International Nutrition Survey 2014

REDCap User Guide

Version: September 5th, 2014

Introduction

This REDCap Manual functions as a resource for successful completion of electronic case report forms (eCRFs) for the International Nutrition Survey. 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 International Nutrition Survey. 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 for the Best of the Best award.

Methods Centre Contacts

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

Registration

- The online Site and User Registration Form for the International Nutrition Survey opened September 2nd 2014 and can be accessed by following the link (https://ceru.hpcvl.queensu.ca/randomize/INS/registration.php).
- This online form matches the paper CRF Site Registration form.

International Nutrition Survey 2014
Site Registration Form

Required fields are marked with a red asterisk (*)

For instructions on completing this form click here

* 1. Primary REDCap Users (Usernames and passwords to access the online data entry system will be assigned to each of the individuals listed below.)

First name	Last name	Email	Telephone	Role in ICU
				▾

[Add User]

To register your site, please provide the following information.

* 2. Did you require ethics approval to participate in INS 2014? ▾

Hospital Information

* 3. Hospital Name:
* 4. Type of Hospital: ▾
* 5. City:
6. Province/State:
* 7. Country: ▾
* 8. Size of hospital (number of beds):

ICU Information

* 9. Does your hospital have multiple ICUs? ▾
* 10. ICU name (Max 20 characters):
* 11. Has this ICU participated in the International Nutrition Survey in previous years?: ▾
* 12. ICU type: ▾
* 13. Case Types: (check all that apply) ☐ Medical ☐ Neurological

Upon completion of the online site registration form you will automatically be assigned a username and password. New participants will receive their new usernames and passwords via a confirmation email. If you participated in the survey in 2011 or 2013, your username from 2011 or 2013 will be reactivated when you sign-up with the same e-mail address as you used for INS 2011 or 2013 and a new password will be emailed to you to reactivate your account. Please note:

- The site and user registration must be completed **once** for **each** ICU.
  - o 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 at your hospital:
  - o Register each ICU separately
  - o Users 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
- Please notify the CERU Project Assistant with any changes in study personnel accessing the web

Web Login

Accessing the Website

The Web Based Data Capture System for the International Nutrition Survey 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/

Logging In

- Ensure that you keep your REDCap login information confidential
- Remember to choose a secure password
    - o Use a combination of uppercase letters, lowercase letters and numbers
- Enter your username and password
- Click the "Login" button:
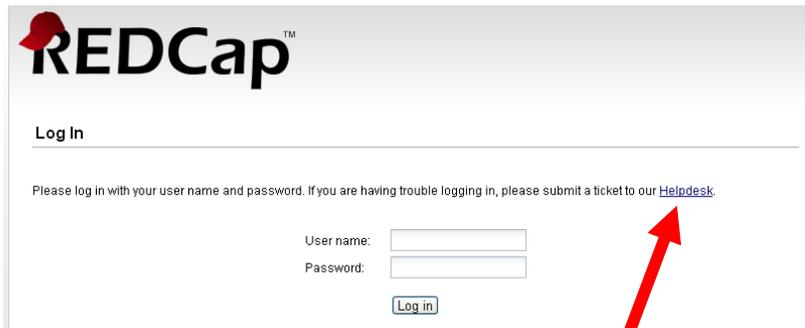
- If you forget your password, contact the Helpdesk.
- If the login information is correct, the user will be brought to the Welcome Home Page.
- Your password can be changed at any time by clicking "My Profile" after logging into REDCap.

