A Randomized Trial of Supplemental Parenteral Nutrition in

Under and Over Weight Critically Ill Patients:

The TOP UP Trial

CRS & REDCap Manual

Intended Audience: Research Coordinators

This study is registered at Clinicaltrials.gov.
Identification number **NCT 01206166**

Funded by:

Sponsor: Dr. Daren Heyland

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Electronic Data Capture Systems

Each site will need to access two different electronic data capture systems for TOP-UP:

1

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

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2

REDCap is a web-based system that will be used as the TOP-UP Study eCRF. REDCap may be accessed via http://www.criticalcarenutrition.com or directly at: https://ceru.hpcvl.queensu.ca/EDC/redcap/

Granting CRS & REDCap Access

- Access to both 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 daily to see if they meet the inclusion criteria or exclusion criteria as listed below.

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

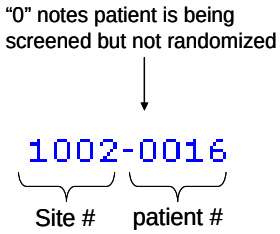
The CRS serves as a screening log and is vital in identifying the screening activity at each site. Hence ALL patients that meet the following criteria MUST be entered into the CRS on a regular basis:

- **All patients meeting inclusion criteria**, these would be either 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 do not meet any exclusion criteria and consent is not obtained (Eligible but not randomized patients)

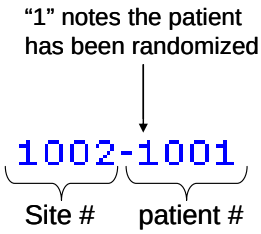
The table below provides several examples of the types of patients.

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**

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:

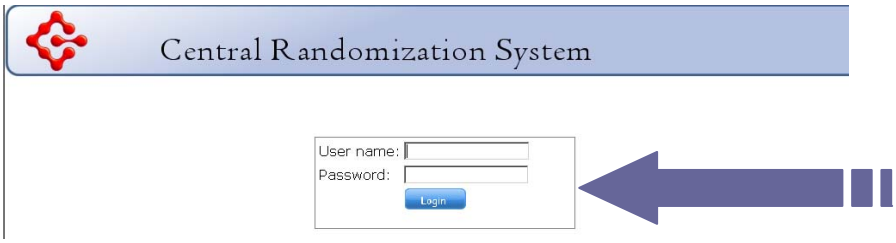


If the patient is subsequently randomized, they will also be issued an enrollment number.
The enrollment numbers are assigned sequentially in an 8-digit format:



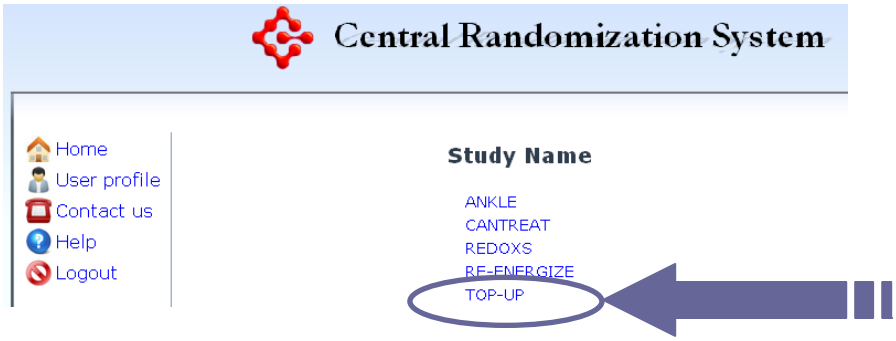
Accessing & Entering a Patie

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



To access the CRS enter your assigned User name and Password. Click **LOGIN**.

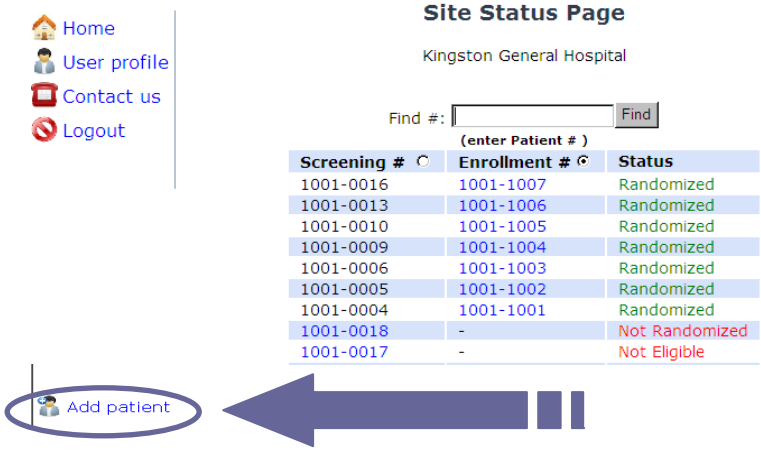
Once you have logged in successfully, you will be brought to the **Home** screen.



The **Home** screen lists all clinical trials for which your site is participating in with CERU that are also using the CRS. Click on **TOP-UP**.

After selecting the TOP-UP 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 the study at your site.

To enter data for a new patient, select the **Add patient** link.



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.

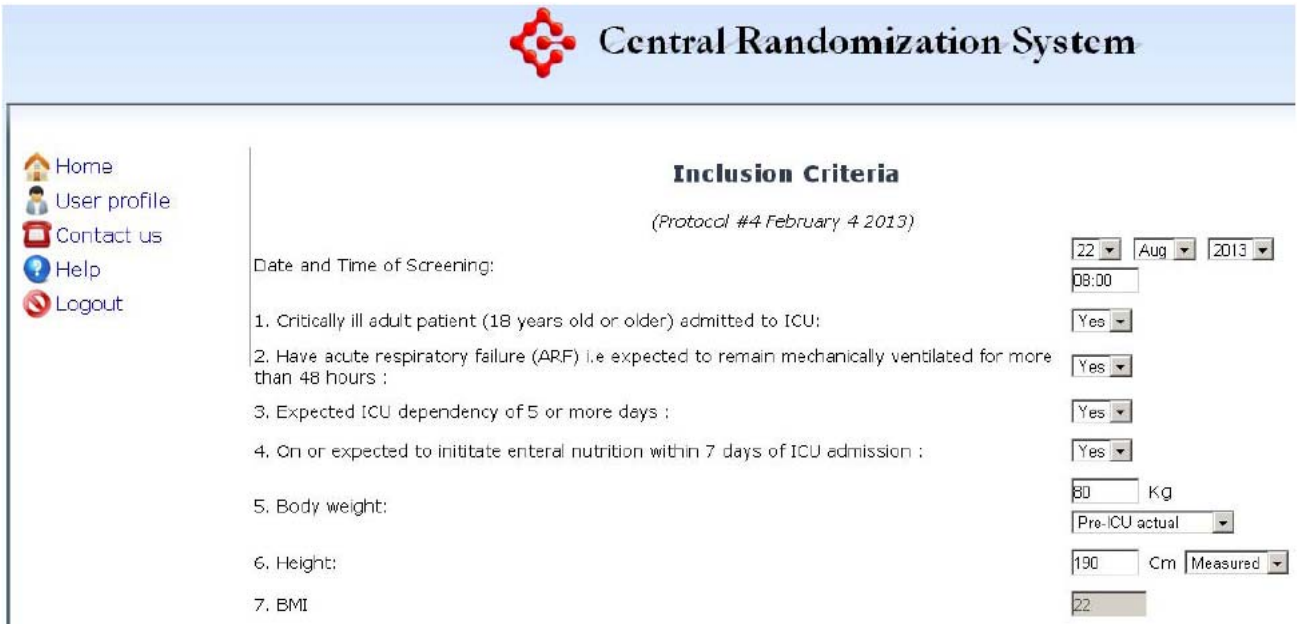
You will be brought to the **Inclusion Criteria form**. Complete the fields in the form as appropriate.

Click on the drop-down boxes to select a "Yes" or "No" response.

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: if you select "NO" to any of the criteria you will not be able to save the form. See Types of Patients to be Entered section for further detail.

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

Inclusion Criteria

Patients must meet all **five** of the criteria at the time of screening to be eligible for the study with the exception of criteria # 2 which os from ICU admission.

#	Inclusion Criteria
1	**Critically ill adult patient (≥18 years) admitted to your ICU**
2	**Have acute respiratory failure (ARF) i.e. expected to remain mechanically ventilated > 48 hrs from ICU admission** This refers to **invasive mechanical ventilation** and is defined as intubation with mechanical ventilation or tracheostomy with mechanical ventilation. This includes **any** positive pressure delivered via an endotracheal tube or a tracheostomy. This **does not** refer to ***non-invasive*** methods of ventilation such as BI-PAP or mask-CPAP. To avoid enrolling patients that are extubated early and given current exclusion criteria # 1 i.e. >72 hours from admission to ICU to time of consent, the following clarification is provided for this revision: ***If screening is done on day 1 (day of ICU admission):*** ***ensure patient is expected to remain mechanically ventilated for 48 hrs from ICU admission*** ***If screening is done on day 2 (day after ICU admission):*** ***ensure that the patient is expected to be ventilated for an additional 24 hrs from screening (equivalent to 48 hrs from ICU admission)*** ***If screening is done on day 3:*** ***and patient was ventilated for 48 hrs but now is extubated, he/she is eligible as long as all other inclusion criteria are met. If patient remains ventilated on day 3, need to ensure that consent is still obtained within 72 hrs from ICU admission.***
3	**Expected ICU dependency of 5 or more days** (as per judgment by the Site Investigator/delegate) ICU dependency defined as need for mechanical ventilation, non invasive ventilation, renal replacement therapy, vasopressors or artificial nutrition because of their underlying illness. **NOTE:** This does **not** include patients that stay in ICU because of lack of availability of beds.
4	**On enteral nutrition or expected to initiate enteral nutrition within 7 days of ICU admission** The "expected to initiate enteral nutrition" refers to the anticipation of the start of enteral nutrition and this is an assessment that is made at the time of screening evaluation in collaboration with the Medical Team. In the event that, at time of screening, the patient was expected to start enteral nutrition within the first 7 days and the patient is randomized, but enteral nutrition does not actually get started within this time frame, the patient still remains in the study.
5	**BMI < 25 or ≥35 based on pre-ICU actual or estimated dry weight** (Refer to **Appendix B** for BMI Chart) **If using estimated weight/height, you may add a buffer of ±1 for the BMI, after rounding, In this case, ENTER THE BUFFERRED BMI into the Central Randomization System.** Example 1: If estimated BMI is 25 after rounding, use a -1 to get a BMI of 24. Record 24 into the CRS Example 2: If estimated BMI is 34 after rounding, use a +1 to get a BMI of 35. Record 35 into the CRS

