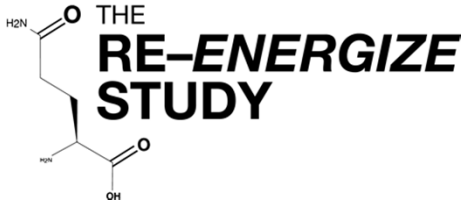
Randomization Number



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

01 September 2016

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 2015-09-08 at 23:59
Study Day 2 = 2015-09-09 from 00:00 to 2015-09-09 at 23:59

8. The duration of data collection and frequency will vary by form and is outlined as follows:

- **To be collected once:** Baseline, Organ Dysfunction, Initial Burn Assessment, Nutrition Assessment/Timing, Final Burn Assessment, Hospitalization Overview, 6 Month Follow-up to include Survival, SF-36, ADL, IADL, and Employment Status questionnaires.
- **To be collected from Study Day 1 (ACU admission) until 10 days post last successful grafting, or until ACU discharge, or 3 months from ACU admission, whichever comes first:**
  Daily: Daily Nutrition, Concomitant Medications, Microbiology (Gram-negative bacteremias).
  Daily from Study Day 1 through Study Day 14 and then weekly: Laboratory
- **To be collected from randomization until 7 days post last successful grafting, or until ACU discharge, or 3 months from ACU admission, whichever comes first:**
  Daily: Daily Monitoring (dose of study intervention received)
- **To be collected upon each occurrence:** Burn Related Operative Procedures, Mechanical Ventilation, Renal Replacement Therapy, Protocol Violations, Serious Adverse events
- **To be collected Weekly/other specified intervals:** Nutrition Assessment/timing,
  Refer to specific instructions for each worksheet.

9. 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 checking the N/A box on the worksheet and in REDCap™.

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

THE RE-*ENERGIZE* STUDY

Randomization Number

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 is made by the surgeon/physician and 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.)
• Frost bite
• Stevens-Johnson Syndrome (SJS)
• Toxic Epidermal Necrolysis (TEN)</td></tr>
</table></td></tr>
<tr><td>2. Patient meets one of the following 3 criteria:</td><td>This assessment is to be made by the surgeon/physician and must be confirmed by the SI or sub-I based on her/his clinical judgment. Refer to Appendix 1. Check only one box to indicate which of the 3 criteria is met.

<u>Eligibility Requirements</u>:
a) Patients 18 - 59 years of age with TBSA <u>></u> 20%.
b) Patients 18 - 59 years of age with TBSA <u>></u> 15% and with inhalation injury*.
c) Patients <u>></u> 60 years of age with TBSA <u>></u> 10% (with or without inhalation injury).

*Diagnosis of inhalation injury requires both of the following 2 criteria:
1. History of exposure to products of combustion
2. Bronchoscopy confirming one of the following:
a) Carbonaceous material
b) Edema or ulceration

When including a patient age 18 – 59 years with a 15% – 19.9 % TBSA with inhalation injury, there must be brochoscopic confirmation of inhalation injury.</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>

THE RE–*ENERGIZE* STUDY

Randomization Number

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 3 criteria:

   a. Patients 18 - 59 years of age with TBSA ≥20% ☐ a.
   b. Patients 18 - 59 years of age with TBSA ≥15% **WITH inhalation injury** ☐ b.
   c. Patients ≥ 60 years of age TBSA ≥ 10% (with or without inhalation injury) ☐ c.

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.

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 of 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

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 continuous administration of glutamine for 24 hours 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 (continuously) for >24 hours prior to randomization	☐ Yes ☐ No
12. Known allergy to maltodextrin, cornstarch, corn, corn products or glutamine	☐ Yes ☐ No

Pre Randomization / Randomization Instructions

<table>
<tr><td>General Instructions</td><td>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.</td></tr>
<tr><td>Patient Eligibility Confirmed by MD</td><td>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.</td></tr>
<tr><td>Consent
Reason consent not obtained

Consent Date and Time

Pre Burn Weight and Height</td><td>Confirm if the SDM or patient was approached for consent.
• If the SDM/patient was not approached for consent, indicate the reason why
<table><tr><th>Reason</th><th>Description</th></tr><tr><td>Next of kin or substitute decision maker not available</td><td>The SDM or legally acceptable representative was not available for consent discussion within the required time frame.</td></tr><tr><td>Missed the patient</td><td>The patient was not identified by the site coordinator in time to approach for consent. Example: the patient was admitted over a long weekend.</td></tr><tr><td>Language Barriers</td><td>The SDM was not approached because of language barriers. A certified translator was not present.</td></tr><tr><td>Family dynamics</td><td>The SDM was not approached due to emotional stress or complicated family dynamics.</td></tr><tr><td>Recommendation of the clinical team</td><td>Clinical team does not recommend putting this patient on the study.</td></tr><tr><td>CRS Unavailable</td><td>The Central Randomization System (CRS) is unavailable.</td></tr><tr><td>Pharmacy Unavailable</td><td>The pharmacy not available to prepare the investigational product.</td></tr><tr><td>Other (Please specify)</td><td>Specify the reason(s) for not obtaining consent that is not listed above. Example: patient received glutamine for >24 hrs before randomization</td></tr></table>▪ If approached for consent, was consent obtained from the SDM/patient?
• If No, record the most important reason consent was not obtained.
o 'Too Overwhelmed', 'Not interested', 'Did not respond (timed out)' or ‘Other' and specify the reason.
• If Yes, record the consent date/time and the patients height and weight
▪ Use patient’s pre-burn dry weight to avoid fluctuations due to large fluid shifts.
▪ Indicate how the weight and height were each obtained:
o Measured (obtained by a weighing scale)
o Estimated (obtained verbally from a healthcare professional or family)
o Record the height in cm and the weight in kg (to the nearest decimal point).</td></tr>
<tr><td>Randomization Date and Time</td><td>Log onto the Central Randomization System (CRS) to obtain the date and time of randomization.</td></tr>
</table>

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 one)	☐ 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	☐ 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/

