Patient ID

THE RE–*ENERGIZE* STUDY

A RandomizEd Trial of ENtERal Glutamine to MinimIZE Thermal Injury

Clinical trials.gov ID #NCT00985205

electronic Case Report Form (eCRF) Worksheets and Instructions

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General Instructions

The following case report form worksheets have been developed to assist the Research Coordinator (RC) at the participating site with data collection. The RC may choose to record the data from the patient's medical chart (source document) on these forms before entering the data in to the electronic data capture system i.e. REDCAP™. The RC may choose to enter data into REDCap™ directly from the medical chart or use her/his own worksheets. Whichever method is used, the instructions on each page detail how and when the data is to be collected.

1. To help you keep track, we recommend documenting the patient randomization number on each worksheet.
2. In this document, **Acute Care Unit (ACU)** is used to refer to both Intensive Care Units and Burn Units.
3. Date format will be year-month-day, entered as YYYY-MM-DD.
   i.e. September 8th 2015 would be entered as: 2015-09-08.
4. All times should be recorded using the 24 hour clock. Midnight is to be entered as 00:00 hrs. Unlike military time, the colon is required between the hour and the minutes.
5. Anywhere that “Other” (specify)" is selected, there must be an entry in REDCap™ (in the space provided) describing what “Other” means.
6. Study days are defined as follows and data **must** be collected according to study days:
   - Study Day 1 = **ACU admission date** (not randomization) and **time** until 23:59 the same day.
   - Study Day 2 = the subsequent day starting at 00:00 to 23:59 that day

   i.e. A patient is admitted to the ACU on Sept 8th, 2015 at 4:00 PM (16:00). The study days would be:
   - Study Day 1 = 2015-09-08 from 16:00 to 23:59 the same date (2015-09-08)
   - Study Day 2 = 2015-09-09 from 00:00 to 23:59 on 2015-09-09 (same date)
   - **NOTE:** Following Study Day 1, each study day should be recorded from midnight to the following midnight.
7. The duration of data collection and frequency will vary by form and is outlined as follows:

- **To be collected once:** Laboratory Units, Baseline, Organ Dysfunction, Hospitalization Overview, 6 Month Follow up to include Survival Assessment, SF-36, ADL, and IADL.
- **To be collected once and then additionally with each occurrence:** Study Intervention, Nutrition Assessment/Timing
- **To be collected daily from randomization until ≥ 7 days post last successful grafting, or until ACU**
- **discharge, or 3 months from ACU admission, whichever comes first:** Daily Monitoring (dose of study intervention received)
- **To be collected daily until ≥ 10 days post last successful grafting (stop of study intervention + 3 days), or until ACU discharge, or 3 months from ACU admission, whichever comes first:** Concomitant Medications.
- **To be collected daily from Study Day 1 through Study Day 14 and then once a week**: Laboratory form.
- **To be collected from Study Day 1 through Study Day 12:** Daily Nutrition form including labs on the form.
- **To be collected upon each occurrence:** Burn Related Operative Procedures, Mechanical Ventilation, Renal Replacement Therapy, Microbiology (Gram-negative bacteremias), Protocol Violations, Serious Adverse Event

Refer to specific instructions for each worksheet.

8. There may be occasions when data is unavailable, not applicable or not known. The measurement may not have been taken, the test not done, or the data may be missing from the source document.
   i.e. T-Bilirubin was not done on a particular study day. If the data is not available for any reason, indicate by selecting "Not Available".

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Screening - Inclusion Instructions

<table>
<tr><td>Inclusion Criteria</td><td><u>Only</u> patients who meet the inclusion criteria should be entered into the Central Randomization System (CRS). Eligibility must be confirmed by the Site Investigator/or sub-Investigator before randomization may occur.</td></tr>
<tr><td>1. Presence of deep 2nd and / or 3rd degree burns requiring skin grafting</td><td>The presence of deep 2nd and / or 3rd degree burns requiring grafting is an assessment that must be confirmed by the SI or sub-I.

<table>
<tr><th>The following burn injuries fulfil this criteria</th><th>The following burn injuries do NOT fulfil this criteria. Do NOT include any of the following:</th></tr>
<tr><td>• Thermal burn injuries
• Scald
• Fire (includes both Flame and Flash)
• Radiation
• Chemical
• Unknown
• Other, Specify_____</td><td>• High voltage electrical contact (see exclusion #7.)
• Frostbite
• Stevens-Johnson Syndrome (SJS)
• Toxic Epidermal Necrolysis (TEN)</td></tr>
</table></td></tr>
<tr><td>2. Patient meets <u>ONE OF</u> the following 4 criteria:</td><td>This assessment must be confirmed by the SI or sub-I based on her or his clinical judgment.

Check <u>only one</u> box to indicate which 1 of the 4 criteria is met.

❑ Patients 18 - 39 years of age with TBSA <u>≥</u> 20%
❑ Patients 18 - 39 years of age with TBSA <u>≥</u> 15% <u>WITH</u> inhalation injury
❑ Patients 40 – 59 years of age with TBSA <u>≥</u> 15%
❑ Patients <u>≥</u> 60 years of age with TBSA <u>≥</u> 10%</td></tr>
<tr><td colspan="2">Consent must be obtained within 72 hours of admission to the ACU.
Refer to exclusion criteria for more details (p.6 – 8)</td></tr>
</table>

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Screening - Inclusion

Inclusion Criteria

A subject will be eligible for inclusion in this study only if both of the following criteria apply

1. Does the participant have deep 2nd and / or 3rd degree burns requiring skin grafting?	❑ Yes ❑ No
2. Does the patient meet one of the following 4 criteria?	❑ Yes ❑ No
❑ Patient aged 18 – 39 years with TBSA burn ≥ 20% ❑ Patient aged 18 – 39 years with TBSA burn ≥ 15% AND inhalation injury ❑ Patient aged 40 – 59 years with TBSA burns ≥ 15% ❑ Patient aged ≥ 60 with TBSA burn ≥ 10%	

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Screening - Exclusion Instructions (1/2)

Record ALL exclusion criteria that the patient meets. If ANY of the twelve criteria below are met, the patient is not eligible.

1. > 72 hours from admission to Acute Care Unit to time of consent

This refers to admission to your ACU. If a patient is transferred from another facility, the clock starts from the time of admission to your unit.

NOTE: Please do not enroll delayed presentation patients who are admitted to your unit greater than 24 hours post burn injury.

2. Patients younger than 18 years of age

There is no upper age limit for enrollment in this study.

3. Renal dysfunction:

- In patients without known renal disease, renal dysfunction is defined as at least one of the following:
  - a serum creatinine >171 µmol/L or >1.93 mg/dL
  - a urine output of less than 500 mL/last 24 hours (or 80 mL/last 4 hours if a 24 hour period of observation is not available).
- In patients with acute on chronic renal failure (pre-dialysis), patients with at least one of the following will be excluded:
  - an absolute increase of >80 µmol/L or >0.9 mg/dL from baseline or pre-admission creatinine
  - urine output of <500 mL/last 24 hours (or 80 mL/last 4 hours)
- Patients with chronic renal failure on dialysis will be excluded.

4. Liver cirrhosis

Child-Pugh Class C liver disease (see chart below for information on calculating Child-Pugh Class)

The Child-Pugh Class C score is obtained by adding the points for all 5 criteria in this table.

Any patient having a score of 10 – 15 falls into Group C (severe hepatic impairment) which would be considered exclusion for this study.

Class A: 5 – 6 points
Class B: 7 – 9 points
Class C: 10 – 15 points

Clinical and Lab Criteria	Points assigned		
	1	2	3
Total Bilirubin SI units	< 2mg/dL or < 34 µmol/L	2 - 3 mg/dL or 34 – 51 µmol/L	> 3 mg/dL or > 51 µmol/L
Serum Albumin SI units	> 3.5 g/dL or > 35 g/L	2.8—3.5 g/dL 28 – 35 g/L	< 2.8 g/dL or < 28 g/L
Prothrombin time or INR	< 4 seconds < 1.7	4 – 6 seconds 1.7 – 2.3	> 6 seconds > 2.3
Ascites*	Absent	Slight	Moderate
Encephalopathy	None	Moderate	Severe
* Refer to ultrasound results. If ascites have been drained in the past, it should be considered Moderate.			

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Screening - Exclusion Instructions (2/2)

5. Pregnant or lactating

Urine / blood tests for pregnancy will be done on all females of childbearing age by each site as part of standard ACU practice.

6. Contraindication for enteral nutrition (EN)

This includes intestinal occlusion / perforation, or intra-abdominal injury.

Being NPO is not a contraindication for enteral nutrition.

7. Patient with injuries from high voltage electrical contact.

External burns from an electrical arc or “slap” as well as thermal injuries from low voltage electrical contact are acceptable for the study.

8. Patients who are moribund

Defined as a patient who is not expected to survive the next 72 hours.

An isolated DNR does not fulfill this criterion.

9. Patients with extreme body size:

This includes patients with a BMI < 18 or > 50 kg/m^2.

10. Enrollment in another industry sponsored ACU / ICU intervention study

Co-enrollment in academic studies will be considered on a case-by-case basis.

11. Received glutamine supplement for > 24 hours prior to randomization

This refers to regular glutamine administration for a period of 24 hours or more prior to randomization.

12.Known allergy to maltodextrin, cornstarch, corn, corn products or glutamine.

If the patient meets all inclusion criteria and does NOT meet any of the exclusion criteria, the patient is eligible for randomization and you may proceed to the Pre-randomization / Randomization form.

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Screening—Exclusion

Exclusion Criteria

1. > 72 hours from admission to <u>your</u> Acute Care Unit to time of consent	☐ Yes ☐ No
2. Patients younger than 18 years of age	☐ Yes ☐ No
3. Renal Dysfunction • In patients without known renal disease, renal dysfunction defined as a serum creatinine >171 µmol/L or >1.93 mg/dL or a urine output of less than 500 mL/last 24 hours (or 80 mL/last 4 hours if a 24 hour period of observation is not available) • In patients with acute on chronic renal failure (pre-dialysis), an absolute increase of >80 µmol/L or >0.9 mg/dL from baseline or pre-admission creatinine or a urine output of <500 mL/last 24 hours (or 80 mL/last 4 hours). • Patients with chronic renal failure on dialysis.	☐ Yes ☐ No
4. Liver cirrhosis (Child-Pugh class C liver disease).	☐ Yes ☐ No
5. Pregnant or lactating (urine/blood tests for pregnancy will be done on all women of childbearing age by each site as part of standard ACU practice).	☐ Yes ☐ No
6. Contra-indication for EN (intestinal occlusion or perforation, intra-abdominal injury).	☐ Yes ☐ No
7. Patients with injuries from high voltage electrical contact.	☐ Yes ☐ No
8. Patient who is moribund (not expected to survive the next 72 hours).	☐ Yes ☐ No
9. Patients with extreme body sizes: BMI < 18 or > 50 kg/m^2	☐ Yes ☐ No
10. Enrollment in another industry sponsored ACU intervention study (co-enrollment in academic studies will be considered on a case by case basis).	☐ Yes ☐ No
11. Received glutamine supplement for >24 hours prior to randomization.	☐ Yes ☐ No
12. Known allergy to maltodextrin, cornstarch, corn, corn products or glutamine.	☐ Yes ☐ No

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Pre Randomization / Randomization Instructions

General Instructions	This form is to be filled out on the Central Randomization Systems (CRS). If inclusion criteria are present AND no exclusion criteria are met the patient is considered eligible for randomization into the study. Complete all fields as indicated.
Patient Eligibility Confirmed by SI or sub-I	Indicate eligibility of the patient has been confirmed with the site investigator (SI) or sub-investigator (sub-I) by "YES" or "NO" to the question "Did you confirm eligibility of the subject with the site investigator, or sub-investigator?". You must select "Yes" to continue entering data on the Pre-Randomization form. Enter the name of the physician who confirmed patient eligibility. This individual should be listed on the Site Delegation of Authority Log.
Was SDM / Subject Approached for Consent **Reason Not Approached For Consent**	Was the patient or substitute decision maker (SDM) approached for consent? Select "YES" or "NO". If "NO", select the primary reason the SDM or patient was not approached for consent. If "Other" is selected, explain the reason not approached for consent. ❑ Next of kin or SDM not available ❑ Missed subject ❑ Language barriers ❑ Family dynamics ❑ Recommendation of clinical team ❑ CRS unavailable ❑ Pharmacy unavailable ❑ Other, please specify _____
Consent Obtained **Reason Consent Not Obtained**	Was consent obtained from the SDM or patient? Select "YES" or "NO" If "NO", select the primary reason consent was not obtained. If "Other" is selected, explain the reason consent was not obtained in the text box provided. ❑ Too Overwhelmed ❑ Not interested ❑ Did not respond (timed out) ❑ Other, please specify _____
Consent Date and Time	If consent was obtained, record the consent date (YYYY-MM-DD) and time (HH:MM, 24hr clock).
Height and Weight	Record the patient's height and weight. Record up to two decimal points, i.e. 82.67 kg ▪ Enter patient's height in either centimetres or inches. Select unit of measurement. ▪ Enter the patient's pre-burn dry weight in either kilograms or pounds. Select the unit. ▪ Indicate how height and weight were obtained by selecting one of the following: o Measured (i.e. obtained by a weighing scale) o Estimated (i.e. by patient, family or healthcare professional) o Unknown (i.e. no documentation to indicate how the value was obtained)
Save and Randomize	Click the "Save" button at the bottom of the completed Pre-Randomization form to randomize your patient.
Randomization Confirmation	The Randomization Confirmation page will display the randomization number; randomization date and time; height; weight; BMI; and dosing weight for the patient.