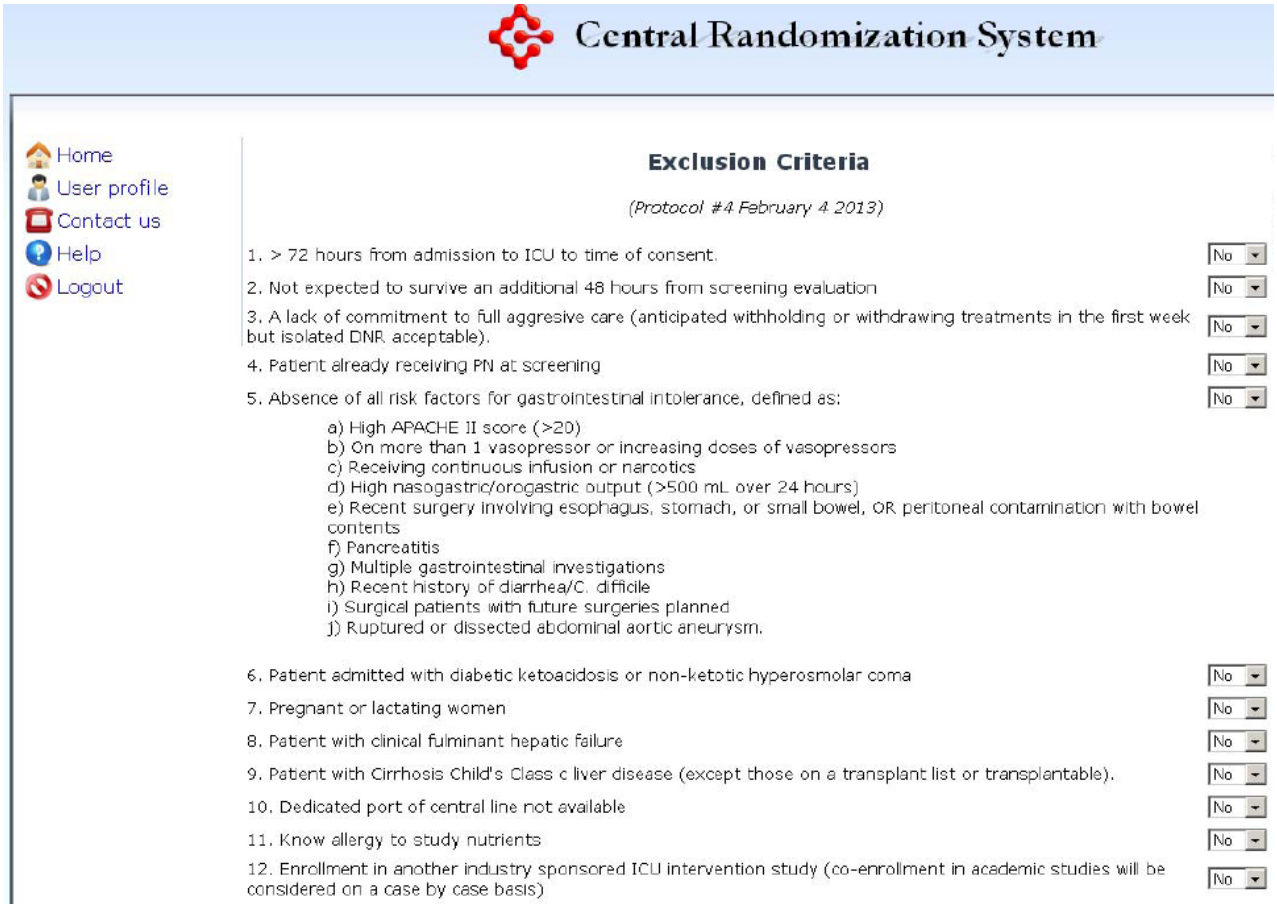
*Consent **must** be obtained **within 72 hrs** of admission to the ICU.*

Complete the exclusion criteria fields as appropriate.

Click on the drop-down boxes to select a “Yes” or “No” response for each criterion.

If you click “Yes” to any one criteria, this patient is not eligible for the study.
Click **SAVE**. No futher data entry required.

If you click “No” to all criteria, this patient is eligible. Click **SAVE**, then proceed to the Pre-Randomization Form.



Remember to:

- **Only** enter patients who meet **ALL** 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 any of the exclusion criteria are met, the patient is not eligible to participate in the study.

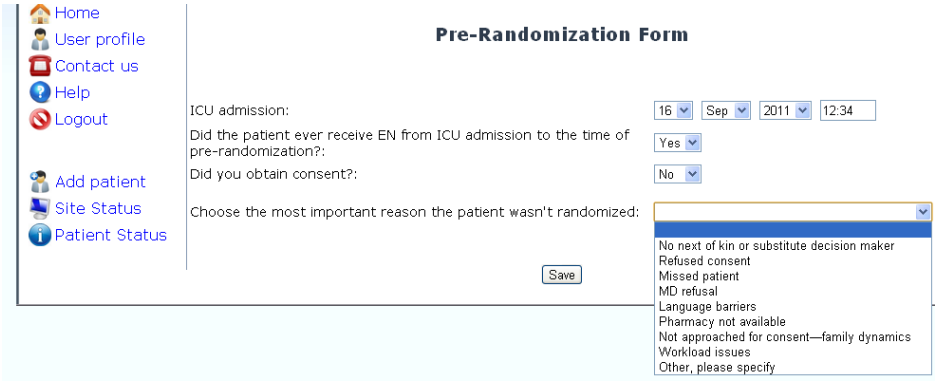
#	Exclusion Criteria
1	**> 72 hrs from admission to ICU to time of consent.** The 72 hr window refers to admission to your ICU. In the event that the patient is transferred to your ICU from another ICU, the 72 hr starts from the admission to your ICU.
2	**Not expected to survive an additional 48 hours from screening evaluation**
3	**Lack of commitment to full, aggressive care (anticipated withholding or withdrawing treatments in the first week but isolated DNR acceptable)**
4	**Patients already receiving PN at screening**
5	**Absence of all risk factors for gastrointestinal intolerance, defined as:** a) High Apache II score (>20) b) On more than 1 vasopressor or increasing doses of vasopressors c) Receiving continuous infusion of narcotics d) High nasogstric/orogastric output (>500 mL over 24 hours) e) Recent surgery involving esophagus, stomach, or small bowel, OR peritoneal contamination with bowel contents f) Pancreatitis g) Multiple gastrointestinal investigations h) Recent history of diarrhea/C. difficile i) Surgical patients with future surgeries planned j) Ruptured or dissected abdominal aortic aneurysm
6	**Patients admitted with Diabetic Ketoacidosis or non-ketotic hyperosmolar coma**

7	**Pregnant or lactating patients**
8	**Patients with clinical fulminant hepatic failure.** Clinical fulminant hepatic failure is defined as: • absence of cirrhosis/chronic liver disease and • presence of coagulopathy (prothrombin time > 15 sec or INR >1.5) and • presence of any grade of hepatic encephalopathy within 26 weeks of the first symptoms in a patient with acute liver injury • **NOTE:** This criterion applies to **only** those patients who, in the opinion of the Site Investigator/delegate, are deteriorating or are at high risk of dying due to clinical fulminant hepatic failure. If the patient meets this criterion but, in the opinion of the Site Investigator/delegate, is improving significantly and is not expected to die because of the clinical fulminant hepatic failure, he/she may be eligible and this exclusion criterion would not apply. In this event, proper documentation from the Site Investigator is needed for confirmation of the patient's prognosis. Refer to Protocol Clarification memo dated May 7th, 2012
9	**Patients with Cirrhosis Child's Class C Liver Disease** (except those on a transplant list or transplantable)
10	**Dedicated port of central line not available**
11	**Known allergy to study nutrients (soy, egg or olive products)**
12	**Enrollment in another industry sponsored ICU intervention study** (co-enrollment in academic studies will be considered on a case by case basis)

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.

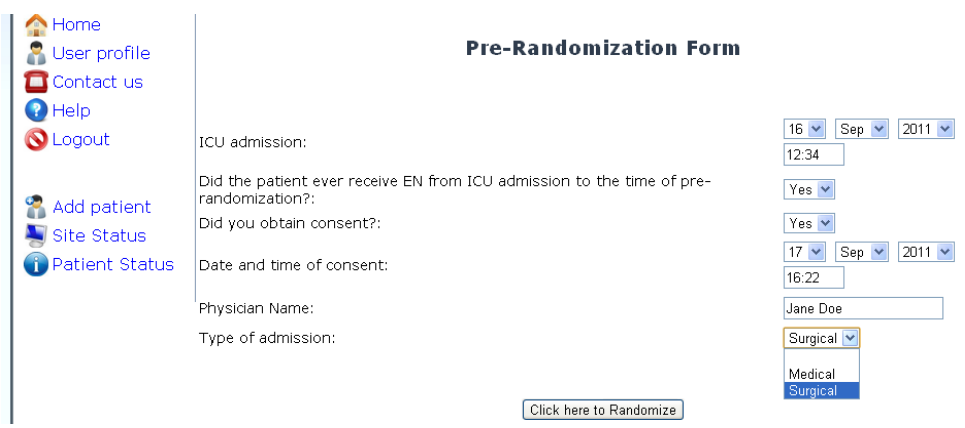
If consent was NOT obtained, complete the following form as shown below.



Choose one of the following reasons for NOT obtaining consent:

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

If consent IS obtained, complete the following form as shown below.

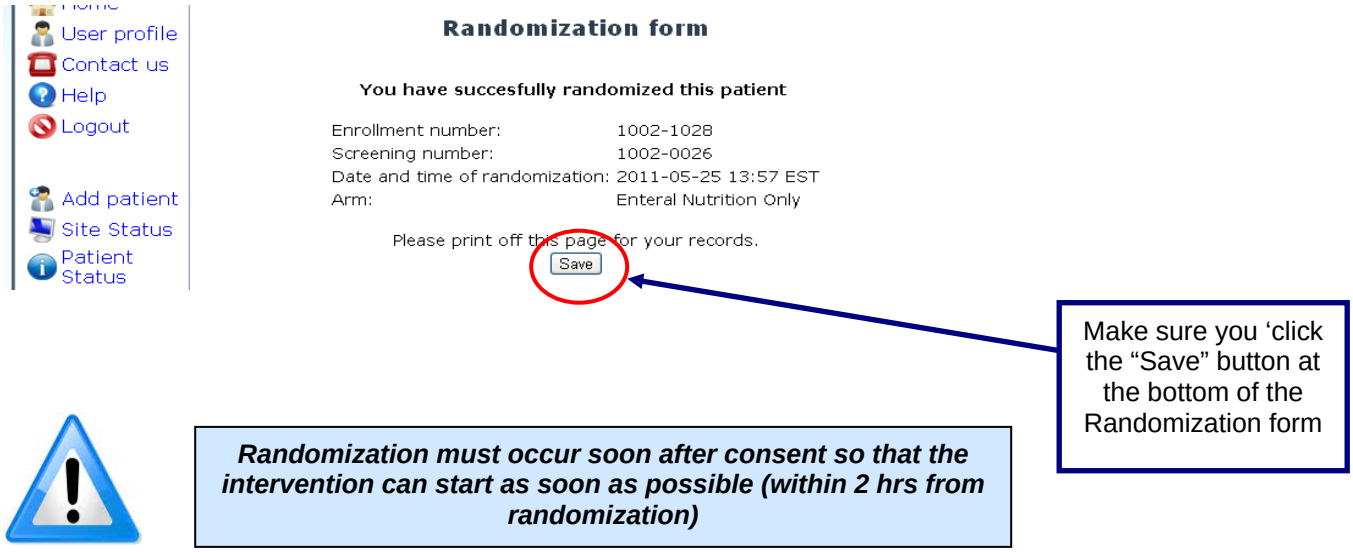


Dates are to be entered in the DD-MMM-YYYY format.

