Randomized Trial of ENTERal Glutamine to minimize Thermal Injury

CRS & REDCap Manual

Intended Audience: Research Coordinators & Pharmacists

This study is registered at Clinicaltrials.gov.
Identification number NCT00985205

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Electronic Data Capture Systems

Each site will need to access two different electronic data capture systems for RE-ENERGIZE:

1. **Central Randomization System (CRS)**
   - The Central Randomization System (CRS) is a web-based system that will be used to screen and randomize eligible patients into the RE-ENERGIZE Study.
   - The CRS may be accessed directly at: https://ceru.hpcvl.queensu.ca/randomize or via: http://www.criticalcarenutrition.com

2. **REDCap**
   - REDCap is a web-based electronic data capture system that will be used as the RE-ENERGIZE Study electronic Case Report Forms (eCRFs).
   - REDCap may be accessed directly at: https://ceru.hpcvl.queensu.ca/EDC/redcap/ or via: http://www.criticalcarenutrition.com

Granting CRS & REDCap Access

- Access to both the CRS and REDCAP will be granted to the Research Coordinator/delegate upon documentation of proper training of study procedures and receipt of Ethics Approval documentation and other essential documents.
- Research Coordinators that are granted access to the CRS and REDCAP must appear on the Delegation of Authority Log as described in the Implementation Manual.
Screening & Randomization

Screening & Eligibility

The Research Coordinators are expected to screen patients admitted to their ICU/burn unit daily to see if they meet the inclusion criteria or exclusion criteria as listed below. All screening data should be entered into the Central Randomization System (CRS).

For eligible patients, the screening data must be entered onto the CRS in a timely manner in order to randomize the patient and start the study intervention as soon as possible.

Since patient eligibility and suitability must be determined by the Site Investigator/delegate, sites are encouraged to use the Inclusion/Exclusion criteria mock eCRFs to document screening and confirmation of eligibility by a physician.

Types of Patients to be entered into the CRS

The CRS serves as a screening log and is vital in identifying the screening activity at each site. Hence ALL patients that meet the following criteria MUST be entered into the CRS on a regular basis:

- **All patients meeting inclusion criteria**, these would be all of the following:
  - patients that meet an exclusion criteria or
  - patients that do not meet any exclusion criteria and consent is obtained (Randomized patients) or
  - patients that do not meet any exclusion criteria and consent is not obtained (Eligible but not randomized patients)

The table below provides several examples of the types of patients.

<table>
<thead>
<tr>
<th>Inclusion Criteria Present</th>
<th>Exclusion Criteria Present</th>
<th>Informed Consent Obtained</th>
<th>Enter into CRS</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>✗</td>
<td>✗</td>
<td>Do not approach for consent as inclusion criteria not met</td>
<td>✗</td>
<td></td>
</tr>
<tr>
<td>✓</td>
<td>✓</td>
<td>Do not approach for consent as exclusion criteria met</td>
<td>✓</td>
<td>Ineligible patient</td>
</tr>
<tr>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
<td>Randomized patient</td>
</tr>
<tr>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✓</td>
<td>Eligible but not randomized patient</td>
</tr>
</tbody>
</table>

For each patient entered into the CRS, the system will issue a screening number. The screening numbers are assigned sequentially in an 8-digit format:

“4” indicates the patient is being screened but not randomized

1002 - 4005

Site #, patient #
If the patient is subsequently randomized, they will also be issued an enrollment number. The enrollment numbers are assigned sequentially in an 8-digit format:

“5” indicates the patient has been randomized

1002 - 5005

Site #  patient #

Accessing & Entering a Patient in the CRS

URL: https://ceru.hpcvl.queensu.ca/randomize

Once you have logged in successfully, you will be brought to the Home screen.

After selecting the RE-ENERGIZEv3 study from the Home page, you will be brought to the Site Status Page. This page is a listing of all patients screened and randomized to version 3 of the study, protocol dated March 26th 2012, at your site.
To enter data for a new patient, select the **Add patient** button on the bottom left of the screen.

