and time of screening	Enter the date and time the patient is screened
Inclusion Criteria	Each patient **must meet all five** of the inclusion criteria at the time of screening to be eligible, with the exception of criteria # 2 which is from time of ICU admission. Eligibility must be confirmed by the Site Investigator/delegate.
1. Critically ill adult ICU patient	Patients must be ≥18 years old and must be admitted to the ICU
2. Acute Respiratory Failure (ARF)	Patients must have acute respiratory failure (ARF) i.e. expected to remain mechanically ventilated > 48 hours **from ICU admission**. This refers to **invasive mechanical ventilation** and is defined as intubation with mechanical ventilation or tracheostomy with mechanical ventilation. This includes **any** positive pressure delivered via an endotracheal tube or a tracheostomy. This **does not** refer to ***non-invasive*** methods of ventilation such as BI-PAP or mask-CPAP.
3. Expected ICU Dependency of 5 of more Days	Patient must be expected to be ICU dependent for 5 or more days (as per judgement by the Site Investigator/delegate). ICU dependency defined as need for mechanical ventilation, non-invasive ventilation, renal replacement therapy, vasopressors, or artificial nutrition because of an underlying illness (not patients that stay in ICU because of lack of availability of beds in a step down unit or on the ward).
4. On or expected to initiate enteral nutrition within 7 days of ICU admission	The "expected to initiate enteral nutrition" refers to the anticipation of the start of enteral nutrition and is an assessment that is made at the time of screening evaluation in collaboration with the Medical Team. In the event that, at the time of screening, the patient was expected to start enteral nutrition within the first 7 days and the patient is randomized, but enteral nutrition does not actually get started, the patient still remains in the study.
5. BMI < 25 or ≥ 35	To calculate the BMI (Body Mass Index), you must need the patients weight in kg and height in meters. **Dry Body Weight** The weight must be based on pre-ICU actual weight or an estimated dry weight. indicate by placing a √ whether the weight is: • Pre-ICU actual weight (documented in chart) or • Pre-ICU estimated weight (from family or practitioner) Record weight in kg (to the nearest decimal point). **Height** Record height in cm (to the nearest decimal point). The height in inches can be converted to cms by multiplying X 2.54. Indicate by placing a √ whether the height is: • measured (by yourself or other staff) or • estimated (obtained verbally from a healthcare professional or family). **BMI (Body Mass Index)** A Body Mass Index must be calculated at the time of screening to determine eligibility. Record the BMI in the box. BMI is calculated as follows: BMI = weight in kg divided by (height in meters)^2 *Example: The patient's pre ICU admission actual weight is 120 kg and he is 5'10" tall.* *Height = 60 inches + 10 inches = 70 X 2.54 = 177.8 cms ÷100 = 1.778 meters* *BMI is therefore 120 ÷(1.778)^2 = 120 ÷3.16 =* ***38*** *(rounded off to nearest whole number)* Alternatively, you may refer to the BMI charts or the Protein and Energy Calculator excel spreadsheet provided (see Study Tools section of your Study Binder) . **IMPORTANT NOTE: If using estimated weight/height, you may add a buffer of ±1 for the BMI, after rounding, In this case, ENTER THE BUFFERRED BMI into the CRS.** Example 1: If estimated BMI is 25 after rounding, use a -1 to get a BMI of 24. Record 24 into the CRS Example 2: If estimated BMI is 34 after rounding, use a +1 to get a BMI of 35. Record 35 into the CRS

Screening—Inclusion

Date and time of screening 2 0 Y Y M M D D H H : M M (24 hour clock)

Inclusion criteria

1. Critically ill adult patient (≥ 18 years) admitted to ICU ☐ Yes

2. Has acute respiratory failure (ARF) i.e. expected to remain mechanically ventilated for more than 48 hours **from ICU admission** ☐ Yes

To avoid enrolling patients that are extubated early and given exclusion criteria # 1 i.e. >72 hours from admission to ICU to time of consent, the following clarification is provided:
If screening is done on day 1 (day of ICU admission):
ensure patient is expected to remain mechanically ventilated for 48 hrs from ICU admission

If screening is done on day 2 (day after ICU admission):
ensure that the patient is expected to be ventilated for an additional 24 hrs from screening (equivalent to 48 hrs from ICU admission)

If screening is done on day 3:
***and patient was ventilated for 48 hrs but now is extubated, he/she is eligible as long as all other inclusion criteria are met*. If patient remains ventilated on day 3, need to ensure that consent is still obtained within 72 hrs from ICU admission.**

3. Expected ICU dependency of 5 or more days ☐ Yes

4. On or expected to initiate enteral nutrition within 7 days of ICU admission ☐ Yes

5. BMI <25 or ≥ 35 based on pre-ICU actual or estimated dry weight ☐ Yes

Dry Body Weight ☐ Pre-ICU actual ☐ Pre ICU estimated _ _ _ • _ kg

Height ☐ measured ☐ estimated _ _ _ • _ cm

BMI _ _

Exclusion Criteria

Record all exclusion criteria that the patient meets.

If any one of the twelve criteria below are met at the time of randomization, then the patient is NOT ELIGIBLE.

1. >72 hours from admission to ICU to time of consent. This refers to the time in your ICU.

2. Not expected to survive an additional 48 hrs from screening evaluation

3. A lack of commitment to full aggressive care (anticipated withholding or withdrawing treatments in the first week but isolated DNR acceptable)

4. Patients already receiving PN at screening

5. Absence of ALL risk factors for gastrointestinal intolerance, defined as:
   a) High Apache II Score (>20)
   b) On more than 1 vasopressor or increasing doses or vasopressors
   c) Receiving continuous infusion of narcotics
   d) High nasogastric/orogastric output (>500 mL over 24 hours)
   e) Recent surgery involving esophagus, stomach, or small bowel OR peritoneal contamination with bowel contents
   f) Pancreatitis
   g) Multiple gastrointestinal investigations
   h) Recent history of diarrhea/C. Difficile
   i) Surgical patients with future surgeries planned
   j) Ruptured or dissected abdominal aortic aneurysm

   The patient MUST have at least 1 risk factor for gastrointestinal intolerance, as defined above, to qualify for this study.
   If the patient does not have any of the above risk factors for gastrointestinal intolerance, place a check in the "Yes" box.
   If the patient has any of the above risk factors for gastrointestinal intolerance, place a check in the "No" box.

6. Patients admitted with diabetic ketoacidosis or non-ketotic hyperosmolar coma

7. Pregnant or lactating patients. Urine/blood tests for pregnancy will be done on all women of childbearing age by each site as part of standard of ICU practice.

8. Patients with clinical fulminant hepatic failure.

   Clinical fulminant hepatic failure is defined as:
   1) Absence of cirrhosis/chronic liver disease **AND**
   2) Presence of coagulopathy (prothrombin time > 15 sec or INR >1.5) **AND**
   3) Presence of any grade of hepatic encephalopathy within 26 weeks of the first symptoms in a patient with acute liver injury

   Clarification: The above criterion applies to **only** those patients who, in the opinion of the Site Investigator/delegate, are deteriorating or are at high risk of dying due to clinical fulminant hepatic failure

9. Patients with Cirrhosis Child's Class C Liver Disease (except those on a transplant list or transplantable).

10. Dedicated port of central line not available

11. Known allergy to study nutrients (i.e. soy, eggs or olive products)

12. Enrollment in another industry sponsored ICU intervention study (co-enrollment in academic studies will be considered on a case by case basis). If patient is enrolled in another industry sponsored ICU intervention study specify name(s) of study: _____

If the patient does NOT meet any of the above exclusion criteria, patient is eligible for enrollment and you may proceed to the Pre-randomization form.

Screening—Exclusion

Exclusion Criteria

1. >72 hours from admission to ICU to time of consent	☐ Yes	☐ No
2. Not expected to survive an additional 48 hrs from screening evaluation	☐ Yes	☐ No
3. A lack of commitment to full aggressive care (anticipated withholding or withdrawing treatments in the first week but isolated DNR acceptable)	☐ Yes	☐ No
4. Patients already receiving PN at screening	☐ Yes	☐ No
5. Absence of All gastrointestinal risk factors, defined as: a) High Apache II Score (>20) b) On more than 1 vasopressor or increasing doses or vasopressors c) Receiving continuous infusion of narcotics d) High nasogastric/orogastric output (>500 mL over 24 hours) e) Recent surgery involving esophagus, stomach, or small bowel OR peritoneal contamination with bowel contents f) Pancreatitis g) Multiple gastrointestinal investigations h) Recent history of diarrhea/C. Difficile i) Surgical patients with future surgeries planned j) Ruptured or dissected abdominal aortic aneurysm If you check “No” to this exclusion criteria, the patient MUST have at least one of these risk factors. If none of the above risk factors are present the patient meets this exclusion criteria.	☐ Yes	☐ No
6. Patients admitted with diabetic ketoacidosis or non-ketotic hyperosmolar coma	☐ Yes	☐ No
7. Pregnant or lactating patients	☐ Yes	☐ No
8. Patients with clinical fulminant hepatic failure	☐ Yes	☐ No
9. Patients with Cirrhosis Child’s Class C Liver Disease (except those on a transplant list or transplantable)	☐ Yes	☐ No
10. Dedicated port of central line not available	☐ Yes	☐ No
11. Known allergy to study nutrients (soy, eggs or olive products)	☐ Yes	☐ No
12. Enrolment in another industry sponsored ICU intervention study (co-enrollment in academic studies will be considered on a case by case basis) If yes specify name(s) of study_____	☐ Yes	☐ No

Pre-Randomization / Randomization Instructions

General Instructions	If all inclusion criteria are present **AND** no exclusion criteria are met the patient is considered eligible for randomization into the study.
ICU admit date and time	Enter the date (format YYYY-MM-DD) and time (00:00 hrs) the patient is actually admitted to the ICU.
Did the patient ever receive EN?	Indicate whether or not the patient ever received EN from ICU admission to the time of pre-randomization by placing a ✓ in the appropriate box, "Yes" or "No".
Did you obtain consent?	Place a ✓ in either the "Yes" or "No" box to indicate whether or not Consent was obtained.
If "Yes", date and time of consent	If "YES", enter date and time of consent (YYYY-MM-DD and 00:00 hrs)
If "No", indicate reason	If "NO", choose the most important reason why the patient wasn't randomized: • No next of kin or substitute decision maker (SDM) • Refused consent • Missed the patient • MD refusal • Language Barriers (translator not available) • Pharmacy not available • Not approached for consent—Family dynamics (stress/discord) • Workload issues • Other, please specify:_____
Patient eligibility confirmed by MD?	Place a ✓ in either the "Yes" or "No" box to indicate whether or not patient eligibility was confirmed by an MD.
Name of physician	Enter the name of the physician who confirmed patient eligibility. This individual should be listed on your Site Delegation of Authority Log.
Type of admission	Place a ✓ in only ONE of the following categories: ❒ Medical ❒ Surgical Medical admission is defined as a patient admitted to the ICU for treatment without any surgical intervention (includes patients admitted from a cardiology/radiology intervention suite). Surgical admission is defined as a patient admitted to the ICU from the operating room directly or a recovery unit following a surgical procedure. This includes "Elective" or planned procedures.

Randomization

Date and time of Randomization	Record the date and time randomization occurred (YYYY-MM-DD and 00:00 hrs)

Pre Randomization

ICU admit date and time 2 0 Y Y M M D D H H M M (24 hour clock)

Did the patient ever receive EN from ICU admission to the time of pre-randomization? ☐ Yes ☐ No

Did you obtain consent? ☐ Yes ☐ No

If YES Date and time of consent 2 0 Y Y M M D D H H M M (24 hour clock)

If NO choose the most important reason the patient wasn't randomized

☐ No next of kin or substitute decision maker	☐ Language barriers
☐ Refused consent	☐ Pharmacy not available
☐ Missed patient	☐ Not approached for consent—family dynamics
☐ MD refusal	☐ Workload issues

☐ Other, please specify: _____

Patient eligibility confirmed by MD? ☐ Yes ☐ No

Name of physician: _____

Type of admission ☐ Medical ☐ Surgical

Randomization

Date and time of randomization 2 0 Y Y M M D D H H : M M (24 hour clock)

Barthel ADL Index (Baseline) Instructions

General Instructions	The Barthel ADL (Activities of Daily Living) Index establishes how independent the patient was prior to this episode of acute illness. The index should be used a record of what a patient could do at baseline i.e. 24-48 hrs hours preceding the ICU admission or before the patient got sick. Ask the patient's next of kin/relative/friend or nurse, whomever is the best person to help you rate these activities. You may also use direct observation, if needed. • If the patient receives supervision to perform the activity, this means that the patient is dependent • Middle categories of rating imply that the patient supplies over 50 percent of the effort • If aids are used to be independent, consider the patient to be independent Retain a hard copy of the completed Barthel Index in the patients file for source verification purposes.
Duration of Data Collection	This index should be completed at baseline once after consent. Every attempt should be made to obtain this information from the next of kin/caregiver as soon as possible after admission to ICU.
Date completed	Record the date and time the interview completed in the format YYYY-MM-DD.

Barthel ADL Index (Baseline)

Activity		Score
FEEDING	0 = Unable 5 = Needs help cutting, spreading butter, etc., or required modified diet. 10 = Independent	
BATHING	0 = Dependent 5 = Independent	
GROOMING	0 = Needs help with personal care 5 = Independent face/hair/teeth/shaving (implements provided)	
DRESSING	0 = Dependent 5 = Needs help but can do about half unaided 10 = Independent (including buttons, zips, laces, etc)	
BOWELS	0 = Incontinent (or needs to be given enemas) 5 = Occasional accident 10 = Continent	
BLADDER	0 = Incontinent, or catheterized and unable to manage alone 5 = Occasional accident 10 = Continent	
TOILET USE	0 = Dependent 5 = Needs some help, but can do something alone 10= Independent (on and off, dressing, wiping)	
TRANSFERS (BED TO CHAIR AND BACK)	0 = Unable, no sitting balance 5 = Major help (one or two people, physical), can sit 10 = Minor help (verbal or physical) 15 = Independent	
MOBILITY (ON LEVEL SURFACES)	0 = Immobile or < 50 yards 5 = Wheelchair independent, including corners, > 50 yards 10 = Walks with help of one person (verbal or physical) > 50 yards 15 = Independent (but may use any aid; for example, stick) > 50 yards	
STAIRS	0 = Unable 5 = Needs help (verbal, physical, carrying aid) 10 = Independent	
	TOTAL (0-100)	_____

Date index completed 2 0 Y Y M M D D

General Instructions	The SF-36 is a quality of life questionnaire that should be completed with the patient's family/next of kin at baseline (admission to ICU, after consent has been obtained). Copy the SF-36 from (**Appendix 11**) and record the responses on the hard copy. Retain the hard copy in the patients file for source verification purposes.
Duration of Data Collection	The SF-36 will need to be completed once at baseline as soon as possible after consent is obtained. Remember: consent is to be obtained within 72 hrs of ICU admission.
Date of interview	Record the date the interview completed in the format YYYY-MM-DD. If not done, indicate the reason. • Patient died - provide date of death on the Hospitalization Overview form (Pg 43) • Substitute Decision Maker (SDM) refused. If selected enter the date of refusal • SDM withdrew. If selected enter the date of withdrawal • Other (specify) - If the SF-36 was not completed for any other reason, please specify
Nutritional Assessment **Usual Weight**	**Nutritional Assessment** questions must be obtained from the family/next of kin at the time of consent or soon thereafter. **Please note that the responses to these questions may be subjective and are based on the family/next of kin's judgment.** Record the patient's usual weight as obtained from the family. If the patient has been unwell prior to ICU admission, this would be the weight prior to becoming ill. **NOTE:** this usual weight may or may not be the same as the Dry Weight collected for the Inclusion Criteria on page 5.
Total Calories Prescribed	This is the total calories that will be provided by the target goal rate (i.e. maximum rate/volume determined at the initial assessment) for EN/PN or combined EN + PN according to the dietitian's/ MDs assessment. Record this in kilocalories (kcals) and include calories from protein (total kcals, not only non-protein kcals). For eg. If the dietitian/MD recommends a starting rate of 25 mL/hr on day 1 with a final rate of 75 mL/hr by day 3, calculate the calories that the **final rate would provide** = 75mL/hr X 24.
Total Protein Prescribed	This is the total protein that will be provided by the target goal rate (i.e. maximum rate/volume determined at the initial assessment) for EN/PN or combined EN + PN according to the dietitian's/ MDs assessment. Record this in grams. For eg. If the dietitian/MD recommends a starting rate of 25 mL/hr on day 1 with a final rate of 75 mL/hr by day 3, calculate the grams of protein that the **final rate would provide** = 75mL/hr X 24.
Unplanned weight loss in the last 3 months	This question is designed to assist the family member to recall if the patient has experienced any unplanned weight loss recently. Please prompt the patient's family members to recall details about weight loss e.g. • Ask if the patient complained of loss of appetite, digestive problems, chewing or swallowing difficulties, ill-fitting clothing etc. • Use specific times frames e.g. does the patients appear to be thinner than at Christmas time? Check the appropriate box, either Yes or No. If Yes, record the amount of weight the patient lost in either lbs or Kgs, as obtained from the family/ next of kin. If the patient has lost weight but the amount is not known, check the "do not know" box.