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.

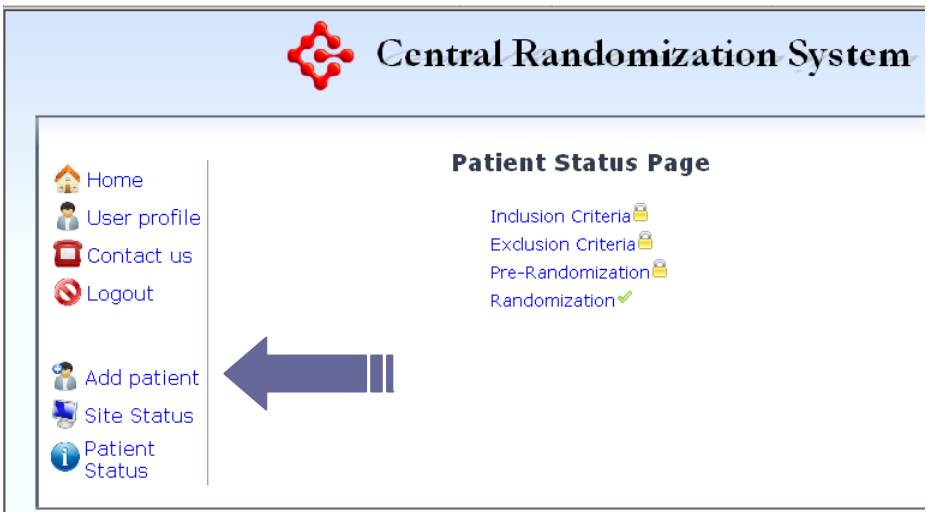
Once you click on the **"Click here to Randomize"** button, the patient will be randomized to the TOP-UP Study (see next page).

Randomization



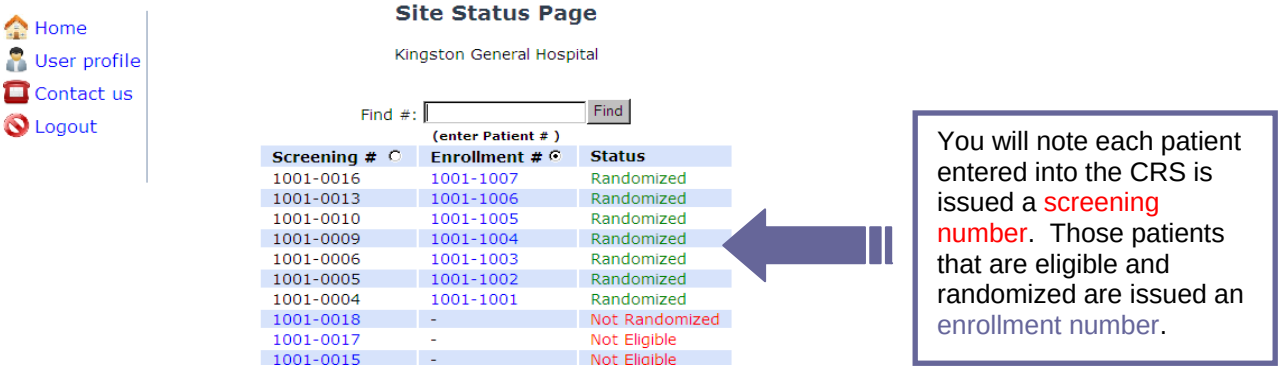
Randomization must occur soon after consent so that the intervention can start as soon as possible (within 2 hrs from randomization)

Upon randomization, you will see the group that the patient has been randomized to. You may print a copy of the Randomization Form and file in the Patient Folder/Study files.
The Patient Status Page indicates that data entry for this patient is complete.

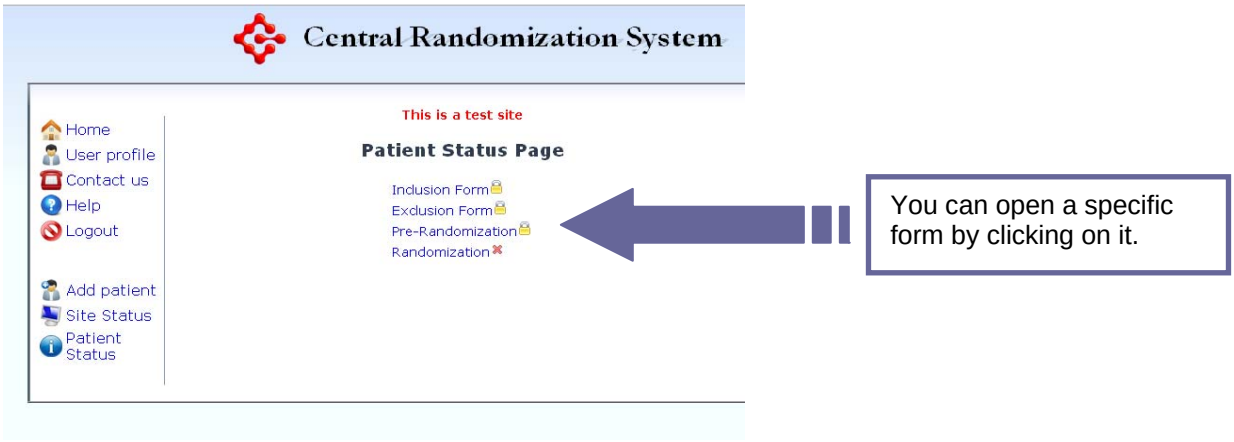


Site Status

The Site Status Page shows you all the patients screened and entered on the CRS. Click on the “Site Status” link to view this.



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



Each form has a status assigned:

Status	Symbol	Description
Completed	✓	All data has been completed and saved.
Not Completed	✗	Data has not yet been entered on the form.
Locked	🔒	The patient has been randomized and the data is no longer able to be edited by the site user.

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

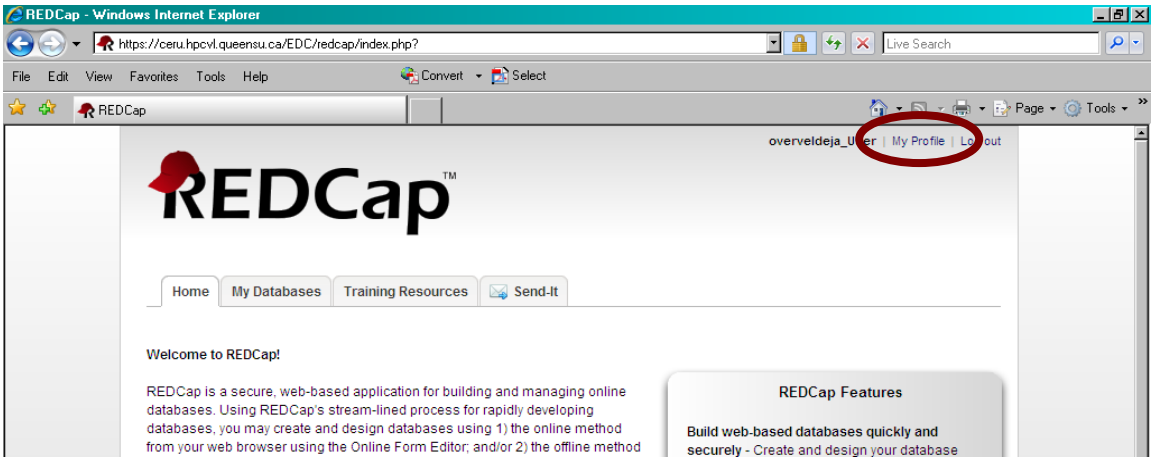
REDCap Data Entry

The REDCap (**Research Electronic Data Capture)** is a web-based system used for the TOP-UP 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.

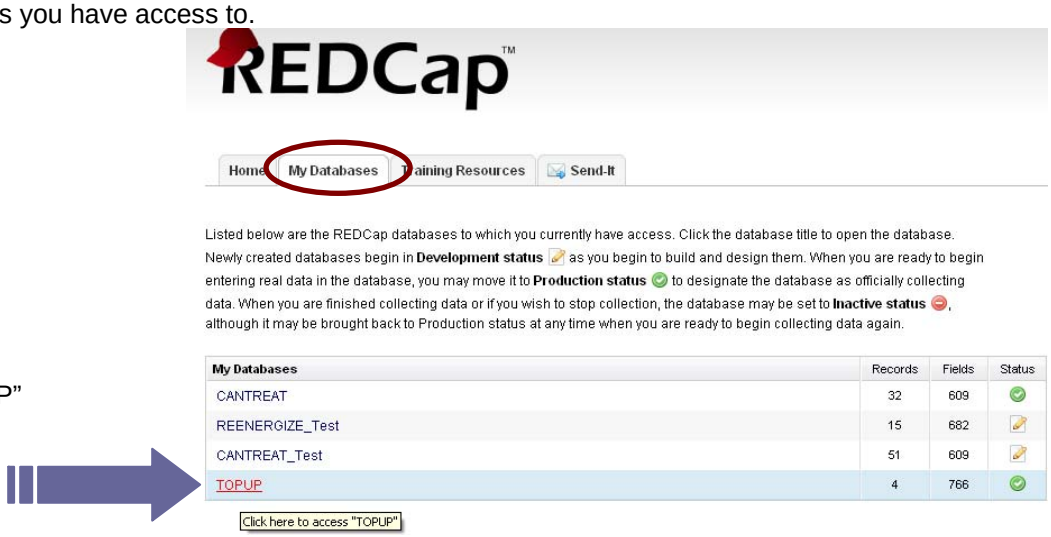


Navigating REDCap

My Databases

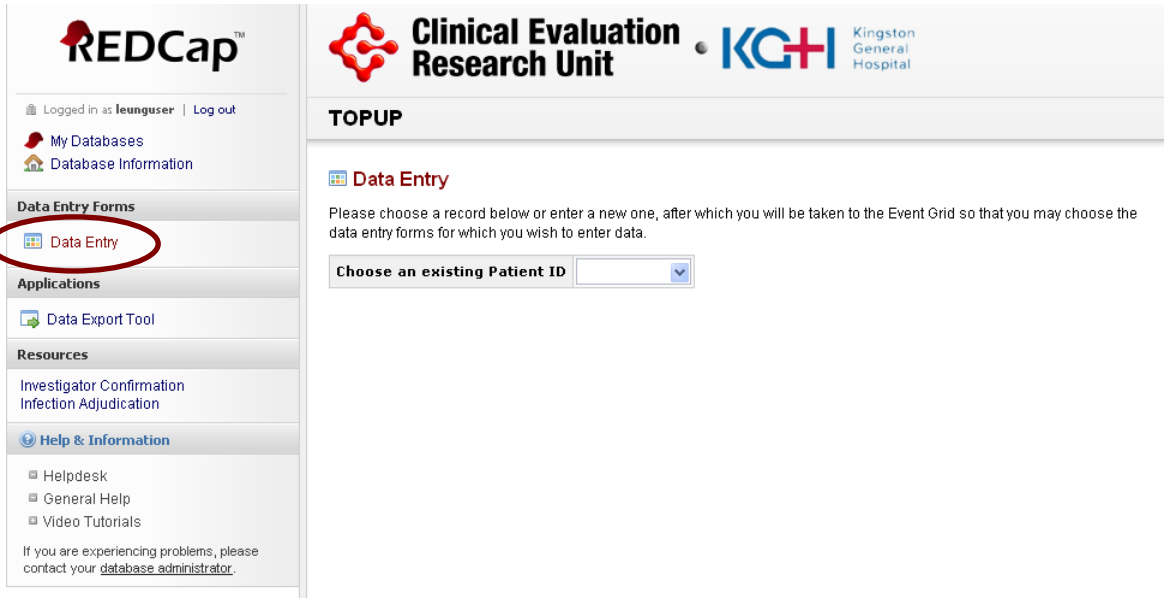
After you log into REDCap, you will be brought to the Home screen. Select the "My Databases" tab to see a list of the CERU studies you have access to.

