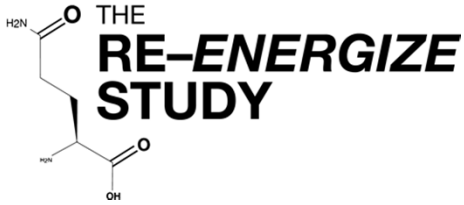
Randomization Number



A RandomizEd Trial of ENtERal Glutamine to MinimIZE Thermal Injury

Clinical trials.gov ID #NCT00985205

electronic Case Report Form (eCRF) Worksheets and Instructions

Please direct questions to:
Maureen Dansereau
Project Leader
Tel: 613-549-6666 ext. 6686
Email: danserem@kgh.kari.net

19 July 2017

THE RE-*ENERGIZE* STUDY

Randomization Number

Table of Contents

General Instructions

The following case report form worksheets have been developed to assist the research coordinator at the participating site with data collection. The Research Coordinator (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 that detail how and when the data is to be collected applies.

Note: The appearance of these worksheets and the order in which they appear may vary slightly from REDCap™.

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. For example, 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 admit date** (not randomization) and **time** until 23:59 the same day.
   Study Day 2 = the subsequent day starting at 00:00 to 23:59 that day

Example: A patient is admitted to the 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)

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 Events

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.

   Example: T-Bilirubin was not done on a particular study day.

   If the data is '**Not Available**' for any reason, indicate by selecting 'Not Available'.

THE RE-*ENERGIZE* STUDY

Central Randomization System (CRS)

The following pages (4 - 10 inclusive) refer to the data to be entered into the Central Randomization System (CRS).

Access the CRS at the following web address:

https://ceru.hpcvl.queensu.ca/CRS/

Enter all patients who meet the Inclusion Criteria.

Inclusion Criteria Present	Exclusion Criteria Present	Informed Consent Obtained	Enter into CRS	Comments
✖	✖	Do not approach for consent as inclusion criteria not met	✖	
✓	✓	Do not approach for consent as exclusion criteria met	✓	Ineligible patient
✓	✖	✓	✓	Randomized patient
✓	✖	✖	✓	Eligible but not randomized patient

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 can occur.</td></tr>
<tr><td>1. Presence of 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 <u>fulfill</u> this criteria</th><th>The following burn injuries do NOT fulfill this criteria</th></tr>
<tr><td>Thermal burn injuries:
• Scald
• Fire (includes both Flame and Flash)
• Radiation
• Chemical
• Unknown
• Other, Specify_____</td><td>Do NOT include injuries from any of the following:
• 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 one of the following 4 criteria:</td><td>This assessment must be confirmed by the SI or sub-I based on her/his clinical judgment. Check only one box to indicate which of the 4 criteria is met.

<u>Eligibility Requirements</u>:
a) Patients 18 - 39 years of age with TBSA burn <u>></u> 20%.
b) Patients 18 - 39 years of age with TBSA burn <u>></u> 15% and with inhalation injury*.
c) Patients 40 – 59 years of age with TBSA burn <u>></u> 15%
d) Patients <u>></u> 60 years of age with TBSA burn <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.</td></tr>
</table>

Screening—Inclusion

Inclusion Criteria

1. Presence of Deep 2nd and/or Deep 3rd degree burns requiring grafting	☐ Yes ☐ No
2. Patient meets one of the following 4 criteria: a. Patients 18 - 39 years of age with TBSA burn ≥ 20% b. Patients 18 - 39 years of age with TBSA burn ≥ 15% WITH inhalation injury c. Patients 40 - 59 years of age with TBSA burn ≥ 15% d. Patients ≥ 60 years of age TBSA burn ≥ 10%	☐ Yes ☐ No ☐ a. ☐ b. ☐ c. ☐ d.

THE RE–*ENERGIZE* STUDY

Randomization Number

Screening - Exclusion Instructions

Record all exclusion criteria that the patient meets.

If any one of the twelve criteria below are met, then 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. An exception would be a patient who has been at another facility for an extended period of time, post burn, prior to admission to your unit.

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 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 or 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) will be required.

   - Patients with chronic renal failure on dialysis will be excluded.

4. Liver cirrhosis: Child-Pugh Class C liver disease (see chart below)

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 has been drained in the past, it should be considered Moderate.			

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. Contra-indication for Enteral Nutrition: intestinal occlusion or perforation, abdominal injury.

   Being NPO is not a contraindication for Enteral Nutrition.

7. Patient with injuries from high voltage electrical contact.

   NOTE: *Thermal injuries from low voltage electrical contact are acceptable for the study.*

8. Patients who are moribund: Not expected to survive the next 72 hours. (An isolated DNR does not fulfill this criteria.)

9. Patients with extreme body size: BMI <18 or >50 kg/m^2

10. Enrollment in another industry sponsored ACU 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 above exclusion criteria, patient is eligible for randomization and you may proceed to the Pre-randomization/Randomization form.

THE RE–*ENERGIZE* STUDY

Randomization Number

Screening—Exclusion

Exclusion Criteria

1. >72 hours from admission to (your) 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 or 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) will be required. - Patients with chronic renal failure on dialysis will be excluded.	☐ 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

THE RE–*ENERGIZE* STUDY

Randomization Number

Pre Randomization / Randomization Instructions

General Instructions	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 MD	Confirm eligibility of the patient with the site investigator or sub-investigator. Enter the name of the physician who confirmed patient eligibility. This individual should be listed on the Site Delegation of Authority Log.
Approached for Consent **Reason not approached for consent**	Was the SDM or patient **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, enter text explaining the reason not approached for consent. ☐ Next of kin or SDM not available ☐ Missed patient ☐ Language barriers ☐ Family dynamics ☐ Recommendation of the 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, enter text explaining the reason consent was not obtained. ☐ Too Overwhelmed ☐ Not interested ☐ Did not respond (timed out) ☐ Other, please specify _____
Consent Date and Time	If consent was obtained, record the consent date and time: ▪ Enter date in the format *yyyy-mm-dd* ▪ Enter the time using the 24 hr clock in the format *hh:mm*
Height and Pre-Burn Weight	Record the patient's height and weight. Record up to two decimal points, eg. 82.67 kg ▪ Enter the patient's height in either centimetres or inches. Select the unit of measure. ▪ Enter the patient's pre-burn dry weight in either kilograms or pounds. Select the unit. ▪ Indicate how the height and weight were each obtained: o Measured (obtained by a weighing scale) o Estimated (by patient, family or healthcare professional) o Unknown (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.