Food intake prior to ICU admission	This question is designed to assist the family member to recall if the patient reduced their food intake in the week prior to ICU admission (for any reason).
	Please prompt the patient's family member to recall details about food intake e.g.
	• Estimate the proportion of the meals the patient ate in the preceding week, if they ate
	  • Less than ¼ of what the patient usually eats
	  • ¼ to ½ of what the patient usually eats
	  • More than ½ to ¾ of what the patient usually eats
	  • More than ¾ to all of what the patient usually eats
	  • Do not know or cannot estimate
	Choose the appropriate box.
	Every attempt must be made to obtain this information from the family member/next of kin

Baseline SF-36 / Nutritional Assessment

Baseline SF-36

Date of interview completed
(Record responses on copy of SF-36 Appendix 11) 2 0 Y Y M M D D

Reason not done

- ☐ Patient died
- ☐ SDM refused 2 0 Y Y M M D D
- ☐ SDM withdrew 2 0 Y Y M M D D
- ☐ Other (specify) _____

Nutritional Assessment

Usual Weight ___ ___ ___ ☐ Kg ☐ lbs

Total Calories Prescribed ___ ___ ___ ___ kcal

Total Protein Prescribed ___ ___ gm

Has your family member experienced any unplanned weight loss in the last 3 months?

☐ Yes OR ☐ No

If Yes, how much?

___ ___ ___ ☐ Kg ☐ lbs OR ☐ Do not know

What has your family member's food intake been in the week prior to ICU admission?

- ☐ less than 1/4 of what the patient usually eats
- ☐ 1/4 to 1/2 of what the patient usually eats
- ☐ More than 1/2 to 3/4 of what the patient usually eats
- ☐ More than 3/4 to all of what the patient usually eats
- ☐ Do not know or can not estimate. **(Every attempt must be made to obtain this information from the family member/next of kin)**

Baseline Instructions

Age	Record patient's age at the time of enrollment into the study.
Sex	Place a √ in the appropriate box (male or female).
APACHE II	Go the following website http://www.sfar.org/scores2/apache22.html to calculate the APACHE II score. Record the calculated score. Reminder to use variables within the first 24 hrs of this ICU admission. If variables are not available from the first 24 hrs, go outside the 24 hr window and use data closest to ICU admission.
Ethnic group	Choose the appropriate patient ethnicity from the following list: 1) White 2) Black or African American 3) Hispanic 4) Asian or Pacific Islander 5) Native 6) Other (specify)_____
Comorbidities	Refer to the comorbidities taxonomy **(Appendix 1)** and record all those present. Only those comorbidities found on the taxonomy listing should be recorded. If no comorbidities from this list are present, record this as "None".
Primary ICU diagnosis	Refer to Appendix 2 for the Admission Diagnosis and choose the most pertinent diagnosis that **resulted in the patient's admission to ICU**. Only ONE diagnosis can be chosen. Remember, symptoms are not an admission diagnosis (e.g. respiratory distress, hypotension, etc…). To use the taxonomy (Appendix 2), choose from the Medical or Surgical admission sections. **Ensure that this is the same type of admission recorded on the pre-randomization section of the Central Randomization System (CRS).** Then choose the appropriate body system followed by the corresponding ICU admission diagnosis. If "other" is selected, please specify the diagnosis. **Example**: A patient was admitted to hospital for an elective cholecysectomy. Post-operatively the patient experiences a cardiac arrest on the ward and was subsequently admitted to the ICU. This patient would be classified and entered as as: **Type of admission**: MEDICAL **Body System**: Cardiovascular **ICU Diagnosis**: Cardiac Arrest
Estimated Abdominal/ Pelvic Injury Severity Score	**This section is to be filled out only if trauma is present.** Based on the injury descriptions in the table below, record the corresponding Abdominal Injury Score (AIS) code (highest). • Injuries described as "probable", "possible", "impression of" or "rule out" should not be coded unless they are substantiated in the medical record. • Surgical procedures and other treatment interventions should not be used to determine the severity of injury • When uncertain about the severity of the injury, code conservatively (i.e. lowest AIS code) **AIS Code Injury Description: Abdominal or Pelvic Contents** **AIS 1** - Muscle ache; Seat belt abrasion, etc. **AIS 2** - Major contusion of abdominal wall **AIS 3** - Contusion of abdominal organs; Extraperitoneal bladder rupture; Retroperitoneal hemorrhage, avulsion of ureter or laceration of urethra; Thoracic or lumbar spine fractures without neurological involvement. **AIS 4** - Minor lacerations of intra-abdominal contents (to include ruptured spleen, kidney, and injuries to tail of pancreas); Intraperitoneal bladder rupture; Avulsion of the genitals; Thoracic and/or lumbar spine fractures with paraplegia. **AIS 5** - Rupture, avulsion or severe laceration of intra-abdominal vessels of organs, except kidneys, spleen or ureter.
Prednisone	Did the patient receive > 5mg/day of oral prednisone for >28 days prior to hospital admission? Check "Yes", "No" or "Unknown".
GI Intolerance Risk Factors	Does the patient have any of these risk factors for gastrointestinal (GI) intolerance (at baseline)? Check "Yes" or "No" If "Yes", place a "✓ " in the box next to each of the risk factors that are present (select ALL that apply): 1. High APACHE II Score (>20) 2. On more than 1 pressor, or increasing doses of pressors 3. Receiving continuous infusion of narcotics 4. High NG/OG output (>500 mls over 24 hours) 5. Recent surgery involving esophagus, stomach, or small bowel OR peritoneal contamination with bowel contents 6. Pancreatitis; 7. Multiple GI investigations 8. Recent history of diarrhea/C. difficile 9. Surgical patients with future surgeries planned 10. Abdominal Aortic Aneurysm - ruptured or dissected (emergency vascular surgery) 11. Other (please specify) If you choose "other", provide specifics in the space provided
Hospital admit date and time	Enter the date and time patient admitted to the hospital (this current hospitalization). This is the time of initial presentation to the emergency department or hospital ward, whichever is the earliest. If the patient is admitted directly to the ICU, this date and time becomes the Hospital admit date and time.
ICU admit date and time	Enter the date and time the patient is actually admitted to the ICU. **Ensure that this is the same date and time of ICU admission as recorded on the pre-randomization section of the Central Randomization System (CRS). Discrepancies may require all daily forms to be re-entered.**

Baseline

Age _ _ **Sex** ☐ Male ☐ Female **APACHE II** _ _

Ethnic group

☐ White ☐ Black or African American ☐ Hispanic ☐ Asian or Pacific Islander ☐ Native ☐ Other (specify) _____

Comorbidities ☐ None

1) _____ 4) _____ 7) _____

2) _____ 5) _____ 8) _____

3) _____ 6) _____ 9) _____

Primary ICU diagnosis Type of Admission ☐ Medical ☐ Surgical

Body System _____ ICU Admission Diagnosis _____

If trauma present,
Estimated Abdominal/Pelvic Injury Severity Score

☐ No injury ☐ AIS 1 ☐ AIS 2 ☐ AIS 3 ☐ AIS 4 ☐ AIS 5

Did the patient receive >5mg/day of oral prednisone for > 28 days prior to hospital admission?

☐ Yes ☐ No ☐ Unknown

Does the patient have any of these risk factors for G.I. intolerance (at baseline)? ☐ Yes ☐ No

If "Yes", place a check in the box(es) next to each of the risk factor(s) listed below that apply :

☐ 1. High APACHE II Score (>20)

☐ 2. On more than one pressor, or increasing doses of pressors

☐ 3. Receiving continuous infusions of narcotics

☐ 4. High NG/OG output (>500 mls over 24 hrs)

☐ 5. Recent surgery involving esophagus, stomach, or small bowel OR peritoneal contamination with bowel contents

☐ 6. Pancreatitis

☐ 7. Multiple G.I. investigations

☐ 8. Recent history of diarrhea/C. difficile

☐ 9. Surgical patients with future surgeries planned

☐ 10. Abdominal Aortic Aneurysm - ruptured or dissected (emergency vascular surgery)

☐ 11. Other (please specify): _____

Hospital admit date and time 2 0 Y Y M M D D H H M M (24 hour clock)

ICU admit date and time 2 0 Y Y M M D D H H M M (24 hour clock)

Nutrition Timing Instruction

General Instructions	These data are collected to determine the timing of initiation of enteral nutrition (EN), study parenteral nutrition and non study parenteral nutrition (PN).
Duration of Data Collection	This will need to be completed once at initiation and permanent discontinuation of enteral nutrition, study nutrition and non-study nutrition.
Enteral Nutrition **Start** **Stop**	Indicate whether EN was started in the ICU, Yes (Y) or No (N). Although the response for most patients will be yes, there may be rare instances where EN was never received i.e. early death, withdrawal of care, etc. If Yes, specify the date in the format YYYY-MM-DD and time in 00:00 format If No, choose either of these options: • No • EN started prior to ICU admission and continued in the ICU. Do **not** record date and time. For the stop date of EN, choose one of the following options: • Still ongoing at day 28 in the ICU. Do **not** record date and time. • Stopped in ICU by day 28. Record date and time. • Still on EN when transferred to the ward PRIOR to (and including) 7 days post randomization*. Record date and time. • Still on EN and transferred to the ward AFTER 7 days post: Do **not** record date and time.
Study Parenteral Nutrition **Start** **Stop**	Indicate whether Study PN was started in the ICU, Yes (Y) or No (N). If Yes, specify the date in the format YYYY-MM-DD and time in 00:00 format **NOTE: If patient was randomized to the supplemental PN group but never received the study PN, this will likely be considered as Protocol Violation. Please inform the Project Leader asap.** Record the actual stop date of the study PN in the YYYY-MM-DD format and time in 00:00 format
Non- Study Parenteral Nutrition **Start** **Stop**	Indicate whether non study PN was started in the ICU, Yes (Y) or No (N). If Yes, specify the date in the format YYYY-MM-DD and time in 00:00 format **NOTE: Receiving non study PN, even though may be clinically indicated, in the first 7 days post randomization is considered to be a Protocol Violation. Proceed to the Protocol Violation form** For the stop date of non study PN, choose one of the following options: • Still ongoing at day 28 in the ICU. Do **not** record date and time. • Stopped in ICU by day 28. Record date and time. • Still on non study PN when transferred to the ward PRIOR to (and including) 7 days post randomization*. Record date and time. • Still on non study PN and transferred to the ward AFTER 7 days post: Do **not** record date and time. ***7 days post randomization = day of randomization PLUS an additional 7 FULL days.**

Nutrition Timing

Enteral Nutrition

	Date	Time
Start Was enteral nutrition started in the ICU? ☐ Yes (specify date) →	2 0 Y Y M M D D	H H M M (24 hour clock)
☐ No		
☐ EN started prior to ICU admission & continued in the ICU.		
Stop ☐ Still ongoing at day 28 in the ICU **OR** ☐ Stopped in the ICU by day 28 (specify date) → **OR** ☐ Still on EN and transferred to the ward PRIOR to (and including) 7 day post randomization (specify date) → **OR** ☐ Still on EN and transferred to the ward AFTER 7 days post randomization	2 0 Y Y M M D D	H H M M (24 hour clock)

Study Parenteral Nutrition

	Date	Time
Start Was study parenteral nutrition started in the ICU? ☐ Yes (specify date) →	2 0 Y Y M M D D	H H M M (24 hour clock)
☐ No		
Stop Date →	2 0 Y Y M M D D	H H M M (24 hour clock)

Non-Study Parenteral Nutrition

	Date	Time
Start Was non-study parenteral nutrition started in the ICU? ☐ Yes (specify date) →	2 0 Y Y M M D D	H H M M (24 hour clock)
☐ No		
Stop ☐ Still ongoing at day 28 in the ICU **OR** ☐ Stopped in the ICU by day 28 (specify date) → **OR** ☐ Still on non study PN when transferred to the ward PRIOR to (and including) 7 days post randomization (specify date) → **OR** ☐ Still on non-study PN and transferred to the ward AFTER 7 days post randomization	2 0 Y Y M M D D	H H M M (24 hour clock)

Invasive Mechanical Ventilation	
Invasive mechanical ventilation start date and time #1	Record the actual start of invasive mechanical ventilation in this institution, even if this occurs in your emergency room prior to ICU admission. This refers to the first time that invasive mechanical ventilation was started and may not be the same time that the patient was intubated. For a patient that is mechanically ventilated prior to admission to your hospital, this start date should be same date and time of hospital admission (or ER admission in your hospital).
Mechanical Ventilation Stop #1	Record the final stop date and time that mechanical ventilation was discontinued. Do **not** record episodes of temporary ventilation (defined as <48 hrs i.e. needed for operating procedures, etc) For patients that are on and off the ventilator, the patient is considered to be ventilator free if they are successfully breathing without mechanical ventilation for > 48 hours. In this event, record the date and time the ventilation was actually discontinued (i.e. in this instance, the start of the 48 hrs). Patients will be considered breathing **without** mechanical ventilation in any of these instances: • extubated and on face mask (nasal prong) • intubated or breathing through a t-tube • tracheostomy mask breathing. • continuous positive airway pressure (CPAP) <=5cmH2O without pressure support or intermittent mandatory ventilation assistance. For stop date of mechanical ventilation, choose one of the following options: • Same as death date.time. Do **not** record date or time. • At 6 months, still ventilated in hospital (refers to your hospital). Do **not** record date or time. • Actual stop date and time. Record date and time. If patient is transferred out of the ICU to another institution and is still receiving mechanical ventilation then record the transfer date and time as the mechanical ventilation discontinuation date and time.
Mechanical ventilation re-instituted?	Indicate if mechanical ventilation was re-instituted after 48 hrs from the last mechanical ventilation stop date/time, Yes (Y) or No (N). If Yes, proceed to next row, if not, proceed to Dialysis section
Mechanical Ventilation start #2 **Stop #2**	If the patient is restarted on invasive mechanical ventilation after being extubated successfully for 48 hrs, record the start date and time. Record the stop date of the second episode of mechanical ventilation using the same options as listed above for the first episode.
Mechanical Ventilation start #3 and stop #3	Follow the same instructions as listed above for the 3rd episode of Mechanical Ventilation, if applicable.
Dialysis	

Dialysis during ICU
 	
Acute renal failure
 	
Start
 	
Stop
	Did the patient receive dialysis during this ICU stay? This refers to any type of dialysis i.e. hemodialysis, renal replacement therapy, etc)
	If No (to dialysis), stop here (dialysis section is complete)
	If Yes, answer the following question, Yes (Y) or No (N)
	• The first time dialysis was started, was it due to acute renal failure?
	  • If Yes, record the start date of dialysis
	  • If Yes, record stop date of dialysis by choosing one of the following options:
	  • Continued past hospital discharge. Do **not** record date.
	  • At 6 months, still on dialysis in hospital. Do **not** record date.
	  • Actual stop date (in your hospital). Record date and time.
	  • If No (to acute renal failure), stop here (dialysis section is complete)

Invasive Mechanical Ventilation / Dialysis

Invasive Mechanical Ventilation

	Start Date	Start Time	Stop Date	Stop Time
1.	2 0 Y Y M M D D **Actual** start date/time, in this institution	H H M M (24 hour clock)	☐ Same as Death Date/Time ☐ At 6 months, still ventilated in hospital **OR** 2 0 Y Y M M D D	H H M M (24 hour clock)
Was mechanical ventilation re-instituted ≥ 48 hours from the last mechanical ventilation stop date/time?			☐ **Yes** (Continue to next row) ☐ **No** (Proceed to Dialysis section)	
2.	2 0 Y Y M M D D **Actual** start date/time, in this institution	H H M M (24 hour clock)	☐ Same as Death Date/Time ☐ At 6 months, still ventilated in hospital **OR** 2 0 Y Y M M D D	H H M M (24 hour clock)
Was mechanical ventilation re-instituted ≥ 48 hours from the last mechanical ventilation stop date/time?			☐ **Yes** (Continue to next row) ☐ **No** (Proceed to Dialysis section)	
3.	2 0 Y Y M M D D **Actual** start date/time, in this institution	H H M M (24 hour clock)	☐ Same as Death Date/Time ☐ At 6 months, still ventilated in hospital **OR** 2 0 Y Y M M D D	H H M M (24 hour clock)

Dialysis

Did the patient receive dialysis during this ICU stay? ☐ **Yes** (Continue to next row) ☐ **No** (Stop here)

The first time dialysis was started, was it due to acute renal failure? ☐ **Yes** (Continue to next row) ☐ **No** (Stop here)

	Start Date	Stop Date
1.	2 0 Y Y M M D D	☐ Continued past hospital discharge ☐ At 6 months, still on dialysis in hospital **OR** 2 0 Y Y M M D D

Daily Monitoring (EN) Instruction

General Instructions	These data are collected to determine the adequacy of enteral nutrition (calories and protein received)
Duration of Data Collection	The duration of data collection is daily from ICU admit to ICU discharge, death which ever comes first for a maximum of 28 days. If the patient is discharged from the ICU before 7 days post Randomization*, then the duration of data collection will be until hospital discharge, death which ever comes first, for a maximum of 7 days post randomization*. ***7 days post randomization = day of randomization PLUS an additional 7 FULL days.**
Day #	Record the study day number consecutively at the top of each column, starting at D# **1**
Date	Record dates according to study days in the format YYYY-MM-DD.
Prescribed Volume	Record the prescribed volume of enteral (or parenteral or combined EN + PN) in mls. **This MUST be calculated by the dietitian/MD within 48 hrs of randomization and must meet the minimum energy and protein dosing outlined in the protocol**. This prescribed volume is to be re-assessed and adjusted if needed, daily. Refer to the "Protein and Energy Dosing" section in the Implementation Manual. If there is a change in the prescribed order, average the two volumes but account for the # hours actually received. For example, a patient that was switched from 90 ml/h to 60 ml/h at 11am: *1. Calculate the volume that pt received at 90 ml/hr = 90 X 11 hrs = 990 mls* *2. Calculate the volume the pt received at 60 ml/hr = 60 X 13 hrs = 780 mls* *3. Combine the 2 volumes = 990 + 780 mls divided by 24 = 1770/24 = 74 ml/hr. Target rate would be 74 ml/hr.* Choose N/A **only** if the patient is not to receive any EN or PN and add reason why this is so (i.e. on oral feeds). If the patient is discharged from the ICU before day 7, record the volume the patient would have received if he/she were in the ICU for the full day. For all subsequent days after ICU discharge, Continue to enter the 100% goal rate as the prescribed volume.
Enteral Nutrition Today?	For each day, indicate whether the patient received enteral nutrition, Yes (Y) or No (N). If No, choose all the reasons why from the list below: 1. Obtained target rate from study parenteral nutrition 2. NPO for endotracheal extubation or intubation or other bedside procedure 3. NPO for operating procedure 4. NPO for radiology procedure 5. High NG drainage 6. Increased abdominal girth, abdominal distension or pt. discomfort 7. Vomiting, emesis or nausea 8. Diarrhea 9. No enteral access available / enteral access lost, displaced or malfunctioning 10. Inotropes, vasopressor requirement 11. Subject deemed too sick to continue enteral feeding 12. On oral feeds 13. Reason not known
Formula Number & Volume received (ml)	If Yes to Enteral Nutrition, refer to **Appendix 3** and choose the number that corresponds to the type of enteral formula received. If enteral formula is not on Appendix 3, choose Other and specify. Record the corresponding volume of enteral nutrition received in mls for each day. You may record up to 3 different formulas in a day. In the event that the patient receives more than 3 formulas in one day, select the 3 that provide the largest volumes.
Protein Supplement Number & grams	If the patient received a modular protein supplement, record the number corresponding to the type of protein supplement from **Appendix 3.** Record the grams of protein received from this supplement.