You will be brought to the **Inclusion Criteria form**. Complete the fields in the form as appropriate.

Each patient entered in the CRS will also have a status associated with it. There are 4 status levels:
- **In progress**: inclusion data has been entered.
- **Not Eligible**: This patient was excluded.
- **Not Randomized**: This patient was eligible but consent was not obtained.
- **Randomized**: The patient was eligible, consent was obtained and the patient was enrolled into the study.

**Central Randomization System**

**Inclusion Criteria**

Screening Date and time: 10 May 2012

1. Presence of Deep 2nd and/or 3rd degree burns requiring grafting: Yes
2. Age: 42
3. Does the patient have an inhalation injury: Yes
4. Total Burn Surface Area (TBSA): 16%

- Patients 18 - 59 years of age without inhalation injury TBSA ≥ 20%
- Patients 18 - 59 years of age with inhalation injury TBSA ≥ 15%
- Patients ≥ 60 years of age (with or without inhalation injury) TBSA ≥ 10%

Dates are to be entered in the DD-MMM-YYYY format.

All times should be recorded using the 24-hour (military) clock. All times must include a “:” (colon) to be saved. For example 1200 must be entered as 12:00.

Click **SAVE**.

Note: Enter all patients into the Central Randomization System who meet the Inclusion Criteria. See Types of Patients to be Entered section for further detail.
Inclusion Criteria

Patients must meet the inclusion criteria to be enrolled in the study.

<table>
<thead>
<tr>
<th>#</th>
<th>Inclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Deep 2\textsuperscript{nd} and/or deep 3\textsuperscript{rd} degree burns requiring grafting</td>
</tr>
<tr>
<td></td>
<td>The presence of deep 2nd degree and/or deep 3rd degree burns requiring grafting is an assessment that must also be made by the attending surgeon/physician.</td>
</tr>
<tr>
<td></td>
<td>This information must be obtained from the attending surgeon/delegate \textbf{before} randomization can occur.</td>
</tr>
<tr>
<td>2</td>
<td>\textbf{Age} &gt; 18 years old</td>
</tr>
<tr>
<td>3</td>
<td>\textbf{Presence of inhalation injury}</td>
</tr>
<tr>
<td></td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>\textbf{Note}: Answering “No” to this question does not necessarily exclude the patient from the study, refer to Inclusion Criteria #4, Total Burn Surface Area (TBSA), for clarification.</td>
</tr>
<tr>
<td>4</td>
<td>\textbf{Total Burn Surface Area (TBSA)}:</td>
</tr>
<tr>
<td></td>
<td>➢ Ages 18 - 59 without inhalation injury and with TBSA &gt; 20%,</td>
</tr>
<tr>
<td></td>
<td>➢ Ages 18 - 59 with inhalation injury and with TBSA &gt; 15%,</td>
</tr>
<tr>
<td></td>
<td>➢ Ages &gt; 60 with or without inhalation injury and with TBSA ≥ 10%.</td>
</tr>
<tr>
<td></td>
<td>This assessment is to be made by the attending surgeon/physician based on her/his clinical judgment</td>
</tr>
</tbody>
</table>

\textbf{Consent} \textbf{must} be obtained \textbf{within 72 hrs} of admission to the ICU (burn unit)

\textit{To be eligible, admission to the unit must occur \textbf{within 48 hrs} of burn injury. In the event that the patient received standardized burn care and resuscitation prior to admission to ICU, this may be extended to \textbf{96 hrs}. In this case, consent must be obtained within \textbf{24 hrs} of admission to burn ICU}
Complete the exclusion criteria fields as appropriate.