Navigation
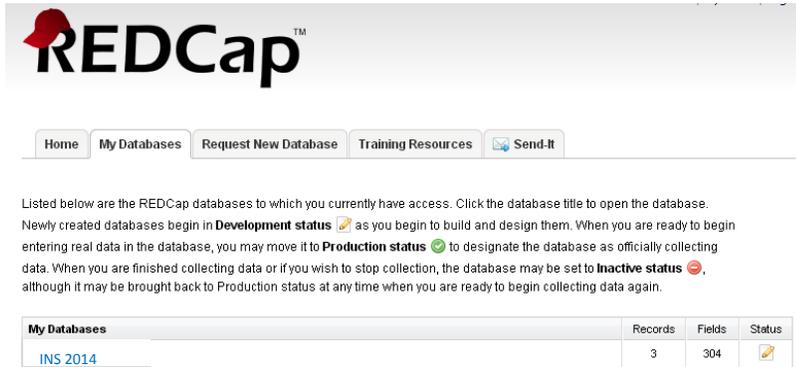
After logging in, click the 'My Databases' tab. This will bring you to the list of studies for which you have access (ie. if you are a TOP UP study site, TOP UP would be listed here, as well). Click on the International Nutrition Survey database.
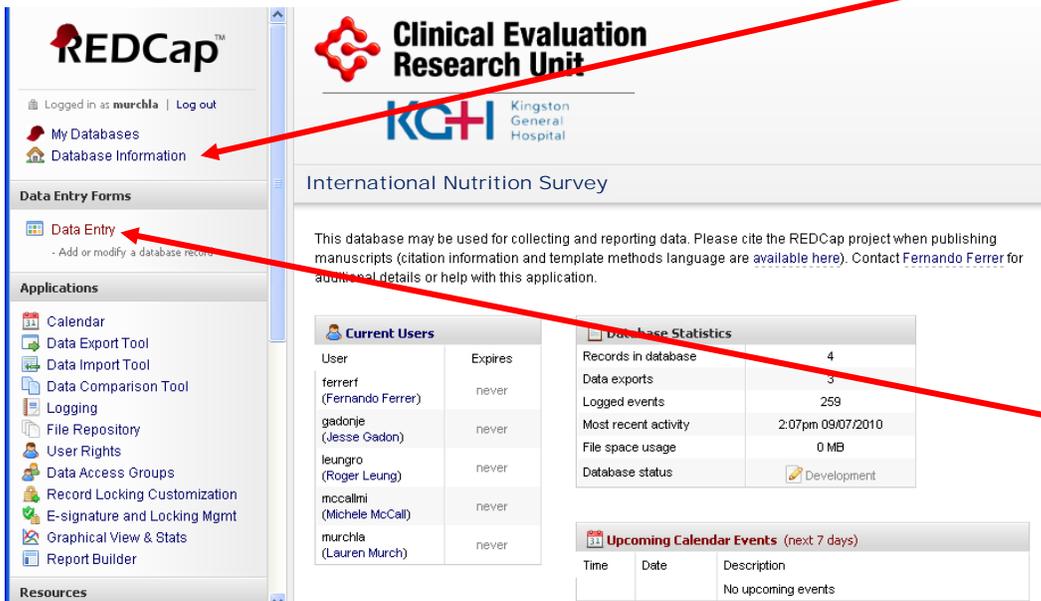
When you click on the International Nutrition Survey database you will be directed to the Database Information screen. Here you will be able to view other users for your site. Click on "Database Information" on the left hand side of the screen to view this page.

Click on "Data Entry" on the left hand side of the screen to select a patient for whom to view or enter data.

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.**
- If a patient has been submitted or finalized, this status will be shown beside the patient ID (see below).

New patients can be created by clicking "Add a new patient".

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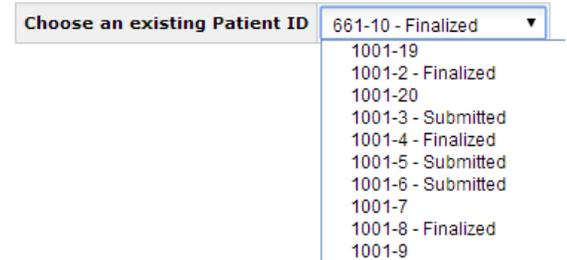
Assignment of Patient ID Numbers

- The site number will be programmed for each site by CERU. This will appear before every patient ID number
    - o e.g. 119 – 3 represents patient 3, who is from site 119

NOTE: It is very important that you record what patient numbers refer to what patients in your screening log in the CRFs.