THE RE–*ENERGIZE* STUDY

Randomization Number

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 patient ☐ Language barriers ☐ Family dynamics ☐ Recommendation of the clinical team ☐ CRS unavailable ☐ Pharmacy unavailable ☐ Other, please specify _____
If 'Yes', was consent obtained from the SDM/patient?	☐ Yes ☐ No
If 'No', choose the most important reason why consent was not obtained (select the primary reason)	☐ 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) (24 hour clock)	
Height _____ ☐ cm or ☐ inches	☐ Measured ☐ Estimated ☐ Unknown
Weight _____ ☐ kg or ☐ lbs	☐ 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

THE RE-*ENERGIZE* STUDY

Data Collection

REDCap™
(Electronic Data Capture System)

REENERGIZE - Definitive

Access REDCap™ at the following web address:

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

THE RE–*ENERGIZE* STUDY

Randomization Number

Baseline Instructions

General Instructions	Complete all of the information by selecting the appropriate box and entering the required data for each field as indicated. These data are to be collected once, at baseline.
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 RE-ENERGIZE 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 • White or Caucasian • Other (please 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.
Comorbidities	Select all comorbidities on the list provided. Only those comorbidities found on the taxonomy listing should be recorded. If no comorbidities are present, select 'No comorbidities' History of Alcohol abuse: If a subject has a documented history of alcohol abuse in the medical chart, it should be recorded in the CRF. 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, Yes or No. If you are not able to obtain this information, select 'Not Available'.
Hospital admit	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, this date and time becomes the Hospital admit date and time. If the admit time is not available, enter the time of the first documentation.
ACU admit	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 admit date and time. If the admit time is not available, enter the time of the first chart documentation.
Co-enrollment	Is the patient co-enrolled in another academic ACU study? If Yes, then enter the name(s) of the study(ies).
Date and time of burn	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 Electrical Burns Frost Bite Steven-Johnson Syndrome (SJS) Toxic Epidermal Necrolysis (TEN)
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 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%.
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'.

Baseline

Age (years)	years	
Sex	☐ Female ☐ Male	
Ethnic group	☐ Asian or Pacific Islander ☐ Black or African American ☐ East Indian ☐ Hispanic	☐ Native ☐ White or Caucasian ☐ Other (Please specify): _____
APACHE II		
Comorbidities (If 'Yes', select from the list provided on the next page)	☐ Yes ☐ No	
Tobacco Use	☐ Yes ☐ No ☐ Not Available	
Hospital Admit Date and Time	(yyyy-mm-dd)	(hh:mm) (24 hour clock)
ACU Admit Date and Time	(yyyy-mm-dd)	(hh:mm) (24 hour clock)
Is this patient co-enrolled in another academic ACU study?	☐ Yes ☐ No	
If 'Yes', Please specify:		
Burn Injury Date and Time	(yyyy-mm-dd)	(hh:mm) (24 hour clock) ☐ No Time Available
Type of Burn (Select only one)	☐ Scald ☐ Fire (includes flame and flash) ☐ Chemical ☐ Radiation	☐ Unknown ☐ Other (Please specify): _____
Burn Size expressed as % Total Body Surface Area (TBSA)	%TBSA	
Did the patient receive high dose Vitamin C as part of her/his resuscitation protocol (approximately 66mg/kg/hr)?	☐ Yes ☐ No	

THE RE-*ENERGIZE* STUDY

Randomization Number

Comorbidities

Check all the comorbidities that apply.
If the patient has no comorbidities, check 'No Comorbidities'.

	No Cormorbidities

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

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

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

	Neurologic
	11. Dementia
	12. Hemiplegia (paraplegia)
	13. Neurologic illnesses (such as Multiple sclerosis or 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, 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	These data are collected once at baseline for calculation of modified SOFA score. All data should be collected within the first 24 hours after admission. If data is not available within the first 24 hours, go outside the 24 hour period and record data closest to admission.
Lowest PaO_2/FiO_2 (PF ratio)	Record the lowest PaO_2/FiO_2 (PF ratio) observed on the study day by selecting from the options below. The PaO_2 and FiO_2 values should come from the same blood gas measurement. **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 on the study day by selecting from the 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) ❑ Not Available
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 If 'No', enter MAP (mean-arterial pressure), see below.
MAP (mean arterial pressure)	Indicate the lowest MAP observed during the study day 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 for the study day 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)
Vasopressors Did the patient receive vasopressors?	❑ Yes ❑ No
If 'Yes', select the highest dose received during the study day. 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
MAP (lowest)	❑ < 70 mmHg ❑ ≥ 70 mmHg
Urine output	❑ < 200 mL/day ❑ 200 - 499 mL/day ❑ ≥ 500 mL/day ❑ Not Available

Invasive Mechanical Ventilation / Renal Replacement Therapy (Dialysis) Instructions

General Instructions Duration of Data Collection	These data are collected to determine the duration of invasive mechanical ventilation and need for renal replacement therapy (dialysis). These data are to be collected at start and stop of invasive mechanical ventilation and renal replacement therapy (dialysis).
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, even if this occurs at an external institution or in the field before admission to your unit. 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, enter the start date and check the 'Not available' option for time. Do not record episodes of temporary ventilation (defined as <48 hrs i.e. needed for operating procedures, etc).
Stop	After the patient has been successfully breathing without mechanical ventilation for > 48 hours, record the stop date and time mechanical ventilation was discontinued. Patients will be considered breathing without mechanical ventilation in any of these instances: • extubated and on face mask (nasal prong) • intubated or breathing through a t-tube • tracheostomy mask breathing. • continuous positive airway pressure (CPAP) <=5cmH2O without pressure support or intermittent mandatory ventilation assistance. If 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 expired 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 'Yes' or 'No' to the question '*Was mechanical ventilation re-instituted ≥ 48 hours from the last mechanical ventilation stop date/time?'. If 'No', proceed to the RRT (Dialysis) section.* *If the mechanical ventilation was re-instituted ≥ 48 hours after the first episode was discontinued, select 'Yes' to open the data entry fields to record another episode of mechanical ventilation.* Record up to 5 episodes of mechanical ventilation by answering 'Yes' at the end of each previous event recorded.
Mechanical Ventilation Episodes #2 - #5	Follow the instructions for recording start and stop dates of Mechanical Ventilation episodes as outlined in #1 above. Exception: Start Time must be recorded for episodes #2 - #5, there is not a 'Not Available' option. Do not record episodes of temporary ventilation (defined as <48 hrs i.e. needed for operating procedures, etc).
Renal Replacement Therapy (Dialysis)	Indicate whether the patient received RRT during this ACU stay by selecting 'Yes' or 'No'.
Was first RRT start due to Acute Renal Failure?	If 'Yes', respond to 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
RRT (Dialysis) Stop	Select one of the following related to discontinuation of RRT: ❑ 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 permanently discontinued. This may occur on the ward.)