1. >72 hours from admission to ICU to time of consent
2. Patient < 18 years of age
3. Liver cirrhosis - Child’s Class C liver disease
4. Pregnancy
5. Absolute contra-indication for EN
6. Patient admitted to ICU > 48 hours post bum (> 96 hours if field treated)
7. Patient with injuries from high voltage electrical shock
8. Patient who is moribund
9. Patient BMI < 18 or > 50 Kg/m²
10. Enrollment in another industry sponsored ICU intervention study (enrollment in academic studies will be considered on a case by case basis)
11. Received glutamine supplement for >24 hours prior to randomization
12. Known allergy to maltodextrin, corn starch, corn, or corn products

Remember to:

- **Only** enter patients who meet the inclusion criteria.
- Enter the date & time of screening
- You may want to use the mock eCRFs/Worksheets to document screening & eligibility
- To save time, instead of clicking the drop down box, you may press “TAB Y” for Yes and “TAB N” for No
# Exclusion Criteria

Choose all exclusion criteria that apply. If a patient meets any of the exclusion criteria, they are **not eligible** to participate in the study.

<table>
<thead>
<tr>
<th>#</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&gt; 72 hrs from admission to ICU to time of consent</td>
</tr>
<tr>
<td>2</td>
<td>Patients &lt; 18 years of age (age of maturity for an eligible patient to obtain consent is 18 years in Canada and the US)</td>
</tr>
<tr>
<td>3</td>
<td>Liver cirrhosis - Child's class C liver disease</td>
</tr>
<tr>
<td>4</td>
<td>Pregnancy (urine/blood tests for pregnancy will be done on all women of childbearing age by each site as part of standard of ICU practice)</td>
</tr>
<tr>
<td>5</td>
<td>Absolute contra-indication for EN: intestinal occlusion or perforation, abdominal injury. (Intestinal occlusion or perforation, abdominal injury. Being NPO is not considered a contraindication for Enteral Nutrition).</td>
</tr>
<tr>
<td>6</td>
<td>Patients admitted &gt; 48h post burn (for patients that receive standardized burn care and resuscitation prior to admission to ICU, this exclusion criteria may be extended to patients admitted more than 96 hrs post burn: in this case consent must be obtained within 24 hours of admission to burn ICU)</td>
</tr>
<tr>
<td>7</td>
<td>Patients with injuries from high voltage electrical shock</td>
</tr>
<tr>
<td>8</td>
<td>Patients who are moribund (this may be defined as not expected to be in the ICU for more than 48 hours due to imminent death).</td>
</tr>
<tr>
<td>9</td>
<td>Patient BMI &lt; 18 or &gt; 50 kg/m2</td>
</tr>
<tr>
<td>10</td>
<td>Enrollment in another industry sponsored ICU intervention study (co-enrollment in academic studies will be considered on a case by case basis)</td>
</tr>
<tr>
<td>11</td>
<td>Received glutamine supplement for &gt; 24 hours prior to randomization.</td>
</tr>
<tr>
<td>12</td>
<td>Known allergy to maltodextrin, corn starch, corn, or corn products.</td>
</tr>
</tbody>
</table>

**To minimize any potential contamination, patients that have received glutamine for >24 hrs before randomization, should NOT be included.**

*For such patients, please enter them on to the Central Randomization System and add the reason for no consent as “received glutamine for > 24 hrs”*

Patient eligibility must be confirmed by the Site Investigator/MD delegate

If a patient is found to meet an exclusion criterion after the patient is randomized into the study, please contact the Project Leader as soon as you become aware for direction on how to proceed.
Pre-Randomization

Pre-Randomization refers to the period of time between the determination of an eligible patient and randomization of a patient. The patient/next of kin **must** be approached for consent before you complete this form.

If consent is **NOT** obtained, complete the following form as shown below.

Choose one of the following reasons for **NOT** obtaining consent:

<table>
<thead>
<tr>
<th>Reason</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>No next of kin or substitute decision maker</td>
<td>The SDM or legally acceptable representative (LAR) was not available for consent discussion within the required time frame.</td>
</tr>
<tr>
<td>Refused Consent</td>
<td>The SDM or LAR refused participation. It is important to document the reason for the refusal to consent.</td>
</tr>
<tr>
<td>Missed the patient</td>
<td>The patient was not identified by the site coordinator in time to approach for consent. E.g., the patient came in over the weekend.</td>
</tr>
<tr>
<td>MD refusal</td>
<td>The MD feels that the patient is not suitable for the study</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>Pharmacy not available</td>
<td>The SDM was not approached for consent because pharmacy is not available to prepare the investigational product.</td>
</tr>
<tr>
<td>Not approached for consent – Family dynamics</td>
<td>The SDM was not approached due to emotional stress or complicated family dynamics.</td>
</tr>
<tr>
<td>Workload Issues</td>
<td>There was inadequate Research staff present to follow the patient</td>
</tr>
<tr>
<td>Other, please specify</td>
<td>Any other reasons that are not captured above</td>
</tr>
</tbody>
</table>