Event Grid

- The Event Grid shows all eCRFs for a given patient. By default, each eCRF will be represented by a ● on the event grid.
- *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.
- The Event Grid is organized by data entry forms listed vertically and study days listed horizontally.
- You can access any of the eCRFs at any time by clicking on the ● corresponding to the desired form.
- Each patient has an eCRF for:
    - Patient Information,to be filled out for day 1
    - Baseline SOFA Score,to be filled out for the first 24 hours after ICU admission
    - Baseline Nutrition Assessment
    - Daily Nutrition, for Study Day 1 up to Study Day 12
    - Daily Enteral Nutrition, for Study Day 1 up to Study Day 12
    - Daily Parenteral Nutrition, for Study Day 1 up to Study Day 12
    - Daily Nutrition: Supplemental Nutrients, for Study Day 1 up to Study Day 12
    - Outcomes Information eCRF.
- **Patients from burn units have an additional 2 forms that must be completed, listed below**. Sites registered as non-burn units will NOT have access to these eCRFs:
    - o Patient Information (Burn Sites)
    - o Daily Nutrition Data (Burns Sites)

Patient ID "1"

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	Outcomes
Patient Information	🟡												
Patient Information (Burn Sites)	🔴												
Baseline SOFA Score	🔴												
Baseline Nutrition Assessment	🔴												
Daily Nutrition Data	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	
Daily Nutrition Data (Burn Sites)	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	
Daily Enteral Nutrition Data	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	
Daily Parenteral Nutrition Data	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	
Daily Nutrition: Supplemental Nutrients	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	🔴	
Outcomes Information													🔴

Note: The event grid will display the same for all sites but non-burn units will not have access to the two forms with 'Burn Sites' in brackets.

Form Status Legend

🔴	Incomplete
🟡	Unverified
🟢	Complete
🔒	Locked

Database Information

Data Entry Forms
- Data Entry
- Grid

Event: **Day 1**
Data Entry Forms:
- Patient Information
- SOFA Score
- Baseline Nutrition Assessment
- Daily Nutrition Data

Applications

Resources
- Site Registration
- PF Ratio Table
- MAP Calculator
- Unit Converter
- CRFs/Data Collection Instructions
- REDCap Instructions
- Apache II Online Calculator
- Apache II Worksheet
- Other INS Tools
- Site Finalization

Patient Information

Download page as PDF   PDF with saved data

Assign this record to a Data Access Group?
-- Select a group --

Adding new Patient ID "5"

Event Name: **Day 1**

Patient ID	5
Sex	○ Male ○ Female
	reset value
Age	
Hospital Admission Date	YYYY-MM-DD
Hospital Admission Time	HH:MM 24hr
ICU Admission Date	YYYY-MM-DD
* must provide value	
ICU Admission Time	HH:MM 24hr
Was Mechanical Ventilation started prior to admission to	○ Yes

After clicking a 🔴 for an eCRF, 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.

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.
- Resources: We have put some frequently used tools here for your convenience:
  - o Site registration and finalization forms
  - o The study's CRFs and Instructions
  - o Link to an online APACHE II Calculator
  - o Unit conversion Excel file
- Queries: This is where any queries will appear. Clicking on 'Queries for Patient #' will bring you to the Query Module (see page 15 of this manual).
- Help Desk: Click here if you have any **technical** problems with REDCap; our IT team will be happy to assist you. If you have questions regarding the content of REDCap, please contact Margot Lemieux at lemieuxm@kgh.kari.net.

Completion of eCRFs

- Paper CRFs are designed to match the eCRFs as closely as possible
  - Refer to the instructions with the paper CRFs for the information that 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.
- Click 'reset value' next to any data field to clear the data for **that individual data field.**
- At the end of each eCRF, you will be asked to label the form status as incomplete, unverified or complete using a dropdown menu.

  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 is of your data entry for a given patient:
  - RED 🔴 (Incomplete)
    - All forms are automatically colour coded red if no data has been saved.
  - AMBER 🟡 (Unverified)
    - All forms are automatically colour coded yellow if at least 1 piece of data has been saved.
  - GREEN 🟢 (Complete)
    - If you have saved all required information on a form, we recommend manually marking the form as "Complete".

- There are 4 or 5 options at the end of each form to save your progress:

Save and go to Day 2 Daily Nutrition Data	This option will save your progress and bring you to the next form in that Study Day *(if applicable)*
Save and go to Grid	This 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 the current form.
Clear Form	This will clear all of the data you have entered into the form.
Cancel	This option will take you to the Event Grid. All newly entered data will be lost. Only the last saved version will remain.
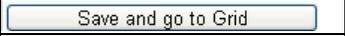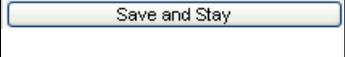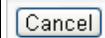
Deleting Data

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

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.