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: We would like to monitor the number of subjects that are enrolled in the study who have a history of alcohol abuse. As such, please note that we have added 'alcohol abuse' to the Comorbidities list under the 'miscellaneous' category. Therefore if a subject has a documented history of alcohol abuse in the medical chart, it should be recorded in the CRF.
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 to be made by the attending surgeon/physician based on her/his clinical judgment and confrimed by the SI/sub-I. (Refer to Appendix 1). Record TBSA in the nearest whole number rounding up from 0.5 and down from 0.4; i.e. if 26.5% is reported, record as 27% and if 26.4% is reported, record as 26%.
Presence of Inhalation Injury	Indicate if the patient has an inhalation injury by selecting 'Yes' or 'No' Smoke inhalation injury is defined as: restricted to injury below the glottis caused by products of combustion. Diagnosis of inhalation injury requires both of the following: 1) history of exposure to products of combustion 2) bronchoscopy revealing one of the following below the glottis • Evidence of carbonaceous material • Signs of edema or ulceration
Vitamin C	Did the patient receive high dose Vitamin C as part of her/his resuscitation protocol (approximated as 66mg/kg/hr)? Y/N

THE RE–*ENERGIZE* STUDY

Randomization Number

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)	☐ 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	
Does the patient have an inhalation injury? *(Must be confirmed by bronchoscopy)*	☐ Yes ☐ No	
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 Parkinsons)

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

	Renal
	17. Moderate or severe renal disease

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

	Cancer/immune
	24. Any Tumor
	25. Lymphoma
	26. Leukemia
	27. AIDS
	28. Metastatic solid tumor

	Psychological
	29. Anxiety or Panic Disorders
	30. Depression

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

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

Organ Dysfunction Instructions

General Instructions	These data are collected once at baseline for calculation of modified SOFA score.
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 ❑ < 500 mL/day ❑ >= 500 mL/day ❑ Not Available

Organ Dysfunction (Baseline)

Date (yyyy-mm-dd)	
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 ❑ < 500 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. Indicate by selecting if start time is 'Not available'. 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 start of the 48 hour period as the stop date and time for this episode of invasive mechanical ventilation. 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, then select 'Still vented at Day 90'.
Mechanical Ventilation #2 Start	If the patient is restarted on Mechanical ventilation ≥ 48 hours after discontinuation of the last episode, select 'Yes' to the question '*Was mechanical ventilation re-instituted ≥ 48 hours from the last mechanical ventilation stop date/time?'* to access the data entry fields for another episode. Record the date and time invasive mechanical ventilation was restarted.
Stop	Record the date and time the invasive mechanical ventilation episode was discontinued (see episode #1 above for further instructions).
Mechanical Ventilation #3 - #5	Follow the instructions as listed for Mechanical Ventilation start # 2 and stop # 2 for the third, fourth, and fifth episodes of mechanical ventilation, if applicable.
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: ❑ 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 at Day 90		
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 at Day 90		
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 vented at Day 90		

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 _____

Burn Grafting Assessment Instructions

General Instructions	An assessment of the burn injury must be completed by the attending surgeon/physician twice during the study; once at the beginning of the study and once at the end of the study duration, defined as 10 days post last successful grafting, or ACU discharge, or 3 months from ACU admission, whichever occurs first.
Date of initial assessment	Record the date the initial grafting assessment was completed by the attending surgeon/delegate.
Initial Grafting Assessment	The surgeon/physician must assess the deep 2nd and/or 3rd degree burn using the Lund and Browder chart (see Appendix 1): to determine the percent Total Body Surface Area (%TBSA) expected to require grafting**. <u>This assessment must be confirmed by the SI or sub-I.</u>** • *Reminder: Deep 2nd and/or 3rd degree burn requiring grafting is an inclusion criteria. This should not be zero.*
Last Successful Graft	Indicate whether the last successful graft was achieved by selecting 'Yes' or 'No' 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 Consent (including consent for data collection) • 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: _____
Date of final/last assessment	Record the date of final/last grafting assessment was completed by the attending surgeon/physician. **<u>The assessment must be confirmed by the SI/sub-I</u>** and should be done at the end of the study duration, defined as 10 days post last successful graft, or ACU discharge, or 3 months after ACU admission, whichever occurs first.
Final/Last Grafting Assessment	A Final Grafting assessment must be completed on all patients, even if the patient is still receiving grafts or expected to receive additional grafts at the time of the assessment. ***Exception:*** *Do not record final assessment if 'Death' or 'Withdrew Consent' selected above.* <u>Area that required grafting</u> At the end of the study period, using the Lund and Browder chart, the surgeon/physician must assess the %TBSA that required grafting during the study period. This assessment must be confirmed by the SI or sub-I. If the patient is still receiving grafts at the time of the assessment, indicate the %TBSA that has required grafting to date. Note: Be sure to record the final assessment in percentage of total body surface area. This should not be 100% unless the patient's entire body received grafting.

THE RE–*ENERGIZE* STUDY

Randomization Number

Burn Grafting Assessment

INITIAL GRAFTING ASSESSMENT	
Date of initial assessment	(yyyy-mm-dd)
Deep partial/full thickness burn (expected to require grafting) *(Deep 2nd and/or 3rd degree burn requiring grafting is an inclusion criteria. This should not be zero.)*	% TBSA

LAST SUCCESSFUL GRAFT	
Was the last successful graft achieved?	☐ Yes ☐ No
If Yes, Date of last successful graft	(yyyy-mm-dd)
If No, reason last successful graft never achieved: If 'death' or 'withdrew consent' is indicated, do not record the Final Assessment.	☐ Death ☐ Withdrew Consent (including consent for data collection) ☐ 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: _____ _____

FINAL GRAFTING ASSESSMENT **to be done at or after 10 days post last successful grafting, or ACU discharge, or 3 months after admission to the ACU**	
Date of final assessment	(yyyy-mm-dd)
Area that required grafting (actual or total at the time of assessment)	% TBSA

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	Record the initial study intervention prescription in grams/day. Each packet contains 5 grams of study intervention. If 10 packets per day are to be given, enter 50 in the prescription box. If the study intervention prescription changes, record the new prescription and date/time the change occurred. NOTE: IP 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.**