If consent **IS** obtained, complete the following form as shown below.
Once you click on the “Randomize” button, the patient will be randomized to the RE-ENERGIZE Study.

Randomization

⚠️ Randomization must occur soon after consent so that the intervention can start as soon as possible (within 2 hrs from randomization)

Central Randomization System

Randomization form

You have successfully randomized this patient

Enrollment number:
1002-5004
1002-4005

Screening number:

Date and time of randomization:
2012-05-11 14:09 EST

Date and time pharmacy/Unblinded staff contacted:

Pre-burn weight:
68.00 Kg

How was pre-burn weight measured

Please print off this page for your records.

Save

You may print a copy of the Randomization Form and file in the Patient Folder/Study files. Click “Save”

March 26th 2012
The Patient Status Page indicates that data entry for this patient is complete. If you do not click “Save” on the Randomization page, the Patient Status Page will continue to show Randomization as incomplete.

Note: All patient data collected following randomization can be entered on to the eCRF (REDCAP)

Click on the “Site Status” button to view all the patients screened and entered on the CRS.

You will note each patient entered into the CRS is issued a screening number. Those patients that are eligible and randomized are issued an enrollment number.

To view a patient, click their enrolment number or their screening number,
You will then be brought to the Patient Status screen. It shows you each data entry form for the patient as well as the status of the form.

Each form has a status assigned:

<table>
<thead>
<tr>
<th>Status</th>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed</td>
<td>✓</td>
<td>All data has been completed and saved.</td>
</tr>
<tr>
<td>Not Completed</td>
<td>✗</td>
<td>Data has not yet been entered on the form.</td>
</tr>
<tr>
<td>Locked</td>
<td>🔐</td>
<td>The patient has been randomized and the data is no longer able to be edited by the site user.</td>
</tr>
</tbody>
</table>

Note: All subsequent data collection must be entered on to the eCRF (REDCAP) as described in the following pages.
REDCap Data Entry

The REDCap (Research Electronic Data Capture) is a web-based system used for the RE-ENERGIZE Study.

REDCap can be accessed at the REDCap login link https://ceru.hpcvl.queensu.ca/EDC/redcap/.

All authorized study personnel must log onto the web site using their own username and password prior to data entry.

Your user password can be changed at any time by clicking “My Profile” after logging into REDCap.
Navigating REDCap

My Databases
After you log into REDCap, you will be brought to the Home screen. Select the “My Databases” tab to see a list of the CERU studies you have access to.

Data Entry Field
The left side of the screen is the main navigation panel where you will see “Data Entry”. Select “Data Entry” to choose from a list of patients that are randomized and ready for data entry.
After you have selected a patient, you will be brought to the Event Grid. The Event Grid gives the user a snapshot of the data entry forms for the patient.

The type of data entry form is listed in the far left column of the table. The study day is listed on the top row of the table. Each dot on the table represents an individual data entry form. Each individual form can be accessed by clicking on the dot. As you can see below, the circled dot is the Daily Monitoring form for study day 3.

Each grid contains 30 study days. The buttons at the top of the grid represent each 30 day segment. To move to a specific set of study days/dates, click the corresponding button or click the ‘Next’ button to navigate to each sequential segment, click the ‘Previous’ button to return to the previous set of study days.
Slide the navigation scroll bar at the bottom of the table to reveal the right side of the Event Grid.