Daily Monitoring (EN) Instruction

Enteral Nutrition interrupted & reasons	For each day, record whether enteral nutrition was interrupted, Yes (Y) or No (N). If Yes, choose **all** the reasons enteral nutrition was interrupted from the following list. 1. Fasting for endotracheal extubation or intubation or other bedside procedure 2. Fasting for operating procedure 3. Fasting for radiology procedure 4. High gastric residual. **If this is chosen, record the highest gastric residual volume of the study day in mls** 5. Increased abdominal girth, abdominal distension or pt. discomfort 6. Vomiting or emesis 7. Diarrhea 8. No enteral access available / enteral access lost, displaced or malfunctioning 9. Inotropes, vasopressor requirement 10. Subject deemed too sick to continue enteral feeding 11. Reason for EN interuption not known
Feeding tube location	For every day, indicate the location of the feeding tube as one of the following. 1. Gastric 2. Small bowel (includes post-pyloric, duodenal or jejunal) 3. No tube in place
Total calories received (Kcals) **Total protein received (gms)**	This refers to the total calories (kilocalories) received from all enteral nutrition for each day and is to be calculated by the dietitian as follows: • Include total calories from all enteral nutrition formulas (vs. non protein calories) • Include calories from protein supplements and other supplements • Do not include calories from propofol (to be included under Parenteral Daily Monitoring) • Do not include calories from intravenous solutions or from oral intake This refers to the total protein received (in grams) from all enteral nutrition for each day and is to be calculated by the dietitian as follows: • Include protein from all enteral nutrition formulas • Include protein from the protein supplements

Daily Monitoring (PN) Instruction

General Instructions	These data are collected daily to determine the adequacy of parenteral nutrition (calories and protein received)
Duration of Data Collection	The duration of data collection is from ICU admit to ICU discharge or death, which ever comes first, for a maximum of 28 days. If the patient is discharged from the ICU before 7 days post randomization*, then the duration of data collection will be until hospital discharge, death which ever comes first for a maximum of 7 days post randomization*. ***7 days post randomization = day of randomization PLUS an additional 7 FULL days.**
Day #	Record the study day number consecutively at the top of each column, starting at D**#1**.
Date	Record dates according to study days in the format YYYY-MM-DD.
Study PN (Olimel) Received	Indicate whether the patient received study parenteral nutrition, Yes (Y) or No (N). If No, record all reasons why not received 1. Obtained target rate of EN 2. Fluid overload 3. No central line access 4. Abnormal blood work 5. Refeeding 6. Other: please specify (provide details in the space provided)
Volume & Interruptions	If Yes, record the volume received from study parenteral nutrition in mls. If received study PN, indicate if it was interrupted? Yes (Y) or No (N) If yes, indicate reasons why interrupted 1. Fluid overload 2. No central line access 3. Abnormal blood work 4. Refeeding 5. Obtained target rate of EN 6. On oral feeds 6. Other: please specify (provide details in the space provided)
Non Study PN	Indicate whether the patient received non-study parenteral nutrition, Yes (Y) or No (N).
Type **Volume**	If Yes, record if multichamber solution, Yes (Y) or NO (N). Multichamber solution refers to solutions that have amino acids, lipids and dextrose mixed together. Non multichamber solutions refer to either single bag systems or custom made solutions. If Yes to multichamber solution, record the corresponding number of the type of multichamber solution. If No to multichamber solution, record the type of amino acid, dextrose and lipid received by referring to **Appendix 4.** Record the volume of each of the solutions received in mls. Choose "Other" if the type is not listed in Appendix 4 and specify the name of the solution(s) received.
Total calories received (Kcals)	This refers to the total calories (kilocalories) received from the non study parenteral nutrition for each day and is to be calculated by the dietitian as follows: • include calories from protein (vs. non protein calories) • do not include the calories from IV solutions not used for parenteral nutrition • do not record the calories from propofol (volume to be recorded separately below). • do not include calories from the study parenteral solution
Total protein received (gms)	This refers to the total protein (grams) received from the non study parenteral nutrition for each day and is to be calculated by the dietitian as follows: • include protein from non study parenteral nutrition • do not include the calories from IV solutions not used for parenteral nutrition • do not record the calories from propofol (volume to be recorded separately below). • do not include protein from enteral sources (to be recorded under enteral nutrition) • do not include protein from the study parenteral nutrition **NOTE: Receiving non study PN or IV lipids, even though may be indicated, in the first 7 days post randomization is considered to be a Protocol Violation**
Propofol **Calories**	Indicate whether a continuous infusion ≥ 6 hrs pf propofol was received, Yes (Y) or No (N). Record this regardless of whether the patient received EN or PN. Do NOT include intermittent doses of propofol. If Yes, records the calories received (kcals) from propofol. **To convert mls to calories, multiply mls X 1.1**
Protocol Violation today?	Refer to the Protocol Violation Case report Form for more instructions and deadlines for reporting to CERU. If the percent of prescribed volume is <80% or >120% within the first 7 days from randomization, this is a protocol violation. Exceptions: Day of randomization, day of ICU discharge and days subsequent to ICU discharge.
SAE today?	Record Yes (Y) or No (N) if an unexpected serious adverse event (SAE) occurred. In the event that a SAE (serious and unexpected) has occurred, a SAE form must be completed and faxed to CERU 613-548-2428 within 24 hours. Refer to the SAE forms page 50 & 53 for more details.

Daily Monitoring (EN)

Day #	D#	D#	D#	D#	D#	D#	D#
Date YYYY-MM-DD							
Prescribed volume (mls) of EN (or parenteral or combined) or N/A							
ENTERAL NUTRITION							
Received today? Y or N							
If No, record all reasons for not receiving EN							
Formula # 1 / Volume received (ml)							
Formula # 2 / Volume received (ml)							
Formula # 3 / Volume received (ml)							
Protein Supplement # / grams received							
Was EN interrupted today? Y or N							
If Yes, record all that apply (see taxonomy) If 2°GRVs, record volume (mls)							
Feeding tube location	☐ Gastric ☐ Small bowel ☐ No tube	☐ Gastric ☐ Small bowel ☐ No tube	☐ Gastric ☐ Small bowel ☐ No tube	☐ Gastric ☐ Small bowel ☐ No tube	☐ Gastric ☐ Small bowel ☐ No tube	☐ Gastric ☐ Small bowel ☐ No tube	☐ Gastric ☐ Small bowel ☐ No tube
Total calories received from EN (kcal)							
Total protein received from EN from EN (g)							

1	0			-				
Site Number					Enrollment Number			

Daily Monitoring (PN)

Day #	D#	D#	D#	D#	D#	D#	D#
Date YYYY-MM-DD							
PARENTERAL NUTRITION							
Study PN (Olimel) Received today? Y or N							
If N, record all reasons for not receiving Study PN? (see taxonomy)							
If Y, record volume received (ml)							
If Y, was study PN interrupted? Y or N							
If Yes, record all reasons for interruptions (see taxonomy)							
Non-Study PN Received today? Y or N (if N, skip to Propofol)							
If Y, multichamber solution Y or N							
If Y to multichamber, Record type / Volume received (ml)							
If N to multichamber, Amino Acid Type / Volume received (ml)							
Dextrose Type / Volume received (ml)							
Lipid Type / Volume received (ml)							
Total cals received from non–study PN (kcals)							
Total protein received from non-study PN (g)							
Propofol							
Propofol today? Y or N							
Calories from propofol (kcal)							
Protocol Violation today? Y or N							
SAE today? Y or N							

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Daily Organ Dysfunction Instructions

General Instructions	These data are collected for calculation of SOFA and organ dysfunction scores.
Duration of Data Collection	These data are to be collected from ICU admit to ICU discharge or death, which ever comes first, for a maximum of 28 days. For Study Day 1 or day of discharge, the study day may not be a full 24 hrs period for most data elements (except urine output on Day 1) If the patient is discharged from the ICU before 7 days post randomization*, then the duration of data collection will be until hospital discharge or death, which ever comes first, for a maximum of 7 days post randomization* **(*Day of randomization PLUS an additional 7 FULL days)**.
Day #	Record the study day number consecutively at the top of each column, starting at day 1.
Date	Record dates according to study days in the format YYYY-MM-DD.
Heart rate	Record the highest heart rate observed during the study day.
Core Temperature	Select either °C or °F for how the temperature was recorded throughout the Daily organ data collection. Record the most aberrant core temperature from 37.0°C observed during the study day. This refers to the temperature which deviates from 37.0°C the most. For example, the following core temperatures were recorded on study day 1: 37.7ºC, 37.9ºC, 36.0ºC, 36.8ºC. A core temperature of 36.0ºC should be recorded in the CRF because it deviates the most from 37.0°C. To convert a non-core temperature to a core temperature: Oral temperature + 0.5 °C = core temperature Axillary temperature + 1.0°C = core temperature.
MAP	Enter the lowest MAP observed during the study day. This value should only be recorded if the patient is NOT receiving any vasopressors (i.e. dopamine, dobutamine, norepinephrine, epinephrine, phenylephrine or vasopressin). If the patient is receiving vasopressors then enter "N/D" on the CRF.
Respiratory Rate	Enter the highest mechanical and/or spontaneous respiratory rate observed during the study day.
Urine output (mL)	Place a √ in the appropriate volume range for urine output for the study day i.e. 0 - 199 mls 200 - 499 mls or ≥ 500 mls **NOTE: for Study Day 1, since this will be a partial day i.e. from ICU admission until 23:59 hrs, use the urine output extrapolated for the full 24 hour period vs. the actual urine output.** Example: If the patient gets admitted to ICU at 18:00 hrs and has a total urine output of 400 mls from 18:00-23:59 hrs, calculate the total urine output as 1600 mls vs. 400 mls. Record as ≥ 500 mls
Total 24 hrs fluid balance	Record the cumulative balance in and out balance in mls. This is not limited to urine output and includes all fluids recorded on the nursing flowsheet. For Study day 1, do **not** extrapolate to 24 hrs period as the balance from partial day is adequate.
Did the patient have diarrhea today?	Diarrhea is defined as either **>5 bowel movements/day or >750ml/day.**
Vasopressors/ Inotropes	Record the highest hourly dose infused in the study day for each of the following vasopressor/ inotropes (in the units requested) received during the study day. **Use the following units**, **you may need to calculate the correct units** Dopamine (µg/kg/min) Epinephrine (µg/kg/min) Milrinone (µg/kg/min) Dobutamine (µg/kg/min) Phenylephrine (µg/min) Norepinephrine (µg/kg/min) Vasopressin (units/min) Place a **forward slash** in the column if no vasopressor/inotropes were administered that day.

Daily Organ Dysfunction

Day #	D#	D#	D#	D#	D#	D#	D#
Date (YYYY-MM-DD)							
Heart Rate (highest)							
Temperature (most aberrant) ☐ °C ☐ °F							
MAP (lowest)							
Respiratory Rate (highest)							
Urine output: 0 - 199 mls/day							
200 - 499 mls/day							
≥ 500 mls/day							
Total 24hr Fluid Balance							
Did the patient have diarrhea today? Y or N							
Dopamine Highest dose µg/kg/min							
Dobutamine Highest dose µg/kg/min							
Norepinephrine Highest dose ☐ µg/kg/min or ☐ µg/min							
Epinephrine Highest dose ☐ µg/kg/min or ☐ µg/min							
Phenylephrine Highest dose ☐ µg/kg/min or ☐ µg/min							
Vasopressin Highest dose units/min							
Milrinone Highest dose µg/kg/min							

Daily Laboratory/Intra Abdominal Pressure (IAP) Instruction

General Instructions	These data are collected for an assessment of selected daily blood work and intra-abdominal pressures (elevated pressures may indicate cardiovascular, respiratory or renal compromise).
Duration of Data Collection	These data are to be collected from ICU admit to ICU discharge or death, which ever comes first, for a maximum of 28 days. If the patient is discharged from the ICU before 7 days post randomization*, then the duration of data collection will be until hospital discharge or death, which ever comes first, for a maximum of 7 days post randomization* ***7 days post randomization = day of randomization PLUS an additional 7 FULL days**. If labs are not done for a particular day, you may wish to place a " N/D " in the appropriate box.
Day #	Record the study day number consecutively at the top of each column, starting at day 1.
Date	Record dates according to study days in the format YYYY-MM-DD.
PaO_2/FiO_2	Record the **lowest (worst)** PaO_2/FiO_2 (PF ratio) observed on the study day, regardless of ventilation status. The PaO_2 and FiO_2 values should come from the same blood gas measurement. You may refer to **Lowest PF Ratio Table** in **Appendix 5**. If the patient is on a mask or cannula, please use the **Conversion Table for FiO2** in **Appendix 6**.
T-bilirubin	Record the **highest** serum total bilirubin observed on the study day. Indicate the units the result was recorded in.
Serum Creatinine	Record the **highest** serum creatinine observed on the study day. Indicate the units the result was recorded in.
Urea highest	Record the **highest** serum urea observed on the study day. Indicate the units the result was recorded in.
Platelets lowest	Record the **lowest** serum platelets observed on the study day. Indicate the units the result was recorded in.
WBC highest	Record the **highest** white blood count observed on the study day. If there is only one value recorded for the 24 hr period then record the one value as the highest and lowest. Indicate the units the result was recorded in.
WBC lowest	Record the **lowest** white blood count observed on the study day. If there is only one value recorded for the 24 hr period then record the one value as the highest and lowest. Indicate the units the result was recorded in.
Total number of blood sugars taken today.	Record the total number of blood sugars taken on the study day. Include those from both serum and capillary.
Number of hyperglycemic events today	Record the total number of hyperglycemic events (≥ 10 mmol/L or ≥ 180 mg/dL) on the study day from serum and capillary blood sugars.
Number of hypoglycemic events today	Record the total number of hypoglycemic events (≤ 2.2 mmol/L or ≥ 40 mg/dL) on the study day from serum and capillary blood sugars.
Intra-abdominal Pressure Readings	Record the worst (highest) intra abdominal pressure reading that is available, during the study day (in mm Hg). If no pressure readings are available for the day, you may place a " N/D " in the appropriate box.

Daily Laboratory and IA Pressure

Day #	D#	D#	D#	D#	D#	D#	D#
Date (YYYY-MM-DD)							
PaO2/FiO2 (lowest)							
K^+ (Lowest) ☐ **mEQ/L** ☐ **mmol/L**							
Phosphate (Lowest) ☐ **mg/L** ☐ **mmol/L**							
T-bilirubin (highest) ☐ **mg/dL** ☐ **µmol/L**							
Creatinine (highest) ☐ **mg/dL** ☐ **µmol/L**							
Urea highest ☐ **mg/dL** ☐ **mmol/L**							
Platelets lowest ☐ **10^3/µL** ☐ **10^9/L**							
WBC highest ☐ **10^3/µL** ☐ **10^9/L**							
WBC lowest ☐ **10^3/µL** ☐ **10^9/L**							
Total number of blood sugars taken today. (capillary and serum)							
Number of hyperglycemic events (≥ 10 mmol/L or ≥ 180 mg/dL)							
Number of hypoglycemic events (< 3.5 mmol/L or < 63 mg/dL)							
IAPressure (worst) reading mmHg							

Weekly Laboratory Instruction

General Instructions	These data are collected to assess the safety of supplemental nutrition.
Duration of Data Collection	These data are to be collected weekly from ICU admit to ICU discharge, death which ever comes first for a maximum of 28 days (4 weeks). **Weekly Laboratory Collection Periods** / **Week 1** / **Week 2** / **Week 3** / **Week4** Study Day / 1-7 / 8-14 / 15-21 / 22-28 If a week is incomplete due to ICU discharge or death, record the highest/lowest values for the applicable study days. *For example, if a patient was discharged from the ICU on day 10, record the applicable highest/ lowest lab values from study day 8-10 into week 2.* If labs are not done for a particular day, you may wish to place a " N/D " in the appropriate box.
Day #	Record the study day number consecutively at the top of each column, starting at day 1.
Date	Record dates according to study days in the format YYYY-MM-DD.
Albumin (Lowest)	Record the **lowest** serum albumin observed in that study week. Indicate the units the result was recorded in.
Prealbumin (Lowest)	Record the **lowest** serum prealbumin observed in that study week. Indicate the units the result was recorded in.
CRP (Highest)	Record the **highest** serum C-reactive protein (CRP) observed in that study week in mg/L.
AST (Highest)	Record the **highest** serum aspartate aminotransferase (AST) observed in that study week in IU/L.
ALT (Highest)	Record the **highest** serum alanine aminotransferase (ALT) observed in that study week in IU/L.
ALP (Highest)	Record the **highest** serum alkaline phosphatase (ALP) observed in that study week IU/L.
Triglycerides (Highest)	Record the **highest** serum triglycerides observed in that study week. Indicate the units the result was recorded in.