THE RE–*ENERGIZE* STUDY

Randomization Number

Invasive Mechanical Ventilation

		Date (yyyy-mm-dd)	Time (24 hour clock)
Mechanical Ventilation # 1			
Did the patient ever receive invasive mechanical ventilation?	☐ Yes (Record start date & time)		
	If start time is not available		☐ Not available
	☐ No		
Mechanical ventilation stop:	☐ Record stop date & time		
	☐ Same as death date & time		
	☐ Still vented 3 months post ACU admission		
Mechanical Ventilation # 2			
Was mechanical ventilation re-instituted ≥48 hours from the last ventilation discontinuation date/time?	☐ Yes (Record start date & time)		
	☐ No		
Mechanical ventilation stop:	☐ Record stop date & time		
	☐ Same as death date & time		
	☐ Still vented 3 months post ACU admission		
Mechanical Ventilation # 3, #4, #5			
Was mechanical ventilation re-instituted ≥48 hours from the last ventilation discontinuation date/time?	☐ Yes (Record start date & time)		
	☐ No		
Mechanical ventilation stop:	☐ Record stop date & time		
	☐ Same as death date & time		
	☐ Still 3 months post ACU admission		

Renal Replacement Therapy (Dialysis)

Did the patient receive renal replacement therapy (dialysis) during this ACU stay?	☐ Yes ☐ No
The first time renal replacement therapy (dialysis) was started, was it due to acute renal failure?	☐ Yes (Continue to the next row) ☐ No (Do not complete below)
-Start Date	Date _____
-Stop Date ☐ Same as death date & time ☐ At 3 months, still on renal replacement therapy (dialysis) in hospital ☐ Continued past hospital discharge ☐ Actual stop date →	Date _____

Study Intervention

General Instructions	Study intervention is to be started within 2 hours of randomization.
Duration of Data Collection	These data are to be collected when study supplements are first started and when study supplements are finally 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 started in the format yyyy-mm-dd and hh:mm
Study Intervention started more than 2 hours from Randomization	If the study intervention is started more than 2 hours after randomization, select 'Yes' and 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 and 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 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?'* to open the data entry fields to record the new prescription. Enter the Date and Time the prescription change occurred. Enter the dosing weight associated with the new prescription. Select the new prescription in grams per day. Record up to 6 prescriptions by selecting 'Yes' to the question *'Did the study intervention prescription change?'* after each prescription entry. **NOTE:** Study Intervention prescription should not change. **EXCEPTION: If the patient has a change in body weight sufficient for the clinical team to alter dosage of clinical treatments, the study treatment should also be adjusted. This decision is made by the Site Investigator.**

THE RE–ENERGIZE STUDY

____
Randomization Number

Study Intervention

Date and Time first dose of study intervention administered	(yyyy-mm-dd)	(hh:mm) (24 hour clock)
Was Study Intervention started > 2 hours from Randomization?	☐ Yes ☐ No	
If Yes, indicate the reason:	☐ Pharmacy delay ☐ Patient NPO for surgery ☐ Awaiting tube placement and/or verification ☐ Patient not available (procedure) ☐ Nurse not available ☐ Other (specify): ________________	
Date and Time the last dose of study intervention administered	(yyyy-mm-dd)	(hh:mm) (24 hour clock)
Initial Study Intervention Prescription	grams/day	
Did the study intervention prescription change?	☐ Yes	
If Yes, record: Date and Time of the change	(yyyy-mm-dd)	(hh:mm) (24 hour clock)
Dosing weight for this prescription (kg)	kg	
Prescription in grams per day	20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100 grams/day	
Did the study intervention prescription change?	☐ Yes	
If Yes, record: Date and Time of the change	(yyyy-mm-dd)	(hh:mm) (24 hour clock)
Dosing weight for this prescription (kg)	kg	
Prescription in grams per day	20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100 grams/day	
Did the study intervention prescription change?	☐ Yes	
If Yes, record: Date and Time of the change	(yyyy-mm-dd)	(hh:mm) (24 hour clock)
Dosing weight for this prescription (kg)	kg	
Prescription in grams per day	20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100 grams/day	

Daily Monitoring

General Information **Duration of Data Collection**	These data are collected to determine the compliance to the prescribed dose of the study intervention and to identify any dose related Protocol Violations. Study intervention is to be started within 2 hours of randomization. Given the material affect on the study, these data are to be collected daily as close to REAL TIME as possible and 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.
(recommended) Prescribed # grams per day	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 investigational product (IP) 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.
# Times IP administered	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, from 5 to 30, 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.
Route	Select the route by which the study intervention was administered at each interval, EN or PO.
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	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 received. Record the percentage in the space provided.
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'. A protocol violation with the delivery of the study intervention 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: Prescribed Dose: 35g/day; 80% Prescribed: 28g Dose received: Day 6: 30g; Day 7: 20g; Day 8: 30g Total dose received over 3 days = 80g 3 day average dose is 80 g/ 3 = 26.67g Report Day 7: Dose received is < 80% AND 3 day average is < 80 % Do Not report Day 6 or Day 8: 3 day average is <80% BUT Dose received 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 section in these worksheets for detailed instructions.

THE RE–*ENERGIZE* STUDY

Daily Monitoring

Randomization Number

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 Instructions

Duration of Data Collection	These data are 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 mos. 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. If there is no value available for that study week, record N/A.
Date	Enter the dates corresponding to the calendar day. Enter the data on the corresponding date in REDCap™.
Creatinine, serum (highest)	Record the highest serum creatinine observed on the study day.
T-bilirubin (highest)	Record the highest serum total bilirubin observed on the study day.
Urea (highest)	Record the highest serum urea observed on the study day.
Glucose closest to 08:00	Record the glucose closest to 8:00 AM, ± 6 hrs (i.e. from 02:00 to 14:00 hrs), observed on the study day. 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'.	

THE RE–*ENERGIZE* STUDY

Randomization Number

Laboratory

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

General Instructions	These data are collected to determine how well the patient is being fed, i.e. the nutritional adequacy (% calories and protein received/prescribed) and the timing of initiation of nutrition. **Work with your dietitian,** or person responsible for assessing and monitoring the nutritional needs of patients**, to obtain this information.**
Duration of Data Collection	These data need to be calculated at baseline (ACU admission or at the first dietitian assessment) through study Day 12.
Baseline Assessment	Use the patient's pre-burn dry weight or usual weight when calculating energy and protein needs. For Obese patients, if your standard practice is to adjust for obesity, follow 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] **Prescribed energy needs** are to be calculated by using Indirect Calorimetry, a predictive equation, or a simple weight-based formula but on average, should not lead to a prescription of less than 30 kcal/kg. **Prescribed Protein needs** are to be calculated by using the following: • If > 50% burns, use 1.5g/kg/day to 2.5g/kg/day • If < 50% burns, use 1.2 g/kg/day to 2 gm/kg/day Note: Energy and protein requirements are independent of the formula prescribed. Do NOT change prescription to accommodate a formula change.
Prescription Date	Enter the date of the prescription in the format yyyy-mm-dd.
Prescribed Energy and Protein needs	Enter the prescribed daily energy needs in calories (kcal). Enter the prescribed daily protein needs in grams.
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 prescription date and 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 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 and time EN was started. If EN started after Day 12, select EN not initiated during first 12 days in ACU
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.)
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 and time 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 d/c on PN, record ACU d/c as stop date & time.)