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Patient ID _____

Pre Randomization

Did you confirm eligibility of the patient with the site investigator, or sub-investigator?	☐ Yes ☐ No
Please indicate the name of the physician who confirmed patient eligibility	
Was SDM / patient approached for consent?	☐ Yes ☐ No
If "NO", please indicate why SDM/patient was not approached for consent (select the primary reason)	☐ Next of kin or SDM not available ☐ Missed subject ☐ Language barriers ☐ Family dynamics ☐ Recommendation of clinical team ☐ CRS unavailable ☐ Pharmacy unavailable ☐ Other, please specify _____
If "YES" was consent obtained from the SDM/patient?	☐ Yes ☐ No
If "NO", select the primary reason consent was not obtained	☐ Too overwhelmed ☐ Not interested ☐ Did not respond (timed out) ☐ Other, please specify _____
If "YES", record the following:	
Consent Date (YYYY-MM-DD)	
Consent time (HH:MM, 24hr)	
Height _____ ☐ cm or ☐ inches	How was height obtained? ❑ Measured ❑ Estimated ❑ Unknown
Weight _____ ☐ kg or ☐ lbs	How was weight obtained? ❑ Measured ❑ Estimated ❑ Unknown

Randomization

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

Pharmacy must be notified as soon as patient is randomized

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Data Collection

REDCap™
(Electronic Data Capture System)

REENERGIZE - Definitive

Access REDCap™ at the following web address:

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

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Baseline Instructions (1/2)

Duration of Data Collection	This data is to be collected once, at the beginning of the patient's study period.
Age	Enter the age of the patient in years at the time of screening. Patients must be ≥ 18 years of age to be eligible to participate in the study.
Sex	Select the appropriate box (female or male).
Ethnic Group	Choose the appropriate patient ethnicity from the following list: • Asian or Pacific Islander • Black or African American • East Indian • Hispanic • Native (i.e. First Nations; Aboriginal; Indigenous) • White or Caucasian • Other (specify)_____
APACHE II Score	Go to the following website http://www.sfar.org/scores2/apache22.php to calculate the APACHE II score. Record the calculated score. Use variables within the first 24 hrs of this ACU admission. If variables are not available from the first 24 hrs, go outside the 24 hr window and use data closest to ACU admission. **NOTE:** Ensure the units that you are using for serum sodium, potassium and white blood count are correct. **NOTE:** A partial APACHE score is preferable to no score. If you do not have all the needed variables, simply input the variables you do have.
Comorbidities?	Indicate if the patient has comorbidities by selecting “Yes” or “No”. • If “YES”, select all comorbidities on the list provided. Only the comorbidities found on the taxonomy listing should be recorded. • If the patient has comorbidities not listed on the taxonomy, select “NO” to “Comorbidities?” **NOTE:** If a subject has a documented history of **alcohol abuse** in the medical chart, it should be recorded in REDCap™. If alcohol abuse is not documented in the chart, do not record it as a comorbidity.
Tobacco Use	Indicate whether the patient is a current smoker or uses tobacco by selecting “YES” or “NO”. If you are not able to obtain this information, select "Not Available".
Hospital Admission	Enter the date and time of hospitalization. This is the time of initial presentation to your emergency department or hospital ward, whichever is the earliest. If the patient is admitted directly to the ACU, “ACU Admission” date and time is the same as “Hospital Admission” date and time. If the admission time is not available, enter the time of the first documentation.
ACU Admission	Enter the date and time of ACU admission. If the patient is admitted directly to the ACU, this date and time is the same as the hospital admission date and time. If the admission time is not available, enter the time of the first chart documentation. **NOTE:** This date is very important, as it will be used to generate the dates on the REDCap™ grid.

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Baseline Instructions (2/2)

Co-enrollment	Is the patient co-enrolled in another academic ACU study? If "YES", then enter the name(s) of the study / studies.
Burn Injury Date and Time	Enter the date and time the burn injury occurred. If the time of the burn is not available, select "No time available"
Type of Burn	Select the type of burn that best describes the nature of the thermal burn injury from the list below (select only one). Frostbite is NOT considered a type of burn for this study. • Scald • Fire (Includes both flame and flash burns) • Chemical • Radiation • Unknown • Other (please specify) _____ **Do NOT Include:** Frost Bite Steven-Johnson Syndrome (SJS) Toxic Epidermal Necrolysis (TEN) High Voltage Electrical (internal injury) Burns
Burn Size Expressed as % TBSA	Record the total burn size as percent Total Body Surface Area (%TBSA). This assessment is made by the attending surgeon / physician based on her / his clinical judgment and confirmed by the SI / sub-I, if it is not the same person. Record TBSA in the nearest whole number rounding up from 0.5 and down from 0.4; i.e. 26.5% is recorded as 27% and 26.4% is recorded as 26%. See Appendix 1: Lund-Browder Diagram for a guide on how to calculate the TBSA.
High Dose Vitamin C Resuscitation	Indicate whether the patient received high dose Vitamin C as part of her / his resuscitation protocol (approximated as 66mg/kg/hr) by selecting "YES" or "NO".

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Baseline

Age	years	
Sex	☐ Female ☐ Male	
Ethnic Group	☐ Asian or Pacific Islander ☐ Black or African American ☐ East Indian ☐ Hispanic ☐ Native ☐ White or Caucasian ☐ Other (specify):	
APACHE II Score (Range: 5 – 60)		
Comorbidities If "YES", select from the list on the next page	☐ Yes ☐ No	
Tobacco Use	☐ Yes ☐ No ☐ Not Available	
Hospital Admission Date and Time	Date (YYYY-MM-DD)	Time (HH:MM 24hr)
ACU Admission Date and Time	Date (YYYY-MM-DD)	Time (HH:MM 24hr)
Is the patient co-enrolled in another academic ACU study?	☐ Yes ☐ No	
If "YES", Please specify:		
Burn Injury Date and Time If time is not available, select "Not available"	Date (YYYY-MM-DD)	Time (HH:MM 24hr) ☐ Not available
Type of Burn (Select only one)	☐ Scald ☐ Fire (includes flame and flash) ☐ Chemical ☐ Radiation ☐ Unknown ☐ Other (specify):	
Burn Size expressed as % Total Body Surface Area (%TBSA)		
Did the patient receive high dose Vitamin C as part of her / his resuscitation protocol (approximately 66mg/kg/hr)?	☐ Yes ☐ No	

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Comorbidities

Comorbidities?	☐ Yes ☐ No

Check all comorbidities the patient has listed in the taxonomy.
If the patient has no comorbidities listed in the taxonomy, select "No" to "Comorbidities?"

	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 or TIA)

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

	Neurologic
	11. Dementia
	12. Hemiplegia (paraplegia)
	13. Neurologic illnesses (such as Multiple sclerosis or Parkinson"s)

	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 or 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)
	37. Alcohol Abuse

Organ Dysfunction Instructions

General Instructions	This data is collected to determine modified SOFA score at baseline.
Duration of Data Collection	This data is collected once at baseline. All data should be collected within the first 24 hours after admission. If data is not available within the first 24 hours, go outside the 24 hour period and record data closest to admission.
Lowest PaO_2 / FiO_2 (PF ratio)	Record the lowest PaO_2 / FiO_2 (PF ratio) observed in the first 24 hours after admission by selecting from the options below. The PaO_2 and FiO_2 values should come from the same blood gas measurement. **If no PF ratio, record N/A** by selecting the first option**.** ❑ ≥ 400 mmHg **or N/A** ❑ 300 – 399 mmHg ❑ 200 – 299 mmHg ❑ 100 – 199 mmHg with respiratory support ❑ < 100 mmHg with respiratory support
Lowest Platelets	Record the lowest serum platelets observed in the first 24 hours after admission by selecting from options below. **If no Platelet Data, record N/A** by selecting the first option**.** ❑ ≥ 150 x 10^9/L (10^3/μL) **or N/A** ❑ 100 - 149 x10^9/L (10^3/μL) ❑ 50 - 99 x10^9/L (10^3/μL) ❑ 20 - 49 x10^9/L (10^3/μL) ❑ < 20 x10^9/L (10^3/μL)
Vasopressors	Indicate whether the patient received vasopressors or not be selecting “YES” or “NO”. If “YES”, select the highest dose received from the 3 groupings below: ❑ Dopamine ≤ 5 μg/kg/min or Dobutamine (any dose) ❑ Dopamine 6 - 15 μg/kg/min or Epinephrine ≤ 0.1 μg/kg/min or Norepinephrine ≤ 0.1 μg/kg/min ❑ Dopamine > 15 μg/kg/min or Epinephrine > 0.1 μg/kg/min or Norepinephrine > 0.1 μg/kg/min
Mean Arterial Pressure (MAP)	If the patient did not receive vasopressors, indicate the lowest MAP observed in the first 24 hours after admission by selecting from the options below: ❑ < 70 mmHg ❑ ≥ 70 mmHg If the MAP is not available you can calculate it using the formula ***MAP = 1/3 lowest systolic BP + 2/3 corresponding diastolic BP*** Or use the tool on the website: http://www.mdcalc.com/mean-arterial-pressure-map/
Urine Output (mL)	Indicate the volume range of urine output in the first 24 hours after admission by selecting from the list below: ❑ < 200 mL/day ❑ 200 - 499 mL/day ❑ ≥ 500 mL/day ❑ Not Available

Organ Dysfunction (Baseline)

Date (YYYY-MM-DD)	
Lowest PaO2/FiO2 (PF ratio)	❑ ≥ 400 mmHg **or N/A** ❑ 300 – 399 mmHg ❑ 200 – 299 mmHg ❑ 100 – 199 mmHg with respiratory support ❑ < 100 mmHg with respiratory support
Lowest Platelets	❑ ≥ 150 x 10^9/L (10^3/µL) **or N/A** ❑ 100 - 149 x10^9/L (10^3/µL) ❑ 50 - 99 x10^9/L (10^3/µL) ❑ 20 - 49 x10^9/L (10^3/µL) ❑ < 20 x10^9/L (10^3/µL)
Did the patient receive vasopressors?	❑ Yes ❑ No
If "YES", select the highest dose received during the first 24 hours after admission If "NO", enter MAP below.	❑ Dopamine ≤ 5 µg/kg/min or Dobutamine (any dose) ❑ Dopamine 6 - 15 µg/kg/min or Epinephrine ≤ 0.1 µg/kg/min or Norepinephrine ≤ 0.1 µg/kg/min ❑ Dopamine > 15 µg/kg/min or Epinephrine > 0.1 µg/kg/min or Norepinephrine > 0.1 µg/kg/min\
Mean Arterial Pressure (lowest)	❑ < 70 mmHg ❑ ≥ 70 mmHg
Urine output	❑ < 200 mL/day ❑ 200 - 499 mL/day ❑ ≥ 500 mL/day ❑ Not Available