Weekly Laboratory

Day #	D#	D#	D#	D#	D#	D#	D#
Date (YYYY-MM-DD)							
Albumin (Lowest) ☐ **g/dL** ☐ **g/L**							
Prealbumin (Lowest) ☐ **mg/dL** ☐ **mg/L**							
CRP (Highest) mg/L							
AST (Highest) IU/L							
ALT (Highest) IU/L							
ALP (Highest) IU/L							
Triglycerides (Highest) ☐ **mg/dL** ☐ **mmol/L**							

Weekly Ultrasounds & Muscle Function at Outcomes Instruction

Weekly Ultrasounds

General Instructions

These data are collected to determine the effect of extra calories and protein on muscle function strength.
The femoral ultrasound is done to assess the muscle layer thickness (MLT) of the M. vastus intermedius and M rectus femoris. Each ultrasound is to be repeated and is to be done by the site investigator or designated clinician (RN specialist, Research Coordinator, RN or Fellow).
Refer to the **Ultrasound Test Manual** for more details.

Duration of Data Collection

The duration of data collection varies per test from once at baseline, ICU/Hospital discharge to weekly. The specified time frames are outlined in the table below

Muscle Function Testing	STUDY DAY					
	Baseline*	Week 2 (8-14)	Week 3 (15-21)	Week 4 (22-28)	ICU Discharge	Hospital Discharge
Ultrasound (If in ICU)**	✓	✓	✓	✓		
Hand Grip Strength					✓	✓
6-min Walk Test						✓

*baseline ultrasound is to be done within 72 hrs of ICU admission
** in the event the patient is discharged from the ICU to the hospital prior to the completion of the week 2 ultrasound, you must complete the week 2 ultrasound on the ward. No subsequent ultrasounds are needed.

NOTE: the scheduled ultrasounds that are to be done weekly. Additional ultrasounds may need to be done within 72 hrs of any Abdominal/Pelvis CT scans that are clinically indicated (refer to Abdominal/Pelvis CT Scan and Accompanying Ultrasounds CRF).

Weekly Study Ultrasounds

Record the date the Ultrasound was done in the format YYYY-MM-DD.
Record the results in cms as follows (may transfer from ultrasound worksheet):

- Left femoral 2/3rd reading
- Left femoral midpoint reading
- Right femoral 2/3rd reading
- Right femoral midpoint reading

Record the person who performed the ultrasound

Repeat the ultrasound (at the same time, done by other clinician).

- Above steps are to be repeated by designated clinician

If the ultrasound is not done, explain why not done.

Repeat all the above procedures for week 2 (day 8-14), 3 (day 15-21) and 4 (day 22-28)

Muscle Function at Outcomes

Hand Grip Strength at ICU Discharge and at Hospital Discharge

Take 3 consecutive readings at:

- ICU discharge (within 1 week of anticipated ICU discharge) on the dominant hand AND
- Hospital discharge (within 1 week of anticipated hospital discharge) on the dominant hand.

Refer to **Implementation Manual** for instructions on how to perform this procedure.
Record the date the procedure was done in the format YYYY-MM-DD in the box corresponding to the associated event; ICU discharge or Hospital discharge.
Record the 3 readings taken at each event in the spaces provided after the corresponding date.

If not done, explain why not done.

6 minute walk test at Hospital Discharge

This should be done prior to hospital discharge (within 1 week of anticipated hospital discharge).
Refer to **Implementation Manual** for further instructions on how to perform this procedure.
Record the date the procedure was done in the format YYYY-MM-DD.
Record the total distance the patient walked in meters.

If Not done, indicate a brief reason.

Weight at discharge

Record the patient's weight at the time of the 6 minute walk test (hospital discharge).

Weekly Ultrasounds & Muscle Function at Outcomes

Weekly Study Ultrasounds								
	Date done YYYY-MM-DD	Femoral Ultrasound			Repeat Femoral Ultrasound			If Not done, reason
		Left Reading (cm)	Right Reading (cm)	Done by (Name)	Left Reading (cm)	Right Reading (cm)	Done by (Name)	
Baseline		2/3rd	2/3rd		2/3rd	2/3rd		
		midpoint	midpoint		midpoint	midpoint		
Week 2 (Day 8-14)		2/3rd	2/3rd		2/3rd	2/3rd		
		midpoint	midpoint		midpoint	midpoint		
Week 3 (Day 15-21)		2/3rd	2/3rd		2/3rd	2/3rd		
		midpoint	midpoint		midpoint	midpoint		
Week 4 (Day 22-28)		2/3rd	2/3rd		2/3rd	2/3rd		
		midpoint	midpoint		midpoint	midpoint		

Hand grip strength	Date done YYYY-MM-DD	Reading 1	Reading 2	Reading 3	If Not done, reason
At ICU discharge					
At Hospital discharge					

6 minute walk test	If Yes, date done YYYY-MM-DD	Distance in meters	If Not done, reason
Prior to hospital discharge			

Weight ☐☐☐ ☐ lbs OR ☐ Kg

Abdominal/Pelvis CT Scans & (Accompanying) Femoral Ultrasounds Instructions

General Instructions	These data are also collected to determine the effect of extra calories and protein on muscle function strength. The Abdominal/Pelvis CT scan determines muscle mass (at 3rd lumbar vertebrae) which is a predictor of lean tissue mass.
Duration of Data Collection	The duration of data collection follows the CT Scans that are done for clinical reasons. CT scans including L3 done for clinical reasons within ± 1-2 days of ICU admission and all subsequent CT scans throughout the ICU admission are to be collected. Whenever a Abdominal/Pelvis CT Scan is done for clinical reasons (not to be done for the study), an accompanying femoral ultrasound is also to be done. The time frame for this accompanying ultrasound is 72 hrs (from the Abdominal/Pelvis CT Scan), however if the Weekly Scheduled Ultrasounds has been done within this time frame, the accompanying ultrasound does not need to be done.
Abdominal/Pelvis CT Scans	If No CT Scans are done during the ICU stay (maximum 28 days), you do not need to collect any data. **NOTE:** on REDCAP, you will need to indicate "No" daily to the question "Was there an Abdominal/Pelvis CT Scan done today?" If an Abdominal/Pelvis CT Scan is done, record date of each CT scan done. Request the Radiology department provide a copy of all **DE-IDENTIFIED** CT scan images. Batch all scans and send to: Marina Mourtzakis, PhD Dept of Kinesiology, BMH 1117 200 University Ave W University of Waterloo Waterloo, ON N2L 1A3 Phone: 519-888-4567 x38459 Email: mmourtza@uwaterloo.ca
Femoral ultrasound (accompanying)	**IF** there was an Abdominal/Pelvis CT Scan done, an accompanying femoral ultrasound should be done within 72 hrs (Weekly Ultrasound measurements taken within 72 hrs of the CT Scan may be recorded here). Record the date the Ultrasound was done in the format YYYY-MM-DD. Record the results in cms as follows (may transfer from ultrasound worksheet): • Left femoral 2/3rd reading • Left femoral midpoint reading • Right femoral 2/3rd reading • Right femoral midpoint reading Record the person who performed the ultrasound Repeat the ultrasound (at the same time, done by other clinician). • Above steps are to be repeated by designated clinician

TOP UP

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Site Number Enrollment Number

Abdominal/Pelvis CT Scans & (Accompanying) Femoral Ultrasounds

☐ No CT Scans done this ICU admission

OR

CT Scans Including L3	Accompanying Ultrasounds						
		Femoral Ultrasound			Repeat Femoral Ultrasound		
Date done YYYY-MM-DD	Date done YYYY-MM-DD	Left Reading (cm)	Right Reading (cm)	Done by (Name)	Left Reading (cm)	Right Reading (cm)	Done by (Name)
		2/3rd	2/3rd		2/3rd	2/3rd	
		midpoint	midpoint		midpoint	midpoint	
		2/3rd	2/3rd		2/3rd	2/3rd	
		midpoint	midpoint		midpoint	midpoint	
		2/3rd	2/3rd		2/3rd	2/3rd	
		midpoint	midpoint		midpoint	midpoint	
		2/3rd	2/3rd		2/3rd	2/3rd	
		midpoint	midpoint		midpoint	midpoint	
		2/3rd	2/3rd		2/3rd	2/3rd	
		midpoint	midpoint		midpoint	midpoint	
		2/3rd	2/3rd		2/3rd	2/3rd	
		midpoint	midpoint		midpoint	midpoint	
		2/3rd	2/3rd		2/3rd	2/3rd	
		midpoint	midpoint		midpoint	midpoint	
		2/3rd	2/3rd		2/3rd	2/3rd	
		midpoint	midpoint		midpoint	midpoint	

☐ CT Scans sent to University of Waterloo contact.

General Instructions	These data are to be collected to describe rehabilitation practices of patients enrolled to The TOP-UP trial. The Research Coordinator may have to obtain this information from the following sources: Physiotherapist Nursing flowchart Bedside nurse
Duration of Data Collection	These data are to be collected daily from ICU admit to ICU discharge, death which ever comes first for a maximum of 28 days.
Passive Range of Motion Exercises	These data only pertain to patients that are unresponsive or unable to assist. Passive range of motion exercises refer to those that are done on a patient by the caregiver (physio/RN) i.e. shoulder flexion, shoulder abduction, shoulder external rotation/internal rotation, elbow flexion/extension, elbow supination or elbow pronation. Appropriate limbs (or condition) refer to those in which the range of motion is not contra-indicated (e.g. non-injured arm, hip that does not have a femoral line, patient that is not agitated, according to your institution's standard practices). If at least one of these exercises are done on the appropriate limbs, record Yes (Y) or No (N) or N/A (data not available) in the box.
The following data only pertain to patients that are awake and able to assist.	
Assisted Range of Motion Exercises	Assisted range of motion exercises refer to those that the patient does with manual assistance. Record Yes (Y) or No (N) or N/A (data not available) in the box.
Active Range of Motion Exercises	Active range of motion exercises refer to those that are done independently by the patient. Record Yes (Y) or No (N) or N/A in the box.
Bed Mobility Activities	Bed mobility activities include any exercise done in bed, including transferring from lying to sitting, sitting at edge of bed, rolling or cycling. Record Yes (Y) or No (N) or N/A in the box.
Transfer training/ pre-gait exercises	Transfer training activities refer to those that involve any activities related to the transfer of the patient such as: • repetition of sit-to-stand transfers • transfers from bed to chair or bed to commode. • Pre-gait exercises refer to those that are done prior to walking including weight shifting & marching on the spot Record Yes (Y) or No (N) or N/A in the box.
Walking	Walking exercises refer to any exercises done for walking. Record Yes (Y) or No (N) or N/A in the box.

Rehabilitation Practices

Day #	D#	D#	D#	D#	D#	D#	D#
Date YYYY-MM-DD							
1. Were **passive range of motion** exercises done on all appropriate limbs?							
2. Were **assisted range of motion exercises** (with manual assistance) done in the supine position?							
3. Were **active range of motion exercises** (independent) done in the supine position?							
4. Were **bed mobility activities** done (including transferring from lying to sitting, sitting at edge of bed, rolling or cycling)?							
5. Were **transfer training activities** (repetition of sit-to-stand transfers, transfers from bed-chair, bed to commode) or **pre-gait exercises** (weight shifting or marching on the spot) done?							
6. Did the patient go for a **walk**?							

Day #	D#	D#	D#	D#	D#	D#	D#
Date YYYY-MM-DD							
1. Were **passive range of motion** exercises done on all appropriate limbs?							
2. Were **assisted range of motion exercises** (with manual assistance) done in the supine position?							
3. Were **active range of motion exercises** (independent) done in the supine position?							
4. Were **bed mobility activities** done (including transferring from lying to sitting, sitting at edge of bed and rolling)?							
5. Were **transfer training activities** (repetition of sit-to-stand transfers, transfers from bed-chair, bed to commode) or **pre-gait exercises** (weight shifting or marching on the spot) done?							
6. Did the patient go for a **walk**?							

Concomitant Medication Instructions

General Instructions	These data are collected to capture all relevant medications that the patient received that may have a material effect on the measured outcomes of the study.
Duration of Data Collection	The duration of data collection is from ICU admit to ICU discharge, death which ever comes first for a maximum of 28 days.
Day #	Record the study day number consecutively at the top of each column, starting at D1.
Date	Record dates according to study days in the format YYYY-MM-DD.
Insulin	Record the total units received in the 24 hour period from all insulin IV, SC, and bolus. If no insulin was given record "0" in the box.
Motility agents	Indicate if any of the following motility agents (Maxeran, Erythromycin, Motilium, other) were given If Yes indicate all that were received. 1. Maxeran, 2. Erythromycin, 3. Motilium 4. Other, specify: _____
Neuromuscular blocking agents	Indicate if any neuromuscular blocking agents were given If Yes, record drug number and total dose received in mgs per day. You can record up to 2 entries 5. Atracurium 6. Cisatracurium 7. Doxacurium 8. Mivacurium 9. Pancuronium 10. Rocuronium 11. Vecuronium 12. Succinylcholine 13. Other, specify: _____
Corticosteroids IV/PO	Indicate if IV or PO corticosteroids were given If Yes, indicate all that were received and the total dose received for that day. You can record up to 2 entries 14. IV Dexamethasone sodium phosphate (DECADRON) 15. PO Dexamethasone sodium phosphate 16. PO Fludrocortisone acetate 17. IV Hydrocortisone sodium succinate (Solu-cortef) 18. PO Hydrocortisone (Cortef) 19. IV Methylprednisolone sodium succinate (SOLU-MEDROL) 20. PO Prednisolone 21. PO Prednisone 22. IV Triamcinolone acetonide (KENALOG) 23. Other, specify: _____ **NOTE: do not use a steroid equivalency chart**
Supplements	Indicate if any of the following supplements were given, Yes or No If Yes, record all the supplements received (choose the the corresponding number) 24. Enteral supplemental glutamine (refers to glutamine powder, not glutamine enriched formula) 25. IV Antioxidants 26. EN Probiotics (includes prebiotics/synbiotics/probiotics) 27. Trace elements i.e. copper, zinc, manganese, chromium 28. Supplemental IV selenium—**record dose received in micrograms** 29. IV Glutamine-**record name and dose received in grams/day** **NOTE: If the patient received supplemental glutamine (EN/IV) or probiotics before 7 days post randomization*, this is considered as a Protocol Violation** ***7 days post randomization = day of randomization PLUS an additional 7 FULL days.**
Multivitamins	Indicate if any multivitamins were given If yes, record the name and the dose received (maximum of 3 entries)

Concomitant Medications

Day #	D#	D#	D#	D#	D#	D#	D#
Date YYYY-MM-DD							
Insulin							
Total dose in units							
Motility agents							
Record all that were received							
Neuromuscular blocking agents							
NMBAgent # 1 / Total dose received mg							
NMBAgent # 2 / Total dose received mg							
IV/PO Corticosteroids							
Corticosteroids # 1 / Total dose received mg							
Corticosteroids # 2 / Total dose received mg							
Supplements							
Enteral Supplement Glutamine Record Y or N							
IV Antioxidants Record Y or N							
EN Probiotics Record Y or N							
Trace Elements Record Y or N							
Supplemental IV Selenium Record dose received in µg							
IV Glutamine NAME / Total dose received mg or ml							
Multivitamins # 1 NAME / Total dose received mg or ml							
Multivitamins # 2 NAME / Total dose received mg or ml							
Multivitamins # 3 NAME / Total dose received mg or ml							

Antibiotic, Antifungal & Antiviral Instructions

General Instructions	These data are collected to assist in determining the incidence of infections. The term "antibiotics" used in this case report form will be used to refer to all antibiotics, antifungal and antivirals. Record ALL antibiotics the patient receives during the 28 days. You may record up to 2 antibiotics per page. If the antibiotic was held for >48 hours and then restarted then enter it as a new entry. The exception is if drug levels are high (vancomycin) in which case a new entry is not required. If Vancomycin was held for ≥ 7 days and then restarted, then record it as a new entry. • Do not record antibiotics ordered but never received • Do not record any changes in dose/route/frequency as a separate entry.
Duration of Data Collection	The duration of data collection is from ICU admit to ICU discharge plus 3 days, death which ever comes first for a maximum of 28 days. **In the event the patient gets discharged from the ICU before 28 days,** continue to collect the data for an additional 3 days after ICU discharge, to a maximum of 28 days. **In the event the patient gets discharged to the floor before 7 days post randomization*,** continue to collect the data until 10 days post randomization (duration of study intervention + 3 additional days). ***7 days post randomization = day of randomization PLUS an additional 7 FULL days.**
No Antibiotics given	If no antibiotics were ever given then place a check in the box on the upper left hand corner.
Entry #	This refers to the sequential number of antibiotic that the patient received in the calendar day. Record the first antibiotic received on the day as 1, 2, 3, 4, 5 and 6.
Start Date and Time	Complete the date and time the antibiotic was actually given (i.e. not when the order was written) as follows: • Actual start date in the ICU format of YYYY-MM-DD and time as 00:00 OR • If started before ICU admission, check the appropriate box
Antibiotic Name	Refer to **Appendix 7 Antibiotics** and choose the number that corresponds to the antibiotic prescribed.
Dose	Record the dose of antibiotics given.
Unit	Record the appropriate units given from the list below 1) µg 4) Units 2) mg 5) Other: (provide details in the space provided) 3) g
Route	Record the appropriate route given from the list below. 1) IV 4) Inhaled 2) PO/NG 5) Subcutaneous 3) IM 6) PR (per rectum)
Frequency	Record the appropriate frequency given from the list below. 1) OD 4) QID 2) BID 5) q___hrs 3) TID
Stop Date and Time	Complete the date and time the antibiotic was stopped (i.e. not when the order was written) as follows: • **Actual** stop date in the format of YYYY-MM-DD and time as 00:00, even if this occurs after ICU discharge and in your hospital
Suspicion of ICU acquired infection questions	The determination of a suspicion of infection has been programmed into the electronic data capture system (edcs) REDCap. Refer to the CRS & REDCap Manual. To help determine the suspicion of an ICU acquired infection, the following question must be answered: **"Was this antibiotic started after 72 hours of admission to ICU?"** If the response is **no**, no adjudication is needed and you do not complete any other questions for this antibiotic on this form. If the response is **yes**, for each antibiotic started, the following two questions must be answered: **1) Is this antibiotic given for prophylaxis?** Prophylaxis refers to prevention; it is not the same thing as empiric treatment. For example, administering a dose of cefazolin to a patient going into the OR is considered prophylactic. Therefore the answer to this question is "YES." If an antibiotic is administered empirically in the setting of a suspected infection, then the answer to this question should be "NO." **2) Is this a substitute for an antibiotic previously ordered for an infection that occurred within the first 72 hours of ICU admission?** If the response is **yes** to either one, no adjudication is needed and you do not complete the infection adjudication for this antibiotic. If the response is **no** to both, proceed to the infection adjudication and instructions. Since the responses to these questions have a material affect on the presence of a newly acquired ICU infection, these questions MUST be answered by the Site investigator/MD delegate.

