



REDCap User Guide

Version: September 30, 2010

Introduction

This REDCap Manual functions as a resource for successful completion of electronic case report forms (eCRFs) for the PEP uP Study. The manual is formatted to provide information on using and navigating the REDCap system to enter study data. It does not contain detailed information about each data point. For detailed information on collecting data for the study, consult the paper CRFs and their associated instructions.

ECRFs are the primary mode of data capture used in the PEP uP Study. You are expected to enter data online as soon as it becomes available. Paper CRFs are tools to assist in capturing the required data elements prior to online data entry.

Important: Please keep **ALL** paper CRFs/worksheets/documents that you use as these will be referred to at the time of source verification.

In the event that additional clarification is required, please contact the project assistant, Lauren Murch at 613-549-6666 ext. 4146 or murchl@kgh.kari.net.

Methods Centre Contacts

CERU Contacts	
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All questions related to data collection procedures should be directed to the Project Assistant.

General Guidelines

Accessing the Website

- The Clinical Evaluation Research Unit (CERU) will provide a username and password only to authorized personnel who are participating in the PEP uP Study.
- Once the Site and User Registration form is completed the Project Assistant will assign usernames and passwords to individuals requiring REDCap access
- Please notify the CERU Project Assistant with any changes in study personnel accessing the web.
- The Web Based Data Capture System for the PEP uP Study can be accessed by following the REDCap login link on the www.criticalcarenutrition.com website, or directly at <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.

Patient ID Numbers

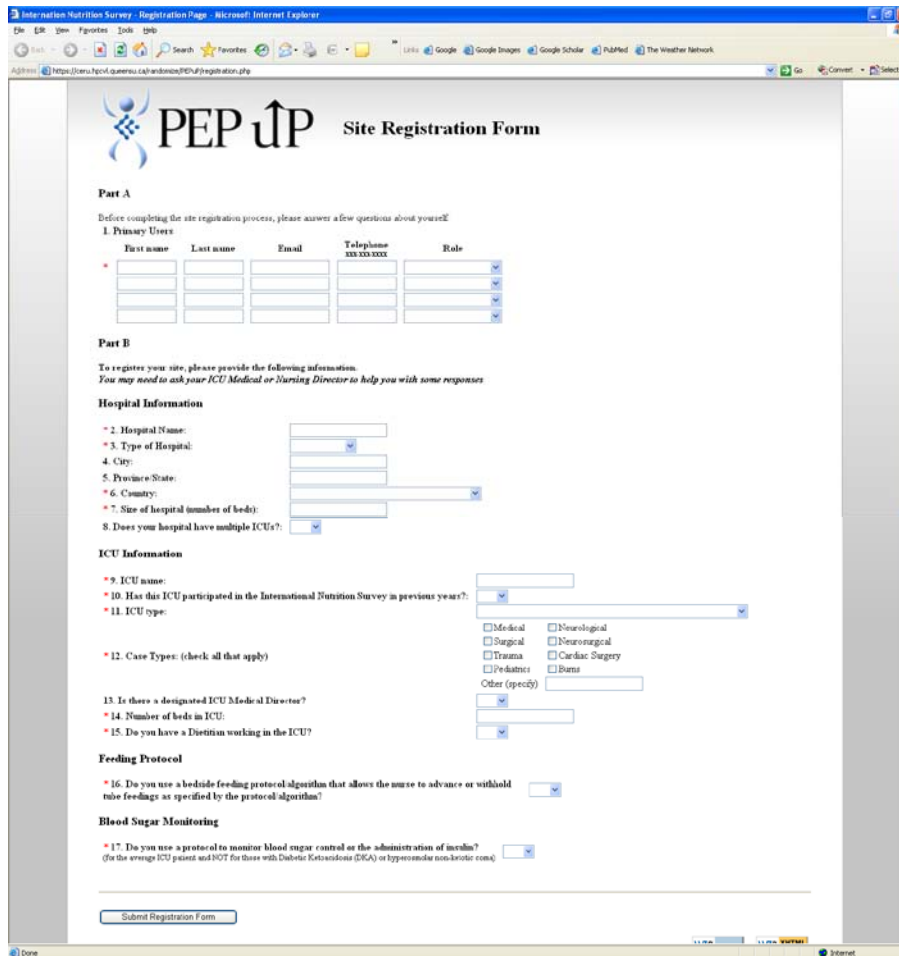
- The site number will be programmed for each site by CERU. This will appear before every patient ID number
 - e.g. 9 – 3 represents patient 3, who is from site 9
- All patients in the study (not just for your site) are automatically numbered consecutively by REDCap. This means that if several sites are entering data at the same time, your patients will not be numbered sequentially
 - e.g. If site 9 creates patient 3, and then site 10 creates a new patient, this patient will be patient 4. If site 9 creates another patient, it will appear as patient 5. There will be no patient 4 at site 9.
- **It is very important that you record what patient numbers refer to what patients in your screening log.**

Duration of Data Collection

- Daily Data should be collected **every day** from ICU admission (Study Day 1) until the first of the following occurs:
 - Death
 - ICU Discharge
 - 12 days from ICU admission
- Outcomes Data is collected up to 60 days after ICU admission (Study Day 60).