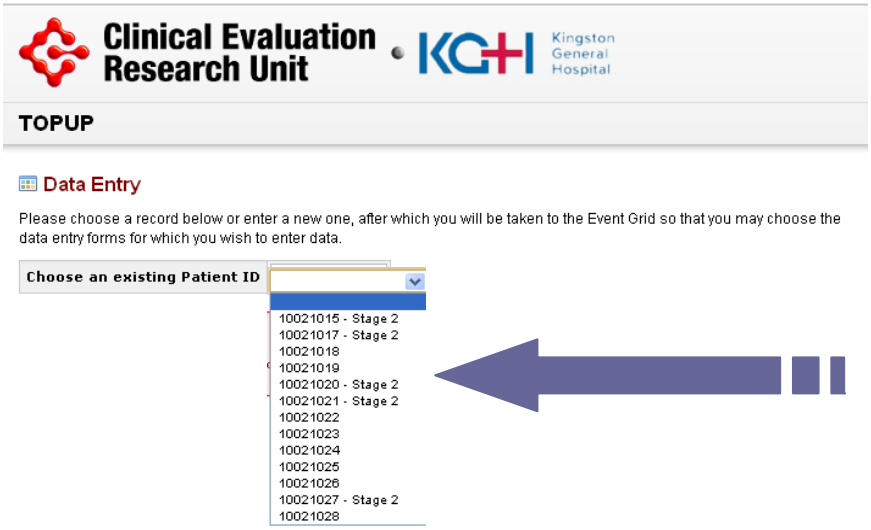
Select "TOP-UP"



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.



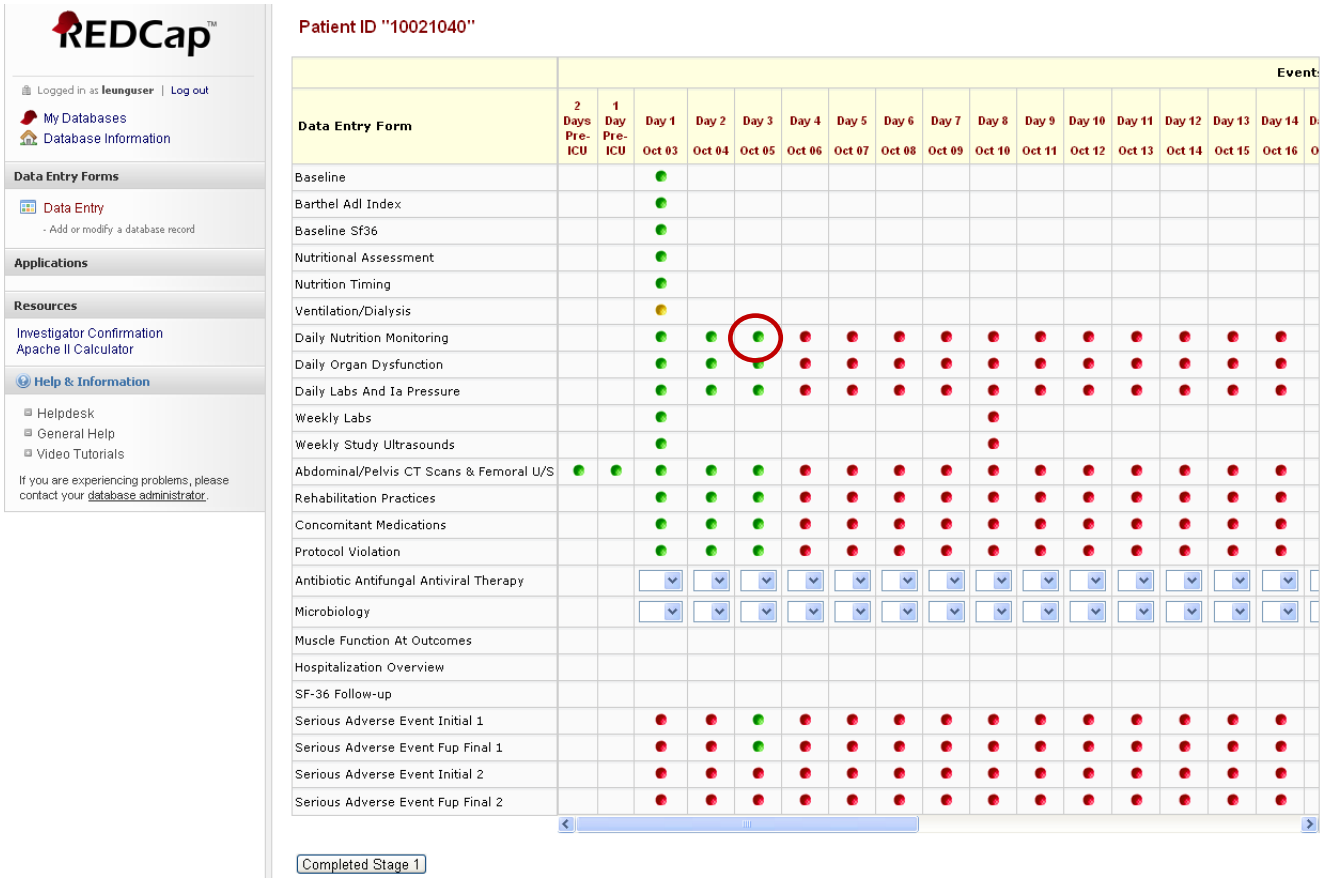


Click on the drop-down menu to select a randomized patient.

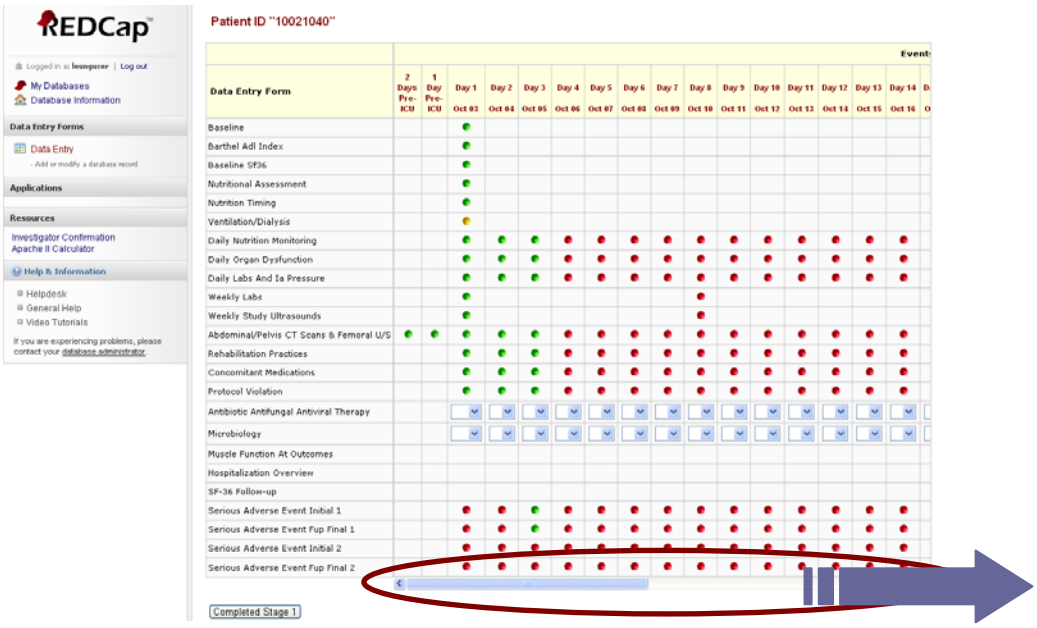
Event Grid Field

After you have selected a patient, you will be brought to the Event Grid. The Event Grid gives the user a snap shot 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.

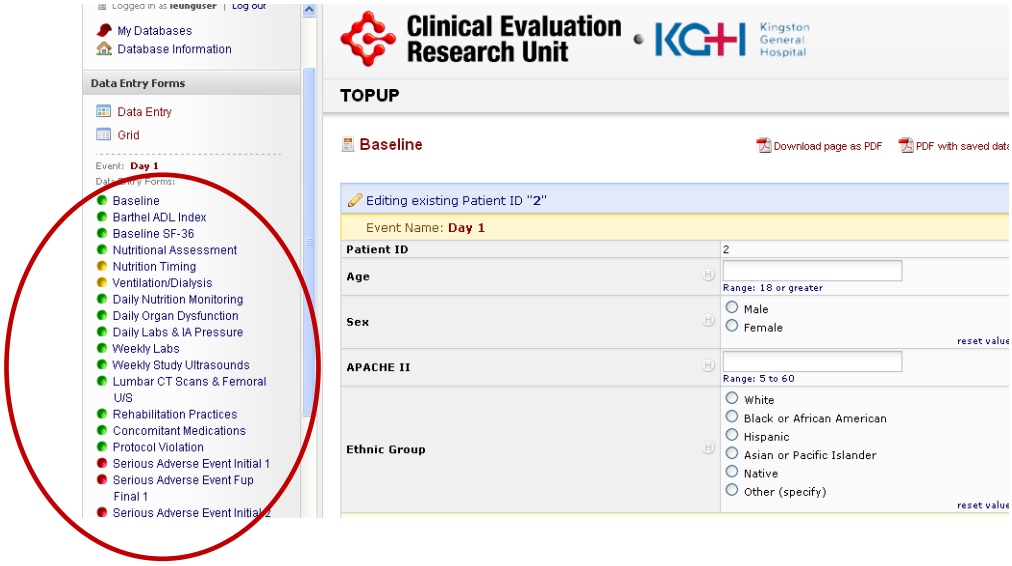


Slide the navigation scroll bar at the bottom of the table to reveal the right side of the Event Grid.



