Site Registration Form and Instructions

General Instructions

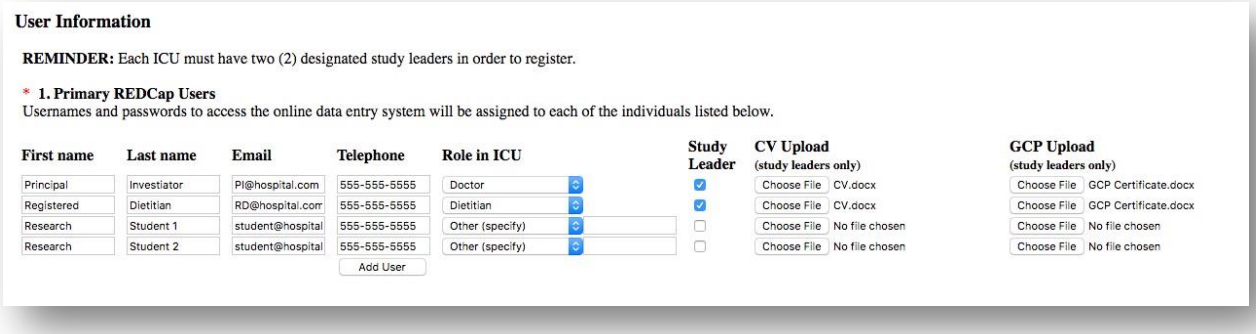
When attaching documents: Documents that are uploaded to this registration application must be in either an MS Word (.docx) or PDF (.pdf) format. Each file must not exceed 2MB in size.

Completing and submitting this application is the first step in the registration process. After it is submitted, it will be reviewed by the coordinating centre. Once the registration has been reviewed and approved, you will receive a confirmation email to let you know that your ICU has been formally registered.

A paper copy of this registration form is available as an appendix at the end of this document.

Completing the Application Form

Site and Study Team Member Qualifications



User Information

REMINDER: Each ICU must have two (2) designated study leaders in order to register.

* **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	Study Leader	CV Upload (study leaders only)	GCP Upload (study leaders only)
Principal	Investiator	PI@hospital.com	555-555-5555	Doctor	☑	Choose File CV.docx	Choose File GCP Certificate.docx
Registered	Dietitian	RD@hospital.com	555-555-5555	Dietitian	☑	Choose File CV.docx	Choose File GCP Certificate.docx
Research	Student 1	student@hospital	555-555-5555	Other (specify)	☐	Choose File No file chosen	Choose File No file chosen
Research	Student 2	student@hospital	555-555-5555	Other (specify)	☐	Choose File No file chosen	Choose File No file chosen

Add User

1. Please complete all of the fields for each local study team member.

   Each registered ICU should have two (2) designated study leaders. One study leader will be an ICU physician, and the other can be either an ICU dietitian or ICU research coordinator.
   - The "Study Leader" checkbox should be selected for these individuals.
   - In order to confirm your site is knowledgeable about critical care nutrition, each study leader must upload their CV and Good Clinical Practice (GCP), or equivalent, training certificate.

Add a new row to the table by selecting the "ADD USER" button.

PLEASE NOTE: The email address entered for each person will be linked to the electronic data capture system (i.e. REDCap) for the study. This is the system that will allow you to randomize patients and

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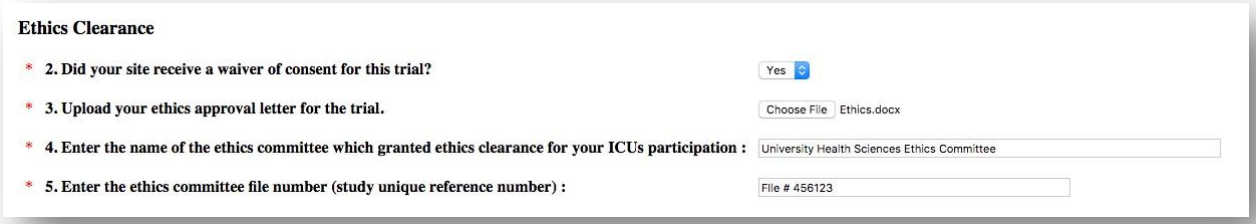
enter data. As such, be sure you are using an email address where you can receive password resets and system emails.