Registration

- The Site and User Registration Form for the PEP uP Study can be accessed by following the link on the www.criticalcarenutrition.com website, or directly at <https://ceru.hpcvl.queensu.ca/randomize/PEPuP/registration.php>



Part A

Before completing the site registration process, please answer a few questions about yourself!

1. Primary Users

First name	Last name	Email	Telephone xxx xxx xxxx	Role
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Part B

To register your site, please provide the following information.
You may need to ask your ICU Medical or Nursing Director to help you with some responses

Hospital Information

* 2. Hospital Name:

* 3. Type of Hospital:

4. City:

5. Province/State:

* 6. Country:

* 7. Size of hospital (number of beds):

8. Does your hospital have multiple ICUs?:

ICU Information

* 9. ICU name:

* 10. Has this ICU participated in the International Nutrition Survey in previous years?:

* 11. ICU type:

* 12. Case Types: (check all that apply)

Medical Neurological
 Surgical Neurosurgical
 Trauma Cardiac Surgery
 Pediatrics Burns
 Other (specify)

13. Is there a designated ICU Medical Director?

* 14. Number of beds in ICU:

* 15. Do you have a Dietitian working in the ICU?

Feeding Protocol

* 16. Do you use a bedside feeding protocol algorithm that allows the nurse to advance or withhold tube feedings as specified by the protocol algorithm?

Blood Sugar Monitoring

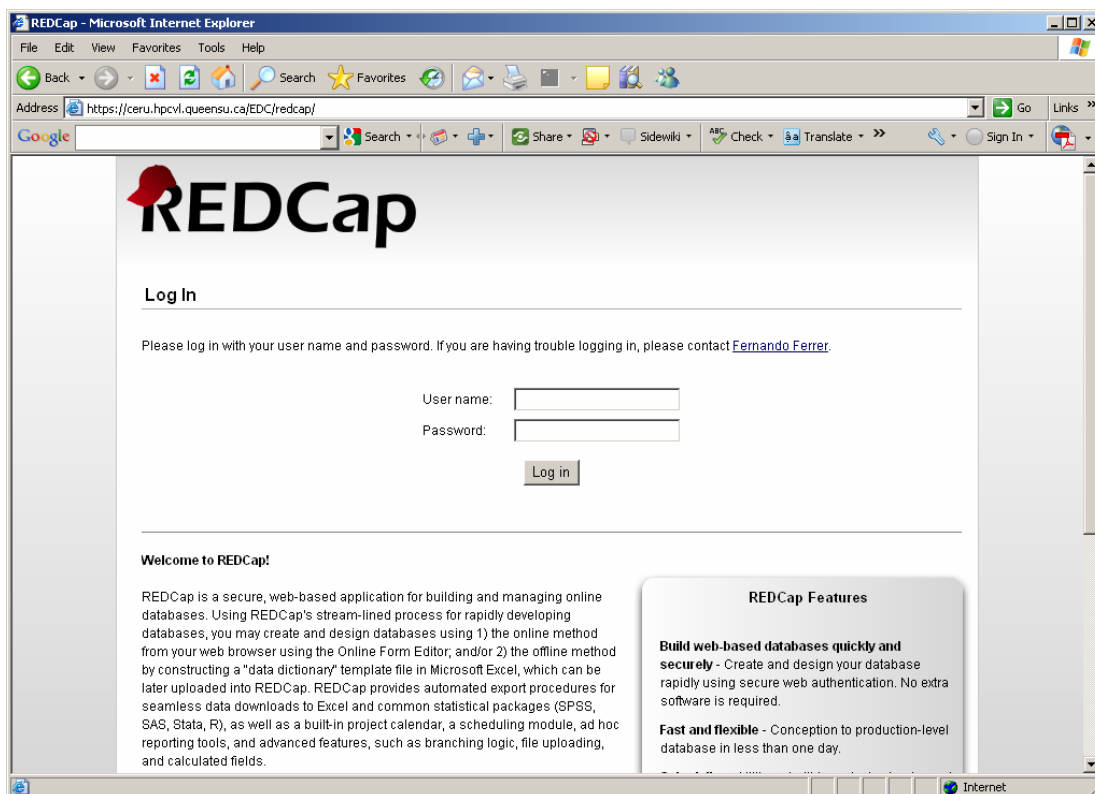
* 17. Do you use a protocol to monitor blood sugar control on the administration of insulin?
(for the average ICU patient and NOT for those with Diabetic Ketoacidosis (DKA) or hyperosmolar non-ketotic coma)

Completion of the online user registration form will notify the Project Assistant, and the Project Assistant will assign REDCap usernames and passwords to each person indicated on the registration form. Users will receive their usernames and passwords via email. This may take up to 2 business days, though every effort will be made to assign you a username as quickly as possible.