Antibiotics, Antifungals & Antivirals

☐ NO ANTIBIOTICS GIVEN

	Dose	Unit	Route	Frequency	Suspicion of Infection Questions (Go to REDCap for e-version of this form)
Entry number for this calender day ☐☐ Antibiotic name _____ Other (specify) _____ Start date and time 2 0 Y Y M M D D H H M M (24 hour clock) ☐ Started before ICU admission Stop date and time 2 0 Y Y M M D D H H M M (24 hour clock)					Was this antibiotic started **>** 72 hours from ICU admission? ☐ Yes ☐ No → **Adjudication NOT required for this entry number.** **Answer the two questions below.** ☐ Yes ☐ No Was antibiotic given for prophylaxis? ☐ Yes ☐ No Substitute for antibiotic previously ordered for an infection within 72 hrs of ICU admission? **If you answered NO to both questions, the Site Investigator will need to adjudicate this suspicion.**
Entry number for this calender day ☐☐ Antibiotic name _____ Other (specify) _____ Start date and time 2 0 Y Y M M D D H H M M (24 hour clock) ☐ Started before ICU admission Stop date and time 2 0 Y Y M M D D H H M M (24 hour clock)					Was this antibiotic started **>** 72 hours from ICU admission? ☐ Yes ☐ No → **Adjudication NOT required for this entry number.** **Answer the two questions below.** ☐ Yes ☐ No Was antibiotic given for prophylaxis? ☐ Yes ☐ No Substitute for antibiotic previously ordered for an infection within 72 hrs of ICU admission? **If you answered NO to both questions, the Site Investigator will need to adjudicate this suspicion.**

Microbiology Instructions

General Instructions	These data are collected to assist in determining the incidence of infections. Record **all positive cultures.** **Do not record routine surveillance swabs or cultures.** Exception: if a swab was done for a clinical reason, i.e. an abscess and it is positive then record it. But do not record surveillance swabs for VRE or MRSA. • Do not record cultures that are considered to be a contaminant or reported as No growth or Common Mixed Flora EXCEPT for blood cultures. • Record one sample (culture) and up to 3 organisms from the same sample per page.
Duration of Data Collection	The duration of data collection is from ICU admit to ICU discharge plus 3 days, death which ever comes first for a maximum of 28 days. **In the event the patient gets discharged from the ICU before 28 days,** continue to collect the data for an additional 3 days after ICU discharge, to a maximum of 28 days. **In the event the patient gets discharged to the floor before 7 days post randomization*,** continue to collect the data until 10 days post randomization (duration of study intervention + 3 additional days). ***7 days post randomization = day of randomization PLUS an additional 7 FULL days.**
Entry #	This refers to the sequential number of the positive culture antibiotic that the patient received in the calendar day. Record the first antibiotic received on the day as 1, 2, 3, 4, 5 and 6.
Date and Time	Complete the date and time the sample was collected (i.e. not when the results were reported) in the date format of YYYY-MM-DD and time format of 00:00. If no time available, check the appropriate box.
Sample Type	From the taxonomy choose the number that corresponds to the sample type. 1) Sputum expectorated 2) Nasotracheal/Endotracheal/Tracheal aspirate 3) Bronchoscopy specimen protected brush 4) Bronchoalveolar lavage (BAL) 5) Bronchial washing 6) Blood 7) Tissue wound culture 8) Urine 9) Pleural fluid 10) Other (please specify)
Was sample taken after 72 hrs of ICU admission?	To help determine the suspicion of an ICU acquired infection, the following question must be answered: **"Was this sample taken after 72 hours of admission to ICU?".** If the response is **no**, • An adjudication is not needed and you do not need to complete an infection adjudication form. • Complete the right hand side column for organism data for this culture. If the response is **yes**, • Complete the left hand side column for organism data for this culture.
Organism #	Record all the pathogens reported in the hospital microbiology report. For the first organism documented in the report, in the boxes after Organism #1, record the name of the organism from **Appendix 8 Microbiology Organisms.** If "other" is to be selected, write the organism in the space provided. Continue to record all subsequent organisms sequentially in the boxes after Organism #2, Organism #3, etc. e.g.Enterococcus faecalis. **NOTE: a gram negative Bacilli is not synonymous with the bacterial species Bacillus**.
Quantitative Results	If applicable record the colony forming units (cfus) reported as: 1) $>10^4$ cfu/ml or $> 10^7$ cfu/L 2) $<10^4$ cfu/ml or $< 10^7$ cfu/L 3) >15 cfu/ml 4) None reported 5) Other specify
Suspicion of ICU acquired infection questions	The determination of a suspicion of infection has been programmed into the electronic data capture system (edcs) REDCap. Refer to the CRS & REDCap Manual. For each organism that grows from the positive culture, the following question must be answered: **"Is this organism a manifestation of an infection that occurred within the first 72 hrs of ICU admission?"** If the response is **yes,** choose one of the following: **Relapse/Recurrent** (an infection in which the microorganism was present on the initial culture, was eradicated and then the same organism that was responsible for the initial infection returns) **OR Persistent** (an infection in which the microorganism that was present on the initial culture persists on subsequent cultures). Do not proceed to the infection adjudication for this organism. Proceed to enter further organism data for this culture. If the response is **no**, proceed to the infection adjudication. Complete all other organism data for this culture. Since the responses to these questions have a material affect on the presence of a newly acquired ICU infection, the responses to these questions MUST be provided by the Site investigator/delegate.

☐ NO MICROBIOLOGY

Microbiology

Record one culture and up to 3 organisms reported for that culture per page.

Entry number for this calendar day ☐

Date and time sample was collected 2 0 Y Y M M D D H H M M (24 hour clock)

☐ No time available

Sample type _____ Other (specify) _____

Was this sample taken >72 hours from ICU admission? ☐ **If Yes, Complete this column below**	☐ **If No, complete this column below. There is no suspicion of a newly acquired infection and no adjudication is needed**
Organism #1 _____ See Appendix 8 Other (specify) _____ **Quantitative Results** _____ Is this organism a manifestation of an infection that occurred within the first 72 hrs of ICU admission? ☐ Yes **If Yes, choose one of the following** ☐ Relapse/Recurrent ☐ Persistent ☐ No **If No, the Site Adjudicator will need to adjudicate this suspicion. (Go to REDCap for e-version of this form)**	**Organism #1** _____ See Appendix 8 Other (specify) _____ **Quantitative Results** _____
Organism #2 _____ See Appendix 8 Other (specify) _____ **Quantitative Results** _____ Is this organism a manifestation of an infection that occurred within the first 72 hrs of ICU admission? ☐ Yes **If Yes, choose one of the following** ☐ Relapse/Recurrent ☐ Persistent ☐ No **If No, the Site Adjudicator will need to adjudicate this suspicion. (Go to REDCap for e-version of this form)**	**Organism #2** _____ See Appendix 8 Other (specify) _____ **Quantitative Results** _____
Organism #3 _____ See Appendix 8 Other (specify) _____ **Quantitative Results** _____ Is this organism a manifestation of an infection that occurred within the first 72 hrs of ICU admission? ☐ Yes **If Yes, choose one of the following** ☐ Relapse/Recurrent ☐ Persistent ☐ No **If No, the Site Adjudicator will need to adjudicate this suspicion. (Go to REDCap for e-version of this form)**	**Organism #3** _____ See Appendix 8 Other (specify) _____ **Quantitative Results** _____

Hospitalization Overview Instructions

General Instructions	These data are collected to determine clinical outcomes related to length of stay, duration of ventilation and mortality.
Duration of Data Collection	These data are to be collected once.

ICU discharge	Answer the question "Did the patient die in ICU?" by choosing one of the options:
	• Yes
	  • provide date and time
	  • record the cause of death.
	  • Do **not** proceed to Hospital Discharge.
	• No, Patient discharged
	  • provide date and time of discharge. Proceed to Hospital Discharge section below.
	• No, patient still alive at 6 months
	  • do **not** record date and time. Do **not** proceed to Hospital Discharge.

Hospital discharge
 	
Discharged to
	Only complete this section if you have responded "No, Patient discharged" to the above question "Did the patient die in the ICU".
	
	Answer the question "Did the patient died in hospital?" by choosing one of the options:
	• Yes
	  • provide date and time
	  • If time not available, check the box
	  • record the cause of death
	• No, Patient discharged
	  • provide date and time of discharge. If no time available, check box
	  • Choose where the patient got discharged to i.e.
	  • Ward in another hospital
	  • ICU in another hospital
	  • Long term care facility
	  • Rehabilitation unit
	  • Home
	  • Other, specify (please provide details in space provided)
	• No, patient still alive at 6 months
	  • do **not** record date and time.
	
	If the hospital discharge is the same as the death date and time, tick the NO box and enter the date and time the patient was actually discharged from hospital.
	
	For patients who are discharged to a Rehabilitation ward within the institution, the date and time the patient is discharged from the hospital to the Rehabilitation ward is the hospital discharge date and time. IF Yes, tick the box and leave the date and time fields blank.
	.

Cause of Death	Document the cause of death from a post mortem report. If this is not available, record cause of death from the death certificate.

Hospitalization Overview

		Date	Time	Cause of Death
Did patient die in ICU?	☐ Yes →	Death date: 2 0 Y Y M M D D	H H M M (24 hour clock) →	
	☐ No, patient discharged →	ICU Discharge Date: 2 0 Y Y M M D D	H H M M (24 hour clock)	
	☐ No, patient still in the ICU at 6 months (stop here)			
Did patient die in Hospital?	☐ Yes →	Death Date: 2 0 Y Y M M D D	H H M M (24 hour clock) →	
	☐ No, patient discharged →	Hospital Discharge Date: 2 0 Y Y M M D D	H H M M (24 hour clock) OR ☐ No time available	
	☐ No, patient still in the hospital at 6 months (stop here)			
Discharged to	☐ Ward in another hospital ☐ ICU in another hospital ☐ Long term care facility ☐ Rehabilitation Unit ☐ Home ☐ Other specify_____			

Barthel ADL Index (Hospital Discharge) Instructions

General Instructions	The Barthel ADL (Activities of Daily Living) Index establishes how independent the patient is at the time of hospital discharge. The index should be used a record of what a patient can do at discharge, not a record of what a patient could do. Ask the patient's next of kin/relative/friend or nurse, whomever is the best person to help you rate these activities. You may also use direct observation, if needed. • If possible, use the patient's performance over the preceding 24-48 hours. • The need for supervision renders the patient not independent. • Middle categories imply that the patient supplies over 50 percent of the effort • Use of aids to be independent is allowed.
Duration of Data Collection	The Barthel ADL Index should be completed at hospital discharge (within 1 week of hospital discharge)
Date completed	Record the date and time the index was completed in the format YYYY-MM-DD.

Barthel ADL Index (Hospital discharge)

Activity		Score
FEEDING	0 = Unable 5 = Needs help cutting, spreading butter, etc., or required modified diet. 10 = Independent	
BATHING	0 = Dependent 5 = Independent	
GROOMING	0 = Needs help with personal care 5 = Independent face/hair/teeth/shaving (implements provided)	
DRESSING	0 = Dependent 5 = Needs help but can do about half unaided 10 = Independent (including buttons, zips, laces, etc)	
BOWELS	0 = Incontinent (or needs to be given enemas) 5 = Occasional accident 10 = Continent	
BLADDER	0 = Incontinent, or catheterized and unable to manage alone 5 = Occasional accident 10 = Continent	
TOILET USE	0 = Dependent 5 = Needs some help, but can do something alone 10= Independent (on and off, dressing, wiping)	
TRANSFERS (BED TO CHAIR AND BACK)	0 = Unable, no sitting balance 5 = Major help (one or two people, physical), can sit 10 = Minor help (verbal or physical) 15 = Independent	
MOBILITY (ON LEVEL SURFACES)	0 = Immobile or < 50 yards 5 = Wheelchair independent, including corners, > 50 yards 10 = Walks with help of one person (verbal or physical) > 50 yards 15 = Independent (but may use any aid; for example, stick) > 50 yards	
STAIRS	0 = Unable 5 = Needs help (verbal, physical, carrying aid) 10 = Independent	
	TOTAL (0-100)	_____

Date index completed 2 0 Y Y M M D D

SF 36 and 3 & 6 month follow-up Instructions

General Instructions	The SF-36 is an interview of quality of life that should be completed with the patient's family/next of kin. Copy the SF-36 from (**Appendix 11**) and record the responses on the hard copy. Retain the hard copy in the patients file for source verification purposes.
Duration of Data Collection	The follow-up should be completed at : • **3 months** from date of ICU admission (within 2 weeks before or 6 weeks after 3 months from ICU admission: i.e.: **Anytime from 2.5 months to 4.5 months after ICU admission**. • **6 months** from date of ICU admission ± 6 weeks, i.e.: **Anytime from 4.5 months to 7.5 months after ICU admission**. If the patient dies in ICU or hospital it is not necessary to complete this form nor complete the SF-36 3 month & 6 month Follow-up surveys.
Date of interview	Record the date the interview completed in the format YYYY-MM-DD.
By whom	Indicate with whom the interview was conducted, patient or family/caregiver.
Reason not completed	If not done, indicate the reason. • Patient died — Provide date of death. Please obtain from a family member of needed. • Patient died, date of death unknown — Enter the date the patient was last known to be alive. • Refused — If selected enter the date of refusal. **Refused** means the subject does not want to complete the questionnaire during the acceptable study window due to stress, time constraints, emotional instability, etc. This does not mean that the subject is withdrawing from subsequent interviews. **If patient refuses at 3 months, please re-approach the patient at 6 months for the next interview** • Withdrew — If selected enter the date of withdrawal. **Withdrew** means the patient has withdrawn from the study. • Lost to follow-up — If selected enter the date last contact was made • Missed — Coordinator missed assessment window

SF-36 and 3 & 6 Month Follow-up

3 Month

Date of interview completed
(Record responses on copy of SF-36 Appendix 10) 2 0 Y Y M M D D

Completed by ☐ Patient ☐ Family/Caregiver

Reason not done

- ☐ Patient died (Actual date of death) 2 0 Y Y M M D D
- ☐ Patient died, date of death unknown (Date last known to be alive) 2 0 Y Y M M D D
- ☐ Patient refused 2 0 Y Y M M D D
- ☐ Patient withdrew 2 0 Y Y M M D D
- ☐ Lost to follow-up 2 0 Y Y M M D D
- ☐ Missed

6 Month

Date of interview completed
(Record responses on copy of SF-36 Appendix 10) 2 0 Y Y M M D D

Completed by ☐ Patient ☐ Family/Caregiver

Reason not done

- ☐ Patient died (Date of death) 2 0 Y Y M M D D
- ☐ Patient died unknown (Date last known to be alive) 2 0 Y Y M M D D
- ☐ Patient refused 2 0 Y Y M M D D
- ☐ Patient withdrew 2 0 Y Y M M D D
- ☐ Patient lost to follow-up 2 0 Y Y M M D D

Protocol Violation Instructions

Protocol violation definition	**For THE TOP UP Study, a Protocol Violation occurs when any of the following have occurred:** 1) **Supplemental group only:** Investigational Product (IP) Daily dose delivered is < 80% or > 120% prescribed volume 2) Dispensing/dosing error 3) Enrollment of a patient that does not fulfill inclusion/exclusion criteria 4) Unapproved procedures performed 5) Received non-study PN before 7 days post randomization 6) **EN group only:** Received study PN before 7 days post randomization* 7) Received non-study IV lipids received before 7 days post randomization* 8) Received supplemental glutamine (EN/IV) before 7 days post randomization* 9) Received probiotics before 7 days post randomization*
Duration of Reporting	Protocol violations # 1, # 5-10 inclusive are to be reported if they occur before 7 days post randomization*. All other protocol violations are to be reported if they occur during the study period i.e from **randomization** to ICU discharge, death whichever comes first for a maximum of 28 days. ***7 days post randomization = day of randomization PLUS an additional 7 FULL days.**
General Instructions	Complete Protocol Violation forms on a prospective basis and fax a copy to the Project Leader at (613) 548-2428.
When to report	Protocol violations are to be reported within 24 hrs of becoming aware of the event
Date violation occurred/ discovered	Enter the date when the violation occurred. **NOTE: When entering on to REDCAP, ensure that the violation is entered on the study day that the violation occurred (vs. discovered).** record the date that protocol violation occurred Enter the date when the violation was identified by site research staff.
Local Investigator aware	Indicate whether the local qualified investigator has been made aware of this violation.