Invasive Mechanical Ventilation Instructions

General Instructions	This data is collected to determine the duration of invasive mechanical ventilation.
Duration of Data Collection	This data is to be collected at start and stop of invasive mechanical ventilation events.
Invasive Mechanical Ventilation #1 **Start**	Indicate whether the patient received invasive mechanical ventilation during this ACU stay by selecting "YES" or "NO". If "YES", enter the actual start date and time of invasive mechanical ventilation, <u>even if this occurs at an external institution or in the field before admission to your unit</u>. This may not be the same time that the patient was intubated, but should be the time invasive mechanical ventilation was started. If the start time is not available, select “Not Available”. Record the first episode of mech. ventilation, even if it is <48 hours in duration.
Stop	After the patient has been successfully breathing without mechanical ventilation **for <u>≥</u> 48 hours,** record the date and time mechanical ventilation was discontinued. Patients are considered breathing without mech. 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) ≤ 5cm H_2O without pressure support or intermittent mandatory ventilation assistance If the patient is transferred out of the ACU to another institution and is still receiving mechanical ventilation, record the transfer date and time as the mechanical ventilation discontinuation date and time. If the patient died while mechanically ventilated, select “Same as death date & time”. If the patient is still mechanically ventilated 3 months after ACU admission, select "Still vented 3 months post ACU admission".
Was Mechanical Ventilation Re-instituted?	Answer the question “*Was mechanical ventilation re-instituted <u>≥</u> 48 hours from the last mechanical ventilation stop date / time?”* by selecting “YES” or “NO”. **<u>NOTE:</u>** Do <u>NOT</u> record episodes of temporary ventilation re-institution. This is defined as ventilation occurring for **< 48 hrs**, (i.e. needed for operating procedures, etc). If “YES”, record another episode of mechanical ventilation in the data entry fields for the next ventilation event. Record up to 5 episodes of mechanical ventilation. If “NO”, proceed to the RRT (Dialysis) section.
Mechanical Ventilation Episodes #2 - #5	Follow the instructions for recording start and stop dates/times of mechanical ventilation episodes as outlined in the section “Invasive Mechanical Ventilation #1” above. **<u>EXCEPTION</u>**: Start Time must be recorded for episodes #2 - #5, there is not a "Not Available" option. **<u>NOTE:</u>** Do <u>NOT</u> record episodes of temporary ventilation. This is defined as ventilation occurring for **< 48 hrs**, (i.e. needed for operating procedures, etc).

Ventilation Event 1		
Did the patient ever receive invasive mechanical ventilation?		☐ Yes ☐ No
Start	Date (YYYY-MM-DD)	
	Time (HH :MM, 24hr)	If time is not available, select ☐ Not Available
Stop	☐ Actual stop date and time _____(YYYY-MM-DD) _____(HH:MM, 24hr) ☐ Same date and time as death ☐ Still vented 3 months post ACU admission	
Ventilation Event 2		
Was mech. ventilation re-instituted ≥48 hrs from last mechanical ventilation stop date/time? **NOTE**: Do **NOT** record episodes of temp. ventilation (< 48hrs) **unless** it is the first episode		☐ Yes ☐ No
Start	Date (YYYY-MM-DD)	
	Time (HH:MM, 24hr)	
Stop	☐ Actual stop date and time _____(YYYY-MM-DD) _____(HH:MM, 24hr) ☐ Same date and time as death ☐ Still vented 3 months post ACU admission	
Ventilation Event 3, 4, 5		
Was mech. ventilation re-instituted ≥48 hrs from last mechanical ventilation stop date/time? **NOTE**: do **NOT** record episodes of temp. ventilation (< 48hrs) **unless** it is the first episode		☐ Yes ☐ No
Start	Date (YYYY-MM-DD)	
	Time (HH:MM, 24hr)	
Stop	☐ Actual stop date and time _____(YYYY-MM-DD) _____(HH:MM, 24hr) ☐ Same date and time as death ☐ Still vented 3 months post ACU admission	
Was mech. ventilation re-instituted ≥48 hrs from last mechanical ventilation stop date/time? **NOTE**: Do **NOT** record episodes of temp. ventilation (< 48hrs) **unless** it is the first episode		☐ Yes ☐ No

Patient ID

Renal Replacement Therapy (Dialysis) Instructions

General Instructions	This data is collected to determine the need for and duration of renal replacement therapy (dialysis).
Duration of Data Collection	This data is to be collected at start and stop of renal replacement therapy (dialysis).
Renal Replacement Therapy (Dialysis)	Indicate whether the patient received renal replacement therapy (dialysis) during this ACU stay by selecting "YES" or "NO“.
The First Time RRT Was Started, Was it Due to Acute Renal Failure?	If the patient did receive RRT (dialysis) during this ACU stay, answer the question **“***The first time renal replacement therapy (dialysis) was started, was it due to acute renal failure?”* by selecting "YES" or "NO".
RRT (Dialysis) **Start**	If "YES", record the date RRT (dialysis) started in the format (YYYY-MM-DD) If “NO”, do not record the RRT (dialysis) stop date.
Stop	Select one of the following options related to the discontinuation of RRT (dialysis): ❑ Same as death date & time ❑ At 3 months, still on renal replacement therapy (dialysis) in hospital ❑ Continued past hospital discharge ❑ Actual stop date (Record the date dialysis was <u>permanently</u> discontinued. This may occur on the ward.)

Patient ID

Renal Replacement Therapy (Dialysis)

Did the patient receive renal replacement therapy (dialysis) during this ACU stay?		☐ Yes ☐ No
If yes, the first time renal replacement therapy was started, was it due to acute renal failure?		☐ Yes ☐ No
Start	Date (YYYY-MM-DD)	
Stop	☐ Same date and time as death ☐ At 3 months, still on renal replacement therapy (dialysis) in hospital ☐ Continued past hospital discharge ☐ Actual stop date (YYYY-MM-DD)	

Study Intervention Instructions

Duration of Data Collection	This data is to be collected when study supplements are first started and when study supplements are stopped. In addition, any prescription changes will be recorded on this form.
Study Intervention Start Date and Time	Enter the date and time study supplements were first administered in the format YYYY-MM-DD and HH:MM, 24hrs. **NOTE**: Study intervention is to be started within 2 hours after randomization.
Study Intervention Started More Than 2 Hours After Randomization	If the study intervention is started more than 2 hours after randomization, select "YES" to the question "*Was study intervention started > 2 hours after randomization?".* Then choose the reason from the list provided: ❑ Pharmacy delay ❑ Patient NPO for surgery ❑ Awaiting tube placement and/or verification ❑ Patient not available (procedure ❑ Nurse not available ❑ Other (specify): _____ If you select "Other", you must provide an explanation in the space provided.
Study Intervention Stop Date and Time	Enter the date and time study supplements were finally stopped in the format YYYY-MM-DD and HH:MM, 24hrs. The stop date should be at the end of the study period, i.e. ≥ 7 days after the last successful grafting operation or at discharge from ACU or 3 months from ACU admission, whichever occurs first.
Study Intervention Prescription	Select the initial study intervention prescription in grams per day from the dropdown list: **20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100** Each packet contains 5 grams of study intervention. If 10 packets per day are prescribed, select 50 from the prescription dropdown box.
Study Intervention Prescription Changes	If the study intervention prescription changes, select "YES" to the question *"Did the study intervention prescription change?",* then fill out the following information: • Enter the Date (YYYY-MM-DD) and Time (HH:MM, 24hr) the prescription change occurred. • Enter the dosing weight (kg) associated with the new prescription. • Select the new prescription in grams per day (g/day) from the dropdown list. Record up to 6 prescriptions by selecting "YES" to the question *"Did the study intervention prescription change?"* after each prescription entry to enter more prescription changes. **NOTE**: Study Intervention prescription is based on pre-burn dry weight and should not change. **EXCEPTION**: If the patient has a change in body weight sufficient for the clinical team to adjust dosage of clinical treatments, the study treatment dose may also be adjusted. This decision should be made by the Site Investigator.

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Study Intervention

Patient ID ____________________

Start Date and Time First Dose of Study Intervention	(YYYY-MM-DD)	(HH:MM. 24hr)
Was Study Intervention started > 2 hours after Randomization?	☐ Yes	
If YES, select the reason:	☐Pharmacy Delay ☐Patient NPO for surgery ☐ Awaiting tube placement and/or verification ☐ Patient not available (procedure) ☐ Nurse not available ☐ Other (specify): ____________________	
Stop Date and Time Last Dose of Study Intervention	(YYYY-MM-DD)	(HH:MM. 24hr)
Initial Study Intervention Prescription (g/day)		
Did the study intervention prescription change?	☐ Yes	
If YES, record the following: Date and Time of the change	(YYYY-MM-DD)	(HH:MM. 24hr)
Dosing weight for this prescription (kg)	kg	
New Prescription (g/day)	20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100	
Did the study intervention prescription change?	☐ Yes	
If YES, record the following: Date and Time of the change	(YYYY-MM-DD)	(HH:MM. 24hr)
Dosing weight for this prescription (kg)	kg	
New Prescription (g/day)	20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100	
Did the study intervention prescription change?	☐ Yes	
If YES, record the following: Date and Time of the change	(YYYY-MM-DD)	(HH:MM. 24hr)
Dosing weight for this prescription (kg)	kg	
New Prescription (g/day)	20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100	

Daily Monitoring Instructions (1/2)

General Information	This data is collected to determine the compliance of the study intervention to the prescribed dose and to identify any dose related Protocol Violations. Study intervention is to be started within 2 hours of randomization.
Duration of Data Collection	This data is to be collected daily as follows: • Study Intervention: from randomization to ≥ 7 days post last successful grafting operation, or until ACU discharge, or until 3 months from ACU admission, whichever comes first. • Dose related Protocol Violations: for duration of study intervention administration. **NOTE: Please try to collect this data as close to real time as possible.**
Prescribed # Grams Per Day (Recommended)	To assist in determining the daily percentage of IP received, record at the top of each daily monitoring worksheet the number of grams per day of study product the patient is to receive. **NOTE**: This data is not entered on the Daily Monitoring forms in REDCap™.
Date	Enter the date for which the data is being collected. Enter the data in REDCap™ on the date corresponding to the date you entered on the worksheet.
How Many Times Was The Study Intervention Given Today?	Select the number of times, from 0 to 10, the study intervention was given on this study day. The same number of entry fields will appear on the form in REDCap™ for that day.
# Grams Given	Select the # grams given (5g to 30g) at each interval as documented in the medical chart. Each packet of IP contains 5 grams. If dose is recorded in the medical chart as *# of packets administered*, multiply # of packets by 5 and select the # of grams administered. **# grams administered = # of packets administered * 5g**
Route	Select the route by which study intervention was administered at each interval: enterally (EN) or orally (PO). **NOTE:** EN refers to administration of study intervention via tube.
Total Grams Received Today	To assist in calculating the percentage received, add the number of grams given at each interval and record the total given each day. **NOTE**: This data is not entered in REDCap™.
Percentage of Study Intervention Received Today	Divide the total number of grams actually given by the number of grams prescribed per day (you should record the prescribed g/day on the top of the daily monitoring worksheet) to determine the percentage of study intervention. Record percentage. **Percentage of IP received = total number of grams given / number of grams prescribed**

Daily Monitoring Instructions (2/2)

Dose Related Protocol Violation **Protocol Violation (IP dosing <80% over a 3 day average)**	Indicate if there is a dose related protocol violation for the day by selecting "YES" or "NO" to the question "*Was there a dose related Protocol Violation today?"* A dose related protocol violation occurs when the patient receives **< 80%** of the prescribed daily dosage over a 3 day average. Report a dose related protocol violation when BOTH of the following are true: • Dose received on the indicated day is < 80% prescribed • Dose received over a 3 day average is < 80% prescribed **Example:** **Dose received** Prescribed Dose: 35g/day Day 6: 30g 80% Prescribed: 28g Day 7: 20g Day 8: 30g Total dose received over 3 days = 80g 3 day average dose is 80 g/ 3 = 26.67g = 76.2% Report Day 7: Dose received is < 80% AND 3 day average is < 80 % Do NOT report Day 6 or Day 8: the 3 day average is <80% but the dose received on those days is NOT <80% **If < 80% is received over a 3 day average, complete the Protocol Violation Form in REDCap™ within 24 hours of becoming aware.** Refer to the Protocol Violations (PVs) section of these worksheets for detailed instructions for reporting PVs.