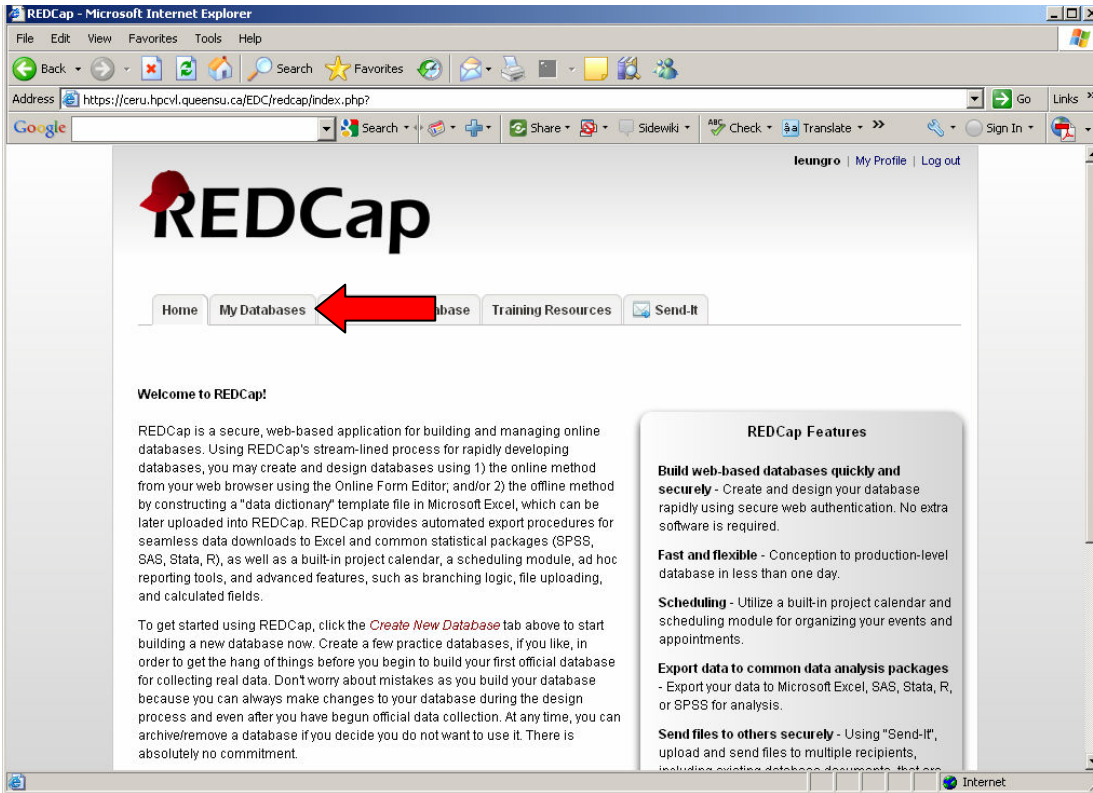
- The site and user registration must be completed **once** for each ICU.
 - Please ensure only one person registers each ICU, and provides all the contact details for each individual from that ICU that needs a username and password
- If you have multiple ICUs:
 - You should register each ICU separately
 - You will receive a separate username for each ICU
- All users must log onto the website using their own username and password prior to data entry