Type of violation or incident	**For the Supplemental PN group only:**
	Was the protocol violation related to either <80% or > 120 % volume? Yes (Y) or No (N):
	Exceptions: Day of randomization, day of ICU discharge and days subsequent to ICU discharge.
	• If Yes, check the box for the type of violation:
	  • Yes, < 80% prescribed
	  • Record the % PN/EN received
	  • Check the reason why received < 80% prescribed volume by checking the appropriate box
	  • No central line access
	  • Held for procedure/OR
	  • Refeeding syndrome
	  • Abnormal blood work
	  • Other, specify details or attach Note to file/incident report
	  • Yes, > 120 % prescribed
	  • Record the % PN/EN received
	  • Record a reason for why received >120% prescribed volume
	For both EN only and Supplemental PN groups (except **):
	• Record all other types of violations from the list below
	  • Dispensing/dosing error (an incorrect dose/product was given to patient)
	  • Enrollment of a patient that does not fulfill inclusion/exclusion criteria
	  • Unapproved procedures performed (failure to obtain consent)
	  • Received non-study PN before 7 days post randomization*
	  • **Received study PN before 7 days post randomization* (EN group only)****
	  • Received non-study IV lipids before 7 days post randomization*
	  • Record the total time and volume of lipids received (mls)
	  • Received supplemental glutamine (EN/IV) before 7 days post randomization*
	  • Provide details of the glutamine given
	  • Received probiotics before 7 days post randomization*
	  • Provide details of the probiotics given
	  • Other, please specify (briefly describe the details of the protocol violation

Details	Describe all details and the action taken by the Research Coordinator /responsible delegate to prevent violation/problem from recurring.

Protocol Violation Report

1. **Date violation occurred** 2 0 Y Y M M D D

2. **Date violation discovered** 2 0 Y Y M M D D

3. **Is the local site investigator aware of the violation?** ☐ Yes ☐ No

4. **Was the Protocol Violation related to either < 80% or > 120% volume (Supplemental PN group only) ?**	☐ Yes, <80% Prescribed	Percent of PN/EN received: _____ % Reason for violation (check all that apply) ☐ a. No central line access ☐ b. Held for procedure/OR ☐ c. Refeeding syndrome ☐ d. Abnormal blood work ☐ e. Other, specify details or attach Note to File/Incident Report: _____ _____
	☐ Yes, >120% Prescribed	Percent of PN/EN received: _____ % Reason: _____
	☐ No	

5. Other Types of Violations (check all that apply)

☐ a. Dispensing/Dosing error
Details:
_____

☐ b. Enrollment of ineligible patient
Details:
_____

☐ c. Unapproved procedures performed
Details:
_____

☐ d. Received non-study PN before 7 days
Details:
_____

☐ e. Received study PN before 7 days **(EN only group)**
Details:
_____

☐ f. Received non-study IV lipids before 7 days
_____ Total time (min) _____ Volume (ml)

☐ g. Received any of the following before 7 days
☐ i. Supplemental Glutamine (EN/IV)
☐ ii. EN Probiotics
Details: _____
_____

☐ h. Other, please specify: _____
_____

6. Details of protocol violation including action taken by Research Coordinator/Responsible Delegate Study procedures reviewed, RN education, REB notification, Note To File, etc… _____

_____

_____

Serious Adverse Events Initial Report - MUST be completed on REDCap

General Instructions	Serious Adverse Events that are unexpected are to be reported to CERU within 24 hrs of becoming aware of the event. **SAE forms MUST be completed on REDCap** at https://ceru.hpcvl.queensu.ca/EDC/redcap/ or via http://www.criticalcarenutrition.com . Refer to the Serious Adverse Events section of the Implementation Manual for more details. The **worksheet** that follows is provided for your convenience.
Duration of Reporting	Only include those SAEs that occur during the study period i.e. from **randomization** to ICU discharge or death, whichever comes first, for a maximum of 28 days. **In the event the patient gets discharged prior to 7 days,** report SAEs through 7 days post randomization* ***7 days post randomization = day of randomization PLUS an additional 7 FULL days.**
Patient identification	Record the following details: • Your site number • Patient's initials • Gender, select male or female • Height (cm) • Weight (kg) • Patient enrollment number • DOB (date format YYYY-MM-DD)
Names of: Site Investigator & person reporting	Record the name of the Site Investigator in the appropriate box. Record the name of the person reporting the SAE in the appropriate box.
SAE #	Record the sequential SAE # for the patient; i.e. for the first SAE for the patient, enter 01. Record only one event per SAE form, unless the events are combined. For the second SAE for the patient, enter 02.
Description of SAE	Record the event that you are reporting (must be serious and unexpected). • Do NOT record death (outcome) as a SAE but the underlying cause of death. • Do not record respiratory failure as a SAE but what was felt to cause the respiratory failure i.e. sepsis.
Dates of SAE	• Record Date SAE reported and • Date became aware of SAE
Seriousness of the SAE	Record all that apply from the following: patient died; life threatening; requires or prolongs hospitalization; results in persistent or significant disability/ incapacity; may required medical or surgical intervention to prevent one of the other outcomes; congenital anomaly/birth defect or other serious medical event
Outcomes	Record the most appropriate at the time of the initial report: • complete recovery/return to baselines (include date of recovery, if available at time of report) • alive with sequelae • death (include date of death) • SAE persisting • unknown/lost to follow up
Date and times	Record the date and time for each of the following: • Onset of SAE • ICU admission • Start of study supplement • Stop of study supplement (if study supplement has not been stopped, leave this field blank).
Action taken	Record all that apply from the following: None; Uncertain; procedure or physical therapy; blood of blood products; prescription drug therapy; non-prescription drug therapy; hospitalization; IV fluids or Other
Action taken with study intervention	Record one of the following: • none (including not on study supplements) • dose reduced, interrupted or therapy delayed (include date/time) • study supplements stopped permanently due to SAE (include date/time).
Relationship of SAE to the study intervention	Record one of the options for the relationship of the event to the study intervention based on the assessment made at the time of the initial report: • **Not related:** A serious adverse event that is clearly due to extraneous causes (disease, environment, etc.) and does not meet the criteria for drug relationship listed under "Possibly" or "Probably". • **Unlikely related:** A serious adverse event that is more likely due to other causes than study supplement. • **Possibly related***:* Suggests that the association of this SAE with the study supplement is unknown and the event is not reasonably supported by other conditions. • **Probably related***:* Suggests that a reasonable temporal sequence of this SAE with study supplement administration exists and the association of the event with the study supplement seems likely.

SAE Initial Worksheet
inserted here

Serious Adverse Events Follow Up/Final Report - MUST be completed on REDCap

General Instructions	This Serious Adverse Events Follow-up/Final Report **MUST be completed on REDCap** for every initial SAE reported and faxed to CERU within 10 days from becoming aware of the event. This report may also need to be completed again **on REDCap** upon the resolution of the SAE (Final Report). Refer to the Serious Adverse Events section of the Implementation Manual for more details. The **worksheets** that follow are provided for your convenience. This form must be completed by the Site Investigator/delegate by reviewing the Serious Adverse Events Report (Initial) and the patient's medical chart.
Duration of Data Collection	Only include those SAEs that occur during the study period i.e. from **randomization** to ICU discharge, death whichever comes first for a maximum of 28 days.
Patient identification	Record the following details (please transfer these from the Initial SAE Report) • Your site number • Patient's enrollment number • Patient's initials • SAE #
Past medical history	Record the patient's medical history, comorbid illness and reason for admission to hospital by providing a detailed narrative of this information.
Admitting diagnosis	Record the patient's admitting diagnosis to ICU and chronological events leading to the SAE by providing a detailed narrative of this information.
Chronological events	Record the patient's chronological events leading to the SAE by providing a detailed narrative of this information, attach additional documents if needed.
Concomitant medications	List all medications the patient received in the 48 hours before the onset of the SAE
Lab results and investigations	List all those related to the event, attach additional documents if needed. Indicate if there are no relevant results to report by checking the appropriate box.
Confirmation of unexpectedness	Record all the pertinent clinical features that, in the opinion of the Site Investigator, made him/her think that the event was unexpected (and not due to the progression of underlying disease).
Relationship of SAE to the study intervention	Record one of the options for the relationship of the event to the study intervention based on the assessment made at the time of the follow up/final report: • **Not related:** A serious adverse event that is clearly due to extraneous causes (disease, environment, etc.) and does not meet the criteria for relationship listed under "Possibly" or "Probably". • **Unlikely related:** A serious adverse event that is more likely due to other causes than study supplements. • **Possibly related***:* Suggests that the association of this SAE with the study supplement is unknown and the event is not reasonably supported by other conditions. • **Probably related***:* Suggests that a reasonable temporal sequence of this SAE with study supplement administration exists and the association of the event with the study supplement seems likely.
Rationale for relationship to study intervention	If the event is considered to be related to the study supplement, record the pertinent clinical features that, in the opinion of the Site Investigator, made him/her think that the event was related to the study supplements vs. the progression of underlying disease. Refer to the definitions of degree of relationship to the study supplements (not related, unlikely related, possibly related, probably related).
Outcomes	Record the most appropriate outcomes at the time of this report: complete recovery/return to baselines (include date of recovery); alive with sequelae; death (include date of death); SAE persisting or unknown/lost to follow up
Action taken	Record all that apply from the following: None; uncertain; procedure or physical therapy; blood of blood products; prescription drug therapy; non-prescription drug therapy; hospitalization; IV fluids or Other
Action taken with study intervention	Record one of the following: • none (including not on study supplements) • dose reduced, interrupted or therapy delayed (include date/time) • study supplements stopped permanently due to SAE (include date/time).
Event reported to IRB	Indicate whether the SAE was reported to your Research Ethics Board, Yes, No or n/a.
Further details	List any other details about the SAE that are pertinent.

SAE Follow-up Worksheet
page 1 of 2 inserted here

SAE Follow-up Worksheet
page 2 of 2 inserted here

APPENDIX 1
COMORBIDITIES

0. NONE

MYOCARDIAL
1. Angina
2. Arrhythmia
3. Valvular
4. Myocardial infarction
5. Congestive heart failure (or heart disease)

VASCULAR
6. Hypertension
7. Peripheral vascular disease or claudication
8. Cerebrovascular disease (Stroke orTIA)

PULMONARY
9. Chronic obstructive pulmonary disease (COPD, emphysema)
10. Asthma

NEUROLOGIC
11. Dementia
12. Hemiplegia (paraplegia)
13. Neurologic illnesses (such as Multiple sclerosis or Parkinsons)

ENDOCRINE
14. Diabetes Type I or II
15. Diabetes with end organ damage
16. Obesity and/or BMI > 30 (weight in kg/(ht in meters)^2

RENAL
17. Moderate or severe renal disease

GASTROINTESTINAL
18. Mild liver disease
19. Moderate or severe liver disease
20. GI Bleeding
21. Inflammatory bowel
22. Peptic ulcer disease
23. Gastrointestinal Disease (hernia, reflux)

CANCER/IMMUNE
24. Any Tumor
25. Lymphoma
26. Leukemia
27. AIDS
28. Metastatic solid tumor

PSYCHOLOGICAL
29. Anxiety or Panic Disorders
30. Depression

MUSKOSKELETAL
31. Arthritis (Rheumatoid or Osteoarthritis)
32. Degenerative Disc disease (back disease, spinal stenosis or severe chronic back pain)
33. Osteoporosis
34. Connective Tissue disease

MISCELLANEOUS
35. Visual Impairment (cataracts, glaucoma, macular degeneration
36. Hearing Impairment (very hard of hearing even with hearing aids)

APPENDIX 2
PRIMARY ADMISSION DIAGNOSIS

MEDICAL
Choose from this list if admission category is medical

Cardiovascular / vascular:
1. Cardiogenic shock
2. Cardiac arrest
3. Aortic aneurysm
4. Congestive heart failure
5. Peripheral vascular disease
6. Rhythm disturbance
7. Acute myocardial infarction
8. Hypertension
9. Other CV disease: _____

Respiratory:
10. Parasitic pneumonia (ie.pneumocystis carinii)
11. Aspiration pneumonia
12. Respiratory neoplasm (include larynx, trachea)
13. Respiratory arrest
14. Pulmonary edema (non-cardiogenic)
15. Bacterial / Viral pneumonia
16. Chronic obstructive pulmonary disease
17. Pulmonary embolism
18. Mechanical airway obstruction
19. Asthma
20. Other respiratory disease: _____

Gastrointestinal:
21. Hepatic failure
22. GI perforation/obstruction
23. GI bleeding due to varices
24. GI inflammatory disease (ulcerative colitis, crohn's disease)
25. GI bleeding due to ulcer/laceration
26. GI bleeding due to diverticulosis
27. Pancreatitis
28. Other GI disease: _____

Neurologic:
29. Intracerebral hemorrhage
30. Subarachnoid hemorrhage
31. Stroke
32. Neurologic infection
33. Neurologic neoplasm
34. Neuromuscular disease
35. Seizure
36. Other neurologic disease: _____

Sepsis:
37. Sepsis (other than urinary tract)
38. Sepsis of urinary tract origin

Trauma:
39. Head trauma (with/without multiple trauma)
40. Multiple trauma (excluding head trauma)

Metabolic:
41. Metabolic coma
42. Diabetic ketoacidosis
43. Drug overdose
44. Other metabolic disease:_____

Hematologic:
45. Coagulopathy //neutropeniathrombocytopenia
46. Other hematologic condition: _____

Other:
47. Renal disease:_____
48. Burns
49. Other medical disease: _____

SURGICAL
Choose from this list if admission category is surgical

Vascular / cardiovascular:
50. Dissecting/ruptured aorta
51. Peripheral vascular surgery (no bypass graft)
52. Valvular heart surgery/CABG
52.1 Valvular heart surgery only
52.2 CABG only
53. Elective abdominal aneurysm repair
54. Peripheral artery bypass graft
55. Carotid endarterectomy
56. Other CV disease: _____

Respiratory:
57. Respiratory infection
58. Lung neoplasm
59. Respiratory neoplasm (mouth, sinus, larynx, trachea)
60. Other respiratory disease: _____

Gastrointestinal:
61. GI perforation/rupture
62. GI inflammatory disease
63. GI obstruction
64. GI bleeding
65. Pancreatitis
66. Liver transplant
67. GI neoplasm
68. GI cholecystitis / cholangitis
69. Other GI disease: _____

Neurologic:
70. Intracerebral hemorrhage
71. Subdural/epidural hematoma
72. Subarachnoid hemorrhage
73. Laminectomy/other spinal cord surgery
74. Craniotomy for neoplasm
75. Other neurologic disease: _____

Trauma:
76. Head trauma (with/without multiple trauma)
77. Multiple trauma (excluding head trauma)

Renal:
78. Renal neoplasm
79. Other renal disease: _____

Gynecologic:
80. Hysterectomy

Orthopedic:
81. Hip or extremity fracture

Bariatric Surgery:
82. Laparoscopic Banding
83. Laparoscopic Gastric Bypass
84. Open Gastric Bypass (Roux-en-Y)
85. Vertical Banded Gastroplasty

Other:
86. Other surgical condition:_____

APPENDIX 3
ENTERAL NUTRITION FORMULAS

1. 1000 complete
2. 1200 complete
3. 1800 complete
4. AlitraQ
5. Argiment
6. Boost 1.0 Standard
7. Boost 1.5 Plus Calories
8. Calogen
9. Compleat
10. Crucial
11. Cubison
12. Diabetisource AC
13. Diason
14. Diben
15. DuoCal
16. Edanec
17. Edanec HN
18. Enercal
19. Enercal Plus
20. Ensure
21. Ensure Fibre
22. Ensure HP
23. Ensure Plus
24. Fibersource HN
25. Fresubin
26. Fresubin Diabetes
27. Fresubin Energy
28. Fresubin Energy Fibre
29. Fresubin HEPA
30. Fresubin HP Energy
31. Fresubin Original
32. Fresubin Original Fibre
33. Fresubin Soya Fibre
34. Glucerna
35. Glucerna Select
36. Glutasolve
37. Glutasorb
38. Hepatic-Aid
39. Immun-Aid
40. Immunex Plus
41. Impact
42. Impact 1.5
43. Impact Glutamine
44. Impact with Fiber
45. Intestamin
46. Isosource 1.5 Cal
47. Isosource HN
48. Isosource HN with fibre
49. Isosource VHN
50. Jevity
51. Jevity 1 Cal
52. Jevity 1.2 Cal
53. Jevity 1.5 Cal
54. Jevity 2 with FOS
55. Jevity HiCal
56. Jevity Plus
57. Jevity Plus 1.5 k/cal
58. Jevity Promote
59. Jevity with FOS
60. Juven
61. MCT Oil
62. Microlipid
63. Nepro
64. Novasource Renal
65. Nutren 1.0
66. Nutren 1.0 Fiber
67. Nutren 1.5
68. Nutren 2.0
69. Nutren Glytrol
70. Nutren Pulmonary
71. Nutren Replete
72. Nutren Replete Fiber
73. Nutricomp
74. Nutricomp Diabetes
75. Nutricomp Energy
76. Nutricomp Energy Fibre
77. Nutricomp Hepa
78. Nutricomp Immun
79. Nutricomp Intensive
80. Nutricomp MCT
81. Nutricomp Peptid
82. Nutricomp Standard
83. Nutricomp Standard with Fibre
84. Nutricomp Standard with Fibre D
85. Nutrihep
86. Nutrison 1200 Complete Multi Fibre
87. Nutrison Concentrated
88. Nutrison Energy
89. Nutrison Energy Multi Fibre
90. Nutrison Low Energy Multi Fibre
91. Nutrison Low Sodium
92. Nutrison MCT
93. Nutrison Multi Fibre
94. Nutrison Pre
95. Nutrison Protein Plus
96. Nutrison Protein Plus Multi Fibre
97. Nutrison Soya
98. Nutrison Standard
99. Nutrison1000 Complete Multi Fibre
100. Nutrisorb Low Energy
101. Nutrisorb Low Energy Soy Multi Fibre
102. Optimental
103. Optimental 1.0
104. Osmolite
105. Osmolite 1 Cal
106. Osmolite 1.2 Cal
107. Osmolite 1.5 Cal
108. Osmolite High Protein
109. Osmolite HN
110. Osmolite HN Plus
111. Osmolite with Fiber
112. Oxepa
113. Peptamen
114. Peptamen 1.5
115. Peptamen AF 1.2 with Prebio
116. Peptamen OS
117. Peptamen OS 1.5
118. Peptamen with Prebio 1
119. Peptisorb
120. Perative
121. Pivot 1.5 Cal
122. Polycal Liquid
123. Polycal Powder / Fantomalt
124. Polycose Liquid
125. Polycose powder
126. Portagen
127. Promote
128. Promote with Fiber
129. Pulmocare
130. Pulmocare II
131. Reconvan
132. Renalcal
133. Resource 2.0
134. Resource Arginaid Extra
135. Resource Benecalorie