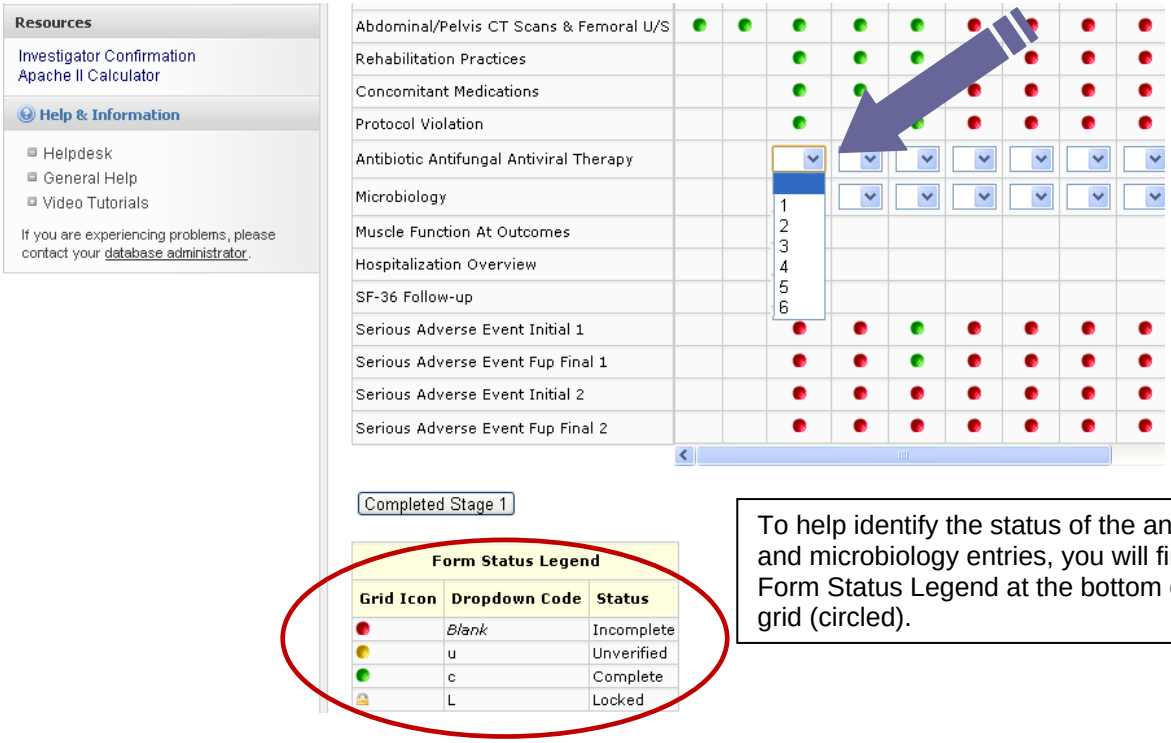
Form Links

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.



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).

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

Form Status and Saving

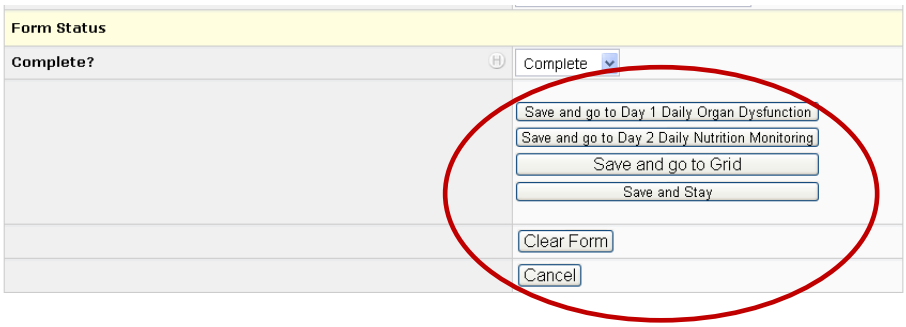
At the end of each form, you will be asked to specify the form status. This legend is to be used to assist you in remembering what data is incomplete, unverified or complete. The status is indicated on the Event Grid Field using the following convention:

Form Status Legend		
Grid Icon	**Dropdown Code**	**Status**
	Blank	Incomplete
	u	Unverified
	c	Complete
	L	Locked

Incomplete	No data has been entered on a form. Blank forms will automatically be set to incomplete.
Unverified	Data entry is partially completed on a form. The Research Coordinator wants to double check data already entered on a form. Partially completed forms will automatically be set to unverified.
Complete	Data entry is complete on a form. Further changes to the data are not anticipated. Only forms manually set to complete will have this status.
Locked	Locked status will appear on all forms after all finalization checks are completed. Data on locked forms can not be changed.

- There may be up to 4 options at the end of each form to save your progress. The following example is for:

Daily Nutrition Monitoring - Study Day 1

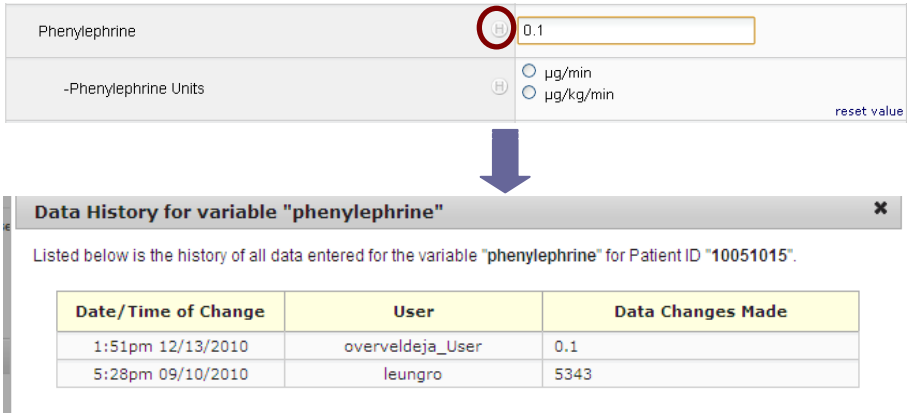


Save and go to Day 1 Daily Organ Dysfunction	This option will save your progress and bring you to the next form on the same study day. Note: In the case of the Antibiotic and Microbiology forms, this option will bring you to the next corresponding Antibiotic/Microbiology form. *For example, if you are 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 semicolon 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, with your cursor or "pointer" in the field **single click** on the left side of the mouse 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 user to see the data entry history for each data field. By clicking on the H, a window will pop up listing the data entry history for the data field.



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 TOP-UP 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

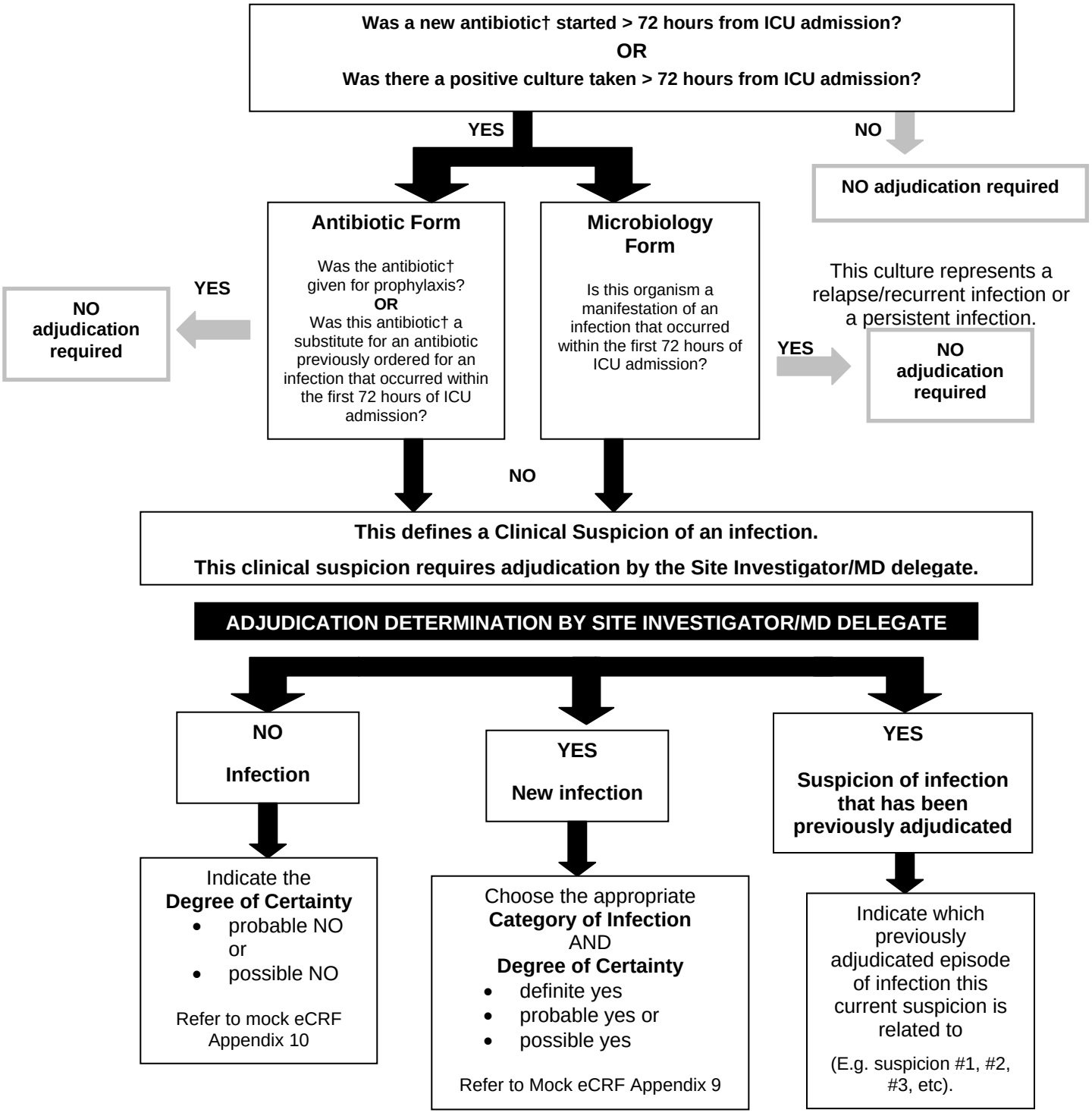
Refer to the algorithm on next page for adjudicating a clinical suspicion of infection.

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 Form mock eCRF
3. Mock eCRF Appendix 9 Categories of Infection
4. Mock eCRF Appendix 10 Definition of No Newly Acquired Infection

Infection adjudication MUST be performed by the Site Investigator, or MD delegate.



† 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.