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 prescription change during the study?	☐ Yes ☐ No	
If Yes, record the new prescription and the date/time of the change	grams/day	
	(yyyy-mm-dd)	(hh:mm) (24 hour clock)
If the prescription changed again, record the new prescription and the date/time of the change	grams/day	
	(yyyy-mm-dd)	(hh:mm) (24 hour clock)

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.
Prescribed # grams per day	At the top of each page record the number of grams per day of investigational product (IP) the patient is to receive. NOTE: This is to assist you in determining the daily percentage of IP received. This data is not captured in REDCap™ on the Daily Monitoring forms.
Date	Enter the date for which the data being collected.
# 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	Add the number of grams given at each interval and record the total number of grams administered for the day (for calculating percentage), 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 (documented at the top of the page) to determine the percentage of study intervention received. Record the percentage in the space provided.
Protocol Violation (IP dosing <80% over a 3 day average)	A protocol violation with the delivery of the study intervention occurs when the patient receives < 80% of the total 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 <u>Example</u>: <u>Dose received</u> Prescribed Dose: 35g/day Day 6: 30g 80% Prescribed: 28g Day 7: 20g Day 8: 30g Total dose received over 3 days = 80g 3 day average dose is 80 g/ 3 = 26.67g Report Day 7: Dose received is < 80% <u>AND</u> 3 day average is < 80 % Do Not report Day 6 or Day 8: 3 day average is <80% <u>BUT</u> Dose received is NOT <80% **In the event that the patient does not receive at least 80% prescribed daily dosage over a 3 day average, a Protocol Violation Form must be completed 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, d/c 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.
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.
PaO_2/FiO_2 (PF ratio)	Record the lowest PaO_2/FiO_2 (PF ratio) observed on the study day. The PaO_2 and FiO_2 values should come from the same blood gas measurement. If no PF ratio record N/A
Glucose closest to 08:00	Record the glucose closest to 8am observed on the study day ± 6 hrs (i.e. from 02:00 to 14:00 hrs).
Ammonia (highest)	Record the highest blood ammonia level reported on the study day.
Albumin (highest)	Record the highest serum albumin observed on the study day.
Lactate (highest)	Record the highest lactate level observed on the study day. If not available record n/a in the box.
Platelets (lowest)	Record the lowest serum platelets observed on the study day.
WBC (highest)	Record the highest white blood count observed on the study day. If there is only one value recorded for the 24 hr period then record the one value as both the highest and lowest.
WBC (lowest)	Record the lowest white blood count observed on the study day. If there is only one value recorded for the 24 hr period then record the one value as both the highest and lowest.
For each requested result above, if there is no value available to record, indicate by entering 'N/A' in the space provided.	

Laboratory

Date (yyyy-mm-dd)					
Creatinine, serum (highest)					
T-bilirubin (highest)					
Urea (highest)					
PaO2/FiO2 (lowest)					
Glucose closest to 08:00 am					
Ammonia (highest)					
Albumin (highest)					
Lactate (highest)					
Platelets (lowest)					
WBC (highest)					
WBC (lowest)					

THE RE–*ENERGIZE* STUDY

Randomization Number

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.
Prescribed Energy and Protein needs	**Contact your dietitian to obtain this information.** These will need to be calculated by the dietitian at baseline (ACU admission or at the first dietitian assessment) and thereafter. **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. Use pre-burn weight. For Obese patients, if your standard practice is to adjust weight for obesity, use the weight you would use. If not, use ideal body weight. Please ask your dietitian for more details. **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 • Use pre-burn weight. For Obese patients, if your standard practice is to adjust weight for obesity, use the weight you would use. If not, use ideal body weight. Please ask you dietitian for more details. If the prescribed energy or prescribed protein intake changes from week to week, record this in the appropriate row (Assessment #2, #3, etc) and record the date the prescription changed. If the prescription changes after the collection of daily data has stopped, you do not need to record the prescription change. If there are no changes in the prescription from baseline, place a check in the 'No change from baseline' box Note: Energy and protein requirements are independent of the formula prescribed. Do NOT change prescription to accommodate a formula change.
Enteral Nutrition	If the patient did not receive enteral nutrition during this ACU admission, place a √ in the box titled 'Never received EN during this ACU admission'. If the patient received Enteral nutrition, record the following: • the start date and time of enteral nutrition. • the stop date and time of enteral nutrition. This refers to the date enteral nutrition was permanently discontinued, not stopped for temporary interruptions. If enteral nutrition is continued beyond ACU discharge, record ACU discharge date and time as the date and time that enteral nutrition was stopped. If the patient is still receiving enteral nutrition in the ACU at 3 months, place a √ in the box titled 'Still on EN at 3 months in ACU'.
Parenteral Nutrition	If the patient did not receive parenteral nutrition during this ACU admission, place a √ in the box titled 'Never received PN during this ACU admission'.. If the patient received parenteral nutrition, record the following: • the start date and time of parenteral nutrition. • the stop date and time of parenteral nutrition. This refers to the date parenteral nutrition was permanently discontinued, not stopped for temporary interruptions. If parenteral nutrition is continued beyond ACU discharge, record ACU discharge date and time as the date and time that parenteral nutrition was stopped. If the patient is still receiving parenteral nutrition in the ACU at 3 months, place a √ in the box titled 'Still on PN at 3 months in ACU'.

THE RE–*ENERGIZE* STUDY

Randomization Number

Nutrition Assessment

Date baseline prescription made 2 0 ___ ___ ___ ___ ___ ___
Y Y Y Y M M D D

Total Calories Prescribed: _____ kcal

Total Protein Prescribed: _____ grams

If the prescription changes for this patient, enter the date and new prescription below:
Note: Energy and protein requirements are independent of the formula prescribed.
Do NOT change prescription to accommodate a formula change.