THE RE–*ENERGIZE* STUDY

Randomization Number

Nutrition Assessment

Baseline **Date prescription made**	(yyyy-mm-dd)	
Prescribed Energy Needs	kcal	
Prescribed Protein Needs	grams	
Was another prescription made?	☐ Yes ☐ No	
Only record prescription changes for this patient made from ACU admission to Study Day 12. **Note: Energy and protein requirements are independent of the formula prescribed.** **Do NOT change prescription to accommodate a formula change**.		
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	
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) (24 hour clock)
EN Stop date and time: If 'Actual EN Stop date & time' selected or if patient discharged from ACU on EN	Select one: ❑ Same as death date & time ❑ Still receiving EN 12 days post ACU admission ❑ Actual EN stop date & time	
Enter date & time:	(yyyy-mm-dd)	(hh:mm) (24 hour clock)
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) (24 hour clock)
PN Stop date and time: If 'Actual PN Stop date & time' selected or if patient discharged from ACU on PN	Select one: ❑ Same as death date & time ❑ Still receiving PN 12 days post ACU admission ❑ Actual PN stop date & time	
Enter date & time:	(yyyy-mm-dd)	(hh:mm) (24 hour clock)

Daily Nutrition Instructions

Randomization Number

General Instructions	These data are collected to determine the adequacy of all types of nutrition (calories and protein) received.
Duration of Data Collection	These data are to be collected daily from **Study Day 1 (ACU admission) until Study Day 12**, or ACU discharge or 3 months after ACU admission, whichever comes first.
Date	Enter the dates corresponding to the calendar day.
Enteral Nutrition Today? ***(If 'No')***	For each day, indicate whether the patient received enteral nutrition (EN), Yes or No. **If 'No'** to Enteral Nutrition, using the list below, indicate ALL the reason(s) the patient did not receive EN on the specified Study day by placing the number(s) in the box(es) provided: ❑ NPO for endotracheal extubation or intubation or other bedside procedure. If 'Other' is indicated, please also check the 'Other' box and specify the reason. ❑ 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 , please specify_____
Enteral Nutrition Today? ***(If 'Yes')*** **Formula**	**If 'Yes'** to EN, 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).
Protein Supplements	Record whether a protein supplement was received, 'Yes' or 'No'. You may record 2 different protein supplements each day. If a protein supplement was received, 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 and protein received from protein supplements.
Do Not use formulas that are listed with (restricted) beside the name in REDCap.	
Parenteral Nutrition	For each day, indicate whether the patient received parenteral nutrition, Yes or No.
Total Kcals **Total Protein**	If 'Yes', record the total calories and grams of protein 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, 'Yes' or 'No'. 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 of EN, PN or neither received.
Total mL	If propofol received, record the **total volume in mL** received the 24 hour period.
Insulin	Record if insulin was received, '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: IV, subcutaneous and bolus.
Opiates	Record if any opiates were received, 'Yes' or 'No'. If the information is not documented, select 'Not Available'.
Motility agents	Record if any motility agents were received, 'Yes' or 'No'. 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

Daily Nutrition

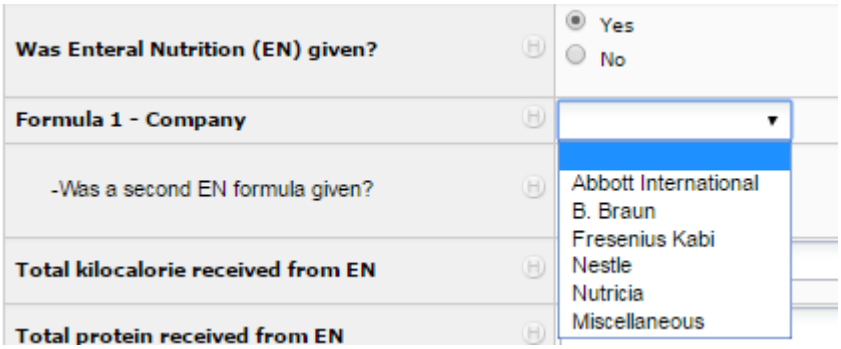
Randomization Number

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

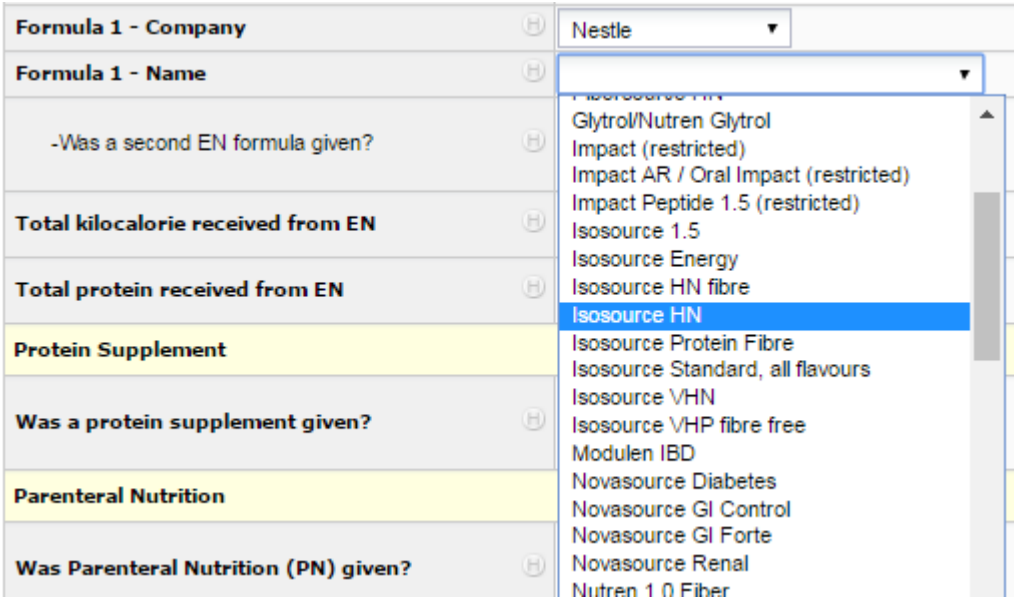
Date (yyyy-mm-dd)				
Enteral Nutrition (EN) given?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If EN NOT received (Select all that apply)				
NPO for endotracheal extubation or intubation or other bedside procedure	☐	☐	☐	☐
NPO for operating procedure	☐	☐	☐	☐
NPO for radiology procedure	☐	☐	☐	☐
High 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 (Please specify)				
If 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				
Total Protein from EN				
Protein Supplement given?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Protein Supplement Name(s)				
Total Calories from Protein Supplement				
Total Protein from Protein Supplement				
Parenteral Nutrition (PN) given?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Total Calories from PN				
Total Protein from PN				
Oral Nutrition given?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Medications				
Propofol received for ≥ 6 hours?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Volume of propofol received (mL)				
Insulin received?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Insulin total dose in units				
Opiates received?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Motility Agents (metoclopramide, erythromycin, domperidone, other) **received?**	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

ENTERAL NUTRITION FORMULAS

There are over 400 EN Formulas listed in REDCap. Select the company, choose ‘Miscellaneous’ if company is not listed.