Web Login

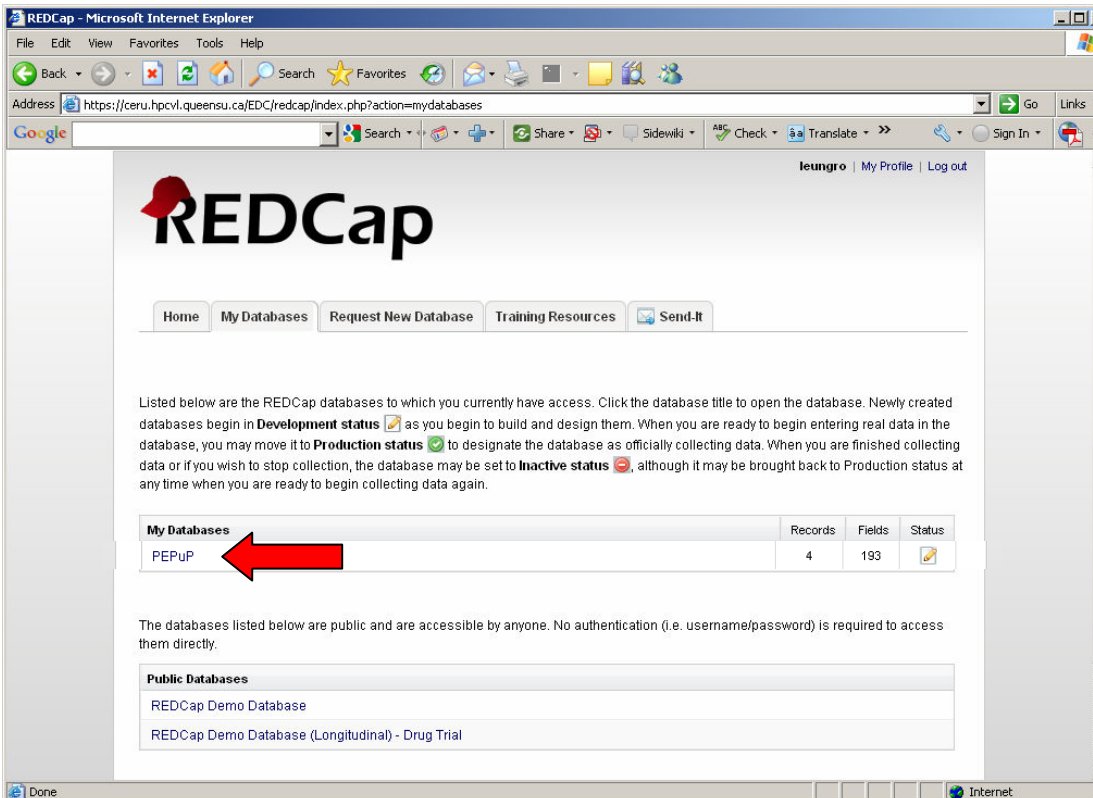
- Ensure that you keep your REDCap login information confidential
- Remember to choose a secure password
 - Use a combination of uppercase and lowercase letters, and numbers
 - Consider using an acronym to remember your password (e.g. “I want to feed patients with the PEP UP Protocol” could be your password: “Iw2fpwtPuP”
- Enter your username and password
- Click the “Login” button
- If the login information is correct, the user will be brought to the Welcome Home Page.
- If you forget your password, contact Fernando Ferrer at ferrerf@kgh.kari.net



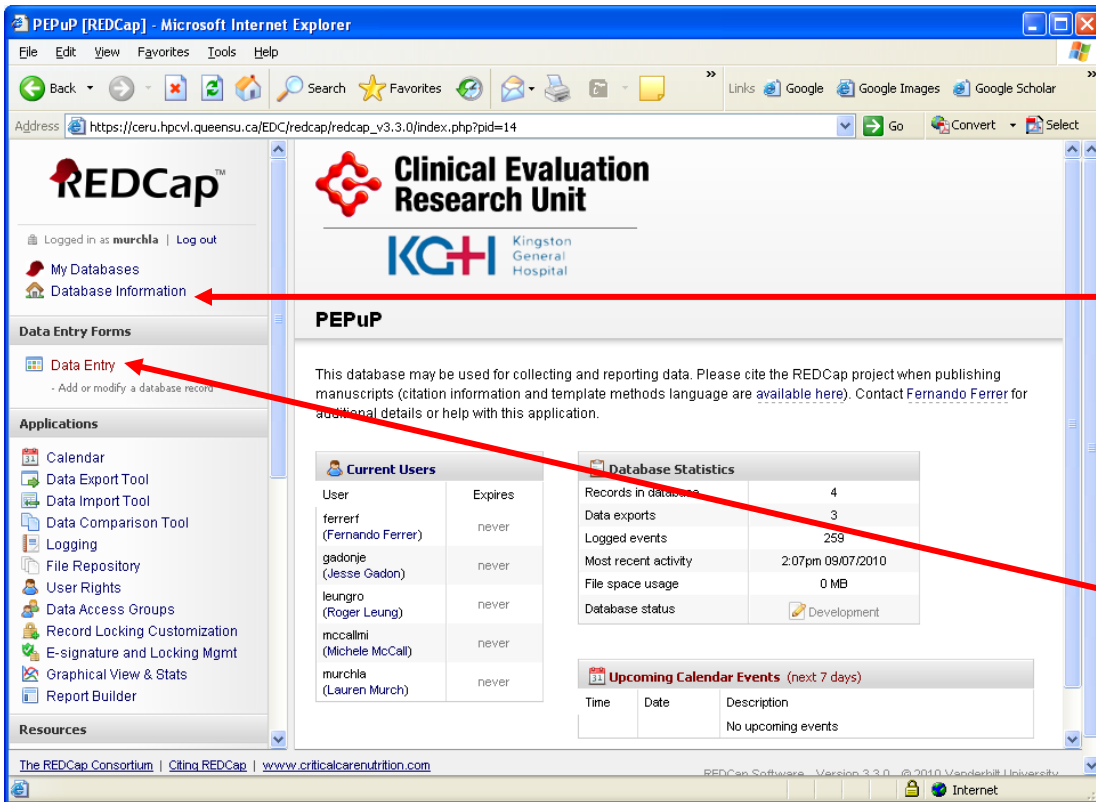
Navigation



After logging in, Click” the “My Database” tab.