APPENDIX 3 con't
ENTERAL NUTRITION FORMULAS

136. Resource Benefiber
137. Resource Diabetic
138. Resource Glutasolve
139. Restore-X
140. Suplena
141. Supportan
142. Survimed OPD
143. Survimed Renal
144. Tolerex
145. Two Cal HN
146. Vital
147. Vital HN
148. Vivonex Plus
149. Vivonex RTF
150. Vivonex TEN
151. Other EN formula specify

Protein Supplements

1. Promod
2. Prosure
3. Resource Beneprotein Instant Protein Powder
4. Protifar
5. Fortimel
6. Propass
7. Argitein
8. Prosource liquid
9. Prosource powder
10. Procel
11. Pro-stat
12. Other protein supplement specify

APPENDIX 4
PARENTERAL NUTRITION FORMULAS

Multi-chamber bags

1. Aminomix 1
2. Aminomix 1 Novum
3. Aminomix 2
4. Aminomix 2 Novum
5. Aminomix 3
6. Aminomix 3 Novum
7. Clinimix E 2.75/10
8. Clinimix E 2.75/5
9. Clinimix E 4.25/10
10. Clinimix E 4.25/25
11. Clinimix E 4.25/5
12. Clinimix E 5/15
13. Clinimix E 5/20
14. Clinimix E 5/25
15. Clinimix N14G30E dual chamber
16. Clinimix N9G20E dual chamber
17. Compleven
18. Kabiven central
19. Kabiven peripheral
20. Nutriflex
21. Nutriflex Lipid
22. Nutrimix Dual Chamber TPN Delivery System
23. Oliclinomel N4-550 E
24. Oliclinomel N4-720 E
25. Oliclinomel N5-800
26. Oliclinomel N6-900 E
27. Oliclinomel N7-1000
28. Oliclinomel N7-1000 E
29. Oliclinomel N8-800
30. Periven
31. SmofKabiven
32. StructoKabiven
33. Other Multi chamber specify

Amino Acids

34. Aminoplasmal – 10%
35. Aminoplasmal – 10% E
36. Aminoplasmal – 15%
37. Aminoplasmal – 15% E
38. Aminoplasmal – 5% E
39. Aminoplasmal Hepa 10%
40. Aminosteril KE 10%
41. Aminosteril N-HEPA 8%
42. Aminosyn
43. Aminosyn – HBC 7%
44. Aminosyn – HF 8%
45. Aminosyn – RF 5.2%
46. Aminosyn – RF 7%
47. Aminosyn – with electrolytes
48. Aminosyn II (amino acid injection)
49. Aminosyn II (dextrose injection)
50. Aminosyn II 10%
51. Aminosyn II 15%
52. Aminosyn II 3.5%
53. Aminosyn II 4.25% – with electrolytes & calcium
54. Aminosyn II 4.25% – without electrolytes
55. Aminosyn II 5%
56. Aminosyn II 7%
57. Aminosyn II 8.5%
58. Aminoven 10%
59. Aminoven 15%
60. Aminoven 5%
61. BranchAmin 4%
62. Clinisol 15% Sulfite free
63. Dipeptiven
64. Glamin/Glavamin
65. Nephrotect 10%
66. Premasol 10% Sulfite free
67. Premasol 6%
68. RenAmin
69. Synthamin 14, 8.5% / 14g N
70. Synthamin 17, 10% / 16.5g N
71. Synthamin 9, 5.5% / 9.1g N
72. Travasol 10%
73. Travasol 5.5%
74. Travasol 8.5%
75. Vamin 14EF
76. Vamin 18EF
77. Vamin Glucose
78. Other Amino Acids specify

Glucose

79. Glucose 5%
80. Glucose 10%
81. Glucose 15%
82. Glucose 20%
83. Glucose 40%
84. Glucose 50%
85. Glucose 70%
86. 10% Dextrose Injection USP
87. 20% Dextrose Injection USP
88. 30% Dextrose Injection USP
89. 40% Dextrose Injection USP
90. 50% Dextrose Injection USP
91. 70% Dextrose Injection USP
92. Other Glucose specify

Lipids

93. ClinOleic 20%
94. Intralipid
95. Intralipid 20% IV Emulsion
96. Intralipid 30% IV Emulsion
97. Lipidem/Lipoplus
98. Lipofundin 20% N
99. Lipofundin MCT/LCT 10%
100. Lipofundin MCT/LCT 20%
101. Lipofundin N 10%
102. Liposyn II
103. Liposyn III
104. Liposyn III 30%
105. Lipovenoes 10% PLR
106. Lipovenoes MCT 10%/20%
107. Omegaven
108. SMOFlipid
109. Structolipid
110. Structolipid 20%
111. Other Lipid specify

APPENDIX 5
Calculation of PaO_2 / FiO_2 ratio

Calculation of P_aO_2 / F_iO_2 ratio

		F_iO_2												
		0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95	1.00
P_aO_2	54	135	120	108	98	90	83	77	72	68	64	60	57	54
mmHg	56	140	124	112	102	93	86	80	75	70	66	62	59	56
	58	145	129	116	105	97	89	83	77	73	68	64	61	58
	60	150	133	120	109	100	92	86	80	75	71	67	63	60
	62	155	138	124	113	103	95	89	83	78	73	69	65	62
	64	160	142	128	116	107	98	91	85	80	75	71	67	64
	66	165	147	132	120	110	102	94	88	83	78	73	69	66
	68	170	151	136	124	113	105	97	91	85	80	76	72	68
	70	175	156	140	127	117	108	100	93	88	82	78	74	70
	72	180	160	144	131	120	111	103	96	90	85	80	76	72
	74	185	164	148	135	123	114	106	99	93	87	82	78	74
	76	190	169	152	138	127	117	109	101	95	89	84	80	76
	78	195	173	156	142	130	120	111	104	98	92	87	82	78
	80	200	178	160	145	133	123	114	107	100	94	89	84	80
	82	205	182	164	149	137	126	117	109	103	96	91	86	82
	84	210	187	168	153	140	129	120	112	105	99	93	88	84
	86	215	191	172	156	143	132	123	115	108	101	96	91	86
	88	220	196	176	160	147	135	126	117	110	104	98	93	88
	90	225	200	180	164	150	138	129	120	113	106	100	95	90
	92	230	204	184	167	153	142	131	123	115	108	102	97	92
	94	235	209	188	171	157	145	134	125	118	111	104	99	94
	96	240	213	192	175	160	148	137	128	120	113	107	101	96
	98	245	218	196	178	163	151	140	131	123	115	109	103	98
	100	250	222	200	182	167	154	143	133	125	118	111	105	100
	102	255	227	204	185	170	157	146	136	128	120	113	107	102
	104	260	231	208	189	173	160	149	139	130	122	116	109	104

Arterial oxygenation goal: P_aO_2 55-80 mm Hg or S_pO_2 88-95%

Use the following F_iO_2 / PEEP combinations to acheive oxygenation goal:

F_iO_2	0.3	0.4	0.4	0.5	0.5	0.6	0.7	0.7	0.7	0.8	0.9	0.9	0.9	1.0
PEEP	5	5	8	8	10	10	10	12	14	14	14	16	18	20-24

AARC Clinical Practice Guideline, In Vitro pH and Blood Gas Analysis and Hemoximetry, Respiratory Care, 38:505-510, 1993

APPENDIX 6
Pulmonary System Conversions

Conversion Table for FiO2 when on mask or cannula	
Nasal Cannula	
100 % O2 flow rate (L/ min)	**FiO2 %**
1	**24**
2	**28**
3	**32**
4	**36**
5	**40**
6	**44**
Oxygen Mask	
100 % O2 flow rate (L/ min)	**FiO2 %**
5-6	**40**
6-7	**50**
7-8	**60**
9	**90**
10	**99+**
Mask with Reservoir Bag	
100 % O2 flow rate (L/ min)	**FiO2 %**
6	**60**
7	**70**
8	**80**

AARC Clinical Practice Guideline, In Vitro pH and Blood Gas Analysis and Hemoximetry, Respiratory Care, 38:505-510, 1993

APPENDIX 7
ANTIBIOTICS

1	Acyclovir	39	Cloxacillin	77	Ofloxacin
2	Amantadine	40	Cycloserine	78	Olsetamivir
3	Amikacin	41	Diamino-diphenyl sulphone	79	Oxacillin
4	Aminosalicylic acid	42	Dicloxacillin	80	Penicillin
5	Amoxicillin	43	Dimenocycline	81	Pentamidine
6	Amoxicillin/clavulinic acid	44	Doxycycline	82	Piperacillin
7	Amphotericin B	45	Ertapenem	83	Piperacillin/Tazobactem
8	Ampicillin	46	Erythromycin	84	Polimyxin B
9	Ampicillin/sulbactam	47	Ethambutal	85	Polimyxin E
10	Anidulafungin	48	Ethionamide	86	Primaquin
11	Anti-HIV therapy-please name:	49	Famcyclovir	87	Pyrazinamide
12	Azithromycin	50	Fusidic Acid	88	Quinopristin+ Dalfopristin
13	Aztreonam	51	Fluconazole	89	Ribavirin
14	Bacitracin	52	Flucytosine	90	Rifabutin
15	Capreomycin	53	Foscarnet	91	Rifampin
16	Carbenicillin	54	Fosfomycin	92	Rimantadine
17	Caspofungin	55	Ganciclovir	93	Spectinomycin
18	Cefaclor	56	Gatifloxacin	94	Streptomycin
19	Cefamandole	57	Gentamicin	95	Sulfadiazine
20	Ceftazidime	58	Imipenem/Cilastatin	96	Sulfamethoxazole
21	Cefazolin	59	Isoniazid	97	Sulfisoxazole
22	Cefepime	60	Itraconazole	98	Teicoplanin
23	Cefixime	61	Kanamycin	99	Telithromicine
24	Cefoperazone	62	Ketoconazole	100	Temocillin
25	Cefotaxime	63	Levofloxacin	101	Tetracycline
26	Cefotetan	64	Linezolid	102	Ticarcillin
27	Cefotiam	65	Meropenem	103	Ticarcillin/clavulinic acid
28	Cefoxitin	66	Metronidazole	104	Tigecycline
29	Cefprozil	67	Mezlocillin	105	Tobramycin
30	Ceftriaxone	68	Micafungin	106	Trimethoprim
31	Cefuroxime	69	Minocycline	107	Trimethoprim-Sulfamethoxazole (Cotrimoxazole)
32	Cephalexin	70	Moxyfloxacin	108	Trovofloxacin
33	Cephalothin	71	Nafcillin	109	Valacyclovir
34	Ciprofloxacin	72	Nalidixic Acid	110	Valganciclovir
35	Clarithromycin	73	Netilmycin	111	Vancomycin
36	Clindamycin	74	Nitrofurantoin	112	Voriconazole
37	Clofazimine	75	Norfloxacin	113	Zanamavir
38	Cloramphenicol	76	Nyastatin	114	OTHER: please specify

APPENDIX 8
MICROBIOLOGY ORGANISMS

Bacteria		
Acinetobacter sp.	1a	baumani
	1b	Other specify
Actinomyces sp.	2	Other specify
Aerococcus sp.	3	Other specify
Aeromonas sp.	4a	aerogenes
	4b	Other specify
Alcaligenes sp.	5a	dentrificans
	5b	foecalis
	5c	xylosodidans
	5d	Other specify
Babesia sp.	6	Other specify
Bacillus sp.	7a	anthracis
	7b	Other specify
Bacteroides sp.	8a	fragilis
	8b	thetaiotamicron
	8c	Other specify
Bartonella sp.	9	Other specify
Borrellia sp.	10a	burgdoferi
	10b	Other specify
Bortetella sp.	11a	pertussis
	11b	Other specify
Burkholderia sp.	12a	cepacia
	12b	mallei
	12c	pseudomallei
	12d	Other specify
Campylobacter sp.	13a	fetus
	13b	jejuni
	13c	Other specify
Capnocytophaga sp.	14	Other specify
Chlamydia sp.	15a	pneumoniae
	15b	trachomatis
	15c	Other specify
Citrobacter sp.	16a	freundii
	16b	koseri
	16c	Other specify

Bacteria (con't)		
Clostridium sp.	17a	botulism
	17b	difficile
	17c	perfringes
	17d	septicum
	17e	tetani
	17f	Other specify
Corynobacterium sp.	18	Other specify
Coxiella sp.	19a	burnetti
	19b	Other specify
Diphteroids sp.	20	Other specify
Ehrlichia sp.	21	Other specify
Eikenella sp.	22a	corrodens
	22b	Other specify
Enterobacter sp.	23a	aerogenes
	23b	cloacae
	23c	Other specify
Enterococcus sp.	24a	avium
	24b	fecalis
	24c	foecium
	24d	Other specify
Erysipelothrix sp.	25a	rhusiopatheia
	25b	Other specify
Escherichia sp.	26a	coli
	26b	Other specify
Francisella sp.	27a	tularensis
	27b	Other specify
Fusobacterium sp.	28	Other specify
Hafnia sp.	29	alvei
Helicobacter sp.	30a	pylori
	30b	Other specify
Haemophilus sp.	31a	influenzae (beta-lactamase positive)
	31b	influenzae (beta-lactamase negative)
	31c	parainfluenzae
	31d	Other specify

APPENDIX 8 con't
MICROBIOLOGY ORGANISMS

Bacteria (con't)		
Klebsiella sp.	32a	pneumonia
	32b	oxytoca
	32c	Other specify
Legionella sp.	33a	pnemophillia
	33b	Other specify
Listeria sp.	34a	monocytogenes
	34b	Other specify
Moraxella sp.	35a	catarrhalis
	35b	Other specify
Morganella sp.	36a	morganii
	36b	Other specify
Mycoplasma sp.	37	Other specify
Neisseria sp.	38a	gonorrhoeae
	38b	meningitidis
	38c	Other specify
Nocardia sp.	39a	asteroides
	39b	Other specify
Other Bacteria specify	40	Other specify
Pasteurella sp.	41a	moltocida
	41b	Other specify
Peptostreptococcus/ Pepto-coccus sp.	42a	prevotti
	42b	Other specify
Porphyromonas sp.	43	Other specify
Prevotella sp.	44a	melaningogenica
	44b	Other specify
Propionibacterium sp.	45	Other specify
Proteus sp.	46a	mirabilis
	46b	Other specify
Providencia sp.	47a	Other specify
Pseudomonas sp.	48a	aeruginosa
	48b	fluorescens
	48c	Other specify
Ralstonia sp.	49	Other specify
Rhodococcus sp.	50a	equi
	50b	Other specify

Bacteria (con't)		
Rickettsia sp.	51a	ricketsii
	51b	Other specify
Salmonella sp.	52	Other specify
Serratia sp.	53a	liquefaciens
	53b	marcescens
	53c	Other specify
Shigella sp.	54a	dysenteriae
	54b	Other specify
Staphylococcus sp.	55a	Methicillin Resistant Staph Aureus (MRSA)
	55b	Methicillin Sensitive Staph Aureus (MSSA)
	55c	aureus
	55d	capitis
	55e	Coagulase Negative
	55f	epidermadis
	55g	haemolyticus
	55h	hominis
	55i	warneri
	55j	Other specify
Stenotrophomas sp.	56a	maltophillia
	56b	Other specify
Streptococcus sp.	57a	anginosus
	57b	bovis or infantarius
	57c	Group A (pyogenes)
	57d	Group B (agalactiae)
	57e	Group G (dysgalactiae)
	57f	mutans
	57g	pneumoniae
	57h	viridans
	57i	Other specify
Streptobacillus sp.	58a	moniliformis
	58b	Other specify
Vibrio sp	59a	cholerae
	59b	Other specify
Yersinia sp.	60a	enterocolitica
	60b	pestis
	60c	Other specify

APPENDIX 8 con't
MICROBIOLOGY ORGANSIMS

Fungi/Yeast		
Aspergillus sp.	61a	flavus
	61b	fumigatus
	61c	niger
	61d	Other specify
Bipolaris sp.	62	Other specify
Blastomyces sp.	63	dermatitidis
Candida sp.	64a	albicans
	64b	glabrata
	64c	krusei
	64d	parapsilosis
	64e	torulopsis
	64f	tropicalis
	64g	Other specify
Coccidiomycosis sp.	65	Other specify
Pneumocystis sp.	66	carinii or jirovecii
Rhodoturla sp.	67	mucilaginosa
Not specified	68	Not specified
Other Fungi/Yeast specify	69	Other specify

Virus		
Adenovirus	70	
Cytomegalovirus	71	
Hepatitis sp.	72a	A
	72b	B
	72c	C
	72d	Other specify
Herpes sp.	73a	Simplex 1
	73b	Simplex 2
HIV	74	
Influenza	75a	A
	75b	B
Other Virus specify	76	Other specify
Mycobacteria		
Avium-Intracellulare (MAI)	77	
Tuberculosis	78	
Other Mycobacteria specify	79	Other specify

APPENDIX 9
CATEGORIES OF INFECTION

This document outlines the categories of infection that may be considered “outcomes” in a clinical trial. We have attempted to operationalize the definitions developed by the International Sepsis Forum Consensus Conference (CCM 2005;33:1538-1548) and in doing so, have made modifications to those definitions. Furthermore, given the uncertainty around the diagnosis of infection, we have consistently used the terminology, ‘Definite’(a), ‘Probable’(b), and ‘Possible’(c) for each type of infection. The categories of infection are as follows:

Category 1	**Deep surgical wound infection**
Category 2	**Incisional (or superficial) surgical wound infection**
Category 3	**Skin and soft-tissue infection (non-surgical) (SSTS)**
Category 4	**Catheter-related blood stream infections (CRI)**
Category 5	**Primary blood stream infections (BSI)**
Category 6	**Lower urinary tract infection**
Category 7	**Upper urinary tract infection**
Category 8	**Intra abdominal infection**
Category 9	**Sinusitis**
Category 10	**Lower respiratory tract infection (excluding pneumonia)**
Category 11	**ICU Acquired Pneumonia**
Category 12	**Other**

APPENDIX 9-1
CATEGORIES OF INFECTION

Category 1 - **Deep surgical wound infection**

Deep surgical wound infection must meet the following criterion:

Infection occurs at operative site within 30 days after surgery if no implant is left in place or within 1 year if implant is in place

AND

infection appears related to surgery

AND

infection involves tissues or spaces at or beneath fascial layer or a deeper anatomical space opened during the surgical procedure.