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



Burn Related Operative Procedures Instructions

General Instructions	These data are collected to determine the frequency and type of burn related operative procedures that the patient undergoes during the study. **Note**: These data only need to be completed on study days that a burn related operative procedure is performed.
Duration of Data Collection	Record all burn related operative procedures from Study Day 1 (ACU admit) to ≥ 10 days post last successful grafting (stop of study IP + 3 days) or ACU discharge or 3 months from ACU admission, whichever comes first.
Date	Enter the date corresponding to the calendar day that the operative procedure was performed.
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 appropriate box.
Type of Operative Procedure	Select the type(s) of operative procedure(s) performed on the date indicated from the taxonomy provided. If a procedure was performed that is not in the taxonomy, 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 (example amputation) _____

Burn Related Operative Procedures

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 Instructions

General Instructions	These data are collected to capture relevant medications that the patient received that may have a material effect on the measured outcomes of the study. Note: administration of propofol; insulin; opiates, and motility agents is recorded on the Daily Nutrition form.
Duration of Data Collection	Record all concomitant medications started from ACU admission until ≥ 10 Days after the last grafting operation (stop of study IP + 3 days) or discharge from the ACU or 3 months after admission to the ACU, whichever comes first.
Date	Enter the date corresponding to the calendar day.
Heart Rate **Highest** **Lowest**	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 concomitant medications were received, 'Yes' or 'No'. If the information is not documented, select 'Not Available'. Select 'Yes' to open the form and record the concomitant medications received.
Oxandrolone, Nandrolone and Testosterone	Indicate if Oxandrolone, Nandrolone, or Testosterone was received by selecting the appropriate 'Yes' 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, 'Yes' or 'No'. If the information is not documented, select 'Not Available'.

THE RE–ENERGIZE STUDY

Concomitant Medications

____
Randomization Number

Page #:_____

Date (yyyy-mm-dd)					
Heart Rate					
Highest Heart Rate					
Lowest Heart Rate					
Concomitant Medications					
Were Concomitant Medications 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, Oxandrolone ☐ Yes, Nandrolone ☐ Yes, Testosterone ☐ No ☐ Not available	☐ Yes, Oxandrolone ☐ Yes, Nandrolone ☐ Yes, Testosterone ☐ No ☐ Not available	☐ Yes, Oxandrolone ☐ Yes, Nandrolone ☐ Yes, Testosterone ☐ No ☐ Not available	☐ Yes, Oxandrolone ☐ Yes, Nandrolone ☐ Yes, Testosterone ☐ No ☐ Not available	☐ Yes, Oxandrolone ☐ Yes, Nandrolone ☐ Yes, Testosterone ☐ 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					
Highest Heart Rate					
Lowest Heart Rate					
Concomitant Medications					
Were Concomitant Medications 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, Oxandrolone ☐ Yes, Nandrolone ☐ Yes, Testosterone ☐ No ☐ Not available	☐ Yes, Oxandrolone ☐ Yes, Nandrolone ☐ Yes, Testosterone ☐ No ☐ Not available	☐ Yes, Oxandrolone ☐ Yes, Nandrolone ☐ Yes, Testosterone ☐ No ☐ Not available	☐ Yes, Oxandrolone ☐ Yes, Nandrolone ☐ Yes, Testosterone ☐ No ☐ Not available	☐ Yes, Oxandrolone ☐ Yes, Nandrolone ☐ Yes, Testosterone ☐ 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

<table>
<tr><td>General Instructions & Duration of Data Collection</td><td>These data are collected to assist in determining the incidence of ACU acquired infections. Record Gram negative bacteremias only.

Only record venous or arterial blood cultures that test positive for Gram negative bacteria that occurred >72 hours after ACU admission until ≥ 10 days post last successful grafting (stop of study IP + 3 days) or ACU discharge or 3 months after ACU admission, whichever comes first.

Do not include blood from a catheter line tip.</td></tr>
<tr><td>Date sample collected</td><td>Record the date the sample was collected (i.e. not when the results were reported) in the date format of yyyy-mm-dd.</td></tr>
<tr><td>Time sample collected</td><td>Record the time the sample was collected (i.e. not the time the results were reported) in the format of hh:mm.</td></tr>
<tr><td>Gram Negative Culture Species</td><td>Select all Gram negative bacteremias reported each study day, refer to the table below. Do Not record Gram Positive bacteria reported, see table below:
<table>
<tr><th colspan="4">Gram Negative Bacteria</th></tr>
<tr><td>1</td><td>Acinetobacter sp.</td><td>23</td><td>Legionella sp.</td></tr>
<tr><td>2</td><td>Aeromonas sp.</td><td>24</td><td>Moraxella sp.</td></tr>
<tr><td>3</td><td>Alcaligenes sp.</td><td>25</td><td>Morganella sp.</td></tr>
<tr><td>4</td><td>Bacteroides sp.</td><td>26</td><td>Mycoplasma sp.</td></tr>
<tr><td>5</td><td>Bartonella sp.</td><td>27</td><td>Neisseria sp.</td></tr>
<tr><td>6</td><td>Bortetella sp.</td><td>28</td><td>Pasteurella sp.</td></tr>
<tr><td>7</td><td>Burkholderia sp.</td><td>29</td><td>Porphyromonas sp.</td></tr>
<tr><td>8</td><td>Campylobacter sp.</td><td>30</td><td>Prevotella sp.</td></tr>
<tr><td>9</td><td>Capnocytophaga sp</td><td>31</td><td>Proteus sp.</td></tr>
<tr><td>10</td><td>Chlamydia sp.</td><td>32</td><td>Providencia sp.</td></tr>
<tr><td>11</td><td>Citrobacter sp.</td><td>33</td><td>Pseudomonas sp.</td></tr>
<tr><td>12</td><td>Coxiella sp.</td><td>34</td><td>Ralstonia sp.</td></tr>
<tr><td>13</td><td>Ehrlichia sp.</td><td>35</td><td>Rickettsia sp.</td></tr>
<tr><td>14</td><td>Eikenella sp.</td><td>36</td><td>Salmonella sp.</td></tr>
<tr><td>15</td><td>Enterobacter sp.</td><td>37</td><td>Salmonella sp.</td></tr>
<tr><td>16</td><td>Escherichia sp.</td><td>38</td><td>Serratia sp.</td></tr>
<tr><td>17</td><td>Francisella sp.</td><td>39</td><td>Shigella sp.</td></tr>
<tr><td>18</td><td>Fusobacterium sp.</td><td>40</td><td>Stenotrophomonas sp</td></tr>
<tr><td>19</td><td>Hafnia sp.</td><td>41</td><td>Streptobacillus sp.</td></tr>
<tr><td>20</td><td>Helicobacter sp.</td><td>42</td><td>Vibrio sp</td></tr>
<tr><td>21</td><td>Haemophilus sp.</td><td>43</td><td>Yersinia sp.</td></tr>
<tr><td>22</td><td>Klebsiella sp.</td><td>44</td><td>Other, please specify</td></tr>
</table>
<table>
<tr><th>Gram Positive Bacteria (Do NOT include)</th></tr>
<tr><td>Actinomyces sp.</td></tr>
<tr><td>Aerococcus sp.</td></tr>
<tr><td>Bacillus sp.</td></tr>
<tr><td>Clostridium sp.</td></tr>
<tr><td>Corynobacterium sp.</td></tr>
<tr><td>Diphteroids sp.</td></tr>
<tr><td>Enterococcus sp.</td></tr>
<tr><td>Erysipelothrix sp.</td></tr>
<tr><td>Lactobacillus sp.</td></tr>
<tr><td>Listeria sp.</td></tr>
<tr><td>Nocardia sp.</td></tr>
<tr><td>Peptostreptococcus/ Peptococcus sp.</td></tr>
<tr><td>Propionibacterium sp.</td></tr>
<tr><td>Rhodococcus sp.</td></tr>
<tr><td>Staphylococcus sp.</td></tr>
<tr><td>Streptococcus sp.</td></tr>
</table></td></tr>
<tr><td>Was there another Gram negative culture today?</td><td>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.</td></tr>
</table>