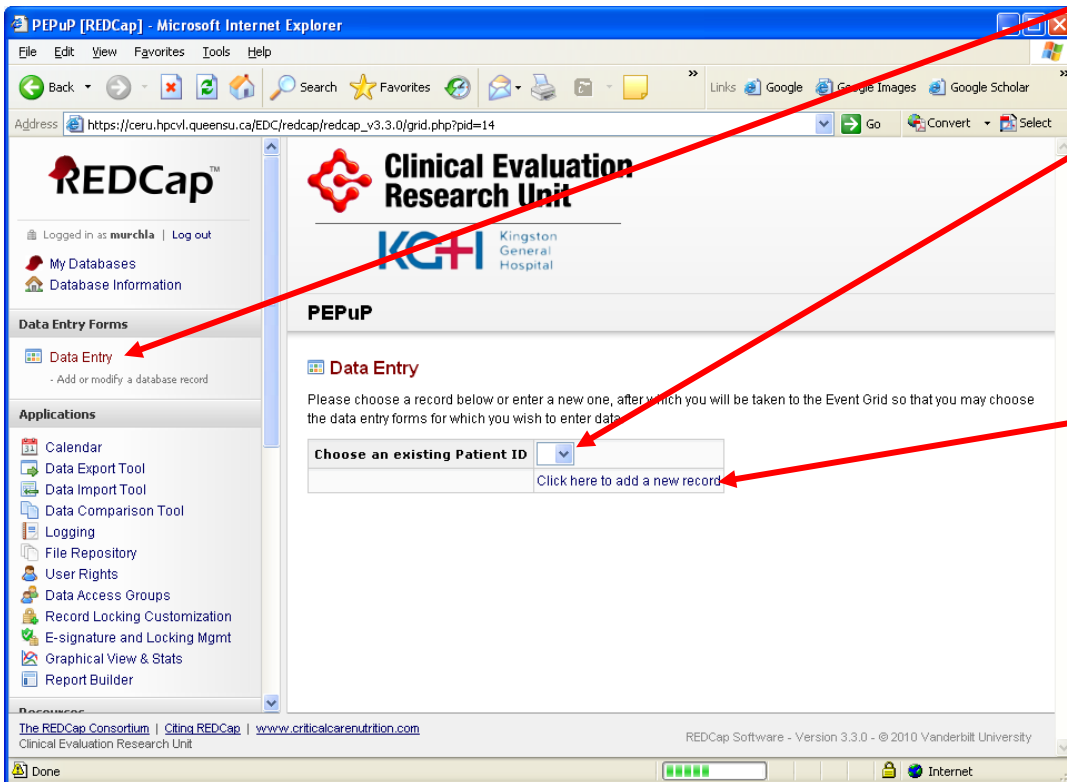
This will bring you to the following screen where you may click on the appropriate study.



When you click on the PEP uP Database you will be directed to this screen (the study's home page).

This Database Information screen will allow you to view other users for your site. Click on "Database Information" on the left hand side of the screen to return to this page at any time.

Click on "Data Entry" on the left hand side of the screen to view/enter patient data.



Click on "Data Entry" at any time from any page to return to this screen.






Current patients can be accessed here using the drop down menu.

- When you click on an existing patient, you will automatically be directed to that patient's Event Grid
















New patients can be created by clicking where it says "Click here to add a new record". Note:

- Only add new patients as you need them, as you **cannot delete patients**
- Record the Patient ID number in your screening log
- When you create a new patient, you will automatically be directed to the Patient Information eCRF