Ethics Clearance



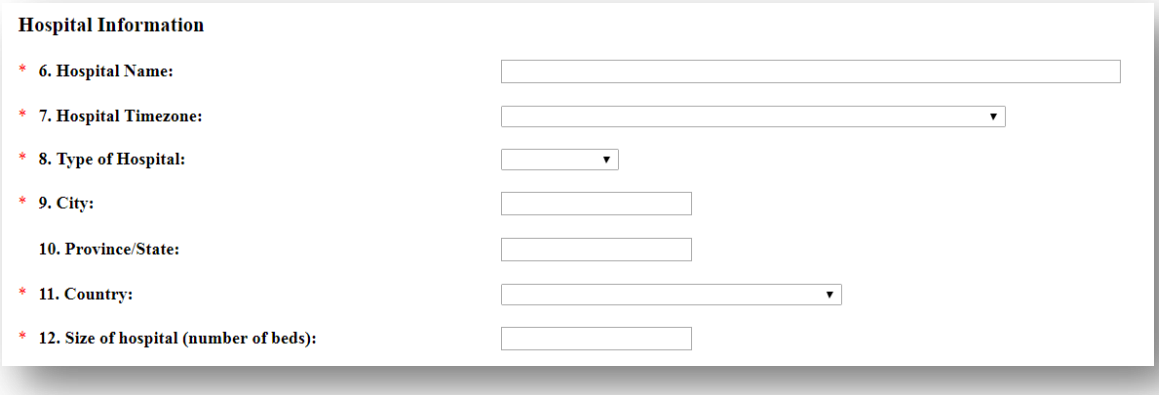
2. Indicate either “Yes” or “No” to whether your site received a waiver of consent for this trial.

3. A copy of your local site ethics clearance (approval) letter is a requirement for inclusion in this collaborative. Please upload your ethics clearance (approval) letter.

4. Enter the name of the ethics committee which granted ethics clearance for your ICUs participation.

5. Enter the ethics committee file number (study unique reference number).

Hospital Information



6. Specify your hospital’s full name, without abbreviations, as you wish for it to appear on your Site Report.

7. Select the correct time zone for your region from the list provided.

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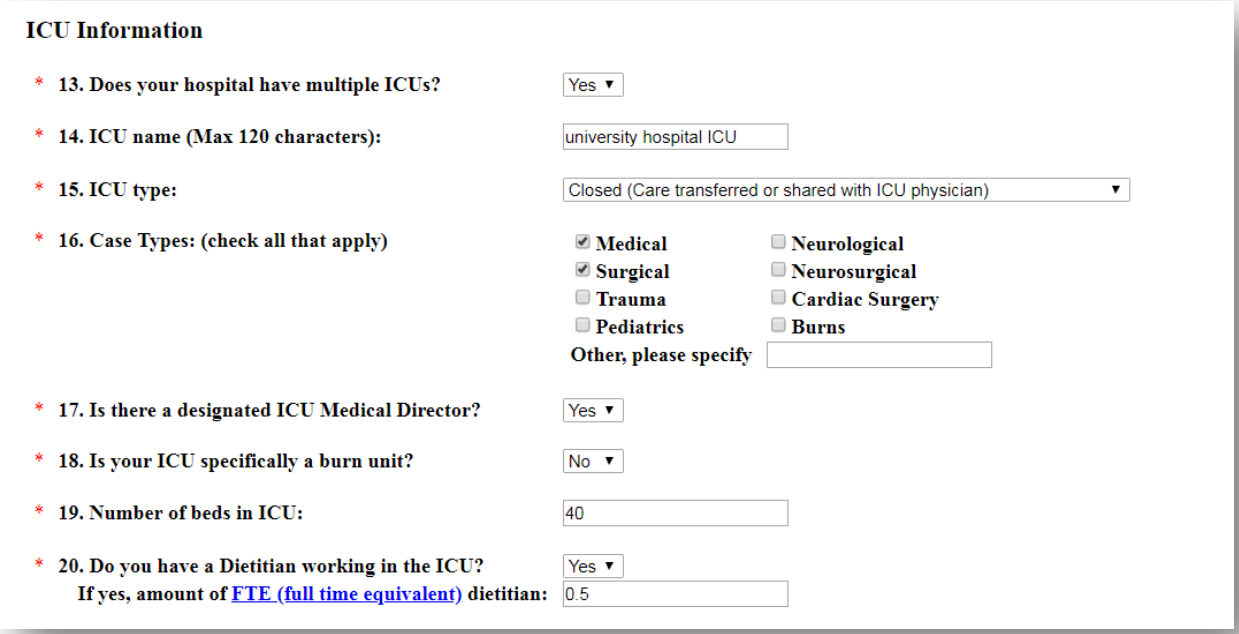
8. Enter the type of hospital, either “Teaching” or “Non-Teaching”. A teaching hospital is a hospital that provides training to medical students and residents. If your hospital only has occasional medical students/residents, select non-teaching hospital.
9. Specify the city
10. Specify Province/state
11. Specify country
12. Enter the total number of beds in your hospital.