THE RE–*ENERGIZE* STUDY

Randomization Number

Microbiology

ONLY record venous or arterial blood cultures that test positive for Gram negative bacterimia.

Date (yyyy-mm-dd)					
1) Time (hh:mm)					
-Gram Negative Culture Number(s)					
2) Time (hh:mm)					
-Gram Negative Culture Number(s)					
3) Time (hh:mm)					
-Gram Negative Culture Number(s)					
4) Time (hh:mm)					
-Gram Negative Culture Number(s)					
5) Time (hh:mm)					
-Gram Negative Culture Number(s)					

Date (yyyy-mm-dd)					
1) Time (hh:mm)					
-Gram Negative Culture Number(s)					
2) Time (hh:mm)					
-Gram Negative Culture Number(s)					
3) Time (hh:mm)					
-Gram Negative Culture Number(s)					
4) Time (hh:mm)					
-Gram Negative Culture Number(s)					
5) Time (hh:mm)					
-Gram Negative Culture Number(s)					

Protocol Violation Instructions

Protocol Violation Definition	**A Protocol Violation 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.** **For THE RE-ENERGIZE Study, a Protocol Violation occurs when any 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 5) Unapproved EN formula given 6) Other, please specify in the space provided.
General Instructions	Complete Protocol Violation (PV) forms in REDCap™ within 24 hours of becoming aware of the violation. Only complete the PV form on days you are reporting a protocol violation.
Duration of Data Collection (when to report)	Protocol violations are to be reported from randomization until ≥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 NOT have to be reported on the following days: ▪ Day of randomization ▪ Day of discharge or end of study treatment (≥ 7 days post last successful graft) ▪ Day of death
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.
Date Violation Occurred	Enter the date when the violation occurred. Enter the PV data in REDCap™ on the Study Day corresponding to the date the PV occurred.
Date Violation Discovered	Enter the date when the violation was identified by site research staff.
Local Investigator Aware?	Indicate whether the local qualified investigator has been made aware of this violation, 'Yes' or 'No'.
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) _____
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.
Action taken by RC	Describe the action taken by the Research Coordinator/responsible delegate to prevent violation/problem from recurring.
Another Protocol Violation to add?	Indicate if you have another Protocol Violation to add, 'Yes' or 'No'. Select 'Yes' to open the next PV form and enter the data. Report up to 6 PVs per day. If you have more than 6 PVs to report on one study day, contact the Project Leader.

THE RE–*ENERGIZE* STUDY

Protocol Violation Form

Randomization Number _____

Date PV occurred	(yyyy-mm-dd)
Are you Reporting a Protocol Violation today?	☐ Yes ☐ No
Protocol Violation #1 **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) _____
Are there supporting files to be emailed (preferred) or faxed? **IMPORTANT:** Remember to de-identify all documents before emailing or faxing.	❑ Yes, by email (preferred) ❑ Yes, by fax ❑ No
Action taken by Research Coordinator/Responsible Delegate	
Another Protocol Violation to add?	☐ Yes ☐ No
Protocol Violation #2 **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) _____
Are there supporting files to be emailed (preferred) or faxed? **IMPORTANT:** Remember to de-identify all documents before emailing or faxing.	❑ Yes, by email (preferred) ❑ Yes, by fax ❑ No
Action taken by Research Coordinator/Responsible Delegate	
Another Protocol Violation to add?	☐ Yes ☐ No

Hospitalization Overview Instructions

General Instructions **Duration of Data Collection**	These data are collected to determine clinical outcomes related to length of stay and mortality. These data are to be collected once.
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 ACU discharge (< 3 mo.) • Still receiving grafts in ACU at 3 months • Other, specify: _____
ACU Stay **Was Consent withdrawn/denied during this ACU stay?**	If consent was withdrawn or denied during this ACU stay, indicate by selecting 'Yes'. Enter the date and time consent was withdrawn/denied and select the type of withdrawal/denial: • 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?	Select the appropriate response to indicate if the patient died during this ACU stay, was discharged, or is still in ACU at 3 months from admission: ▪ **Yes** *Record the death date, time, and cause of death.* *Note: Record the death date and time documented on the death certificate. If this information is not available, record the date and time from the physician note. If the latter is not provided, record the date and time documented in the nurse's charting.* *Document the cause of death from a post mortem report. If this is not available, record cause of death from the death certificate.* ▪ **No, Patient Discharged** *Enter the date and time the patient was actually discharged from the ACU.* ▪ **No, Patient Still in ACU At 3 months**

Was the patient re-admitted to the ACU? (before being discharged from hospital)	Indicate if the patient was readmitted to your ACU from within your hospital. 'Yes' or 'No'. If 'Yes', the patient was re-admitted to your ACU from another ward in your hospital:
	
	• Enter the re-admission date and time.
	• Indicate if consent was withdrawn/denied during this ACU stay. If 'Yes', enter the date and time and the type of withdrawal/denial:
	  o Stop collection (keep previous data)
	  o Stop data collection (discard previous data)
	• Repeat steps above for responses to 'Did the patient die during this ACU stay?'
	