Form Links
You can navigate between forms on the same study day using the form links on the left side navigation menu.
Antibiotics & Microbiology Fields
You will note that the antibiotic and microbiology data entry forms have drop down boxes for each day and the events are listed as 1, 2, 3, 4, 5 & 6 (maximum of 6 entries per day). See arrow below.

You MUST enter the antibiotic and micro data on the same study day as the antibiotic was started or the day the sample was taken.

Form Status and Saving
At the end of each form, you will be asked to specify the form status. This legend is to be used to assist you in remembering what data is either incomplete, unverified or complete. The status is indicated on the Event Grid Field using the following convention:

<table>
<thead>
<tr>
<th>Grid Icon</th>
<th>Dropdown Code</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blank</td>
<td>Incomplete</td>
</tr>
<tr>
<td></td>
<td>u</td>
<td>Unverified</td>
</tr>
<tr>
<td></td>
<td>c</td>
<td>Complete</td>
</tr>
<tr>
<td></td>
<td>L</td>
<td>Locked</td>
</tr>
</tbody>
</table>

To help identify the status of the antibiotic and microbiology entries, you will find a Form Status Legend at the bottom of the grid (circled).
- There may be up to 4 options at the end of each form to save your progress. The following example is for:

**Daily Monitoring - Study Day 1**

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
</table>
| Save and go to Day 1 Daily Organ Dysfunction | This option will save your progress and bring you to the next form on the same study day.  
Note: In the case of the Antibiotic and Microbiology forms, this option will bring you to the next corresponding Antibiotic/Microbiology form.  
*For example, if you are working on the third Antibiotic form on Day four, this option will save and bring you to the fourth Antibiotic form on Day four.* |
| Save and go to Day 2 Daily Nutrition Monitoring | This option will save your progress and bring you to the same form on the next study day.                            |
| Save and go to Grid                         | This option will save your progress and return you to the Event Grid.                                                 |
| Save and Stay                               | This option will save your progress and allow you to continue working on that form.                                   |
| Clear Form                                  | This option will allow you to clear the entire form in case the entire form was completed in error.                  |
| Cancel                                      | This option will take you to the Event Grid screen. All newly entered data will be lost. Only the last saved version will remain |

**NOTE:** Always remember to “Save” before you navigate away from a form. Navigating from a form without saving will result in loss of data.
Data Conventions in REDCap

- Dates should be entered using the YYYY - MM - DD format i.e. 2010 - 07 - 24. A date picker calendar is available to enter dates. Single “click” on the icon and choose the appropriate month and year from the drop down boxes. Then “click” the appropriate day.

- Enter all times using the HH:MM 24-hour period format i.e. 22:37. The colon “:” must be entered. Use leading zeros where applicable i.e. 01:28.

- Midnight should be entered as 00:00

- To access individual forms single click the corresponding “dot” on the event grid.

- To enter data directly into each field, single click on the left side of the mouse pointer and type information. Do NOT press enter after entering data into a field. This will cause the form to automatically save and bring you to a new screen that will allow you to return to the Event Grid.

- There should be NO blanks. If data is NOT available use the “Not Done/Not Available” checkbox options. This includes:
  - Data that is unavailable because the measure wasn’t taken or the test was not done. Example: T-Bilirubin was not done on a particular study day.
  - Data that is not known. This assumes every effort has been made to find the data but it is missing from source documents. Example: A particular data point was NOT entered in the medical chart. Or an ICU flow sheet has gone missing.

- REDCap has an option for users to see the data entry history for each data field. By clicking on the , a window will pop up listing the data entry history for the data field.

### Data Conventions in REDCap

#### Edit data entered on the web

To edit previously saved information, access the appropriate REDCap form, change the appropriate field(s) and save the form. To ensure Good Clinical Practice is maintained, all changes will be tracked and logged by the computer program.

**Once a patient has been randomized they cannot be deleted.**

Please contact the Project Leader for more details.

**Please keep ALL worksheets/documents that you use as these will be referred to at the time of source verification.**
Infection Adjudication

In order to determine the incidence of newly acquired infections in patients enrolled to the RE-ENERGIZE study, an assessment needs to be made by the Site investigator/MD delegate as to whether a newly acquired infection exists and this requires adjudication.