Date baseline prescription made 2 0 ___ ___ ___ ___ ___ ___
Y Y Y Y M M D D

Total Calories Prescribed: _____ kcal

Total Protein Prescribed: _____ grams

Date baseline prescription made 2 0 ___ ___ ___ ___ ___ ___
Y Y Y Y M M D D

Total Calories Prescribed: _____ kcal

Total Protein Prescribed: _____ grams

Nutrition Timing

Enteral Nutrition

☐ Never received EN during this ACU admission

☐ Still on EN at 3 months in ACU

Date and time enteral nutrition started

2 0 ___ ___ ___ ___ ___ ___ : ___ ___
Y Y Y Y M M D D H H M M
(24 hour clock)

Date and time enteral nutrition stopped

2 0 ___ ___ ___ ___ ___ ___ : ___ ___
Y Y Y Y M M D D H H M M
(24 hour clock)

Parenteral Nutrition

☐ Never received PN during this ACU admission

☐ Still on PN at 3 months in ACU

Date and time parenteral nutrition started

2 0 ___ ___ ___ ___ ___ ___ : ___ ___
Y Y Y Y M M D D H H M M
(24 hour clock)

Date and time parenteral nutrition stopped

2 0 ___ ___ ___ ___ ___ ___ : ___ ___
Y Y Y Y M M D D H H M M
(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 10 days post last successful grafting or ACU discharge or 3 months from 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 in a 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 dropdownlist, 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
Total kcals **Total Protein**	Record the total calories (kilocalories) and protein from all the EN formulas received in the study day. • Do not include the calories from IV solutions, e.g. Dextrose (collected separately). • 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'. If protein supplement was received, enter the name of the protein supplement given. If there is more than one protein supplement, record the name of each supplement. Record the total calories and protein received from protein supplements.
Parenteral Nutrition today? **Total Kcals** **Total Protein**	For each day, indicate whether the patient received parenteral nutrition, Yes or No. If yes, record the total calories and grams of protein received from parenteral nutrition. Do not record calories from IV fluids (e.g. Dextrose) or Propofol volume here.
Oral feeding today? **Adequacy of Intake**	Indicate whether the patient received any oral intake today, Yes or No Select the adequacy of intake from oral nutrition as a percentage of prescribed : **0 – 24% / 25 – 49% / 50 – 74% / >75% / Unknown**
Propofol today? **Total mL**	Indicate whether the patient received a continuous infusion of Propofol for ≥ 6hrs, Yes or No. If 'Yes', record the volume of propofol received in mL). This is to be completed for each day regardless of whether the patient received enteral nutrition, parenteral nutrition or neither.

THE RE–ENERGIZE STUDY

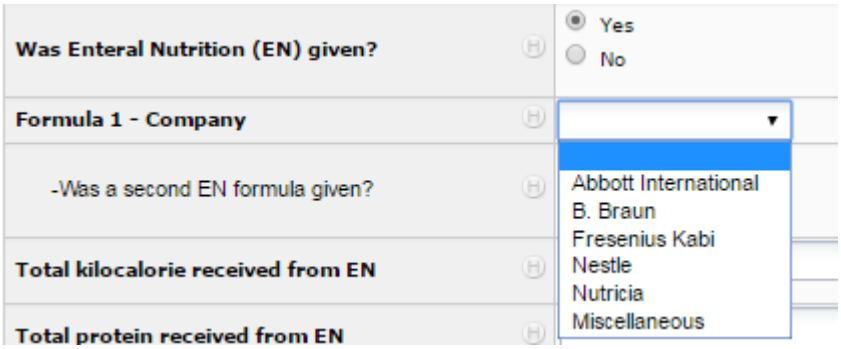
Daily Nutrition

____
Randomization Number
Page #:_____

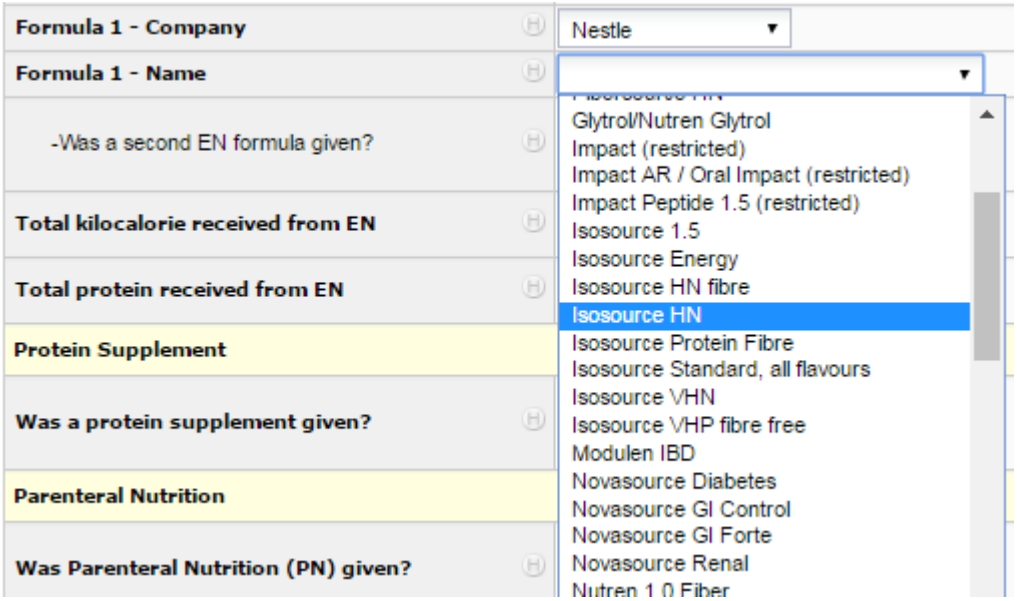
Date (yyyy-mm-dd)					
EN Received	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
If EN NOT received (Select all that apply)					
NPO for endotracheal extubation or intubation or other bedside procedure	☐	☐	☐	☐	☐
NPO for operating procedure	☐	☐	☐	☐	☐
NPO for radiology procedure	☐	☐	☐	☐	☐
High 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)					
Formula 1					
Formula 2					
Formula 3					
Total Kilocalories from EN					
Total Protein from EN					
Protein Supplement	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Protein Supplement Name					
Total Calories from Protein Supplement					
Total Protein from Protein Supplement					
PN Received	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Total Calories from PN					
Total Protein from PN					
Oral Intake	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Adequacy of Intake from oral nutrition (expressed as percent of prescribed)	☐ 0 – 24 % ☐ 25 – 49 % ☐ 50 – 74 % ☐ > 75 % ☐ unknown	☐ 0 – 24 % ☐ 25 – 49 % ☐ 50 – 74 % ☐ > 75 % ☐ unknown	☐ 0 – 24 % ☐ 25 – 49 % ☐ 50 – 74 % ☐ > 75 % ☐ unknown	☐ 0 – 24 % ☐ 25 – 49 % ☐ 50 – 74 % ☐ > 75 % ☐ unknown	☐ 0 – 24 % ☐ 25 – 49 % ☐ 50 – 74 % ☐ > 75 % ☐ unknown
Propofol ≥ 6 hours	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Volume of propofol received (mL)					