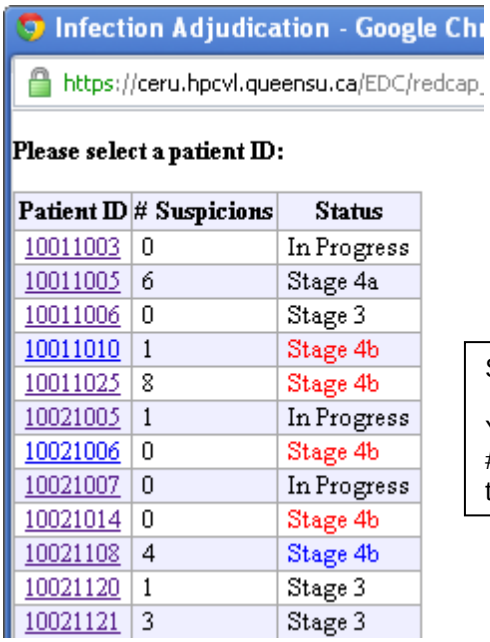
Select "Infection Adjudication"

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

Patients needing an adjudication are in Stage 2 and 4b will be shown in red or blue.

4b red and 4b blue indicate that the initial central adjudication queries (4b red) and subsequent queries (4b blue) need to be addressed by site adjudicator.

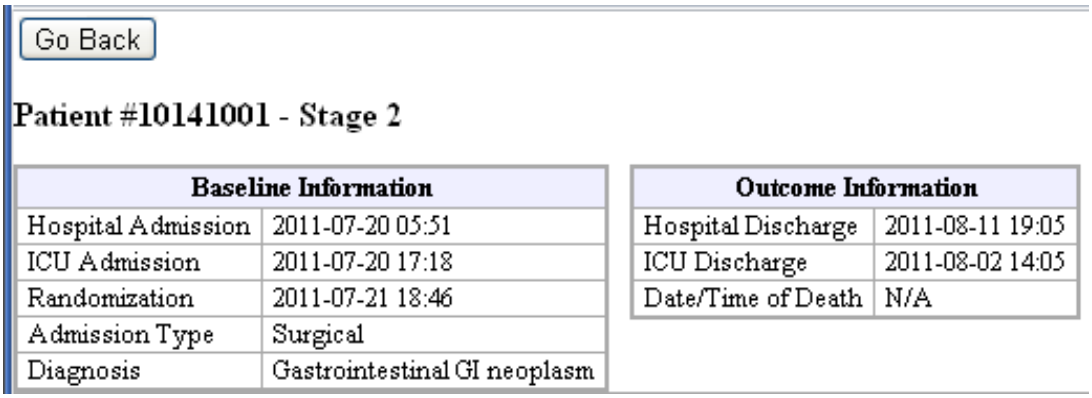
You must complete the infection adjudication for these patients to proceed further.



Select the appropriate patient from the list.

You will note this table that 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.



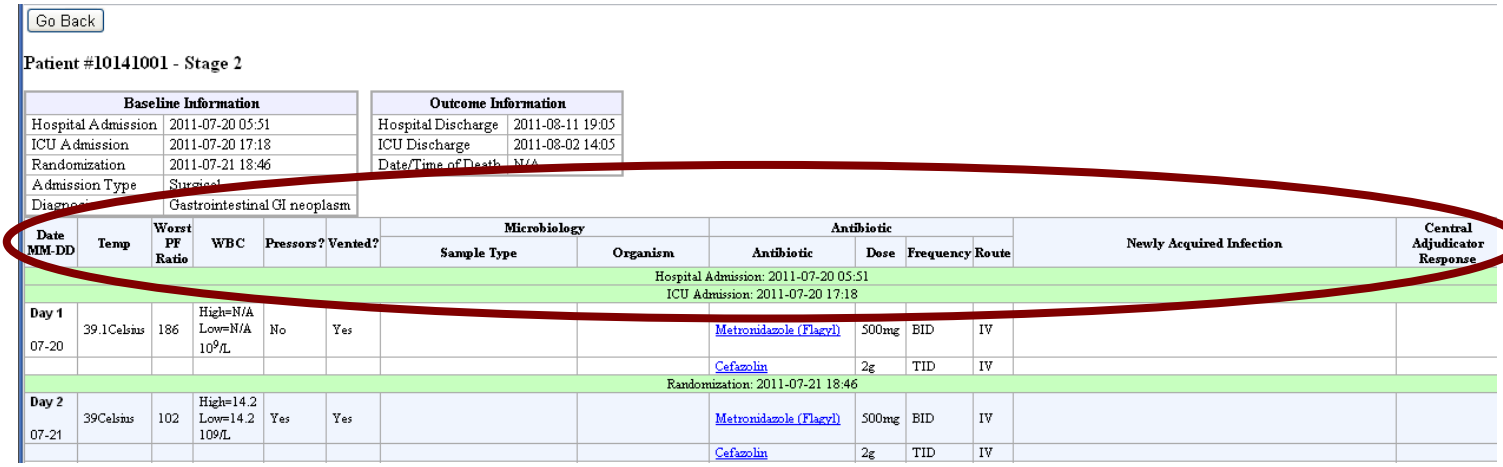
Go Back

Patient #10141001 - Stage 2

Baseline Information	
Hospital Admission	2011-07-20 05:51
ICU Admission	2011-07-20 17:18
Randomization	2011-07-21 18:46
Admission Type	Surgical
Diagnosis	Gastrointestinal GI neoplasm

Outcome Information	
Hospital Discharge	2011-08-11 19:05
ICU Discharge	2011-08-02 14:05
Date/Time of Death	N/A

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



Go Back

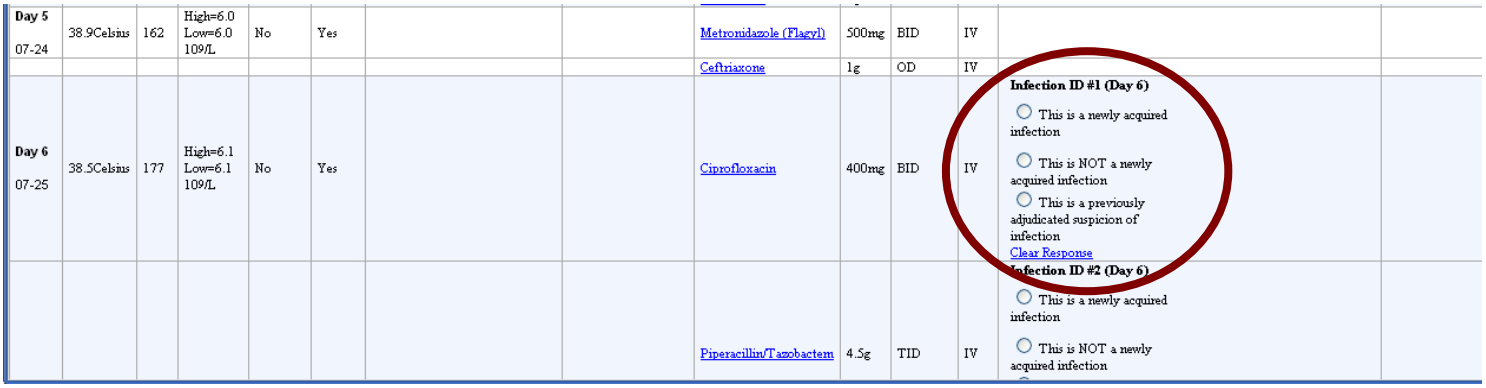
Patient #10141001 - Stage 2

Baseline Information	
Hospital Admission	2011-07-20 05:51
ICU Admission	2011-07-20 17:18
Randomization	2011-07-21 18:46
Admission Type	Surgical
Diagnosis	Gastrointestinal GI neoplasm

Outcome Information	
Hospital Discharge	2011-08-11 19:05
ICU Discharge	2011-08-02 14:05
Date/Time of Death	N/A

Date MM-DD	Temp	Worst PF Ratio	WBC	Pressors?	Vented?	Microbiology		Antibiotic				Newly Acquired Infection	Central Adjudicator Response
						Sample Type	Organism	Antibiotic	Dose	Frequency	Route		
Hospital Admission: 2011-07-20 05:51													
ICU Admission: 2011-07-20 17:18													
Day 1 07-20	39.1Celsius	186	High=N/A Low=N/A 10^9/L	No	Yes			Metronidazole (Flagyl)	500mg	BID	IV		
								Cefazolin	2g	TID	IV		
Randomization: 2011-07-21 18:46													
Day 2 07-21	39Celsius	102	High=14.2 Low=14.2 109/L	Yes	Yes			Metronidazole (Flagyl)	500mg	BID	IV		
								Cefazolin	2g	TID	IV		

Refer to the column on the right called “Newly Acquired Infection” for all the infections that need to be adjudicated



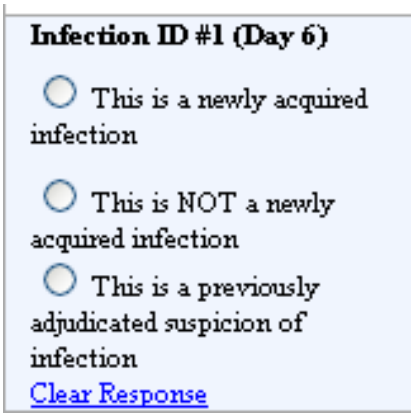
Day 5 07-24	38.9Celsius	162	High=6.0 Low=6.0 109/L	No	Yes			Metronidazole (Flagyl)	500mg	BID	IV	
								Ceftriaxone	1g	OD	IV	
Day 6 07-25	38.5Celsius	177	High=6.1 Low=6.1 109/L	No	Yes			Ciprofloxacin	400mg	BID	IV	**Infection ID #1 (Day 6)** ○ This is a newly acquired infection ○ This is NOT a newly acquired infection ○ This is a previously adjudicated suspicion of infection Clear Response
								Piperacillin/Tazobactem	4.5g	TID	IV	**Infection ID #2 (Day 6)** ○ This is a newly acquired infection ○ This is NOT a newly acquired infection

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.