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Patient ID

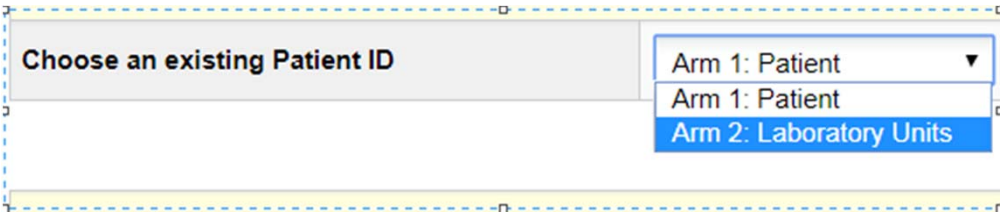
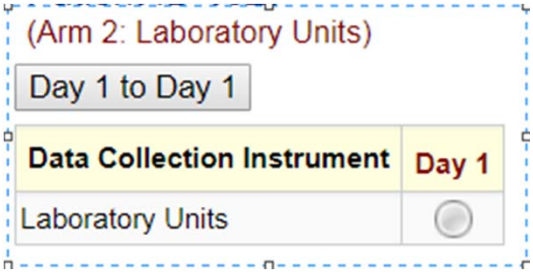
Daily Monitoring

Prescribed # _____ gm/day

Page #:_____

Date YYYY-MM-DD						
# times IP given today (circle one)	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10
1) # grams given (circle one)	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30
Route	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO
2) # grams given (circle one)	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30
Route	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO
3) # grams given (circle one)	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30
Route	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO
4) # grams given (circle one)	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30
Route	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO
5) # grams given (circle)	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30
Route	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO
6) # grams given (circle one)	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30
Route	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO
7) # grams given (circle one)	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30
Route	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO
8) # grams given (circle one)	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30
Route	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO
9) # grams given (circle one)	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30
Route	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO
10) # grams given (circle one)	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30	5 10 15 20 25 30
Route	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO	☐ EN ☐ PO
TOTAL # grams given today					
Percentage of prescribed given	%	%	%	%	%
Protocol Violation	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

Laboratory Units Instructions

General Information	This data is collected to determine which units of measurement specific laboratory tests are reported in at your site.
Duration of Data Collection	This data is only collected **once** from each site, following randomization of the first patient.
Locating the Laboratory Units form in REDCap™	To get to the Laboratory Units page in REDCap™, look under the *"Choose an existing Patient ID"* dropdown tab. Select "Arm 2: Laboratory Units", see screenshot below:  After selecting "*Arm 2: Laboratory Units"*, select your site number from the *"-- select record –"* dropdown tab. **NOTE**: The site number will not appear in the *"-- select record –"* dropdown list until after the first patient has been randomized at the site. Then click on the grey dot on the Laboratory Units grid to open the form and select the units for each lab test indicated, see screenshot below: 
T-Bilirubin	Select the units T-Bilirubin is reported in at your site: **mg/dL** or **µmol/L**
Serum Creatinine	Select the units Serum Creatinine is reported in at your site: **mg/dL** or **µmol/L**
Glucose	Select the units Glucose is reported in at your site: **mg/dL** or **mmol/L**
Urea	Select the units Urea is reported in at your site: **mg/dL** or **mmol/L**

Patient ID

Laboratory Units

T-Bilirubin	❑ mg/dL ❑ µmol/dL
Serum Creatinine	❑ mg/dL ❑ µmol/dL
Glucose	❑ mg/dL ❑ mmol/dL
Urea	❑ mg/dL ❑ mmol/dL

Laboratory Instructions

Duration of Data Collection	This data is to be collected as follows: • **Daily for 2 weeks**: From admission to the ACU through study day 14 • **Weekly**: From day 15 to ≥ 10 days post last successful graft (stop of study intervention plus 3 days), discharge from the ACU, or 3 months after admission, whichever comes first. o Collect weekly lab data from a single day during that study week defined as +/- 24 hours from study day **21, 28, 35, 42, 49, 56, 63, 70, 77, 84 and 90.** o If there is no value available on the specified date, record the value from an adjacent day. o If there is no value available for that study week, record N/A.
Date	Enter the date corresponding to the calendar day (YYYY-MM-DD) that the laboratory samples were **taken**, not the day the results were reported. Record the data on the corresponding date in REDCap™.
Highest Serum Creatinine	Record the highest serum creatinine from that study day.
Highest T-Bilirubin	Record the highest total bilirubin from that study day.
Highest Urea	Record the highest urea from that study day.
Glucose closest to 08:00 A.M.	Record the glucose closest to 8:00 AM, ± 6 hrs (i.e. from 02:00 to 14:00 hrs) from that study day. The value may be from a blood draw or from a bedside glucometer.
For each requested result above, if there is no value available to record, select “Not Available”	

Patient ID

Laboratory

Page #:_____

Date (YYYY-MM-DD)					
Creatinine, serum (highest)					
	☐ Not available	☐ Not available	☐ Not available	☐ Not available	☐ Not available
T-bilirubin (highest)					
	☐ Not available	☐ Not available	☐ Not available	☐ Not available	☐ Not available
Urea (highest)					
	☐ Not available	☐ Not available	☐ Not available	☐ Not available	☐ Not available
Glucose closest to 08:00 A.M.					
	☐ Not available	☐ Not available	☐ Not available	☐ Not available	☐ Not available

Date (YYYY-MM-DD)					
Creatinine, serum (highest)					
	☐ Not available	☐ Not available	☐ Not available	☐ Not available	☐ Not available
T-bilirubin (highest)					
	☐ Not available	☐ Not available	☐ Not available	☐ Not available	☐ Not available
Urea (highest)					
	☐ Not available	☐ Not available	☐ Not available	☐ Not available	☐ Not available
Glucose closest to 08:00 A.M.					
	☐ Not available	☐ Not available	☐ Not available	☐ Not available	☐ Not available

Nutrition Assessment / Timing Instructions (1/2)

General Instructions	This data is collected to determine how well the patient is being fed, including the nutritional adequacy (percentage of prescribed calories and protein received), and the timing of initiation of nutrition. Work with your dietitian, or the person responsible for assessing and monitoring the nutritional needs of patients to obtain this information.
Duration of Data Collection	This data is to be calculated daily from baseline (ACU admission or first dietitian assessment) until study day 12, including that day.
Baseline Assessment	Use the patient's pre-burn dry weight or usual weight when calculating energy and protein needs. For patients with obesity, adjust for obesity using your standard practice. If you do not have an obesity adjustment practice, use the formula below: **Adjusted Body Weight (ABW) = Ideal Body Weight (IBW) based on a BMI of 25 + [(pre-burn dry weight – IBW) x 0.25]** **NOTE**: Energy and protein requirements are independent of the enteral formula(s) prescribed. Do not change energy and protein prescription to accommodate a change in nutritional formula(s).
Prescription Date	Enter the date (YYYY-MM-DD) the prescription was made.
Prescribed Energy Needs	Prescribed energy needs are to be calculated using either indirect calorimetry, a predictive equation, or a simple weight-based formula. On average, calculations should lead to a prescription of ≥30 kcal/kg. Enter the prescribed daily energy needs (kcal).
Prescribed Protein Needs	Prescribed protein needs are to be calculated using the following: • If > 50% TBSA, use 1.5g/kg/day to 2.5g/kg/day • If < 50% TBSA, use 1.2 g/kg/day to 2 gm/kg/day Enter the prescribed daily protein needs (g)
Changes in Prescription	Indicate if the prescription changed by selecting “YES” or “NO” to the question, *“Was another prescription made?”* If “YES”, the data entry fields will open to enter the new prescription information. Enter the date of prescription date, the prescribed energy, and protein needs. Repeat the steps above to enter up to 6 prescriptions. Do **NOT** record changes in prescription after study day 12.
Enteral Nutrition (EN) Received	Indicate if enteral nutrition was given by selecting “YES” or “NO” to the question, *“Was EN received during this ACU admission?”*
EN Start	If EN was received during the first 12 Days after ACU admission: enter the date (YYYY-MM-DD) and time (HH:MM, 24hr) EN was started. If EN started after Day 12 (on Day 13 or after): select “EN not initiated during first 12 days in ACU”

Nutrition Assessment / Timing Instructions (2/2)

EN Stop	Select one of the following related to permanent discontinuation of EN: ❑ Same as death date & time ❑ Still receiving EN > 12 days post ACU admission ❑ Actual EN stop date & time (If EN stopped ≤ 12 days after ACU admission.) **NOTE:** If EN was stopped more than 12 days after ACU admission, do NOT enter the actual EN stop date and time, select the option "Still receiving EN > 12 days post ACU admission".
Parenteral Nutrition Received	Indicate if parenteral nutrition was given by selecting "YES" or "NO" to the question, *"Was PN received during this ACU admission?"*
PN Start	If PN was received, enter the date (YYYY-MM-DD) and time (HH:MM, 24hr) PN was started.
PN Stop	Select one of the following related to permanent discontinuation of PN: ❑ Same as death date & time ❑ Still receiving PN 3 months post ACU admission ❑ Actual PN stop date & time (If patient was discharged while on PN, record ACU discharge as stop date & time).

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Patient ID

Nutrition Assessment

Baseline Assessment		
Date prescription made (YYYY-MM-DD)		
Prescribed Energy Needs (kcal)		
Prescribed Protein Needs (grams)		
Was another prescription made?	☐ Yes ☐ No	
Assessment #2		
Date prescription made (YYYY-MM-DD)		
Prescribed Energy Needs (kcal)		
Prescribed Protein Needs (grams)		
Was another prescription made?	☐ Yes ☐ No	
Assessment #3		
Date prescription made (YYYY-MM-DD)		
Prescribed Energy Needs (kcal)		
Prescribed Protein Needs (grams)		
Was another prescription made?	☐ Yes ☐ No	
Enteral Nutrition		
Was Enteral Nutrition (EN) received during this ACU admission?	☐ Yes, started during first 12 days of ACU admission ☐ Yes, started after first 12 days of ACU admission ☐ No	
If "YES", record EN Start date and time:	(YYYY-MM-DD)	(HH:MM, 24hr)
EN Stop date and time:	❑ Same as death date & time ❑ Still receiving EN 12 days post ACU admission ❑ Actual EN stop date & time (enter below)	
	(YYYY-MM-DD)	(HH:MM, 24hr)
Parenteral Nutrition		
Was Parenteral Nutrition (PN) received during this ACU admission?	☐ Yes, started during first 12 days of ACU admission ☐ Yes, started after first 12 days of ACU admission ☐ No	
If Yes, record PN Start date and time:	(YYYY-MM-DD)	(HH:MM, 24hr)
PN Stop date and time:	❑ Same as death date & time ❑ Still receiving PN 12 days post ACU admission ❑ Actual PN stop date & time (enter below)	
	(YYYY-MM-DD)	(HH:MM, 24hr)

Daily Nutrition Instructions (1/2)

General Instructions	This data is collected to determine the adequacy of all types of nutrition (calories and protein) received.
Duration of Data Collection	This data is to be collected daily from Study Day 1 (ACU admission) until Study Day 12.
Enteral Nutrition	For each day, indicate whether the patient received enteral nutrition (EN) by selecting "YES" or "NO" to the question "*Was Enteral Nutrition (EN) given?"*
If NO	If "NO", indicate **ALL** the reason(s) the patient did not receive EN on the specified day, using the list below: ❑ NPO for endotracheal extubation or intubation or other bedside procedure. ❑ NPO for operating procedure ❑ NPO for radiology procedure ❑ High NG drainage ❑ Increased abdominal girth, abdominal distension or pt. discomfort ❑ Vomiting or emesis ❑ Diarrhea ❑ No enteral access available / enteral access lost, displaced or malfunctioning ❑ Inotropes, vasopressor requirement ❑ Patient deemed too sick for enteral feeding ❑ On oral feeds ❑ Reason not known ❑ Other (specify) _____
If YES **Formula**	If "YES", record the enteral formula received. You may record up to 3 different formulas used each day. Record the first formula received in the spaces provided for "Formula 1" and so on. In the event that the patient receives more than 3 formulas in one day, select the 3 formulas that provide the largest volumes. When entering in REDCap, select the company from the dropdown list, then the formula. If the company is not listed, select "Miscellaneous" and enter the company name. If the formula is not listed, select "Other (specify)" and enter the formula name in the space provided. To open the form to enter another formula, select "YES" to the question "*Was a second EN formula given*?" Repeat steps above to enter a third EN formula.
Total kcals **Total Protein**	Record the total calories (kilocalories) and protein from all the EN formulas received in the study day. • Do NOT record the calories from propofol (volume to be entered separately). • Do NOT include protein supplements as part of this total (collected separately).