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 **Duration of Data Collection**	These data are collected to determine the frequency and type of burn related operative procedures that the patient undergoes during the study. • Record all burn related operative procedures from Study Day 1 (ACU admit) to 10 days post last successful grafting or ACU discharge or 3 months from ACU admission, whichever comes first. Note: This data only needs to be completed on study days that a burn related operative procedure is performed.
Date	Enter the date corresponding to the calendar day that the operative procedure was performed.
Was the Operative procedure planned or unplanned?	Indicate if the patient had a planned or unplanned operative procedure by checking the appropriate box.
Type of Operative Procedure	Indicate from the taxonomy the type(s) of operative procedure(s) performed on the date indicated. Select all that apply. ❑ 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

Page #:_____

Date (yyyy-mm-dd)					
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 (Please specify)					

Date (yyyy-mm-dd)					
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 (Please specify)					

Concomitant Medications Instructions

General Instructions **Duration of Data Collection**	These data are collected to capture all relevant medications that the patient received that may have a material effect on the measured outcomes of the study. Record all concomitant medications started from admission to the ACU until 10 Days after the last grafting operation, or discharge from the ACU, or 3 months after admission to the ACU, whichever comes first.
No concomitant medications were given	If no concomitant medications were given for the duration of the study, then place a √ in the box.
Date	Enter the dates corresponding to the calendar day.
Insulin	Indicate if insulin was given by placing a √ in the box 'Yes' or 'No'. If the information is 'Not Available', indicate by placing a √ in the appropriate box. Record the total units received in the 24 hour period from all insulin IV, SC (subcutaneous) and bolus. If no insulin was given put a forward slash through the box.
Opiates	Indicate if any opiates were given by placing a √ in the box 'Yes' or 'No'. If the information is 'Not Available', indicate by placing a √ in the appropriate box.
Motility agents	Indicate if any of the following motility agents were given by placing a √ in the box 'Yes' or 'No': Metoclopramide Erythromycin Domperidone Other If the information is 'Not Available', indicate by placing a √ in the appropriate box. *Do NOT record stool softeners here.*
Oxandrolone	Indicate if Oxandrolone was given by placing a √ in the box 'Yes' or 'No'. If the information is 'Not Available', indicate by placing a √ in the appropriate box.
Beta-Blockers	Indicate if any Beta-Blockers were given by placing a √ in the box 'Yes' or 'No'. If the information is 'Not Available', indicate by placing a √ in the appropriate box. If 'Yes', indicate which ones and enter does, units, and route: Esmolol Labetolol Metopropol Propanolo Other (pecify)

Concomitant Medications

Randomization Number

Page #:_____

Date (yyyy-mm-dd)					
Insulin given today?	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available
Insulin total dose in units					
Opiates given today?	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available
Motility agents given today?	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available
Oxandrolone given today?	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available
Beta-Blockers given today?	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available	☐ Yes ☐ No ☐ Not Available
If 'Yes', for each Beta-Blocker given, enter the dose, units, and route in the corresponding row below. For units: ☐ µg ☐ mg ☐ g ☐ units ☐ other unit (specify)					
Esmolol dose					
units					
route					
Labetolol dose					
units					
route					
Metoprolol dose					
units					
route					
Propanolol dose					
units					
route					
Other (specify medication)					
(other) dose					
units					
route					

Microbiology Instructions

General Instructions & Duration of Data Collection

These data are collected to assist in determining the incidence of ACU acquired infections.

- **Record only Gram negative blood infections**
  Examples includes:

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

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

Only record venous or arterial blood cultures that test positive for Gram negative bacteria that occurred >72 hours after ACU admission until10 days post last successful grafting or ACU discharge or 3 months from ACU admission, whichever comes first.

Do not include blood from a catheter line tip.

Date	Complete the date the sample was collected (i.e. not when the results were reported) in the date format of yyyy-mm-dd.
Time	Complete the time the sample was collected (i.e. not the time the results were reported) in the format of hh:mm.
Multiple samples	If multiple cultures are taken on the same day, record all different Gram negative bacteria reported. Do not record the same bacteria more than once on each study day, even if reported from specimens collected at different times on that day.
Gram Negative Culture #	Record the number (as per the taxonomy above) of all Gram negative bacteria cultures. If there is more than one Gram negative bacteria culture, record all.

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)					

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)					

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) Unapproved procedures performed 6) Other, please specify in the space provided.
General Instructions	Complete Protocol Violation forms in REDCap™ within 24 hours of becoming aware of the violation.
When to report	Protocol violations are to be reported from randomization until end of the study duration (10 days post last successful grafting or ACU discharge or 3 months from ACU admission, whichever comes first). Protocol Violations that relate to the <80% dosing delivered do NOT have to be reported on the following days: 1) Day of randomization 2) Day of discharge or end of study treatment (7 days post last successful grafting) 3) Day of death
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.
PV#	Enter the number of the protocol violation being reported for the date specified
Type of violation	**Using the options provided, check the box for the type of violation:** • **Dose delivered is <80% prescribed over a 3 day average** • **Dispensing/dosing error** (an incorrect dose/product was given to patient) • **Accidental unblinding** (the integrity of the study blind has been compromised) • **Enrollment of a patient that does not fulfill inclusion/exclusion criteria** • **Unapproved procedures performed** (failure to obtain consent) • **Other, please specify** (briefly describe the type of protocol violation)
Reason for the Violation	Check the appropriate box and briefly describe the reason for the violation on the lines provided. Describe the circumstances surrounding these violations.
Action taken by Research Coordinator	Describe the action taken by the Research Coordinator/responsible delegate to prevent violation/problem from recurring.