A suspicion of infection is determined by the antibiotics received and the data on positive cultures. All antibiotics and cultures that lead to a suspicion of infection will be recorded on the appropriate electronic case report form.

Once a clinical suspicion of an infection has been identified, the Site Investigator/MD delegate MUST adjudicate the data to determine the following:

- Is there an infection or not
- Degree of certainty of the infection
- Category of Infection

Refer to the algorithm on next page for adjudicating a clinical suspicion of infection.

Although the site investigator is responsible for the adjudication, the research coordinator is responsible for facilitating this process.

Refer to the following documents for more details
1. Antibiotic, antifungal & antiviral mock eCRF
2. Microbiology mock eCRF
3. Mock eCRF Appendix 7 Categories of Infection
4. Mock eCRF Appendix 8 Definition of “No” Newly Acquired Infection

Infection adjudication MUST be performed by the Site Investigator, or MD delegate.
Was a new antibiotic† started > 72 hours from ICU admission?  
OR  
Was there a positive culture taken > 72 hours from ICU admission?

- YES
  - **Antibiotic Form**
    - Was the antibiotic† given for prophylaxis?  
    - OR  
    - Was this antibiotic† a substitute for an antibiotic previously ordered for an infection that occurred within the first 72 hours of ICU admission?
  - **Microbiology Form**
    - Is this organism a manifestation of an infection that occurred within the first 72 hours of ICU admission?

- NO
  - NO adjudication required

This culture represents a relapse/recurrent infection or a persistent infection.

This defines a Clinical Suspicion of an infection.  
This clinical suspicion requires adjudication by the Site Investigator/MD delegate.

**ADJUDICATION DETERMINATION BY SITE INVESTIGATOR/MD DELEGATE**

- YES
  - New infection
    - Choose the appropriate Category of Infection AND Degree of Certainty
      - definite yes
      - probable yes or
      - possible yes
    - Refer to Mock eCRF Appendix 7
  - Indicate which previously adjudicated episode of infection this current suspicion is related to  
  (E.g. suspicion #1, #2, #3, etc).

- NO
  - Infection
    - Indicate the Degree of Certainty
      - probable NO or
      - possible NO
    - Refer to mock eCRF Appendix 8

† Refers to antibiotic, antifungal or antiviral
Infection Adjudication Data Entry

Based on the microbiology and antibiotic data entered, REDCAP will automatically trigger suspicions of newly acquired infections. This is done by generating a series of tables that will guide and assist the Site Investigator/Research Coordinator through the various steps of Infection Adjudication. These steps are described below.

You will see the “Infection Adjudication” tab appear in the left hand side under “Resources”. Click on Infection Adjudication and you will see a new window as described below.

![Image of REDCap interface]

The Infection Adjudication link will open a new window listing all your patients.

Patients needing an adjudication are in Stage 2.

You must complete the infection adjudication for these patients to proceed further.

### Infection Adjudication Data Entry

<table>
<thead>
<tr>
<th>Patient ID</th>
<th># Suspicions</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>10141001</td>
<td>2</td>
<td>Stage 3</td>
</tr>
<tr>
<td>10141002</td>
<td>0</td>
<td>Stage 3</td>
</tr>
<tr>
<td>10141003</td>
<td>2</td>
<td>Stage 3</td>
</tr>
<tr>
<td>10141004</td>
<td>5</td>
<td>Stage 2</td>
</tr>
<tr>
<td>10141005</td>
<td>0</td>
<td>Stage 2</td>
</tr>
<tr>
<td>10141006</td>
<td>2</td>
<td>Stage 2</td>
</tr>
<tr>
<td>10141007</td>
<td>0</td>
<td>Stage 2</td>
</tr>
<tr>
<td>10141008</td>
<td>8</td>
<td>Stage 2</td>
</tr>
<tr>
<td>10141009</td>
<td>0</td>
<td>In Progress</td>
</tr>
<tr>
<td>10141010</td>
<td>0</td>
<td>In Progress</td>
</tr>
<tr>
<td>10281001</td>
<td>1</td>
<td>In Progress</td>
</tr>
<tr>
<td>10281002</td>
<td>0</td>
<td>Stage 2</td>
</tr>
<tr>
<td>10281003</td>
<td>4</td>
<td>In Progress</td>
</tr>
</tbody>
</table>

Select the appropriate patient from the list.