Daily Nutrition Instructions (2/2)

Protein Supplements	Record whether a protein supplement was received by selecting "YES" or "NO". You may record 2 different protein supplements each day. If "YES", select the product given from the dropdown list in REDCap™. If the supplement is not listed, select "Other" and enter the company and product name in the space provided. To open the form and enter another protein supplement, select "YES" to the question "*Add another protein supplement?*"" If more than two protein supplements given, record the 2 that provide the most amount of protein.
Total Kcals **Total Protein**	Record the total calories (kcal) and protein (g) received from protein supplements.
Do NOT use formulas that are listed with (restricted) beside the name in REDCap.	
Parenteral Nutrition	Record whether the patient received parenteral nutrition by answering "YES" or "NO" to the question "*Was Parenteral Nutrition (PN) given?"*
Total Kcals **Total Protein**	If "YES", record the total calories (kcal) and protein (g) received from parenteral nutrition. Do NOT record the calories from Propofol (volume to be entered separately).
Oral Feeding	Record if the patient received any oral nutrition by answering "YES" or "NO" to the question *"Was Oral Nutrition given?"* Record oral nutrition regardless of EN or PN given.
Propofol	Record if the patient received a continuous infusion of Propofol for ≥ 6hrs, "YES" or "NO". Record Propofol received each day, regardless if EN, PN or neither were received.
Total mL	If Propofol was received, record the total volume in mL received in the 24 hour period.
Insulin	Record if insulin was received, by selecting "YES" or "NO". If the information is not documented, select "Not Available"
Total units	If insulin was given, record the total units received in the 24 hour period from all insulin, including: IV, subcutaneous and bolus.
Opiates	Record if any opiates were received by selecting "YES" or "NO" to the question *"Were any opiates received today?"*. If the information is not documented, select "Not Available".
Motility agents	Record if any motility agents were received, "YES" or "NO" to the question "Were Motility Agents received today?". If the information is not documented, select "Not Available". Common motility agents include, but are not limited to: metoclopramide; erythromycin; domperidone Do NOT record stool softeners as motility agents.

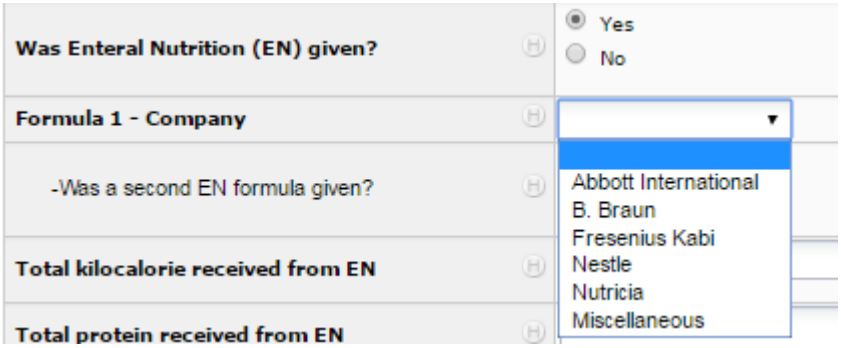
THE RE-*ENERGIZE* STUDY

Patient ID

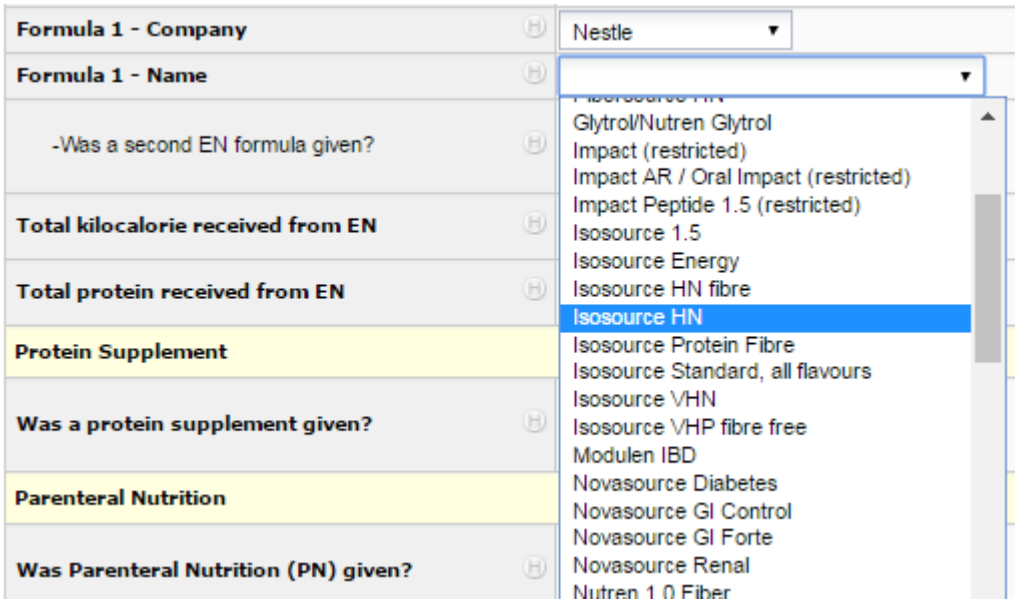
ENTERAL NUTRITION FORMULAS

There are over 400 EN Formulas listed in REDCap.

Select the company. If company is not listed, choose “Miscellaneous”



Select the formula from the dropdown list.
If it is not listed, select “Other (specify)” and enter the formula name in the space provided.



Do NOT use formulas that are listed with (restricted) beside the name in REDCap™

Daily Nutrition (1/2)

Patient ID

(Collect from Study Day 1 through Study Day 12 only)

Page #:_____

Date (YYYY-MM-DD)				
Enteral Nutrition (EN) given?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If <u>NO</u>, EN not received (Select ALL reasons that apply)				
NPO for endotracheal extubation or intubation or other bedside procedure	☐	☐	☐	☐
NPO for operating procedure	☐	☐	☐	☐
NPO for radiology procedure	☐	☐	☐	☐
High NG drainage	☐	☐	☐	☐
Increased abdominal girth, abdominal distension or pt. discomfort	☐	☐	☐	☐
Vomiting or emesis	☐	☐	☐	☐
Diarrhea	☐	☐	☐	☐
No enteral access available / enteral access lost, displaced or malfunctioning	☐	☐	☐	☐
Inotropes, vasopressor requirement	☐	☐	☐	☐
Patient deemed too sick for enteral feeding	☐	☐	☐	☐
On oral feeds	☐	☐	☐	☐
Reason not known	☐	☐	☐	☐
Other (specify)				
If <u>YES,</u> EN received (Complete below)	***Do NOT use formulas with (restricted) beside the name in REDCap™***			
Formula 1 (company and formula name)				
Formula 2 (company and formula name)				
Formula 3 (company and formula name)				
Total Kilocalories from EN (kcal)				
Total Protein from EN (g)				

THE RE–ENERGIZE STUDY

Daily Nutrition (2/2)

Patient ID _____

(Collect from Study Day 1 through Study Day 12 only) ***Page #:_____***

Date (YYYY-MM-DD)				
Was a Protein Supplement given?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Protein Supplement Name(s)				
Total Calories (kcal) from Protein Supplement				
Total Protein (g) from Protein Supplement				
Was Parenteral Nutrition (PN) given?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Total Calories (kcal) from PN				
Total Protein (g) from PN				
Oral Nutrition given?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Medications				
Was Propofol received for ≥ 6 hours?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Volume of propofol received (mL)				
Was Insulin received?	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available
Insulin total dose (units)				
Were Opiates received?	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available
Were Motility Agents received? (metoclopramide. erythromycin, domperidone, other)	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available

Burn Related Operative Procedures Instructions

General Instructions	This data is collected to determine the frequency and type of burn related operative procedures that the patient undergoes during the study. **NOTE**: This data only needs to be completed on study days when a burn related operative procedure is performed. Do NOT open this form in REDCap™ unless you have a burn related operative procedure to report.
Duration of Data Collection	Record all burn related operative procedures from Study Day 1 (ACU admission) to whichever of the following events occur first: • 10 days post last successful grafting (stop of study IP + 3 days) • ACU discharge • 3 months from ACU admission
Date	Enter the date corresponding to the calendar day that the operative procedure was performed (YYYY-MM-DD)
Burn related operative procedure today?	Select "YES" to open the form and record the details of the burn related operative procedure performed on that study day.
Was the Operative procedure planned or unplanned?	Indicate if the patient had a planned or unplanned operative procedure by selecting the corresponding box.
Type of Operative Procedure	Select the type(s) of operative procedure(s) performed on the date indicated from the options provided. Check ALL that apply. If a procedure was performed that is not in the list of options (i.e. an amputation, escharotomy, ect), select “Other, specify” and enter the procedure name in the space provided. Select all procedures performed: ❑ Surgical excision (tangential or fascial) ❑ Excision and temporary covering (xenograft, allograft and artificial skin) ❑ Excision and autograft ❑ Delayed autograft ❑ Excision and primary closure/composite tissue transfer ❑ Other (specify) _____

THE RE–*ENERGIZE* STUDY

Patient ID

Burn Related Operative Procedures

Page #:_____

Date (YYYY-MM-DD)					
Burn related operative procedure today?	☐ Yes	☐ Yes	☐ Yes	☐ Yes	☐ Yes
Was the Operative procedure planned or unplanned?	☐ Planned ☐Unplanned	☐ Planned ☐Unplanned	☐ Planned ☐Unplanned	☐ Planned ☐ Unplanned	☐ Planned ☐Unplanned
Type of Operative Procedure (Select all that apply)					
Surgical excision (tangential or fascial)	☐	☐	☐	☐	☐
Extension and temporary covering (xenograft, allograft and artificial skin)	☐	☐	☐	☐	☐
Excision and autograft	☐	☐	☐	☐	☐
Delayed autograft	☐	☐	☐	☐	☐
Excision and primary closure/composite tissue transfer	☐	☐	☐	☐	☐
Other (specify)					

Date (YYYY-MM-DD)					
Burn related operative procedure today?	☐ Yes	☐ Yes	☐ Yes	☐ Yes	☐ Yes
Was the Operative procedure planned or unplanned?	☐ Planned ☐Unplanned	☐ Planned ☐Unplanned	☐ Planned ☐Unplanned	☐ Planned ☐ Unplanned	☐ Planned ☐Unplanned
Type of Operative Procedure (Select all that apply)					
Surgical excision (tangential or fascial)	☐	☐	☐	☐	☐
Extension and temporary covering (xenograft, allograft and artificial skin)	☐	☐	☐	☐	☐
Excision and autograft	☐	☐	☐	☐	☐
Delayed autograft	☐	☐	☐	☐	☐
Excision and primary closure/composite tissue transfer	☐	☐	☐	☐	☐
Other (specify)					