THE RE–*ENERGIZE* STUDY

Randomization Number

Protocol Violation Form

Date violation occurred (yyyy-mm-dd)

_____

Date violation discovered (yyyy-mm-dd)

_____

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

Protocol Violation # ____ for this date

☐ 1) Dose delivered is <80% prescribed over a 3 day average: _____ % received on indicated day
_____ % received over 3 day average

☐ 2) Dispensing/Dosing error

☐ 3) Accidental unblinding

☐ 4) Enrollment of ineligible patient

☐ 5) Open label glutamine given

☐ 6) Unapproved EN formula given

☐ 7) Other, please specify: _____
_____

Reason for violation (check all that apply)

☐ High gastric residual volumes

☐ Bowel perforation/obstruction

☐ Held for procedure/OR

☐ Other, specify details or attach Note to File/Incident Report:_____
_____
_____
_____

Action taken by Research Coordinator/Responsible Delegate Feeding protocol reviewed, RN education, REB notification, Note To File, etc...

_____

_____

_____

For CERU use only:

Date reviewed: _____

Reviewed by:_____

Further action required: ☐ Yes ☐ No

Action to be taken: _____

_____

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.
ACU discharge **(Did the patient die in ACU?)**	If the patient died in ACU, indicate by selecting 'Yes'. Record the date and time 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.* If the patient was discharged from ACU, select 'No, patient discharged' and enter the date and time the patient was actually discharged from the ACU. Proceed to Hospital discharge. If the patient is still in the ACU at 3 months from ACU admission, select 'No, patient still in ACU at 3 months'. Proceed to Month 6 Follow-up Assessments form.
Hospital discharge **(Did the patient die in Hospital?)**	If the patient died prior to hospital discharge, indicate by selecting 'Yes'. Record the date and time of death. If the patient was discharged from the hospital, select 'No, patient discharged' and enter the date and time the patient was actually discharged from the hospital. Proceed to 'Discharged to'. If the patient is still in the hospital at 3 months from ACU admission, select 'No, patient still in hospital at 3 months'. Proceed to Month 6 Follow-Up Assessments form.
Discharged to	If patient was discharged, select the location the patient was discharged to from the list below: ☐ Ward in another hospital ☐ ACU in another hospital ☐ Long term care facility ☐ Rehabilitation unit ☐ Home ☐ Other, specify _____
Cause of Death	If patient died, document the cause of death from a post mortem report. If this is not available, record cause of death from the death certificate.

THE RE–*ENERGIZE* STUDY

Randomization Number

Hospitalization Overview

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		
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		
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		
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.
Survival Status Obtained Date Source of information Survival Status	 Record the date of the contact or information retrieval. Record the source of the survival status information. -If by the 'Alternate Contact Person', record the relationship between the alternate contact person and the patient -If by an 'Other' source, please specify. Indicate if the patient is Alive or Deceased. -If deceased and the date of death is known, record the date of death. -If deceased and the date of death is unknown, record the last date the patient was known to be alive
Survival Status NOT Obtained	Confirm that all the listed avenues to access the patient survival status were completed. Record all attempts to contact the patient and/or alternate contact person(s) on the '**Month 6 Follow-up Assessments: Contact Log**' Record the last date the patient was known to be alive.

Month 6 Survival Assessments

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, indicate date of death if known (yyyy-mm-dd)	
If deceased but date of death is unknown, indicate 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)**
Date last known to be alive (yyyy-mm-dd)	

THE RE–*ENERGIZE* STUDY

Randomization Number

Month 6 Follow-up Assessments: Contact Log Instructions

General Information **Duration of Data Collection**	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. Contact the patient/alternate person(s) contact 2 weeks prior to book a time for the month 6 follow-up assessment and record the date of contact on the log. Completion of all 4 questionnaires is estimated to take 45 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. SF-36, ADL, IADL and employment status assessments are to be conducted at 6 months (± 14 days) after ACU admission.
Date and Time of Contact	Record the date and time of contact. If you cannot reach the patient/alternate contact person(s) try a different time at each attempt. If the patient was deceased as per the medical records or obituaries before contacts were made, record the date and time the survival status information was retrieved.
Patient Contact Method	Record all methods used to contact the patient. If the patient was deceased as per the medical records or obituaries before any contact attempts were made, select 'Other' and record that the patient was deceased and record your source.
Alternate Contact Person(s) Available	Record if information for an alternate contact person(s) are available. If the patient completed all the assessments or was deceased before any contact attempts were made, select 'Not required'.
Alternate Contact Person(s) Method	If information for a alternate contact person(s) are available, record all methods used to contact the alternate person(s).
Patient Relationship	Record the relationship between the alternate contact person(s) and the patient.
Follow-up's Completed	If an assessment was completed, record whether the patient or the alternate contact person(s) completed the assessment. This may be different from form to form. Note: It is always preferred to complete questionnaires with the patient when possible.
Reason Follow-up not completed	If the follow-up assessments can not be completed, record the reason why. If the patient is deceased, record the date of death or date last known to be alive on the '**Month 6 Survival Assessments**'. Refused is defined as the patient/alternate contact person(s) are unwilling to complete the follow-up questionnaires. This does not include reasons such as 'not a good time' or 'I am not feeling well today' etc. In those cases, set up a new date and time to call the patient/alternate contact person(s).

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)
Date of Contact (yyyy-mm-dd) (If not done, record the reason why)	