Sex	ⓗ ○ Male ○ Female
	reset value
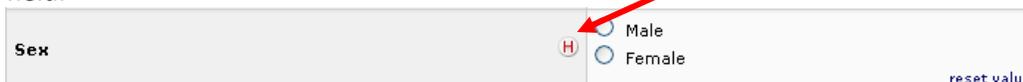
When you click on the ⓗ a window like the one below will pop up:

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	gadonje	2

This window shows:
- When data was entered
- Who entered the data
- What data was entered

Out of Range Values

An out of range pop-up warning may appear if you enter a number in a field that is considered out of range, ie:

The page at https://ceru.... ✖

The value you provided is outside the suggested range. (Range = 18 to 120) Confirm that your value is correct.

OK

The page at https://ceru.hpcvl.qu... ✖

Enter time in the following format HH:MM within the range 00:00-23:59 (e.g. 04:32 or 23:19).

☐ Prevent this page from creating additional dialogues.

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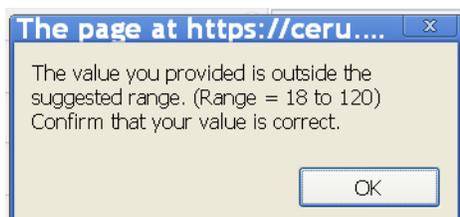
- Click ok
- Check that the value you entered is correct

This will only occur for some data fields. Other queries will occur through the built-in query system (see the **Query Module** on our website (below) or REDCap for more information).

http://criticalcarenutrition.com/index.php?option=com_content&view=article&id=147&Itemid=62

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 and can be viewed by clicking 🅗, as explained previously.

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 all of the data you entered regarding enteral nutrition will be erased when you make this change.

You cannot prevent this change from occurring once the pop-up alert has appeared, but the change will not save until you click the appropriate button.

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 death, ICU discharge or 12 days of ICU admission, whichever comes first.
- Data collection may be partially or fully retrospective if patient's were enrolled into the survey after ICU admission/Study Day 1
- If a patient dies or is discharged from the ICU before Study Day 12, there will be Daily Nutrition Data forms that appear in the Event Grid which are **not** applicable to that patient; leave these forms blank.

e.g. The patient shown here was discharged from the ICU on Study Day 8, so the Daily Nutrition Data forms is 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
- See the paper CRFs and associated instructions for further information on completing this form

Patient Submission and Finalization

Once you have completed the daily data for a patient (i.e. you have completed 12 days of daily nutrition data, or the patient died or was discharged from the ICU prior to day 12), click "Submit." You may submit patients even if the Outcomes Form has not yet been completed.

The Query System

Queries are run at different time points, including:

- As you save individual eCRFs
- When you click "Submit"
- Hourly

At these time points, a series of data checks will be run on all data entered for the patient. Issues arising from these data checks must be resolved before the patient will be finalized. **We recommend resolving queries in real time rather than waiting until patient data is submitted.** This will reduce your workload leading up to the deadline for when patient data must be finalized on REDCap.

Please refer to the **Query Module** available on our website (see link below) and under 'Resources' on REDCap for more information and instructions on solving queries.
http://criticalcarenutrition.com/index.php?option=com_content&view=article&id=147&Itemid=62

If you are unable to resolve a data check, contact Margot Lemieux (lemieuxm@kgh.kari.net).

 We strongly recommend that you enter and finalize patient data on REDCap 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 submit and finalize all 20 patients and discover you have made the same error for several patients, this can become a time consuming problem to fix. By submitting and 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.

Finalizing Patients

Once you have completed the Outcomes Form, "Submitted" a patient (i.e. all the daily data has been completed and you have returned and completed the outcomes form) and any queries have been resolved, the patient will automatically be "Finalized" by the system.

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

Finalizing Data entry at Your Site

Click on the "Site Finalization" link in the "Resources" section of the left-hand navigation panel to access the Site Finalization form.

Once you have completed data collection and data entry for all patients, please finalize data entry at your site by providing the total number of patients screened from each column of your screening log

Once all 5 boxes have been filled in **and** you have zero queries remaining, a check box will appear. Checking the box indicates that your data is complete and accurate to the best of your knowledge.

You may fill in the screening log data at any time, click 'Save' and return to correct the form, if necessary. However, once you check the box indicating that data entry is complete at your site and click 'Save', the form will be locked. Once locked, you will be able to view this form, but you will no longer be able to edit any information on this page.