Concomitant Medications and Daily Heart Rate Instructions

General Instructions	This data is collected to capture the relevant medications that the patient received that may have a material effect on the measured outcomes of the study. It also collects the lowest and highest daily heart rate. This section records only medications relevant to this study (oxandrolone, nandrolone, testosterone, beta-blockers) **NOTE**: Administration of Propofol; insulin; opiates, and motility agents is recorded on the Daily Nutrition form, NOT this form.
Duration of Data Collection	Record concomitant medications, relevant to this study (oxandrolone, nandrolone, testosterone, beta-blockers), daily starting from ACU admission until whichever of the following events occurs first: • ≥ 10 Days after the last grafting operation (stop of study IP + 3 days) • Discharge from the ACU • 3 months after admission to the ACU
Date	Enter the date corresponding to the calendar day in the format (YYYY-MM-DD)
Heart Rate	Record BOTH the highest and the lowest heart rate documented for the patient each study day. If there is only one heart rate documented, record the documented heart rate as both the highest and the lowest for that day.
Were Concomitant Medications received today?	Indicate if any of the following concomitant medications were received by selecting “YES” or “NO”. If the information is not documented, select "Not Available". Select “YES” to open the form and record concomitant medications received. Do not select “YES” if the patient was only given concomitant medications NOT listed below.
Oxandrolone, Nandrolone and Testosterone	Indicate if Oxandrolone, Nandrolone, or Testosterone was received by selecting the appropriate response: ❑ Yes, Oxandrolone ❑ Yes, Nandrolone ❑ Yes, Testosterone ❑ No ❑ Not Available If none of the 3 were received, select “NO” If the information is not documented, select “Not Available”.
Beta-Blockers	Indicate if any Beta-Blockers were received by selecting “YES” or “NO”. If the information is not documented, select "Not Available".

THE RE–*ENERGIZE* STUDY

Concomitant Medications

Patient ID _____

Page #:_____

Date (YYYY-MM-DD)					
Heart Rate – if only one heart rate is documented, record it as both highest and lowest for that day					
Highest Heart Rate					
Lowest Heart Rate					
Concomitant Medications (ConMeds)					
Were ConMeds received today?	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available
Was Oxandrolone, Nandrolone or Testosterone received today?	☐ Yes, Oxan ☐ Yes, Nan ☐ Yes, Test ☐ No ☐ Not available	☐ Yes, Oxan ☐ Yes, Nan ☐ Yes, Test ☐ No ☐ Not available	☐ Yes, Oxan ☐ Yes, Nan ☐ Yes, Test ☐ No ☐ Not available	☐ Yes, Oxan ☐ Yes, Nan ☐ Yes, Test ☐ No ☐ Not available	☐ Yes, Oxan ☐ Yes, Nan ☐ Yes, Test ☐ No ☐ Not available
Were Beta-Blockers received today?	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available

Date (YYYY-MM-DD)					
Heart Rate – if only one heart rate is documented, record it as both highest and lowest for that day					
Highest Heart Rate					
Lowest Heart Rate					
Concomitant Medications (ConMeds)					
Were ConMeds received today?	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available
Was Oxandrolone, Nandrolone or Testosterone received today?	☐ Yes, Oxan ☐ Yes, Nan ☐ Yes, Test ☐ No ☐ Not available	☐ Yes, Oxan ☐ Yes, Nan ☐ Yes, Test ☐ No ☐ Not available	☐ Yes, Oxan ☐ Yes, Nan ☐ Yes, Test ☐ No ☐ Not available	☐ Yes, Oxan ☐ Yes, Nan ☐ Yes, Test ☐ No ☐ Not available	☐ Yes, Oxan ☐ Yes, Nan ☐ Yes, Test ☐ No ☐ Not available
Were Beta-Blockers received today?	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available

Microbiology Instructions

General Instructions	This data is collected to assist in determining the incidence of ACU acquired infections. Record Gram **Negative** Bacteremias only. **Record results from venous or arterial blood cultures only.** Do NOT include blood from a catheter line tip. **NOTE**: Only complete this data on study days corresponding to a blood culture draw that tests positive for a Gram negative bacteria. Do NOT open this form in REDCap™ unless you have a Gram negative bacteremia to report.
Duration of Data Collection	Record Gram negative bacteria that occurred >72 hours after ACU admission until either: ≥ 10 days post last successful grafting (stop of study IP + 3 days), or ACU discharge, or 3 months after ACU admission, whichever comes first.
Date sample collected	Record the date the sample was collected, not when the results were reported (YYYY-MM-DD)
Time sample collected	Record the time the sample was collected, not the time the results were reported (HH:MM, 24hr)
Gram Negative Culture Species	Select all Gram negative bacteria reported each study day. Report the corresponding number in the table below for each gram negative bacteria. Do NOT record Gram positive bacteria. See tables below for reference lists of Gram negative and Gram positive bacteria.
Was there another Gram negative culture today?	Record up to 5 different Gram negative bacteremias each day. Select "YES" to the question "*Was there another Gram negative culture today*?" to open the form and record additional bacteria. Record all different Gram negative bacteria reported. Do NOT record the same bacteria more than once on each study day, even if reported from specimens collected at different times on that day.

Gram Positive Bacteria (Do NOT include)
Actinomyces sp.
Aerococcus sp.
Bacillus sp.
Clostridium sp.
Corynobacterium sp.
Diphteroids sp.
Enterococcus sp.
Erysipelothrix sp.
Lactobacillus sp.
Listeria sp.
Nocardia sp.
Peptostreptococcus/ Peptococcus sp.
Propionibacterium sp.
Rhodococcus sp.
Staphylococcus sp.
Streptococcus sp.

Gram Negative Bacteria			
1	Acinetobacter sp.	23	Legionella sp.
2	Aeromonas sp.	24	Moraxella sp.
3	Alcaligenes sp.	25	Morganella sp.
4	Bacteroides sp.	26	Mycoplasma sp.
5	Bartonella sp.	27	Neisseria sp.
6	Bortetella sp.	28	Pasteurella sp.
7	Burkholderia sp.	29	Porphyromonas sp.
8	Campylobacter sp.	30	Prevotella sp.
9	Capnocytophaga sp	31	Proteus sp.
10	Chlamydia sp.	32	Providencia sp.
11	Citrobacter sp.	33	Pseudomonas sp.
12	Coxiella sp.	34	Ralstonia sp.
13	Ehrlichia sp.	35	Rickettsia sp.
14	Eikenella sp.	36	Salmonella sp.
15	Enterobacter sp.	37	Salmonella sp.
16	Escherichia sp.	38	Serratia sp.
17	Francisella sp.	39	Shigella sp.
18	Fusobacterium sp.	40	Stenotrophomonas sp
19	Hafnia sp.	41	Streptobacillus sp.
20	Helicobacter sp.	42	Vibrio sp
21	Haemophilus sp.	43	Yersinia sp.
22	Klebsiella sp.	44	Other, please specify

THE RE–*ENERGIZE* STUDY

Patient ID

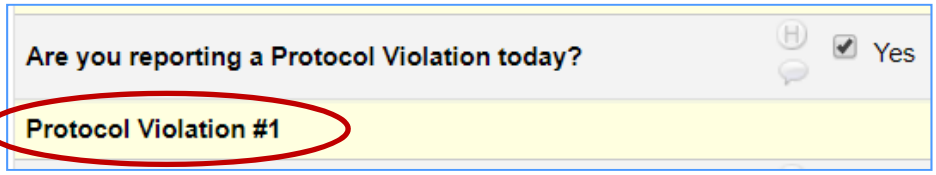
Microbiology

Record <u>ONLY</u> venous or arterial blood cultures that test positive for Gram negative bacteria.
Record Gram negative culture species using corresponding <u>NUMBERS (see list on previous page).</u>

Date (YYYY-MM-DD)					
1) Time (HH:MM, 24hr)					
Gram Negative Culture <u>Species</u>					
2) Time (HH:MM, 24hr)					
Gram Negative Culture <u>Species</u>					
3) Time (HH:MM, 24hr)					
Gram Negative Culture <u>Species</u>					
4) Time (HH:MM, 24hr)					
Gram Negative Culture <u>Species</u>					
5) Time (HH:MM, 24hr)					
Gram Negative Culture <u>Species</u>					

Date (YYYY-MM-DD)					
1) Time (HH:MM, 24hr)					
Gram Negative Culture <u>Species</u>					
2) Time (HH:MM, 24hr)					
Gram Negative Culture <u>Species</u>					
3) Time (HH:MM, 24hr)					
Gram Negative Culture <u>Species</u>					
4) Time (HH:MM, 24hr)					
Gram Negative Culture <u>Species</u>					
5) Time (HH:MM, 24hr)					
Gram Negative Culture <u>Species</u>					

Protocol Violation Instructions (1/2)

Protocol Violation Definition	A Protocol Violation (PV) is defined as *"non-compliance with the study protocol and/or procedures that may impact study participant safety, the integrity of study data and/or study participant willingness to participate in the study"* **A Protocol Violation is reported when <u>ANY</u> of the following have occurred:** 1) *Investigational Product (IP)* Daily dose delivered is < 80% prescribed over 3 day average. 2) IP dispensing/dosing error 3) Accidental unblinding *of IP* 4) Enrollment of a patient that does not fulfill inclusion/exclusion criteria 5) Open label glutamine given 6) Unapproved EN formula given 7) Other, specify
General Instructions	Complete Protocol Violation (PV) forms in REDCap™ within 24 hours of becoming aware of the violation. <u>ONLY</u> complete the PV form on days you are reporting a protocol violation.
Duration of Data Collection	Protocol Violations are to be reported from randomization until <u>≥</u>10 days post last successful graft (stop of study IP + 3 days) or ACU discharge or 3 months after ACU admission, whichever comes first. Protocol Violations that relate to the < 80% dosing delivered do <u>NOT</u> have to be reported on the following days: ▪ Day of randomization ▪ Day of discharge or end of study treatment (<u>≥</u> 7 days post last successful graft) ▪ Day of death
Date Violation Occurred	Enter the PV data in REDCap™ on the study day corresponding to the date the PV occurred.
Are you reporting a protocol violation today?	Select "YES" to "*Are you reporting a protocol violation today?"* to open the form and enter the protocol violation data.
Protocol Violation #	*For your reference only, circle* the PV number (1 - 6) being reported on the study day corresponding to the date the PV occurred. Each day starts with #1. This will correspond to the PV# displayed in REDCap™, see screenshot below: 
Date Violation Discovered	Enter the date the violation was identified by the site research staff (YYYY-MM-DD).
Local Investigator Aware?	Indicate whether the local qualified investigator has been made aware of this violation, "YES" or "NO".

Patient ID

Protocol Violation Instructions (2/2)

Violation	Select one protocol violation per report : ❑ Dose delivered over a 3 day average is < 80 % prescribed ❑ Dispensing/dosing error ❑ Accidental unblinding ❑ Enrollment of a patient that does not fulfill inclusion/exclusion criteria ❑ Open label glutamine given ❑ Unapproved EN formula given ❑ Other (specify) _____
Reason for Violation	If violation was indicated as "Dose delivered over a 3 day average is < 80% prescribed", select ALL that apply under "Reasons for Violation". ❑ High gastric residual volumes ❑ Vomiting / emesis ❑ Bowel perforation / obstruction ❑ Held for procedure ❑ Patient declined / refused study supplement ❑ Other, specify details
Supporting Documentation	Indicate if there are supporting files to be emailed or faxed for this PV by selecting the appropriate response: ❑ Yes, by email (preferred) ❑ Yes, by fax ❑ No **IMPORTANT**: Remember to de-identify any documents before sending them, this includes removing the following information: • Subject name • Subject initials • Medical record number • Date of birth (including only month and year) • Other unique hospital identifiers (i.e. lab accession #)
Action Taken by RC	Describe the action taken by the Research Coordinator/Responsible Delegate to prevent the violation/problem from occurring again.
Another Protocol Violation to Add?	Indicate if you have another Protocol Violation to report by selecting "YES" or "NO". Select "YES" to open the next PV form and enter the data. You may report up to 6 PVs per patient per day. If you have more than 6 PVs to report on one study day, contact the Project Leader.