Event Grid

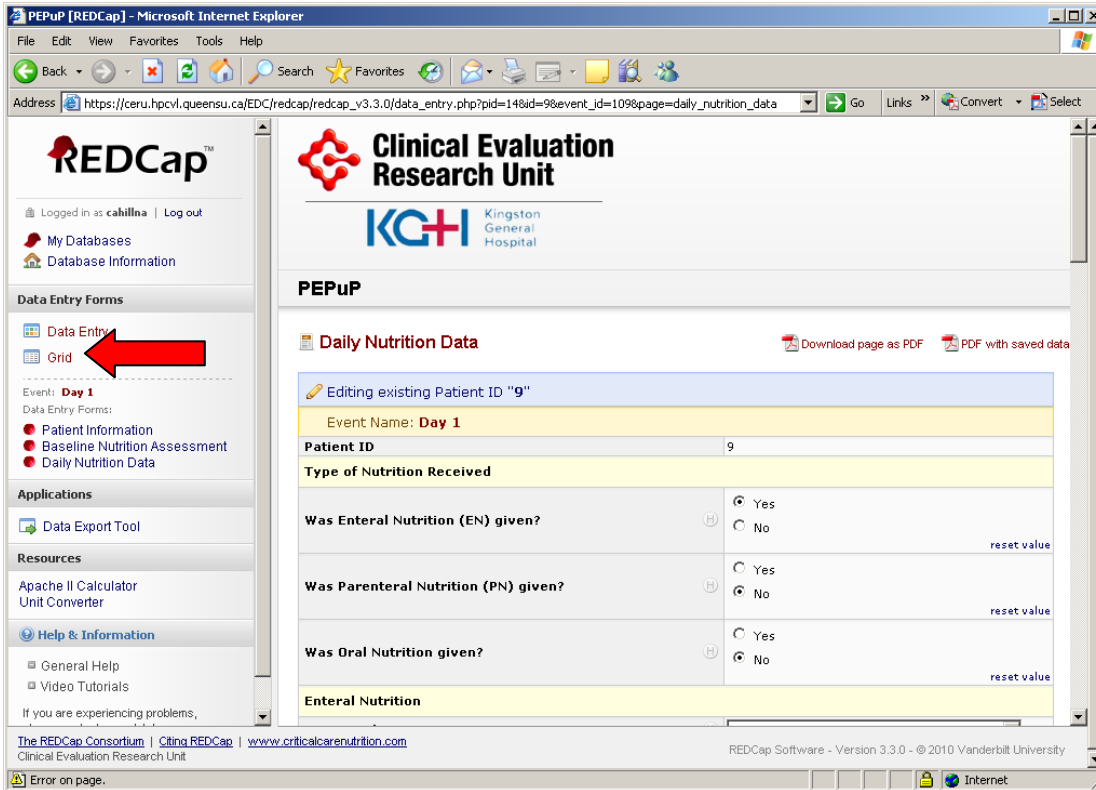
- The Event Grid shows all eCRFs for a given patient. Each eCRF will be represented by a  on the event grid
- By default, every eCRF will initially appear as a RED 
- At the end of each eCRF, you will be asked to label the form status as incomplete, unverified or complete. Changing this option will change how the form is displayed in the Event Grid. These colour-coded labels are meant to help you identify at a glance what the status of your data entry for a given patient is.
 - RED  (Incomplete)
 - If you have not filled in all the required information on a form (e.g. you completed the baseline nutrition form, but did not know a patient’s height) mark the form as “Incomplete” so that you know to go back to it later.
 - AMBER  (Unverified)
 - We suggest you mark any daily nutrition forms which are “not applicable” as AMBER (e.g. a patient was discharged from the ICU on day 10, so daily nutrition data forms for days 11 and 12 are not applicable, and are marked AMBER) so you can tell at a glance that you may disregard these forms for a particular patient.
 - GREEN  (Complete)
 - If you have completed all required information on a form, mark the form as “Complete”.
- Note: you may disregard the text at the top of the Event Grid page where it says “Define My Events”. We have already done this for you.

Patient ID "4"

Data Entry Form	Events for Arm 1: Arm 1													
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 60	
Patient Information														
Baseline Nutrition Assessment														
Daily Nutrition Data														
Outcomes Information														

Finalize

The Event Grid is organized by data entry form types horizontally and study days vertically. Each patient has one patient information eCRF and one baseline nutrition assessment eCRF filled out for day 1, up to 12 daily nutrition data eCRFs, and finally, one outcomes eCRF. You can access any of the eCRFs at any time by clicking on the  corresponding to the desired form.

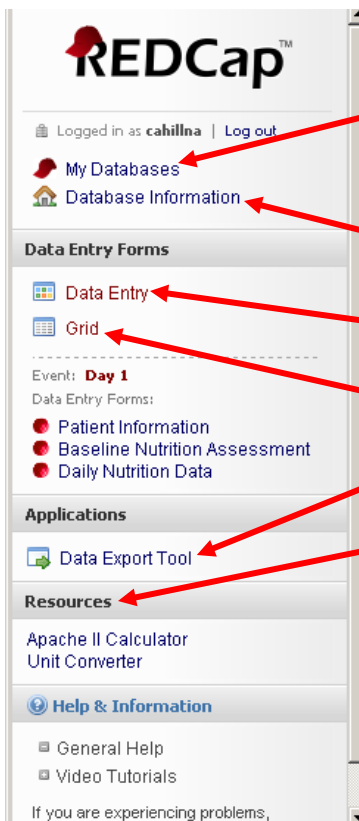


You can click on “Grid” on the left hand navigation menu at any time to return to the Event Grid screen for the current patient.

WARNING: Clicking on “Grid” from any eCRF will not save any of your progress in the eCRF.

Clicking “Save and Exit” or “Cancel” at the bottom of the page will also direct you back to the Event Grid.