	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 contact (please specify)	☐ In person with patient ☐ Called patient (cell) ☐ Called patient (work) ☐ Called patient (home) ☐ Other contact (please specify)	☐ In person with patient ☐ Called patient (cell) ☐ Called patient (work) ☐ Called patient (home) ☐ Other contact (please specify)
Is there an alternate contact person(s) available?	☐ Yes ☐ No ☐ Not Required	☐ Yes ☐ No ☐ Not Required	☐ Yes ☐ No ☐ Not Required
If yes, alternate contact person(s) (alt.) method (Select all that apply)	☐ In person with alt. ☐ Called alt. (cell) ☐ Called alt. (work) ☐ Called alt. (home) ☐ Other contact (please specify)	☐ In person with alt. ☐ Called alt. (cell) ☐ Called alt. (work) ☐ Called alt. (home) ☐ Other contact (please specify)	☐ In person with alt. ☐ Called alt. (cell) ☐ Called alt. (work) ☐ Called alt. (home) ☐ Other contact (please specify)
If yes, alternate contact person(s) relationship (Select all that apply)	☐ Spouse/Partner ☐ Parent ☐ Child ☐ Friend ☐ Other relationship (please specify)	☐ Spouse/Partner ☐ Parent ☐ Child ☐ Friend ☐ Other relationship (please specify)	☐ Spouse/Partner ☐ Parent ☐ Child ☐ Friend ☐ Other relationship (please specify)
Follow-up's Completed			
SF-36	☐ Patient ☐ alternate	☐ Patient ☐ alternate	☐ Patient ☐ alternate
Katz ADL	☐ Patient ☐ alternate	☐ Patient ☐ alternate	☐ Patient ☐ alternate
Lawton IADL	☐ Patient ☐ alternate	☐ Patient ☐ alternate	☐ Patient ☐ alternate
Employment Status	☐ Patient ☐ alternate	☐ Patient ☐ alternate	☐ Patient ☐ alternate
If the follow-up assessments can not be completed, record the reason why (Select one)	☐ Deceased *(Record date on the survival assessment*) ☐ Patient refused ☐ alternate contact person refused (only if patient did not re-consent) ☐ Other (Please 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, IADL and employment status assessments are to be conducted at 6 months (± 14 days) after ACU admission. Every effort must be made to complete these questionnaires. Record all attempts to contact the patient/alternate contact person(s) on the '**Month 6 Follow-up Assessments: Contact Log**'
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.
Employment Status	The Employment Status form is used to assess the effect of the burn injury on the patient's employment status. Read each question to the patient and record her/his response. Where applicable, read the response options to the patient. Allow the patient to make her/his own determination. Read each question sequentially. Follow the instructions on the form regarding skipping questions associated with responses to questions 1, 5, and 6. Indicate the patient's response to each question by marking the corresponding box.
Maintain Worksheets	Keep the completed worksheets with the patient study files, these are your source documentation.

SF-36

Your Health and Well-Being

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Thank you for completing these questions!

Katz Index of Independence in Activities of Daily Living

ACTIVITIES POINTS (1 or 0)	**INDEPENDENCE:** (1 POINTS) *No* supervision, direction or personal assistance	**DEPENDENCE:** (0 POINTS) *With* supervision, direction, personal assistance or total care
BATHING POINTS: _____	**(1 POINT)** Bathes self completely or needs help in bathing only a single part of the body such as the back, genital area or disabled extremity	**(0 POINTS)** Needs help with bathing more than one part of the body, getting in or out of the tub or shower. Requires total bathing.
DRESSING POINTS: _____	**(1 POINT)** Gets clothes from closets and drawers and puts on clothes and outer garments complete with fasteners. May have help tying shoes	**(0 POINTS)** Needs help with dressing self or needs to be completely dressed
TOILETING POINTS: _____	**(1 POINT)** Goes to toilet, gets on and off, arranges clothes, cleans genital area without help	**(0 POINTS)** Needs help transferring to the toilet, cleaning self or uses bedpan or commode
TRANSFERRING POINTS: _____	**(1 POINT)** Moves in and out of bed or chair unassisted. Mechanical transferring aides are acceptable	**(0 POINTS)** Needs help in moving from bed to chair or requires a complete transfer
CONTINENCE POINTS: _____	**(1 POINT)** Exercises complete self control over urination and defecation	**(0 POINTS)** Is partially or totally incontinent of bowel or bladder
FEEDING POINTS: _____	**(1 POINT)** Gets food from plate into mouth without help. Preparation of food may be done by another person	**(0 POINTS)** Needs partial or total help with feeding or requires parenteral feeding
TOTAL POINTS = _____ 6= High (*patient independent)* 0= Low (*patient very dependent)*		

THE RE–*ENERGIZE* STUDY

Randomization Number

Lawton Instrumental Activities of Daily Living (IADLs)

Scoring: For each category, circle the item description that most closely resembles the client's highest functional level (either 0 or 1).

Ability to Use Telephone	Operates telephone on own initiative; looks up and dials numbers	**1**
	Dials a few well-known numbers	**1**
	Answers telephone, but does not dial	**1**
	Does not use telephone at all	**0**
Shopping	Takes care of all shopping needs independently	**1**
	Shops independently for small purchases	**0**
	Needs to be accompanied on any shopping trip	**0**
	Completely unable to shop	**0**
Food Preparation	Plans, prepares, and serves adequate meals independently	**1**
	Prepares adequate meals if supplied with ingredients	**0**
	Heats and serves prepared meals or prepares meals but does not maintain adequate diet	**0**
	Needs to have meals prepared and served	**0**
Housekeeping	Maintains house alone with occasion assistance (heavy work)	**1**
	Performs light daily tasks such as dishwashing, bed making	**1**
	Performs light daily tasks, but cannot maintain acceptable level of cleanliness	**1**
	Needs help with all home maintenance tasks	**1**
	Does not participate in any housekeeping tasks	**0**
Laundry	Does personal laundry completely	**1**
	Launders small items, rinses socks, stockings, etc	**1**
	All laundry must be done by others	**0**
Mode of transportation	Travels independently on public transportation or drives own car	**1**
	Arranges own travel via taxi, but does not otherwise use public transportation	**1**
	Travels on public transportation when assisted or accompanied by another	**1**
	Travel limited to taxi or automobile with assistance of another	**0**
	Does not travel at all	**0**
Responsibility for Own Medications	Is responsible for taking medication in correct dosages at correct time	**1**
	Takes responsibility if medication is prepared in advance in separate dosages	**0**
	Is not capable of dispensing own medication	**0**
Ability to Handle Finances	Manages financial matters independently (budgets, writes checks, pays rent and bills, goes to bank); collects and keeps track of income	**1**
	Manages day-to-day purchases, but needs help with banking, major purchases, etc	**1**
	Incapable of handling money	**0**
Add each circled number from the column on the right:	**TOTAL POINTS = _____**	

THE RE–*ENERGIZE* STUDY

Enrollment Number

Employment Status Questionnaire

1 Have you ever been employed earning wages or salary, either full-time or part-time, including self-employment?

Yes ☐
No ☐
No answer ☐

Interviewer: if 'No' or 'No Answer' skip to Current Employment Status (Question 5 onwards)

2 [If yes] **Which best describes your employment situation just prior to hospital admission** *(Select ONE answer)*?