ICU Information



13. Indicate whether or not your hospital has multiple ICUs. If your site has multiple ICUs, and you wish for more than one to join the collaborative, each ICU must be registered separately.

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14. Specify your ICU's name as you wish for it to appear on your Site Report.

15. Specify the type of ICU (ICU structure), either "Open", "Closed", or "Other, specify". Open ICUs are sites where patients are under the care of an attending physician (e.g. internist, family physician, surgeon) with intensivists (i.e. physician with training in critical care) consulted as necessary. Patients in closed ICUs are under the care of an intensivist or care is shared between the intensivist and another attending physician.

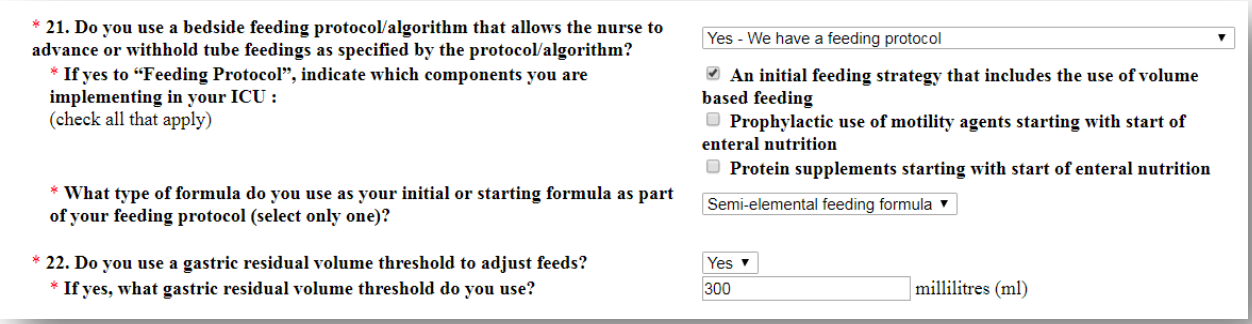
16. Indicate all case types applicable to this ICU.

17. Indicate whether or not your ICU has a designated Medical Director.

18. Is your ICU specifically a burn unit?

19. Indicate how many beds your ICU contains.

20. Specify whether you have a dietitian working in the ICU.
    If yes, please specify the amount of full time equivalent (FTE). This is a measure of the amount of time the dietitian(s) is/are dedicated to the ICU relative to a full time position. Eg: A full-time equivalent (FTE) of 1.0 means that one dietitian works in the ICU full time (i.e. 5 full days per week). A FTE of 0.5 means that one dietitian is in the ICU half time, or two and a half days a week. A FTE of 1.0 could also mean that two dietitians each work half time (0.5 FTE each) in the ICU.



21. Indicate whether you use a bedside feeding protocol/algorithm that allows the nurse to advance or withhold tube feedings. Enteral feeding protocols are defined as: tools designed to enable the bedside nurse to initiate, and/or monitor, and/or modify the administration of EN to individual patients. Implementation of such protocols includes, but is not limited to, the use of pre-printed orders that are signed by a physician when a patient is admitted to the ICU and a bedside algorithm that provides instructions to the bedside nurse on the management of EN. We are not referring to a policy document, but **bedside tools**.