	Record up to 5 ACU admissions (including the 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.

Hospitalization Overview Instructions (continued)

Hospital Stay **Was Consent withdrawn/denied during this Hospital stay?**	If consent was withdrawn or denied during this Hospital stay, indicate by selecting 'Yes'. Enter the date and time consent was withdrawn/denied and select the type of withdrawal/denial: • Stop data collection (keep previous data) • Stop data collection (discard previous data)
Hospital discharge **(Did the patient die in Hospital?)** **d/c Time not available?** **Discharged to**	Select the appropriate response to indicate if the patient died in hospital, was discharged, or is still in hospital at 3 months from admission: ▪ **Yes** *Record the death date, time, and cause of death.* *Note: Record the death date and time documented on the death certificate. If this information is not available, record the date and time from the physician note. If the latter is not provided, record the date and time documented in the nurse's charting. Document the cause of death from a post mortem report. If this is not available, record cause of death from the death certificate.* ▪ **No, Patient Discharged** *Enter the date and time the patient was actually discharged from the Hospital.* *If the hospital discharge time is not documented, 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 _____ ▪ **No, Patient Still in ACU At 3 months**

THE RE–*ENERGIZE* STUDY

Randomization Number

Hospitalization Overview

LAST SUCCESSFUL GRAFT	
Was the last successful graft achieved?	☐ Yes ☐ No ☐ Not Available – Consent withdrawn for data collection
If Yes, Date of last successful graft	(yyyy-mm-dd)
If No, reason last successful graft never achieved:	☐ Death ☐ Withdrew Life Sustaining Therapies ☐ Discharged without receiving a graft ☐ Receiving grafts after ACU discharge (< 3 mo.) ☐ Still receiving grafts in ACU at 3 months ☐ Other, specify: _____

ACU Stay		**Date (yyyy-mm-dd)**	**Time (24 hour clock)**
Was consent withdrawn or denied during the ACU stay?	☐ If yes, record the date and time consent was withdrawn/denied		
Select the type of withdrawal/denial:	❑ 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 in the ACU?	☐ If yes, record the death date/time		
	☐ If the patient discharged from the ACU, record the ACU discharge date/time		
	☐ The patient was still in the ACU at 3 months		
Was the patient re-admitted to the ACU?	☐ If yes, record the date and time the patient was re-admitted		

ACU Stay #2		**Date (yyyy-mm-dd)**	**Time (24 hour clock)**
Was consent withdrawn or denied during the ACU stay?	☐ If yes, record the date and time consent was withdrawn/denied		
Select the type of withdrawal/denial:	❑ Stop data collection (keep previous data) ❑ Stop data collection (discard previous data)		
Did the patient die in the ACU?	☐ If yes, record the death date/time		
	☐ If the patient discharged from the ACU, record the ACU discharge date/time		
	☐ The patient was still in the ACU at 3 months		
Was the patient re-admitted to the ACU?			

Hospitalization Overview (cont.)

Hospital discharge		**Date (yyyy-mm-dd)**	**Time (24 hour clock)**
Was consent withdrawn or denied during the ACU stay?	☐ If yes, record the date and time consent was withdrawn/denied		
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?	☐ If yes, record the death date/time		
	☐ If the patient discharged from the hospital, record the hospital discharge date/time		
	☐ The 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: _____

_____

_____

Month 6 Survival Assessment Instructions

General Information **Duration of Data Collection**	These data are collected to determine survival 6 months after the patient was admitted to the ACU. **Every effort must be made to obtain survival status.** Refer to the Follow-up Procedures manual regarding patient retention procedures. Survival assessment is to be conducted at 6 months (± 14 days) after ACU admission.
Was the Survival Status Obtained?	Record whether the survival status of the patient was obtained, 'Yes' or 'No'.
Date Survival Status Obtained	If 'Yes', record the date of contact or information retrieval in the format *yyyy-mm-dd*.
Source of information	Record the source of the survival status information. ☐ Patient ☐ Alternative contact person(s) (Specify relationship) ☐ Family Physician ☐ Medical Records ☐ Obituaries ☐ Internet ☐ Other (specify) _____
Survival Status	Record the survival status of the patient, 'Alive' or 'Deceased'. ☐ Alive ☐ Deceased
Survival Status NOT Obtained	If 'No', confirm that all the listed avenues to access the patient survival status were completed: ☐ 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) Record all attempts to contact the patient and/or alternate contact person(s) on the '**Month 6 Follow-up Assessments: Contact Log**'
Last date known to be alive	If survival status was not obtained, record the last date the patient was known to be alive.

Month 6 Survival Assessment

Was the Survival Status Obtained?	☐ Yes ☐ No
Survival Status Obtained	
Date of Contact/ Information retrieval	(yyyy-mm-dd)
Source of Information (Select one)	☐ Patient ☐ Alternate Contact Person (Specify relationship) _____ ☐ Family Physician ☐ Medical Records ☐ Obituaries ☐ Internet ☐ Other (Please 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)
Survival Status 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)

Month 6 Follow-up Assessments: Contact Log Instructions

General Information	**Do NOT complete this form if Survival Status was obtained.** Record all contacts and attempted contacts with the patient/alternate contact person(s) for the Month 6 follow-up assessments on this log. There must be at least 3 attempts to conduct the follow-up assessments. Completion of all 3 questionnaires is estimated to take 30 minutes. Each questionnaire may be completed on different days or at different times if need be. It is strongly recommended to schedule time in advance with the patient/alternate contact person(s) to ensure her/his availability.
Duration of Data Collection	These data are collected once 6 months (± 14 days) after ACU admission.
Booking Follow-up Appointment	Indicate if the patient/alternate person(s) was contacted in advance to book an appointment for the follow-up visit, 'Yes' or 'No'. If 'Yes', enter the date the patient/alternate person(s) contacted. If 'No', record the reason in the space provided.
Contact Attempts	Indicate who was attempted to be contacted and how many times. The appropriate number of fields will open in REDCap. ☐ Patient ☐ Alternate contact person(s) ☐ Both Patient and Alternate ☐ No attempts were made If No attempts were made to contact the patient/alternate person(s), record the reason follow-up contact was not attempted: ☐ Missed ☐ No RC at site ☐ Other (specify) _____
Date and Time of Contact	Record the date and time of each contact attempt. If you cannot reach the patient/alternate contact person(s) try a different time at each attempt.
Contact Methods	Record all methods used to contact the patient/alternate person(s).
Alternate Contact Relationship to Patient	Record the relationship of the alternate contact person to the patient, if 'Other' specify in the space provide.