Working - Full Time (at least 32 hours per week) ☐
Working - Part Time ☐
On leave but still employed ☐ *(select N/A for question 4)*
Temporarily laid off ☐ *(select N/A for question 4)*
Unemployed and looking for work ☐ *(select N/A for question 4)*
Wanting to work, but unemployed due to health related reason ☐ *(select N/A for question 4)*
Going to school ☐ *(select N/A for question 3 and 4)*
Keeping house or being home maker ☐ *(select N/A for question 3 and 4)*
Retired ☐ *(select N/A for question 4)*
Receiving/Awaiting approval for disability payments ☐ *(select N/A for question 4)*
Other (specify):_____ ☐
Don't know ☐ *(select N/A for question 3 and 4)*
No Answer ☐ *(select N/A for question 3 and 4)*
Unknown ☐

3 What is your occupation, or what kind of work did you do? (Record up to 3)
Survey administrator: Refer to Occupation List to categorize responses below

1) _____ No Answer ☐ Don't know ☐ N/A ☐ (if question 2 is 6, 7, 11, or 12)
2) _____
3) _____

4 On average, how many hours per week did you work in the 6 months before being hospitalized?

__ __ No Answer ☐ Don't know ☐ N/A ☐ (If question 2 is 3-9, 11 or 12)

5 Which best describes your <u>current</u> employment situation? *(Select ONE answer)*

Retired <u>or</u> disability (or awaiting disability) <u>AND</u> this is same status as at baseline ☐ (Skip to next instrument)

Working - Full Time (at least 32 hours per week) ☐ (select 'Yes' for question 6)

Working - Part Time ☐ (select 'Yes' for question 6)

On sick leave but still employed ☐

Temporarily laid off ☐

Unemployed – presently in a health care facility ☐

Unemployed and Looking for Work ☐

Wanting to work, but unemployed due to health related reason ☐

Going to School (If a participant is both 'going to school' and 'working part time,' ask how many hours for each one and tick whichever option is greater) ☐

Keeping house or being home maker ☐

<u>New</u> Retirement (i.e. started after hospital d/c) ☐

Receiving <u>New</u>/Awaiting <u>New</u> Approval for Disability payments (i.e. started after hospital d/c) ☐

Other (specify):_____ ☐

Don't know ☐

No Answer ☐

Unknown ☐

6 Have you worked at all since you left the hospital?

☐ No → Why have you not worked?_____ *[<u>Skip to next instrument</u>]*

If No, please categorize above text response (see right for options)

☐ Health related reasons
☐ On disability
☐ Retired
☐ In school
☐ Looking for work
☐ Homemaker
☐ No response
☐ Other

☐ Yes [<u>Proceed below</u>]

7 How many weeks after hospital discharge did you return to work? (*record using weeks ONLY*)

__ __ No Answer ☐ Don't know ☐

8 <u>What is your occupation, or what kind of work do/did you do?</u>

Survey administrator: Refer to Occupation List to categorize responses below

_____ No Answer ☐ Don't know ☐ N/A ☐

9 <u>On average, how many hours per week do/did you work?</u>

__ __ No Answer ☐ Don't know ☐ N/A ☐

Continued on next page…

10 During the past FOUR WEEKS, how many complete work days or shifts have you missed due to your Burn Injury?

___ ___ No Answer ☐ Don't know ☐ N/A ☐ (Have not worked in the last 4 weeks)

11 During the past FOUR WEEKS, how many partial days or shifts have you missed due to your Burn Injury, including leaving work early or taking time for doctor's visits?

___ ___ No Answer ☐ Don't know ☐ N/A ☐ (Have not worked in the last 4 weeks)

12 Thinking about your work experience <u>since leaving hospital</u>, have you ever had to make a significant change in your work duties because of your Burn Injury?

(*IF REQUIRES PROMPT: Such changes can include a change in work processes, a change in your mix of responsibilities or other changes in job activities.)*

↙ Yes ☐ No ☐ No Answer ☐ Don't know ☐

[If Yes] Please describe this change:_____

Survey administrator: Categorize response at right:

☐ Decreased hours
☐ Limited physically
☐ Limited cognitively
☐ Stopped work/laid off (describe)
☐ Change in job duties (describe)
☐ No response
☐ Other (describe)

13 During the past FOUR WEEKS, how would you rate your EFFECTIVENESS on the job after your Burn Injury?

100% means your Burn Injury did not affect your job effectiveness

0% means you were unable to work at all because of your Burn Injury.

How would you rate your effectiveness as a percent?

___ ___ ___ % No Answer ☐ Don't know ☐ N/A ☐ (Have not worked in the last 4 weeks)

14 Are you limited in the kind or amount of work you can do because of your Burn Injury

Yes ☐ No ☐ No Answer ☐ Don't know ☐

15 Have you ever had to change your job or occupation because of your Burn?

Yes ☐ No ☐ No Answer ☐ Don't know ☐

<u>Interviewer:</u> If the Answer to Question 5 was # 2 (part-time), ask the question below. Otherwise, skip to next survey instrument

---

16 [If working part time]

Which best describes the reason you are working part time? *(Select ONE answer)*

Related to Burn Injury? ☐
Related to other illness? ☐
Related to other reason? ☐
Don't know ☐
No Answer ☐

Occupation List

Q8 Options (What is your occupation)

1	Management
2	Business and Financial Operations
3	Computer and Mathematical
4	Architecture and Engineering
5	Life, Physical, and Social Science
6	Community and Social Services
7	Legal
8	Education, Training, and Library
9	Arts, Design, Entertainment, Sports, and Media
10	Healthcare Practitioner and Technical
11	Healthcare Support
12	Protective Service
13	Food Preparation and Serving Related
14	Building and Grounds Cleaning and Maintenance
15	Personal Care and Service
16	Sales and Related
17	Office and Administrative Support
18	Farming, Fishing, and Forestry
19	Construction and Extraction
20	Installation, Maintenance, and Repair
21	Production
22	Transportation and Material Moving

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)

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