In all categories, signs and symptoms suggestive of surgical site infection must be present. These include wound erythema and blanching, tenderness, pain, purulent discharge, fever, and leukocytosis.

☐ **a) Definite Infection**

An abscess or other evidence of infection seen on direct examination, during surgery or by histopathologic examination.

OR

Organism isolated from culture of fluid obtained during open procedure or aspiration.

☐ **b) Probable Infection**

Purulent drainage from drain placed beneath fascial layer (no microbial confirmation or Gram stain positive but negative culture).

☐ **c) Possible Infection**

Wound spontaneously dehisces or is deliberately opened by surgeon (no pus or microbial confirmation).

APPENDIX 9-2
CATEGORIES OF INFECTION

Category 2 - **Incisional (or superficial) surgical wound infection**

Incisional (or superficial) surgical wound infection must meet the following criterion:

Infection occurs at incision site within 30 days after surgery

AND

involves skin and subcutaneous tissue above the fascial layer.

In all categories, signs and symptoms suggestive of surgical site infection must be present. These include wound erythema and blanching, tenderness, pain, purulent discharge, fever, and leukocytosis.

☐ **a) Definite Infection**

Organism(s) isolated from culture of fluid from wound closed primarily.

☐ **b) Probable Infection**

Purulent drainage from incision or drain located above fascial layer (no microbial confirmation or Gram stain positive but no positive culture).

☐ **c) Possible Infection**

Surgeon deliberately opens wound.

APPENDIX 9-3
CATEGORIES OF INFECTION

Category 3 - **Skin and soft tissue infection (non-surgical)**

Skin and soft tissue infection (non-surgical) or cellulitis must meet the following criterion:

Infection occurs in skin or soft tissue structures (SSTS) NOT associated with surgical procedures.

☐ **a) Definite Infection**

Compelling clinical and laboratory evidence (such as spreading cutaneous erythema and blanching, or drainage or purulent material, with or without lymphangitis, in association with fever and leukocytosis) of the presence of SSTS infection based on clinical, radiographic, or surgical findings.

AND

Organism isolated from culture from a skin lesion that has drained pus or from a skin aspirate or biopsy of subcutaneous tissues of an erythematous skin lesion (not a simple skin swab).

☐ **b) Probable Infection**

Compelling clinical and laboratory evidence (such as spreading cutaneous erythema and blanching, or drainage or purulent material, with or without lymphangitis, in association with fever and leukocytosis) or the presence of SSTS infection based on clinical, radiographic, or surgical findings.

AND

No microbial confirmation or only positive Gram stain but negative culture.

☐ **c) Possible Infection**

Some clinical evidence of infection, such as mild cutaneous erythema associated with fever, some laboratory evidence (leukocytosis), some radiographic but insufficient evidence to confirm a diagnosis.

AND

No microbial confirmation.

APPENDIX 9-4
CATEGORIES OF INFECTION

Category 4 - **Catheter-related blood stream infections (CRI)**

Catheter-related blood stream infections (CRI) must be associated with an indwelling central line/arterial line (usually placed more than 5-7 days ago) and have an organism isolated from the bloodstream that is not related to infection as some other site (lungs, GI tract, etc.). In addition, patients must have signs of sepsis (fever, chills, hypotension, etc.):

☐ **a) Definite Catheter-related Infection**

1. In association with a central line or arterial line, recognized pathogen (defined as a pathogen not usually regarded as a skin contaminant) isolated from one or more blood culture.

   AND

   Catheter tip positive (>15 CFU/mL) or hub or exit site culture positive with the same organism.

   OR

2. In association with a central line or arterial line, a common skin contaminant[1] isolated from two or more blood cultures (at least one from a venipuncture).

   AND

   Catheter tip positive (>15 CFU/mL) or hub or exit site culture positive with the same organism.

☐ **b) Probable Infection**

1. In association with a central line or arterial line, recognized pathogen (defined as a pathogen not usually regarded as a skin contaminant) isolated from one or more blood culture.

   OR

2. In association with a central line or arterial line, a common skin contaminant isolated from two or more blood cultures (at least one from a venipuncture).

☐ **c) Possible Infection**

One of the following: fever (core temp >38^{0}C), chills, or hypotension in association with a central line or arterial line (with or without a positive catheter tip (>15 CFU/ml) or positive hub or exit site positive).[2]

AND

Patient's clinical course improves with removal or change of the central line or arterial line and institution of appropriate antibiotic therapy.

---

[1] Skin contaminants include diptheroids, Bacillus species, Propionibacterium, coagulase-negative Staphylococci, or micrococci)

[2] A positive catheter tip culture (>15 CFU/mL) or positive exit site culture without systemic symptoms and improvement with removal or change of the central/arterial line and institution of appropriate antibiotic therapy is not considered to be indicative of a central/arterial line infection.

APPENDIX 9-5
CATEGORIES OF INFECTION

Category 5 - **Primary blood stream infections (BSI)**

Primary blood stream infections (BSI) must NOT be associated with a indwelling vascular device or related to infection as some other site (lungs, GI tract, etc.). In addition, patients must have signs of sepsis (fever, chills, hypotension, etc.):

☐ **a) Definite Blood Stream Infection**

1. A recognized pathogen (defined as a pathogen not usually regarded as a skin contaminant) isolated from one or more blood culture.

   OR

2. A common skin contaminant isolated from two or more blood cultures drawn on separate occasions (from venipunctures; must not be associated with a indwelling vascular device).

{there is no definition of 'probably infection' for this category}

☐ **b) Possible Infection**

A common skin contaminant isolated from a blood culture that does not fulfill the definition of 'Definite" BSI.

AND

Patients clinical course improves with institution of appropriate antibiotic therapy.

APPENDIX 9-6
CATEGORIES OF INFECTION

Category 6 - **Lower urinary tract infection (LUTI)**

☐ **a) Definite**

Symptoms (fever - core temp > 38^{o}C), hypotension) and Pyuria ($\geq$10 white blood cells {WBC}/ml

AND

a positive urine culture of $\geq 10^5$ colonies/ml urine with no more than two species of organisms.

AND

No other sources of the patient's signs and symptoms are identified.

☐ **b) Probable**

Symptoms (fever - core temp > 38^{o}C), hypotension).

AND

A urine culture of $\geq 10^5$ colonies/ml urine with no more than two species of organisms.

☐ **c) Possible**[*]

A urine culture of $\geq 10^5$ colonies/ml urine with no more than two species of organisms.

[*] Candida isolated in the urine may be considered indicative of a possible UTI if the attending physician feels that it is significant and institutes management for it (either/both changes the catheter or institutes antifungal therapy)

APPENDIX 9-7
CATEGORIES OF INFECTION

Category 7 - **Upper Urinary Tract Infection**

Upper Urinary Tract Infection includes infections of the urinary tract (kidney, ureter, bladder, urethra, or perinephric spaces).

☐ **a) Definite:**

Organism isolated from culture of fluid (other than urine) or tissue from affected site.

OR

An abscess or other evidence of infection seen on direct examination, during surgery, or by histopathologic examination.

☐ **b) Probable**

Two of the following: fever (core temp >38^{0}C), urgency, localized pain, or tenderness at involved site

AND any of the following:

Purulent drainage from affected site.

Positive Gram stain from fluid from affected site.

Organism isolated from urine or blood culture.

Radiographic evidence of infection.

☐ **c) Possible**

Two of the following: fever (core temp >38^{0}C), localized pain, or tenderness at involved site

AND any of the following:

Physician's diagnosis.

Physician institutes appropriate antimicrobial therapy and patient responds appropriately.

APPENDIX 9-8
CATEGORIES OF INFECTION

Category 8 - **Intra abdominal infection**

Intra abdominal infection includes gallbladder, bile ducts, liver [other than viral hepatitis], spleen, pancreas, peritoneum, subphrenic or subdiaphragmatic space, pelvis or other intra abdominal tissue or area not specified elsewhere, and must meet the following criteria:

☐ **a) Definite**

1. Organism(s) isolated from culture of purulent material from intra abdominal space/structure obtained during surgery or needle aspiration.

   OR

2. Abscess or other evidence of intra abdominal infection (such as soilage of the peritoneal cavity after intestinal perforation) seen during surgery or by histopathologic examination.

   OR

3. Pseudomembranous colitis- Direct visualization of pseudomembranes during sigmoidoscopy or on examination of surgically removed specimens of the colon.

☐ **b) Probable**

1. In the appropriate clinical setting, **organism isolated from blood culture** and:

   Radiographic evidence for intra-abdominal infection.

   OR

   Clinical evidence of intra-abdominal infection (Abdominal Pain, Systemic leukocytosis, tenderness, jaundice).

   OR

   Laboratory evidence of intra-abdominal infection (inflammatory ascitic fluid i.e. > 500 PMN/ml, evidence of billiary obstruction, positive gram stain of fluid from abdominal cavity but negative cultures).

2. Organisms seen on Gram stain of drainage or tissue obtained during surgery or needle aspiration but cultures are negative.

3. Pseudomembranous colitis- Toxin isolated from the stool in the setting of clinical illness compatible with Pseudomembranous colitis (exposure to antibiotics, diarrhea, colonic dilation, toxic megacolon, etc.).

☐ **c) Possible:** one of the following:

1. Upper Gastro-intestinal perforation or penetrating abdominal trauma that is surgically repaired without further evidence of microbiologic confirmation or clinical signs or symptoms supportive of a diagnosis of bacterial or fungal peritonitis.
2. Clinical evidence of intra-abdominal infection with an inflammatory peritoneal fluid (> 500 leucocytes/ml for primary peritonitis and >100 leukocytes/ml for peritoneal dialysis related peritonitis) in the absence of a positive culture (in peritoneal fluid or blood) or gram stain.
3. Organism isolated from culture of drainage from surgically placed drain (e.g., closed suction drainage system, open drain or T-tube drain).
4. Clinical evidence of intra-abdominal infection with persistent signs of systemic inflammation but without clear documented evidence of persistent inflammation within the peritoneal space following secondary bacterial peritonitis.
5. Clinical evidence of intra-abdominal infection with signs of systemic inflammation which improves with the

APPENDIX 9-9
CATEGORIES OF INFECTION

Category 9 - **Sinusitis**

☐ **a) Definite**

Organism isolated from culture of purulent material directly obtained from sinus cavity by antral puncture.

☐ **b) Probable**

One of the following: fever (core temp >38^{0}C), pain or tenderness over the involved sinus, headache, purulent exudate, or nasal obstruction.

AND

Radiographic evidence of infection.

☐ **c) Possible**

Two of the following: fever (core temp >38^{0}C) or pain or tenderness over the involved sinus, headache.

AND

purulent nasal exudate.

APPENDIX 9-10
CATEGORIES OF INFECTION

Category 10 - **Lower respiratory tract infection (excluding pneumonia)**

Lower respiratory tract infection (excluding pneumonia) includes infections such as bronchitis, tracheobronchitis, bronchiolitis, tracheitis, lung abscess, and empyema.

☐ **a) Definite:**

Organism seen on smear or isolated from culture of lung tissue or fluid, including pleural fluid.

☐ **b) Probable:**

1. Lung abscess or empyema seen during surgery or by histopathologic examination but no microbiological confirmation.
2. For bronchitis, tracheobronchitis, bronchiolitis, tracheitis, without evidence of pneumonia, must meet the following criterion:

   Patient has no clinical or radiographic evidence of pneumonia but has fever (core temp >38 C) and increased sputum production.

   AND

   Organism isolated from culture obtained by deep tracheal aspirate or bronchoscopy.

☐ **c) Possible**

Abscess cavity seen on radiographic examination of lung.

APPENDIX 9-11
CATEGORIES OF INFECTION

Category 11 - **ICU-Acquired Pneumonia**

ICU-Acquired Pneumonia includes HAP and VAP. It must be associated with a clinical suspicion of pneumonia defined as new, progressive, or persistent infiltrates on CXR and be associated with signs and symptoms of infection (fever, leukocytosis, worsening oxygenation, purulent secretions, etc.).

☐ **a) Definite Pneumonia**

Radiographic evidence of pulmonary abscess and positive needle aspirate.

OR

Histological proof on open lung biopsy or at post mortem (abscess formation, or consolidation with PMN accumulation).

☐ **b) Probable Pneumonia**

Must be associated with a positive culture of a pathogen known to cause pneumonia. For example, positive cultures for Coagulase Negative Staph. Species or normal oral flora would not be considered as positive since they do not usually cause VAP/HAP. The positive cultures need to come from 1 of the following:

A sputum or an endotracheal aspirate specimen.

A culture of bronchial washings, BAL or PSB regardless of quantitation (if done).

A blood culture of an organism found within 48 hours of the clinical suspicion of VAP/HAP.

A positive pleural fluid culture.

☐ **c) Possible Pneumonia**

No microbial confirmation in the setting of a clinical suspicion for pneumonia as described above, and a clinical course compatible with VAP/HAP including the institution of appropriate antimicrobial therapy.

APPENDIX 9-12
CATEGORIES OF INFECTION

Category 12 - **Other**

If the patient developed an infection which does not fall into any of the previous categories. Please describe below.

☐ **a) Definite**

Clinical evidence of infection and one of the following:

The culture of an organism(s) or positive Gram stain or positive viral cultures from a normally sterile bodily fluid or tissue in the absence of previous surgical intervention (e.g. organism isolated from CSF or synovial fluid).

OR

Positive antigen/RNA/DNA test for pathogens from a normally sterile bodily fluid.

OR

Positive viral/bacterial serology.

☐

b) Probable

Clinical evidence of infection and of one the following:

The culture of a pathogenic organism(s) or positive Gram stain positive or positive viral culture from a body site that is not normally sterile or a specimen obtained from an indwelling drain or catheter placed into a normally sterile body site (e.g. intra-abd. drain).

☐ **OR**

Positive antigen/RNA/DNA test for pathogens from a body site that is not normally sterile.

c) Possible

Clinical evidence of infection but no microbiologic, smear or serological confirmation of infection.

Please describe infection:

_____

_____

APPENDIX 10
DEFINITION OF "NO" NEWLY ACQUIRED INFECTION

If "No" to infection, choose either one, Probable No or Possible No

Probable No

With greater certainty, the Investigator feels the patient is NOT infected. Clinical story is clearly consistent with no infection supported by lack of physiologic response (SIRS), or no positive cultures, or no treatment with antibiotics (short-term prophylaxis OK), and patient gets better.

Examples:

Patient with ischemic heart disease (IHD) admitted to ICU in cardiogenic shock. No positive cultures, no treatment with antibiotics, and patient gets better. Even if the patient dies, if there is no suggestion of infection or no treatment with antibiotics, the patient could still be "probably not infected".

Patient with multiple traumas admitted to ICU on ventilator. Has SIRS for 24-48 hours (probably related to trauma), no organ dysfunction, no positive cultures, only short-term antibiotic prophylaxis, and gets better in a few days.

Clear cut cases related to "colonization" or "contamination" should be categorized here (i.e., cultures that are positive secondary to organisms likely to reflect contamination or colonization that get better with no treatment).

Possible No

Investigator believes the patient is not infected but with some degree of uncertainty. Investigator cannot comfortably rule out infection but thinks it is not likely. Patient may manifest SIRS and organ dysfunction secondary to some other process but was treated with antibiotics.

Examples:

Patient admitted to ICU with severe necrotizing pancreatitis. Patient had SIRS and MODS and is treated with antibiotics from the beginning despite the lack of positive cultures. (prophylaxis for secondary pancreatitic complications).

Patient with ischemic heart disease admitted to ICU in cardiogenic shock. CXR shows a bilateral process compatible with pulmonary edema. Patient receives treatment of IHD and cardiogenic shock and seems to improve. On Study Day 1 while in ICU, patient spikes a fever and is started on antibiotics.

APPENDIX 11
SF-36

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.
Thank you for completing this survey!

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

		Yes, limited a lot	Yes, limited a little	No, not limited at all
a	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c	Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d	Climbing several flights of stairs	☐ 1	☐ 2	☐ 3
e	Climbing one flight of stairs	☐ 1	☐ 2	☐ 3
f	Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g	Walking more than a kilometre	☐ 1	☐ 2	☐ 3
h	Walking several hundred metres	☐ 1	☐ 2	☐ 3
i	Walking one hundred metres	☐ 1	☐ 2	☐ 3
j	Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
a	Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b	Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c	Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d	Had difficulty performing the the work or other activities (for example, it took extra effort)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Cut down on the <u>amount of time</u> you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Did work or other activities <u>less carefully than usual</u>	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?

None	Very mild	Mild	Moderate	Severe	Very severe
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Did you feel full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Have you been very nervous?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g Did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Have you been happy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

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