Patient ID

Protocol Violation Form

Date PV occurred (YYYY-MM-DD)		
Are you reporting a protocol violation today?	☐ Yes ☐ No	
Protocol Violation # (circle one) 1 2 3 4 5 6		
Date Violation Discovered (YYYY-MM-DD)		
Is the local site investigator aware of the violation?	☐ Yes ☐ No	
Violation Select only one per report	❑ Dose delivered over a 3 day average is < 80 % prescribed ❑ Dispensing/dosing error ❑ Accidental unblinding ❑ Enrollment of a patient that does not fulfill inclusion/exclusion criteria ❑ Open label glutamine given ❑ Unapproved EN formula given ❑ Other (specify) _____	
Reason for Violation Check all that apply **NOTE**: Only answer if violation was "Dose delivered over a 3 day average is < 80% prescribed"	❑ High gastric residual volumes ❑ Vomiting / emesis ❑ Bowel perforation / obstruction ❑ Held for procedure ❑ Patient declined / refused study supplement ❑ Other, specify details_____	
Are there supporting files to be emailed or faxed?	❑ Yes, by email (preferred) ❑ Yes, by fax ❑ No	**NOTE:** Remember to de-identify all documents before emailing or faxing.
Action Taken by Research Coordinator/Responsible Delegate		
Another Protocol Violation to Add?	☐ Yes ☐ No	

Hospitalization Overview Instructions (1/2)

General Instructions	This data is collected to determine clinical outcomes related to length of stay and mortality.
Duration of Data Collection	This data is to be collected once, following either: Study Day 90, discharge from ACU and hospital, or death – whichever occurs first.
Last Successful Graft **(*Was the last successful graft achieved?*)**	Indicate whether the last successful graft was achieved by selecting "YES", "NO", or "Not Available – Consent withdrawn for data collection" If "YES", enter the date of the last successful graft in the format YYYY-MM-DD. If "NO", select the reason the last successful graft was never achieved: ❑ Death ❑ Withdrew Life Sustaining Therapies ❑ Discharged without receiving a graft ❑ Receiving grafts after Consent Withdrawn for intervention ❑ Receiving grafts after ACU discharge (< 3 mo) ❑ Still receiving grafts in ACU at 3 months ❑ Other (specify) If the patient chooses to stop taking the study product (withdraws consent for intervention) and is still receiving grafts >3 days after the last dose of study product was received, select *"NO"* and choose *"Receiving grafts after Consent Withdrawn for intervention"*.
Consent withdrawn / denied during this ACU stay?	If consent was withdrawn or denied during this ACU stay, indicate by selecting "YES". If "YES", enter the date and time consent was withdrawn/denied and choose the type of withdrawal/denial from the list below: ❑ Stop intervention, continue data collection ❑ Stop intervention, stop data collection (keep previous data) ❑ Stop intervention, stop data collection (discard previous data)
ACU Stay **(*Did the patient die during this ACU stay?*)**	Select the appropriate response to indicate whether the patient died during this ACU stay, was discharged, or is still in ACU at 3 months after admission. If "**YES**", the patient died during ACU stay, record the death date (YYYY-MM-DD), time (HH:MM, 24hr) and cause of death. (Space provided to record cause of death at the bottom of "Hospital Overview 2/2" worksheet. **NOTE:** Record the date and time documented on the death certificate. If this is not available, record the date and time from the physicians NOTE. If this is not available, record the date and time documented in the nurse's charting **NOTE:** Document the cause of death from a post mortem report. If this is not available, record cause of death from the death certificate. If "**NO, Patient Discharged**", enter the date (YYYY-MM-DD) and time (HH:MM, 24hr) the patient was actually discharged from the ACU. If the patient is still in the ACU 3 months after admission, select "**NO, Patient Still In ACU At 3 months**".

Hospitalization Overview Instructions (2/2)

(**Was the patient re-admitted to the ACU?)** Only record if patient was readmitted to ACU **before** being discharged from hospital	Indicate if the patient was readmitted to your ACU from another ward within your hospital by selecting "YES" or "NO. If "YES" • Enter the readmission date (YYYY-MM-DD) and time (HH:MM, 24hr). • Indicate if consent was withdrawn/denied during this ACU stay, by selecting "YES" or "NO". If "YES", enter the date (YYYY-MM-DD) and time (HH:MM, 24hr), and type of withdrawal / denial by selecting one of the options below: ☐ Stop data collection (keep previous data) ☐ Stop data collection (discard previous data) • Repeat the steps above for the question "Did the patient die during this ACU stay?" • Record up to 5 ACU admissions (including initial admission). Once the patient is discharged from your hospital, do **NOT** record ACU re-admissions. If "NO", the patient was not re-admitted, complete the Hospital Stay data.
Hospital Stay	
Consent withdrawn / denied during this Hospital stay?	**NOTE:** Only answer "YES" if consent was withdrawn/denied for **data collection** (*not IP*) after the patient was discharged from the ACU, but prior to hospital discharge. If "YES", follow the instructions above for consent withdrawn/denied during ACU re-admission.
Did the patient die in Hospital? **Discharge time not available?** **Discharged to?**	Indicate if patient died in hospital by selecting "YES", "No, Patient Discharged", or "No, Patient Still In ACU At 3 months". If "YES", record the death date (YYYY-MM-DD), time (HH:MM, 24hr) and cause of death. • Record the date and time documented on the death certificate. If not available, record the date and time from the physician's note. If not available, use the nurse's charting. • Document the cause of death from a post mortem report. If unavailable, record cause of death from the death certificate. If "**No, Patient Discharged"**, enter the date (YYYY-MM-DD) and time (HH:MM, 24hr) the patient was discharged from the hospital. If the hospital discharge time is not available, select "YES" to "Time not available?" Select the location to which the patient was discharged: ☐ Ward in another hospital ☐ ACU in another hospital ☐ Long term care facility ☐ Rehabilitation unit ☐ Home ☐ Other, specify If the patient is still in the hospital 3 months after admission, select "**No, Patient Still In Hospital At 3 months".**

Patient ID

Hospitalization Overview (1/2)

Last Successful Graft	
Was the last successful graft achieved?	☐ Yes ☐ No ☐ Not Available-Consent withdrawn for data collection
If **Yes**, record date of last successful graft (YYYY-MM-DD)	
If **No**, select reason last successful graft never achieved:	☐ Death ☐ Withdrew Life Sustaining Therapies ☐ Discharged without receiving a graft ☐ Receiving grafts after Consent Withdrawn for intervention ☐ Receiving grafts after ACU discharge (< 3 mo.) ☐ Still receiving grafts in ACU at 3 months ☐ Other, specify:_____

ACU Stay #1		Date (YYYY-MM-DD)	Time (HH:MM, 24hr)
Was consent withdrawn or denied during the ACU stay?	☐ Yes (record date and time)		
Select the type of withdrawal / denial, if applicable:	☐ Stop intervention, continue data collection ☐ Stop intervention, stop data collection (keep previous data) ☐ Stop intervention, stop data collection (discard previous data)		
Did the patient die during this ACU stay?	☐ Yes (record date and time of death)		
	☐ Patient discharged from the ACU (record date and time of discharge)		
	☐ The patient was still in the ACU at 3 months		
Was the patient re-admitted to the ACU?	☐ Yes (record date and time of re-admission) ☐ No		

ACU Stay # (circle one) 2 3 4 5		Date (YYYY-MM-DD)	Time (HH:MM, 24hr)
Was consent withdrawn or denied during the ACU stay?	☐ Yes (record date and time) ☐ No		
Select the type of withdrawal / denial:	☐ Stop data collection (keep previous data) ☐ Stop data collection (discard previous data)		
Did the patient die during this ACU stay?	☐ Yes (record date and time of death)		
	☐ Patient discharged from the ACU (record date and time of discharge)		
	☐ The patient was still in the ACU at 3 months		
Was the patient re-admitted to the ACU?	☐ Yes (record date and time of re-admission) ☐ No		

Patient ID

Hospitalization Overview (2/2)

Hospital Discharge		**Date** (YYYY-MM-DD)	**Time** (HH:MM, 24hr)
Consent withdrawn/denied during the Hospital stay?	☐Yes (record date and time) ☐No		
Select the type of withdrawal/denial:	☐ Stop data collection (keep previous data) ☐ Stop data collection (discard previous data)		
Did the patient die in the hospital?	☐ Yes (record date and time)		
	☐ No, Patient Discharged (record date and time)		
	☐ No, Patient was still in the hospital at 3 months		
If the patient was discharged from the hospital, where was the patient discharged to?	☐ Ward in another hospital ☐ ACU in another hospital ☐ Long term care facility ☐ Rehabilitation unit ☐ Home ☐ Other (Please Specify):		

Cause of Death:

_____

_____

_____

6 Month Follow-Up: Survival Assessment Instructions

General Information	This data is collected to determine survival status 6 months after the patient was admitted to the ACU. **Every effort must be made to obtain survival status.** Refer to the study procedures manual for more information on patient retention procedures.
Duration of Data Collection	Survival assessment is to be conducted at 6 months (± 14 days) after ACU admission.
Was Survival Status Obtained?	Record whether the survival status of the patient was obtained, by selecting "YES" or "NO"
Date Survival Status Obtained	If survival status is known, record the date of contact **or** information retrieval (YYYY-MM-DD).
Source of information	Record the source of survival status information by selecting one of the following: ☐ Patient ☐ Alternative contact person(s) (specify relationship) ☐ Family Physician ☐ Medical Records ☐ Obituaries ☐ Internet ☐ Other (specify) **NOTE:** When providing information for "Alternative contact person(s), do **NOT** include proper names, or any identifying information. Only provide relationship to patient.
Survival Status	Record the survival status of the patient as "Alive" or "Deceased"
Survival Status NOT Obtained	If survival status is not known, confirm all the listed avenues to access patient survival status were used by selecting all that were completed from the list below: ☐ 3 attempts to contact the patient were made (mandatory) ☐ 3 attempts to contact the alternative contact person(s) were made (mandatory if applicable) ☐ Family doctor contacted (mandatory if available) ☐ No medical records on the patient available at month 6 (mandatory) ☐ Internet searches for the patient name did not reveal survival status (mandatory)
Last Date Known to be Alive	If survival status was not obtained, record the last date (YYYY-MM-DD) the patient was known to be alive.