The Left Hand Navigation Pane




From the menu on the left hand side of the page, you can access:

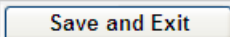

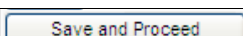
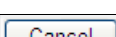
- **My Databases:** Takes you back to the screen showing all studies on REDCap you are involved with. For example, if you are involved in both the International Nutrition Survey and the PEP uP Study, you could potentially have two studies listed here under the same account
- **Database Information:** Takes you back to the “home” screen for the current study.
- **Data Entry:** This is where you access individual patient records for the current study.
- **Grid:** This is where you access individual eCRFs for the current patient.
- **Data export tool:** You can export the data you have entered as a CSV file.
- **Resources:** We have put some frequently used tools here for your convenience:
 - The study’s CRFs and Instructions
 - Link to an online APACHE II Calculator
 - Unit conversion Excel file

Completion of eCRFs

- Create or access individual patients from the Data Entry screen
- Access eCRFs for individual patients using the Event Grid
- Paper CRFs are designed to match the eCRFs as closely as possible
 - See the instructions corresponding to the paper CRFs for detailed instructions on what information is required, and how to complete these forms

Important Notes About Completion of Electronic Case Report Forms

- Dates are to be entered using the YYYY-MM-DD format i.e. 2010-07-24. It is highly recommended that the calendar option be used. Click on the  icon and choose the appropriate month and year from the drop down boxes. Then click on 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 (24:00 hours) should be entered as 00:00
- To enter data directly into each field, click on the desired field 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.
- Unless otherwise instructed, **there should be NO blank fields**. Please make every effort to find the necessary data in the patient charts. If a lot of data is missing on a particular patient (i.e. charts have gone missing) exclude this patient and move onto the next eligible patient.
- At the end of each form, you will be asked for form status as incomplete, unverified or complete. Changing this option will change how the form is displayed in the Event Grid. When you reach the end of a form, review the form carefully to make sure all is complete. Then set the form’s status accordingly. See page 9 (under “Event Grid”) of this manual for guidelines on usage of the RED (● incomplete), AMBER (● unverified) and GREEN (● complete) form status indicators.
- There are 3 or 4 options at the end of each form to save your progress:

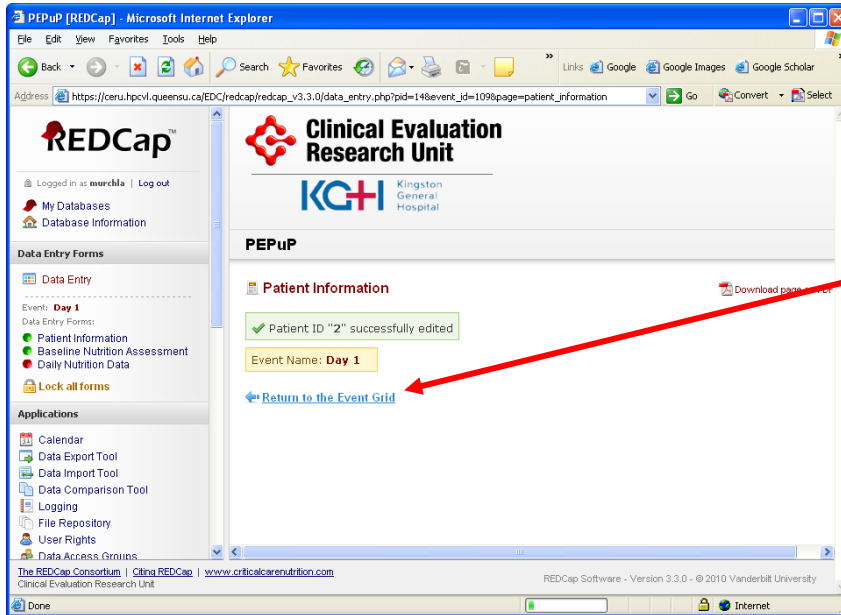
	This will bring you to a screen confirming your progress has been saved, and allow you to return to the Event Grid
	This option will save your progress and allow you to continue working on the current form.
	This option will save your progress and bring you to the next form in that Study Day <i>(if applicable)</i>
	This option will take you to the Event Grid. All newly entered data will be lost. Only the last saved version will remain.

Deleting Data

You cannot delete patients. Please contact the project assistant if you have any queries regarding editing or deleting data.



Saving eCRFs

When you click “Save and Exit” on any eCRF you will be directed to a page that looks like this:



Click here to return to the Event Grid

History

For any data field in any of the eCRFs you may click on the  at any time to view the data history for that field. When you click on the  a window like the one below will pop up:

Data History for variable "height" ✕

Listed below is the history of all data entered for the variable "height" for Patient ID "1".

Date/Time of Change	User	Data Changes Made
3:15pm 09/24/2010	murchla	1.22
10:41am 08/05/2010	leungro	3
1:39pm 08/03/2010	gardonje	2

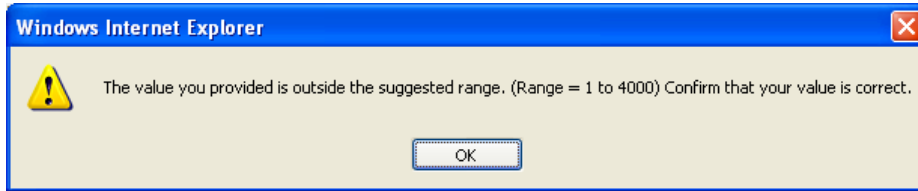
Close

This window shows who entered what data in that field, and when.