You will note this table lists the patient ID, # suspicions of newly acquired infection, and the patient’s data entry status.
An Infection Adjudication Table is automatically generated that lists all the relevant data that has been entered for the patient. The top of the table identifies the patient, number of infections that need to be adjudicated based on the number of clinical suspicions and baseline and outcome data.

### Patient #10141001 - Stage 2

<table>
<thead>
<tr>
<th>Baseline Information</th>
<th>Outcome Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Admission</td>
<td>Hospital Discharge</td>
</tr>
<tr>
<td>2011-07-20 05:51</td>
<td>2011-08-11 19:05</td>
</tr>
<tr>
<td>ICU Admission</td>
<td>ICU Discharge</td>
</tr>
<tr>
<td>2011-07-20 17:18</td>
<td>2011-08-02 14:05</td>
</tr>
<tr>
<td>Randomization</td>
<td>Date/Time of Death</td>
</tr>
<tr>
<td>2011-07-21 18:46</td>
<td>N/A</td>
</tr>
<tr>
<td>Admission Type</td>
<td>Surgical</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>Gastrointestinal GI neoplasm</td>
</tr>
</tbody>
</table>

The next section is the entire table with the clinical data the Site Investigator/MD delegate will use to adjudicate the infection. This data includes the following: Date, Temperature, Worst PF ratio, WBC highest and lowest, Pressors, Ventilation Status, Microbiology data and Antibiotic data.

<table>
<thead>
<tr>
<th>Date (dd/mm/yy)</th>
<th>Temp</th>
<th>WBC</th>
<th>Pressure/Ventilated</th>
<th>Microbiology</th>
<th>Antibiotic</th>
<th>Date</th>
<th>Frequency</th>
<th>Rate</th>
<th>Newly Acquired Infection</th>
<th>Control</th>
<th>Adjudicator</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1 07-20</td>
<td>196</td>
<td>106</td>
<td>No</td>
<td>Gram-negative</td>
<td>Ceftriaxone</td>
<td>2g</td>
<td>TID</td>
<td>IV</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 2 07-21</td>
<td>102</td>
<td>108</td>
<td>No</td>
<td>Gram-negative</td>
<td>Ceftriaxone</td>
<td>2g</td>
<td>TID</td>
<td>IV</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 5 07-24</td>
<td>142</td>
<td>94</td>
<td>No</td>
<td>Gram-negative</td>
<td>Ceftriaxone</td>
<td>2g</td>
<td>BID</td>
<td>IV</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 6 07-25</td>
<td>177</td>
<td>106</td>
<td>No</td>
<td>Gram-negative</td>
<td>Ceftriaxone</td>
<td>4g</td>
<td>TID</td>
<td>IV</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Refer to the column on the right called “Newly Acquired Infection” for all the infections that need to be adjudicated.
The Site Investigator, or MD delegate, is to pick the most appropriate response by referring to the variables in the table in addition to reviewing the patient’s medical chart and condition at the time of infection.

Three response options available for each instance of a clinical suspicion of infection are:

- This is a newly acquired infection
- This is NOT a newly acquired infection
- This is a previously adjudicated suspicion of infection

**This is a newly acquired infection**
Pick this option if the clinical suspicion of infection is considered to be a newly acquired infection. The Site Investigator, or MD delegate, will assign a Category of Infection (Appendix 7 of the Mock eCRF), then the degree of certainty of the infection using the definition from within the assigned Category of Infection.