6 Month Follow-Up: Survival Assessment

Was the Survival Status Obtained?	☐ Yes ☐ No
If Survival Status is Obtained	
Date of Contact / Information Retrieval	(YYYY-MM-DD)
Source of Information (Select one)	☐ Patient ☐ Alternate Contact Person(s) (Specify relationship) _____ ☐ Family Physician ☐ Medical Records ☐ Obituaries ☐ Internet ☐ Other (specify) _____
Survival Status	☐ Alive ☐ Deceased
If deceased, is date of death known?	☐ Yes ☐ No
If "YES", date of death	(YYYY-MM-DD)
If "NO", last date known to be alive	(YYYY-MM-DD)
If Survival Status is NOT Obtained	
Confirm which of the following were completed	☐ **3 attempts to contact the patient** were made (mandatory) ☐ **3 attempts to contact the alternate** contact person(s) were made (mandatory if applicable) ☐ **Family doctor contacted** (mandatory if available) ☐ No **medical records** on the patient available at month 6 (mandatory) ☐ **Internet searches** for the patient name did not reveal survival status (mandatory)
Last date known to be alive	(YYYY-MM-DD)

6 Month Follow-Up: Assessment Questionnaires Instructions (1/2)

General Information	This data is collected to assess the patient's health-related quality of life and activities of daily living at the 6 month follow up interval. Refer to the study procedures manual for more information on patient retention procedures. **NOTE:** Late data is better than missing data. Every effort must be made to complete these questionnaires.
Duration of Data Collection	SF-36, ADL, and IADL status assessments are to be conducted at 6 months (± 14 days) after ACU admission. **NOTE:** Questionnaires should be administered even if patient is still in hospital at 6 months after admission, if possible.
Questionnaire Completed?	For each, indicate if the questionnaire was completed by selecting "YES" or "NO" If "YES", enter the date completed (YYYY-MM-DD) and if it was completed by the Patient or the Alternate contact. If "NO", indicate the reason the questionnaire was not completed: ☐ Deceased (Record date of death on the survival assessment) ☐ Patient Refused ☐ Alternate Refused ☐ Both Patient and Alternate Refused ☐ Not able to reach patient and/or alternate ☐ Withdrew ☐ Missed ☐ Other (specify): _____
SF-36	The SF-36 is used to assess health status and quality of life. 1. Read the explanation at the top of the survey to the patient. 2. Ensure the patient understands that the responses should reflect her/his views about her/his own health. Remember not to interpret the questions for the patient. Each question means what he/she thinks it means, **there is no right or wrong answer.** 3. Read each question to the patient followed by the response options. 4. Record the patient's response on the questionnaire worksheet.
Katz ADL	The Katz ADL is used to assess the level of patient independence related to self-care. The patient's responses should reflect what he/she is **actually able to do**, not what they think they might be able to do under ideal circumstances. 1. Read the definitions of "Independence" and "Dependence" to the patient as stated on the top of the Katz ADL form. 2. Read each of the 6 activities to the patient followed by the independent and dependent descriptions. Allow the patient to make her/his own determination. 3. Based on the patient's response, record either 1 or 0 in the space provided for each activity.

6 Month Follow-Up: Assessment Questionnaires Instructions (2/2)

Lawton IADL	The Lawton IADL is used to assess the level of patient functional ability related to domestic and community activities. The patient's responses should reflect her/his **highest functional level**, not the activities they actual do. For example, if a patient is not the person in the household that does the laundry, but the patient is capable of doing her/his own laundry independently select *"Does personal laundry completely"*. 1. Read each of the 8 activities to the patient followed by the response options. 2. Remind the patient to indicate her/his **highest** functional ability. 3. Allow the patient to make her/his own determination. 4. Circle the corresponding number on the form.
Maintain Worksheets	Keep the completed questionnaire worksheets with the patient study files. This is your source documentation for completion of the questionnaires.

THE RE–*ENERGIZE* STUDY

Patient ID

SF-36 (1/5)

Was the SF-36 completed?	☐ Yes ☐ No
If completed: Date SF-36 completed	(YYYY-MM-DD)
Completed by	☐ Patient ☐ Alternate
If Not completed: Reason not done	☐ Deceased ☐ Patient Refused ☐ Alternate Refused ☐ Both Patient and Alternate Refused ☐ Not able to reach patient and/or alternate ☐ Withdrew ☐ Missed ☐ Other (specify) _____

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 **x** in the one box that best describes your answer.

1. In general, would you say your health is					
Excellent ☐	Very Good ☐	Good ☐	Fair ☐	Poor ☐	Not Done ☐

2. Compared to one year ago, how would you rate your health in general now?					
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 ☐	Not Done ☐

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Patient ID

SF-36 (2/5)

3. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?				
	Yes, limited a lot	Yes, limited a little	No, not limited at all	Not Done
a) <u>Vigorous activities</u>, such as running lifting heavy objects, participating in strenuous sports	☐	☐	☐	☐
b) <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐	☐	☐	☐
c) Lifting or carrying groceries	☐	☐	☐	☐
d) Climbing <u>several</u> flights of stairs	☐	☐	☐	☐
e) Climbing <u>one</u> flight of stairs	☐	☐	☐	☐
f) Bending, kneeling or stooping	☐	☐	☐	☐
g) Walking <u>more than a kilometer</u>	☐	☐	☐	☐
h) Walking <u>several hundred meters</u>	☐	☐	☐	☐
i) Walking <u>one hundred meters</u>	☐	☐	☐	☐
j) Bathing or dressing yourself	☐	☐	☐	☐

Patient ID

SF-36 (3/5)

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	Not Done
a) Cut down on the amount of time you spent on work or other activities	☐	☐	☐	☐	☐	☐
b) Accomplished less than you would like	☐	☐	☐	☐	☐	☐
c) Were limited in the kind of work or other activities	☐	☐	☐	☐	☐	☐
d) Had difficulty performing the work or other activities (for example, it took extra effort)	☐	☐	☐	☐	☐	☐

5. 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 any emotional problems (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	Not Done
a) Cut down on the amount of time you spent on work or other activities	☐	☐	☐	☐	☐	☐
b) Accomplished less than you would like	☐	☐	☐	☐	☐	☐
c) Did work or other activities less carefully than usual	☐	☐	☐	☐	☐	☐

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?					
Not at all	Slightly	Moderately	Quite a Bit	Extremely	Not Done
☐	☐	☐	☐	☐	☐

Patient ID

SF-36 (4/5)

7. How much bodily pain would you say you had during the past 4 weeks?						
Not at all	Very Mild	Mild	Moderate	Severe	Very Severe	Not Done
☐	☐	☐	☐	☐	☐	☐

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside and inside the home and housework)?					
Not at all	Slightly	Moderately	Quite a Bit	Extremely	Not Done
☐	☐	☐	☐	☐	☐

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 your 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	Not Done
a) Did you feel full of life?	☐	☐	☐	☐	☐	☐
b) Has you been very nervous?	☐	☐	☐	☐	☐	☐
c) Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d) Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e) Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f) Have you felt downhearted and depressed?	☐	☐	☐	☐	☐	☐
g) Did you feel worn out?	☐	☐	☐	☐	☐	☐
h) Have you been happy?	☐	☐	☐	☐	☐	☐
i) Did you feel tired?	☐	☐	☐	☐	☐	☐

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Patient ID

SF-36 (5/5)

10. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> 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	Not Done
☐	☐	☐	☐	☐	☐

11. How TRUE or FALSE is <u>each</u> of the following statements is for you?						
	Definitely true	Mostly true	Don"t know	Mostly false	Definitely false	Not Done
a) I seems to get sick a little easier than other people	☐	☐	☐	☐	☐	☐
b) I am as healthy as anyone I know	☐	☐	☐	☐	☐	☐
c) I expect my health to get worse	☐	☐	☐	☐	☐	☐
d) My health is excellent	☐	☐	☐	☐	☐	☐

Thank you for completing these questions!

THE RE-*ENERGIZE* STUDY

Patient ID

Katz Index of Independence in Activities of Daily Living

Was the ADL completed?	☐ Yes ☐ No
If completed: Date ADL completed	(YYYY-MM-DD)
Completed by	☐ Patient ☐ Alternate
If Not completed: Reason not done	☐ Deceased ☐ Patient Refused ☐ Alternate Refused ☐ Both Patient and Alternate Refused ☐ Not able to reach patient and/or alternate ☐ Withdrew ☐ Missed ☐ Other (specify) _____

ACTIVITIES	**INDEPENDENCE:** No supervision, direction or personal assistance	**DEPENDENCE:** With supervision, direction, personal assistance or total care
BATHING	☐ Bathes self completely or needs help in bathing only a single part of the body *such* as the back, genital area or disabled extremity	☐ Needs help with bathing more than one part of the body, getting in or out of the tub or shower. Requires total bathing.
DRESSING	☐ Gets clothes from closets and drawers and puts on clothes and outer garments complete with fasteners. May have help tying shoes	☐ Needs help with dressing self or needs to be completely dressed
TOILETING	☐ Goes to toilet, gets on and off, arranges clothes, cleans genital area without help	☐ Needs help transferring to the toilet, cleaning self or uses bedpan or commode
TRANSFERRING	☐ Moves in and out of bed or chair unassisted. Mechanical transferring aides are acceptable	☐ Needs help in moving from bed to chair or requires a complete transfer
CONTINENCE	☐ Exercises complete self control over urination and defecation	☐ Is partially or totally incontinent of bowel or bladder
FEEDING	☐ Gets food from plate into mouth without help. Preparation of food may be done by another person	☐ Needs partial or total help with feeding or requires parenteral feeding

Patient ID

Lawton Instrumental Activities of Daily Living (IADLs) (1/2)

Was the IADL completed?	☐ Yes ☐ No
If completed: Date IADL completed	(YYYY-MM-DD)
Completed by	☐ Patient ☐ Alternate
If Not completed: Reason not done	☐ Deceased ☐ Patient Refused ☐ Alternate Refused ☐ Both Patient and Alternate Refused ☐ Not able to reach patient and/or alternate ☐ Withdrew ☐ Missed ☐ Other (specify) _____

A. Ability to Use Telephone	☐ Operates telephone on own initiative; looks up and dials numbers ☐ Dials a few well-known numbers ☐ Answers telephone, but does not dial ☐ Does not use telephone at all
B. Shopping	☐ Takes care of all shopping needs independently ☐ Shops independently for small purchases ☐ Needs to be accompanied on any shopping trip ☐ Completely unable to shop
C. Food Preparation	☐ Plans, prepares, and serves adequate meals independently ☐ Prepares adequate meals if supplied with ingredients ☐ Heats and serves prepared meals or prepares meals but does not maintain adequate diet ☐ Needs to have meals prepared and served
D. Housekeeping	☐ Maintains house alone with occasion assistance (heavy work) ☐ Performs light daily tasks such as dishwashing, bed making ☐ Performs light daily tasks, but cannot maintain acceptable level of cleanliness ☐ Needs help with all home maintenance tasks ☐ Does not participate in any housekeeping tasks
E. Laundry	☐ Does personal laundry completely ☐ Launders small items, rinses socks, stockings, etc ☐ All laundry must be done by others

Patient ID

Lawton IADLs (2/2)

F. Mode of transportation	☐ Travels independently on public transportation or drives own car ☐ Arranges own travel via taxi, but does not otherwise use public transportation ☐ Travels on public transportation when assisted or accompanied by another ☐ Travel limited to taxi or automobile with assistance of another ☐ Does not travel at all
G. Responsibility for Own Medications	☐ Is responsible for taking medication in correct dosages at correct time ☐ Takes responsibility if medication is prepared in advance in separate dosages ☐ Is not capable of dispensing own medication
H. Ability to Handle Finances	☐ Manages financial matters independently (budgets, writes checks, pays rent and bills, goes to bank); collects and keeps track of income ☐ Manages day-to-day purchases, but needs help with banking, major purchases, etc ☐ Incapable of handling money

THE RE–*ENERGIZE* STUDY

Patient ID

Investigator Confirmation Instructions

General Instructions	When **ALL** the data collection has been completed, including hospitalization overview, the **Site Investigator** is to sign & date the Investigator Confirmation Form to attest to the following: • The data collection was conducted under her / his supervision according to the protocol • The data and statement are complete and accurate to the best of her / his knowledge Once the Investigator Confirmation Form has been signed and dated, please scan the completed form to: **Maureen Dansereau** Clinical Evaluation Research Unit Maureen.Dansereau@kingstonhsc.ca

THE RE–*ENERGIZE* STUDY

Patient ID

Investigator Confirmation Form

The data collected in the RE-ENERGIZE Case Report Forms was collected in accordance with the study protocol and established procedures. The data was collected under my supervision.

The data and statement are complete and accurate to the best of my knowledge.

Full Name of Investigator

Signature of the Investigator

Date (YYYY-MM-DD)

Patient ID

APPENDIX 1
Lund-Browder Diagram

Therapeutic Guidelines

Lund and Browder chart for calculating the percentage of total body surface area burnt (Fig 14.19)

Region	Partial thickness (%) [NB1]	Full thickness (%)
head		
neck		
anterior trunk		
posterior trunk		
right arm		
left arm		
buttocks		
genitalia		
right leg		
left leg		
Total burn		

NB1: Do not include erythema

Area	Age 0	1	5	10	15	Adult
A = half of head	9½	8½	6½	5½	4½	3½
B = half of one thigh	2¾	3¼	4	4½	4½	4¾
C = half of one lower leg	2½	2½	2¾	3	3¼	3½