Out of Range Values

One of two things will happen if you enter a number in a field which is considered out of range:

Out of range Pop up warning:



- Click ok
- Check that the value you entered is correct

Out of range text field:

Enteral Nutrition	
EN Formula 1	Nestle: Peptamen 1.5
Was a second EN formula given?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Kilocalorie received from EN	5555 XXXX kcal
<p style="color: red;">This value is above or below the expected range. Are you sure this value is correct? Please explain.</p>	

Red text field appears below the numeric field if number in numeric field is out of range

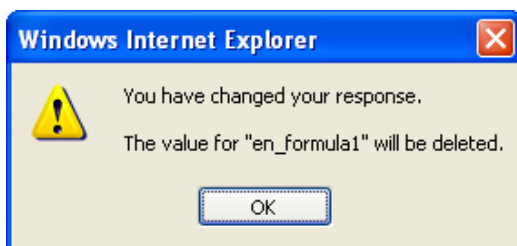
If you enter a new value here which is within the acceptable range, the red text field will disappear

- Check that the value you entered is correct.
- If the out of range value is correct, provide a reason for this value in the red text field
 - E.g. "High calories received from EN is correct because this is a burns patient"

Editing Electronic Case Report Forms

To edit previously saved information, access the appropriate eCRF from the Event Grid, 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.

If you have previously completed a form, and you change data in one field so that other questions on that eCRF are no longer applicable, you will receive an alert that this change is going to result in deletion of data from other fields:



e.g. If you completed the daily nutrition data form and said that the patient received enteral nutrition, but later go back to say that the patient did **not** receive enteral nutrition, you will receive an alert that the data you entered regarding enteral nutrition will be erased when you make this change.

Patient Information and Baseline Nutrition Assessment eCRFs

- These forms are completed **once** for each patient
- Please see the paper CRFs and associated instructions for detailed information on completing these daily nutrition data forms

Completion of Daily Nutrition Data

- Daily Data should be collected **every day** that the patient is in the ICU, from ICU admission (Study Day 1) until the first of the following occurs:
 - Death
 - ICU Discharge
 - 12 days from ICU admission
- If a patient dies or is discharged from the ICU before Study Day 12, there will be forms that appear in the Event Grid which are not applicable to that patient. Simply leave these Daily Nutrition Data forms blank. We also suggest that you set the form status for these forms to AMBER (“unverified”) so that you can see at a glance that they do not apply.

Patient ID "1"

	Events for Arm 1: Arm 1														
Data Entry Form	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 60		
Patient Information	●														
Baseline Nutrition Assessment	●														
Daily Nutrition Data	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Outcomes Information															●

Completed Daily Data

Daily Data Not Completed

Finalize

e.g. The patient shown here was discharged from the ICU on Study Day 8, so Daily Nutrition Data forms will be left blank on Study Days 9-12, and then the outcomes form is completed.

- Please see the paper CRFs and associated instructions for further information on completing these daily nutrition data forms

Outcomes Information

- This form is completed when the first of the following occurs:
 - Death
 - Hospital Discharge
 - 60 days from ICU admission
- You may be able to complete this form before Study Day 60 if the patient dies or is discharged from the hospital before Study Day 60
- See the paper CRFs and associated instructions for further information on completing this form

Patient Finalization

Data Entry Form	Events for Arm 1: Arm 1													
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 60	
Patient Information	●													
Baseline Nutrition Assessment	●													
Daily Nutrition Data	●	●	●	●	●	●	●	●	●	●	●	●		
Outcomes Information														●

Finalize

When you are done entering all data for a patient (i.e. you have set the status of all applicable forms on the event grid to GREEN (complete)), click the “Finalize” button on the Event Grid.

When you click “Finalize” a series of data checks will be run on all data entered for this patient. Issues arising from these data checks must be resolved before the patient may be finalized.

The “Form” column tells you what eCRF the error is located on.

The “Error Message” column describes the issue.

Click on “Go to event” beside a given error message to be directed to the appropriate eCRF.

When you have resolved an error, click on “Finalize” again from the Event Grid to return to this screen, and see if there are any further errors. Once all errors are resolved, the patient will be finalized.

If you are unable to resolve a query, contact the project assistant, Lauren Murch (murchl@kgh.kari.net).

Choose an existing Patient ID

- 9-1 - Finalized
- 9-2 - Finalized
- 9-3 - Finalized
- 9-4
- 9-5
- 9-6
- 9-7

When you have successfully finalized a patient, they will appear as finalized in the drop down menu on the Data Entry page.

We strongly recommend that you finalize patients online as soon as you are able to. This is a good way to ensure you are collecting and entering data correctly. If you wait until the end to finalize all 30 patients and discover you have made the same error for several patients, this can become a time consuming problem to fix. By finalizing patients as you go, you will become more familiar with the data entry process, which will help make the process of data entry more efficient.