**Example:**
On study day 9 the patient is febrile, has an elevated WBC, CXR reveals a new infiltrate. An endotracheal aspirate specimen was sent for culture, *S. aureus* is identified. The infection should be adjudicated as follows:

- This is a newly acquired infection
- Category of Infection = 11- ICU Pneumonia
- Probable YES

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**This is NOT a newly acquired infection**

Pick this option if the clinical suspicion of infection is *not* considered to be an infection. Refer to (Appendix 8 of the Mock eCRF), for associated definitions.

Example:
On study day 17 a blood culture indicates the presence of *Staph Epidermis*. There are no other clinical indicators of infection (i.e. SIRS). A repeat culture is negative. The initial positive culture is thought to be a contaminant. The infection should be adjudicated as follows:

- This is NOT a newly acquired infection
- Probable-NO

**This is a previously adjudicated infection**

Pick this option if this clinical suspicion of infection is associated with an infection already adjudicated. You must also indicate the day and the suspicion # of the associated previously adjudicated infection.

Although infections that occur within the first 72 hrs of ICU admission are not to be considered newly acquired infections and hence are not be adjudicated per se, there is an option to capture this information. If the suspicion of infection was due to an infection that occurred in the first 72 hours after ICU admission, select “Baseline Infection”.

Example:
On study day 19 the patient is febrile, has an elevated WBC and CXR reveals a new infiltrate. An endotracheal aspirate specimen was sent for culture, *Streptococcus pneumoniae* is identified. On study day 20 an antibiotic was initiated to treat the *Strep pneumoniae*. The clinical suspicion triggered on study day 20 with the initiation of an antibiotic is related to a previously adjudicated infection.
The adjudication response for study day 19 is:
- This is a newly acquired infection
- Category of Infection = 11 - ICU Pneumonia
- Probable-Yes

The adjudication response for study day 20 is:
- This is a previously adjudicated infection
- Infection # 6 (same response as study day 19).

**Before** the locking checks are completed (Stage 1), the site may click on the SAVE button to save their adjudication data.

**After** the locking checks are completed (Stage 2) and all incidents of clinical suspicion of infection have been adjudicated for a patient, click on the SAVE & COMPLETED button. This will save the data you have entered.

**No clinical suspicions of infection**

After the locking checks are completed (Stage 2), complete the adjudication form. If there are no clinical suspicions of infection in the right hand column, the adjudication form must still be completed by clicking on the SAVE & COMPLETED button.

**Following the completion of the Infection Adjudication by the Site Investigator, any queries/discrepancies will need to be addressed by the Site Investigator.**

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Stages of Data Entry

To help you determine the status of the patient data, we have designated different stages of data completion. Each stage marks the completion of a specific set of data. The diagram below summarizes the site responsibilities at these various stages.

Stage 1
Enter data on REDCap

Stage 2
Complete Infection Adjudication

Stage 3
Complete 6 month Follow-up

Stage 5
Patient chart closed
Investigator Confirmation Form Completed
Once all data has been completed up to and including hospital overview (6 month follow-up excepted), the user can proceed to “Stage 2”. The “Completed Stage 1” button is found at the bottom of the Grid.

Once the “Completed Stage 1” button has been selected, REDCap will run front-end logic and edit checks. If any data discrepancies are identified the user will see them listed on a new screen.

Once all errors have been addressed by the site and patient is locked, the patient will be in “Stage 2”.

Each error identified must be addressed before you can “Lock” the patient. There is an individual link to the relevant form to address each error noted.

Once a patient is “locked” the site will NOT be able to modify the data. Contact the Project Leader if modifications to the data are required.
Investigator Confirmation

After the completion of all data entry (i.e. Status of “Stage 5”), the Investigator Confirmation form must be completed and forwarded to the Project Leader.

To access the Investigator Confirmation form, select the link from the Resources section on the left side menu.

The form will automatically be populated with the site name and patient enrollment number. Print this form and have the site Investigator sign and date.

By signing, the site Investigator is attesting to the following:

- The data collection and entry was conducted under his/her supervision and in accordance with study procedures.
- The data and statement, including newly acquired hospital infection adjudication are complete and accurate to the best of his/her knowledge.

Forward a scan or fax (613-548-2428) of the signed Investigator Confirmation form. File the original in your study files.