THE RE–*ENERGIZE* STUDY

Randomization Number

Month 6 Follow-up Assessments: Contact Log

	Booking Month 6 Follow-up (should be at least 2 weeks in advanced)
Was the patient/alternate(s) contacted in advance to book an appointment for the follow-up visit?	☐ Yes ☐ No
Date patient/alternate contacted	(yyyy-mm-dd)
Reason appointment not booked	
Who did you contact or attempt to contact for this follow-up?	☐ Patient ☐ Alternate contact person(s) ☐ Both Patient and Alternate ☐ No attempts were made
If no attempts, **Reason follow-up not attempted:**	☐ Missed ☐ No RC (research coordinator) at site ☐ Other (specify) _____

	Attempt 1	**Attempt 2**	**Attempt 3**
Date of Contact (yyyy-mm-dd)			
Time (hh:mm)			
Patient Contact Method (Select all that apply)	☐ In person with patient ☐ Called patient (cell) ☐ Called patient (work) ☐ Called patient (home) ☐ Other (specify)	☐ In person with patient ☐ Called patient (cell) ☐ Called patient (work) ☐ Called patient (home) ☐ Other (specify)	☐ In person with patient ☐ Called patient (cell) ☐ Called patient (work) ☐ Called patient (home) ☐ Other (specify)
Alternate contact person(s) method (Select all that apply)	☐ In person with alt. ☐ Called alt. (cell) ☐ Called alt. (work) ☐ Called alt. (home) ☐ Other (specify)	☐ In person with alt. ☐ Called alt. (cell) ☐ Called alt. (work) ☐ Called alt. (home) ☐ Other (specify)	☐ In person with alt. ☐ Called alt. (cell) ☐ Called alt. (work) ☐ Called alt. (home) ☐ Other (specify)
Relationship of alternate contact person(s) to patient (Select all that apply)	☐ Spouse/Partner ☐ Parent ☐ Child ☐ Friend ☐ Other (specify)	☐ Spouse/Partner ☐ Parent ☐ Child ☐ Friend ☐ Other (specify)	☐ Spouse/Partner ☐ Parent ☐ Child ☐ Friend ☐ Other (specify)

Month 6 Follow-up Assessment Questionnaires

General Information	These data are collected to assess the patients health-related quality of life and activities of daily living at the 6 month follow up interval. Refer to the Follow-up Procedures manual regarding patient retention procedures and suggested telephone scripts.
Duration of Data Collection	SF-36, ADL, and IADL status assessments are to be conducted at 6 months (± 14 days) after ACU admission. Every effort must be made to complete these questionnaires. **NOTE**: Late data is better than missing data.
Questionnaire completed?	For each, indicate if the questionnaire was completed, 'Yes, or 'No'. If 'Yes', enter the date completed and by whom, Patient or Alternate. If 'No', indicate the reason: ☐ Deceased *(Record date 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	Read the explanation at the top of the survey to the patient. Ensure the patient understands 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. Read each question to the patient followed by the response options. 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. Read the definitions of 'Independence' and 'Dependence' to the patient as stated on the top of the Katz ADL form. 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. Based on the patient's response, record either 1 or 0 in the space provided for each activity.
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'*. Read each of the 8 activities to the patient followed by the response options. Remind the patient to indicate her/his highest functional ability. Allow the patient to make her/his own determination. Circle the corresponding number on the form.
Maintain Worksheets	Keep the completed worksheets with the patient study files, these are your source documentation.

THE RE–*ENERGIZE* STUDY

SF-36

_____
RANDOMIZATION NUMBER

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 ☒ 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 ▼
☐	☐	☐	☐	☐	☐

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

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

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 ▼
☐	☐	☐	☐	☐	☐

7. How much bodily pain would you say you had during the past 4 weeks?

None	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	A little bit	Moderately	Quite a bit	Extremely	Note 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?	☐	☐	☐	☐	☐	☐

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

ADL

_____
Randomization Number

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)

Katz Index of Independence in Activities of Daily Living

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

THE RE-ENERGIZE STUDY

IADL

_____
Randomization Number

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)

Lawton Instrumental Activities of Daily Living (IADLs)

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

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

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 REDCAP generated Investigator Confirmation Form has been signed and dated, please send the completed form to: **Maureen Dansereau** Clinical Evaluation Research Unit danserem@kgh.kari.net

THE RE–*ENERGIZE* STUDY

Randomization Number

Investigator Confirmation Form
(Go to REDCAP for e-version)

The data collected in the RE-ENERGIZE Case Report Forms were 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

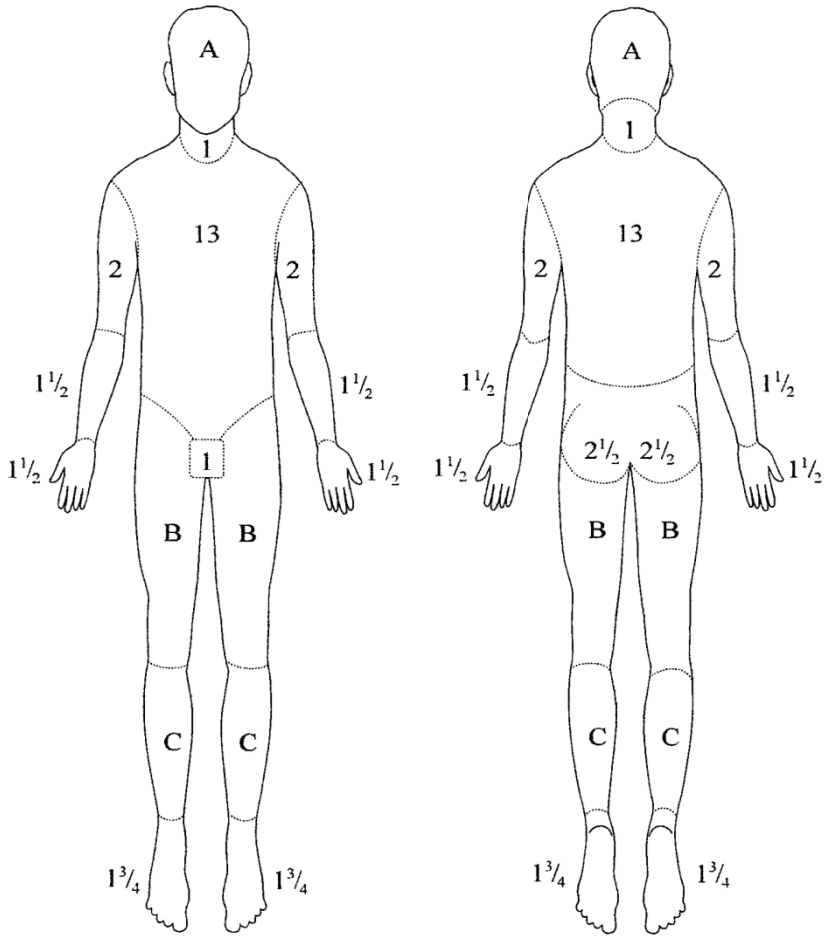
Date (yyyy-mm-dd)

Enrollment Number

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

THE RE-*ENERGIZE* STUDY