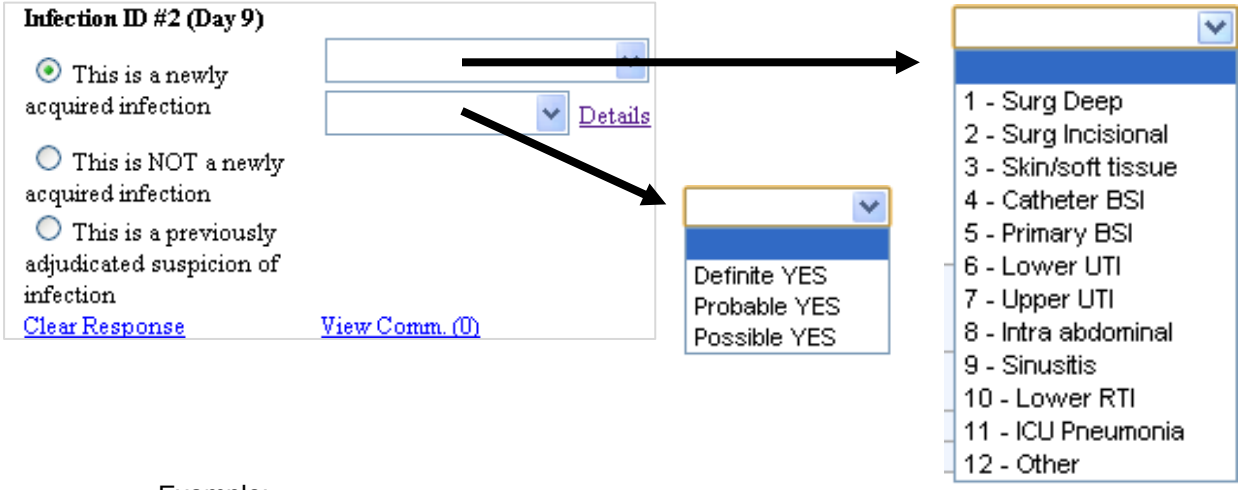
Three response options available for each instance of a clinical suspicion of infection are:

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

As seen in REDCap

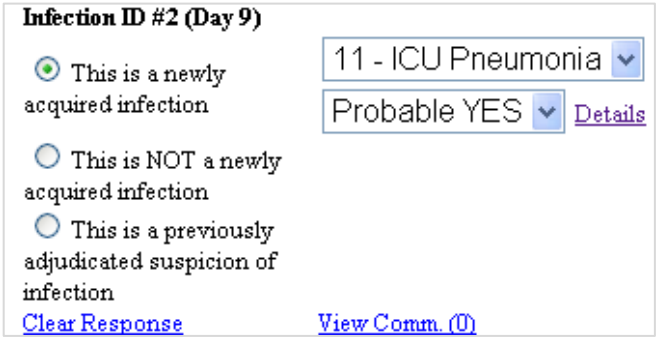


This is a newly acquired infection
Pick this option if the clinical suspicion of infection is considered to be a newly acquired infection. The Site Investigator, or MD delegate, will assign a Category of Infection (Appendix 9 of the Mock eCRF), then the degree of certainty of the infection using the definition from within the assigned Category of Infection.

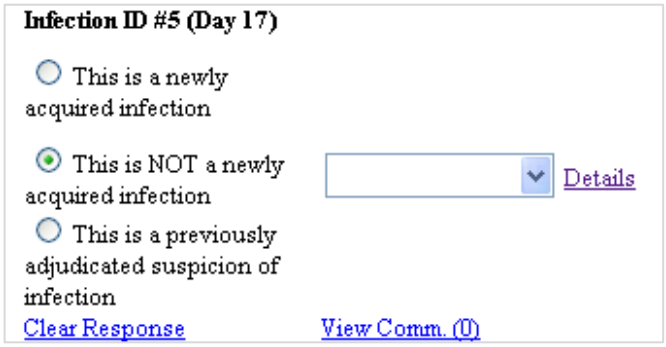


Example:
On study day 9 the patient is febrile, has an elevated WBC, CXR reveals a new infiltrate. An endotracheal aspirate specimen was sent for culture, *S. aureus* is identified. The infection should be adjudicated as follows:

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

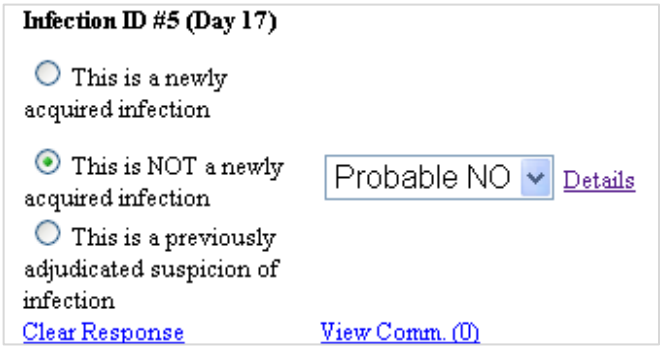


This is NOT a newly acquired infection
Pick this option if the clinical suspicion of infection is not considered to be an infection. Refer to (Appendix 10 of the Mock eCRF), for associated definitions.



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



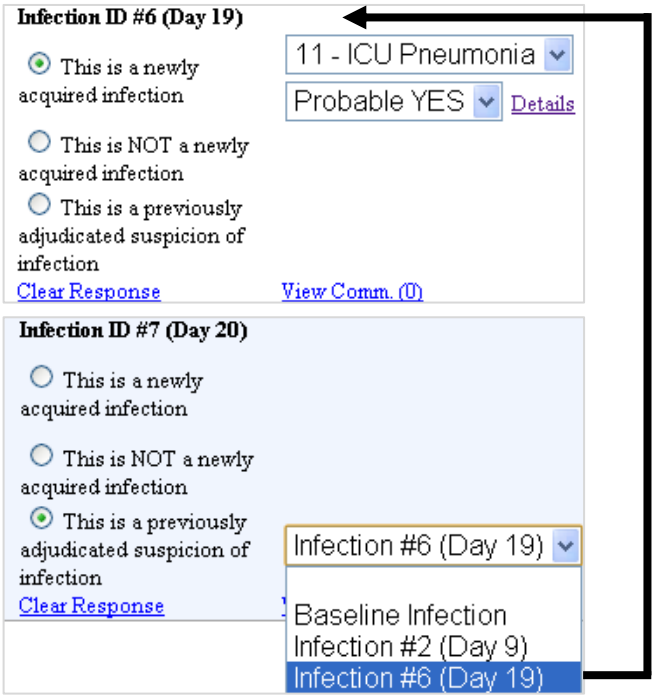
This is a previously adjudicated infection
Pick this option if this clinical suspicion of infection is associated with an infection already adjudicated.You must also indicate the day and the suspicion # of the associated previously adjudicated infection.

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 for the Central Adjudication Process. 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 the patient is febrile, has an elevated WBC and CXR reveals a new infiltrate. An endotracheal aspirate specimen was sent for culture, S. aureus is identified.
On study day 10 an antibiotic was initiated to treat the S. aureus. The clinical suspicion triggered on study day 10 with the initiation of an antibiotic is related to a previously adjudicated infection.

The adjudication response for **study day 19** is:

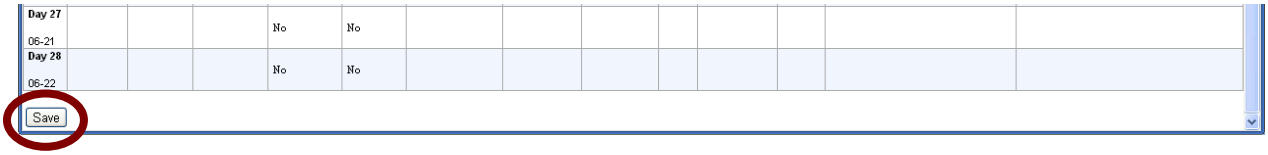
- ✓ This is a newly acquired infection
- ✓ Category of Infection = 11 - ICU Pneumonia
- ✓ Probable-Yes



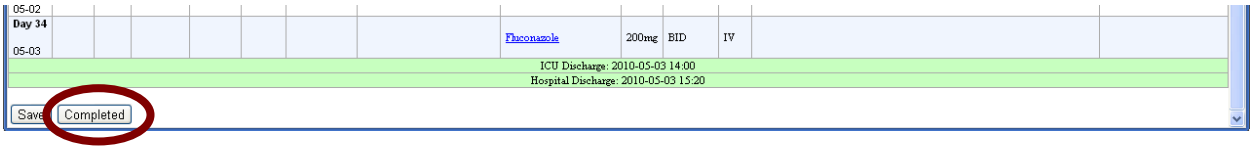
The adjudication response for **study day 20** is:

- ✓ This is a previously adjudicated infection
- ✓ Infection # 1 (same response as study day 19).

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

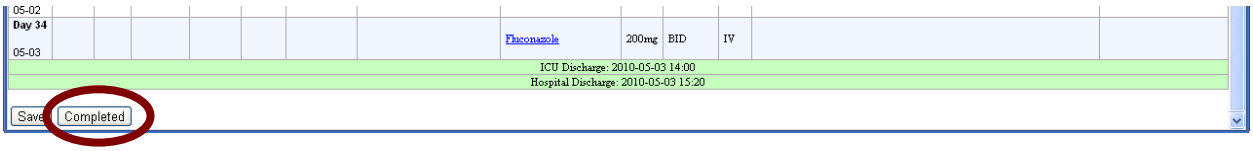


After the locking checks are completed (Stage 2) and all incidents of clinical suspicion of infection have been adjudicated for a patient, click on the COMPLETED button. This will save the data you have entered



No clinical suspicions of infection

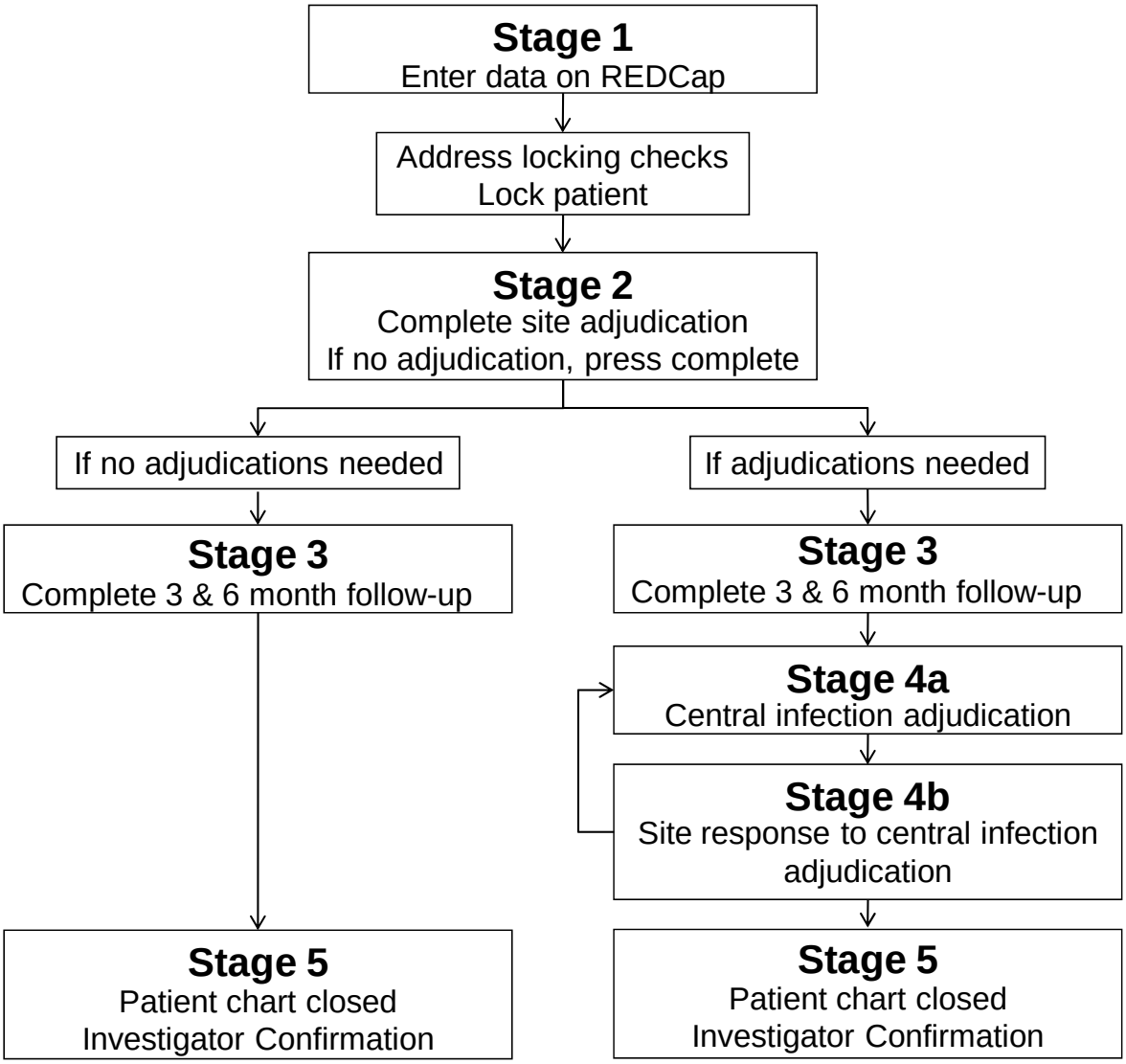
After the locking checks are completed (Stage 2), complete the adjudication form. If there are no clinical suspicions of infection in the right hand column, the adjudication form must still be completed by clicking on the COMPLETED button



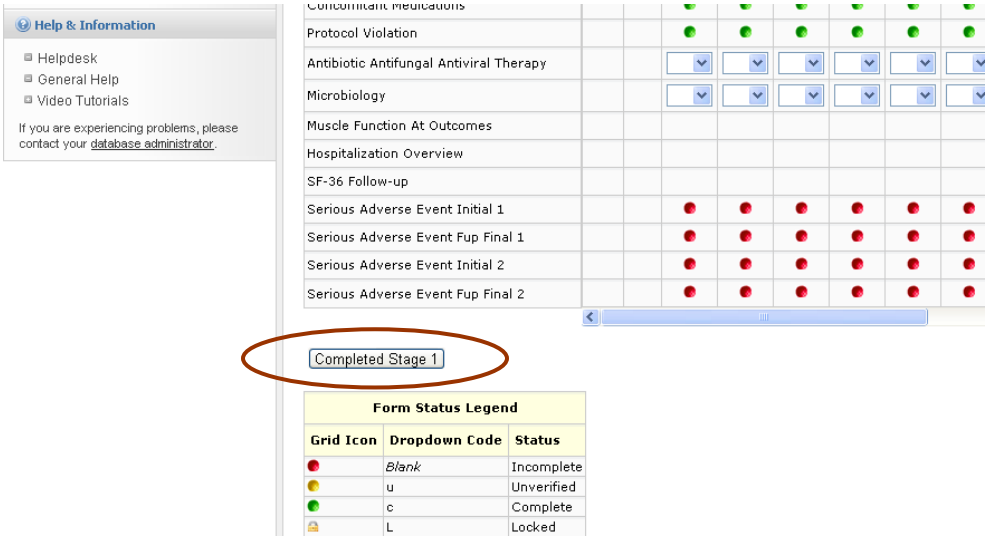
Following the completion of the Infection Adjudication by the Site Investigator, a Central adjudication process will occur in which an external reviewer(s) will review the adjudications done by the Site Investigator. Any queries/discrepancies will need to be addressed by the Site Investigator and the details of this process will be communicated by the Project Leader at CERU when site infection adjudications are completed.

Stages of Data Entry

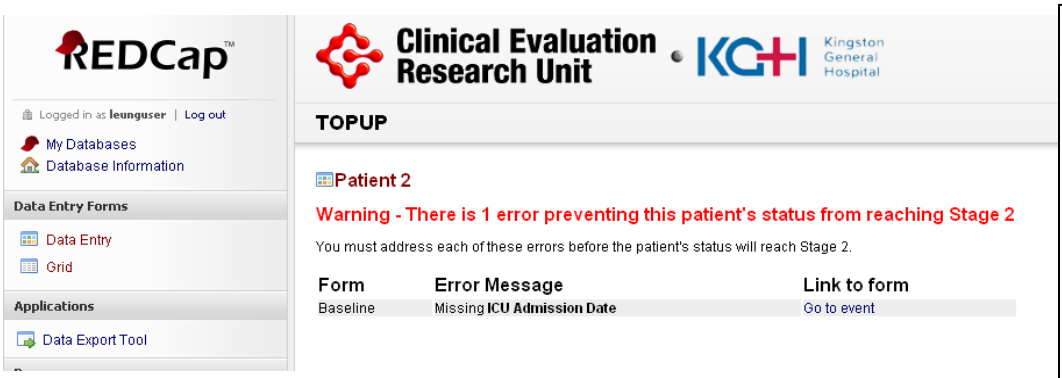
To help you determine the status of the patient data, we have designated different stages of data completion. Each stage marks the completion of a specific set of data. The diagram below summarizes the site responsibilities at these various stages.



Once all data has been completed up to and including hospital overview (except 3 and 6 month follow-up) the user can proceed to “Stage 2”. The “Complete stage 1” button is found at the bottom of the Grid.



Once the “Complete 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.



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.

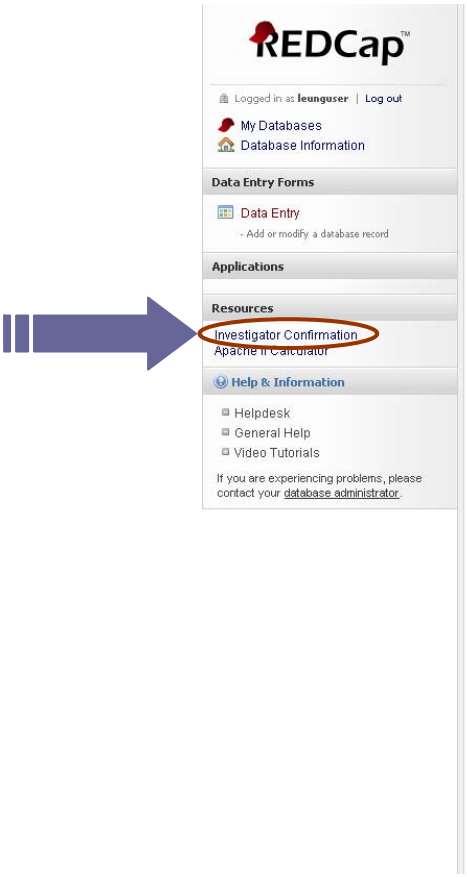
Once all errors have been addressed by the site and patient is locked, the patient will be in “Stage 2”

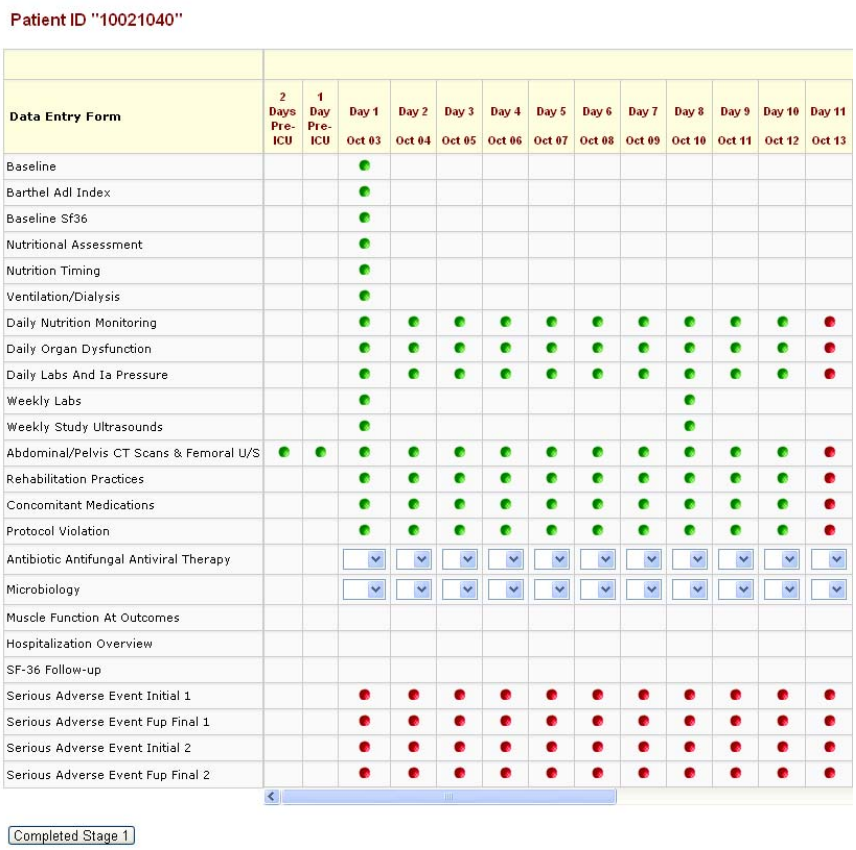
Once a patient is “locked” the site will NOT be able to modify the data.
Contact the Project Leader if modifications to the data are required.

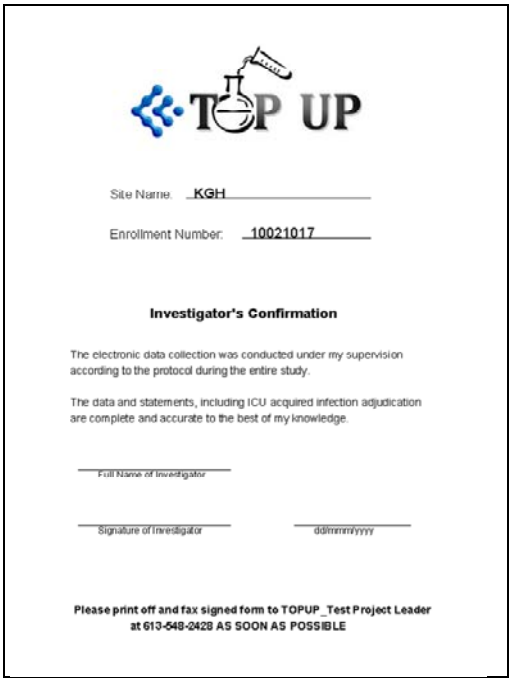
Investigator Confirmation

After the completion of all data entry (i.e. Status of “Stage 5”), the Investigators 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.







TOP UP

Site Name: KGH

Enrollment Number: 10021017

Investigator's Confirmation

The electronic data collection was conducted under my supervision according to the protocol during the entire study.

The data and statements, including ICU acquired infection adjudication are complete and accurate to the best of my knowledge.

Full Name of Investigator

Signature of Investigator dd/mmm/yyyy

Please print off and fax signed form to TOPUP_Test Project Leader at 613-548-2428 AS SOON AS POSSIBLE

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 their knowledge.

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