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If “Yes”, indicate which components you are implementing in your ICU (check all that apply).

If “Yes”, what type of formula do you use as your initial or starting formula as part of your feeding protocol: semi-elemental feeding formula, or polymeric feeding formula, or other type (specify).

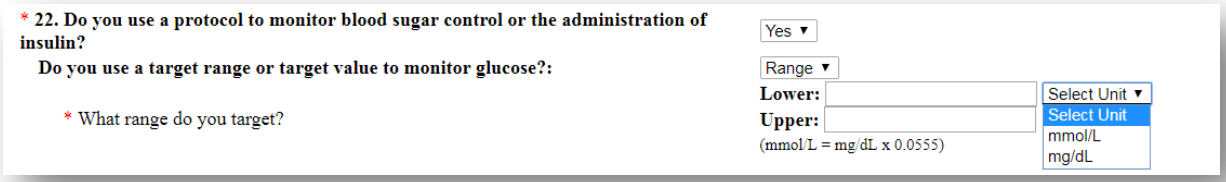
22. Do you use a gastric residual volume threshold to adjust feeds?

    If “yes”, indicate the gastric residual volume threshold in milliliters (mL).

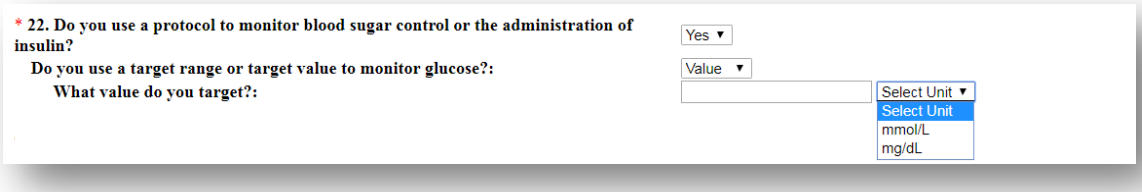
23. Do you use a protocol or algorithm to monitor blood sugar control or the administration of insulin?

    If “yes”, specify whether you use a ‘target range’ or ‘target value’ to monitor glucose.

    If you use a ‘target range’, enter the corresponding values, including units (mmol/L or mg/dL).



    If you use a ‘target value’, enter the corresponding value, including units (mmol/L or mg/dL).



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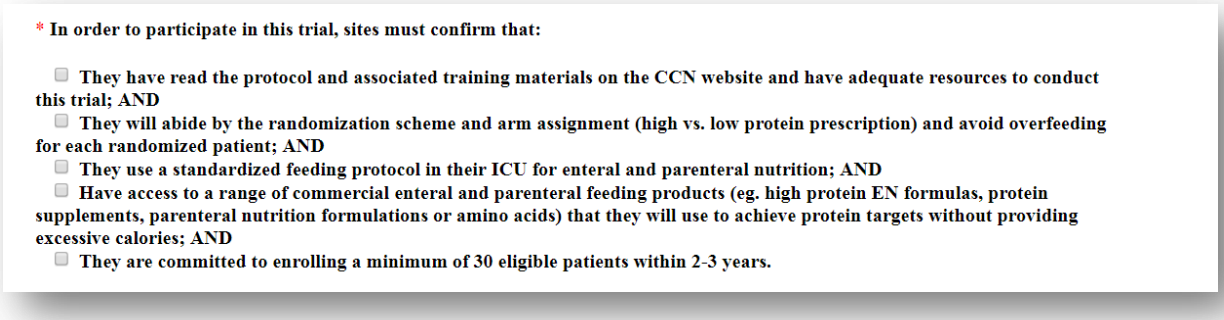
Confirmation

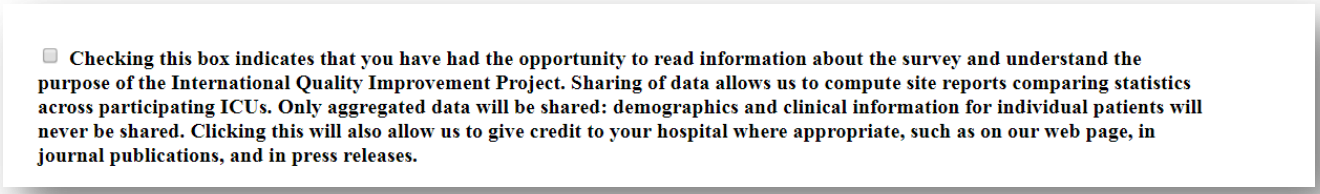


* In order to participate in this trial, sites must confirm that:

- ☐ They have read the protocol and associated training materials on the CCN website and have adequate resources to conduct this trial; AND
- ☐ They will abide by the randomization scheme and arm assignment (high vs. low protein prescription) and avoid overfeeding for each randomized patient; AND
- ☐ They use a standardized feeding protocol in their ICU for enteral and parenteral nutrition; AND
- ☐ Have access to a range of commercial enteral and parenteral feeding products (eg. high protein EN formulas, protein supplements, parenteral nutrition formulations or amino acids) that they will use to achieve protein targets without providing excessive calories; AND
- ☐ They are committed to enrolling a minimum of 30 eligible patients within 2-3 years.

In order to participate in this trial, sites must confirm that they understand and agree to all 5 of the criteria listed.

Signoff

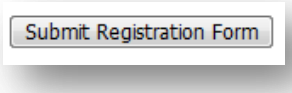


☐ Checking this box indicates that you have had the opportunity to read information about the survey and understand the purpose of the International Quality Improvement Project. Sharing of data allows us to compute site reports comparing statistics across participating ICUs. Only aggregated data will be shared: demographics and clinical information for individual patients will never be shared. Clicking this will also allow us to give credit to your hospital where appropriate, such as on our web page, in journal publications, and in press releases.

Checking this box indicates you:

1. You have had the opportunity to read information about the EFFORT Trial and understand the purpose of this international project;

2. The data submitted by your site via the electronic data collection system (REDCap) allows us to disseminate and publish information and make it available for the purpose of scholarship:
    a. We will compute site reports comparing statistics across all participating sites;
    b. Only aggregated data will be shared. Individual patient information such as demographics and/or clinical information will NEVER be shared;
    c. You are allowing us to give your site credit, when appropriate, such as on our website, in journal publications and in press releases.



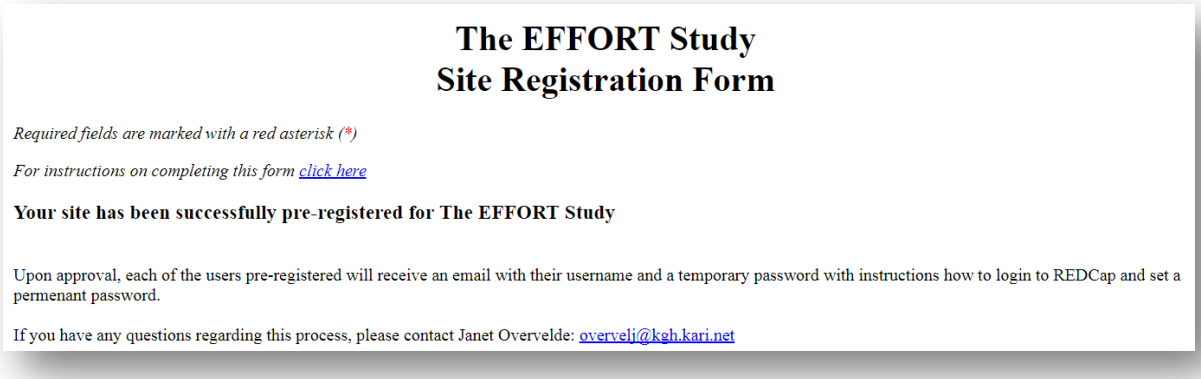
Submit Registration Form

Site Registration Form and Instructions

Select the 'SUBMIT REGISTRATION FORM' button to send this application to the coordinating centre for review and approval.

Submission Confirmation Email

After you use the 'SUBMIT REGISTRATION FORM' to complete your registration form. You will see the following screen.



The EFFORT Study
Site Registration Form

Required fields are marked with a red asterisk (*)

For instructions on completing this form click here

Your site has been successfully pre-registered for The EFFORT Study

Upon approval, each of the users pre-registered will receive an email with their username and a temporary password with instructions how to login to REDCap and set a permenant password.

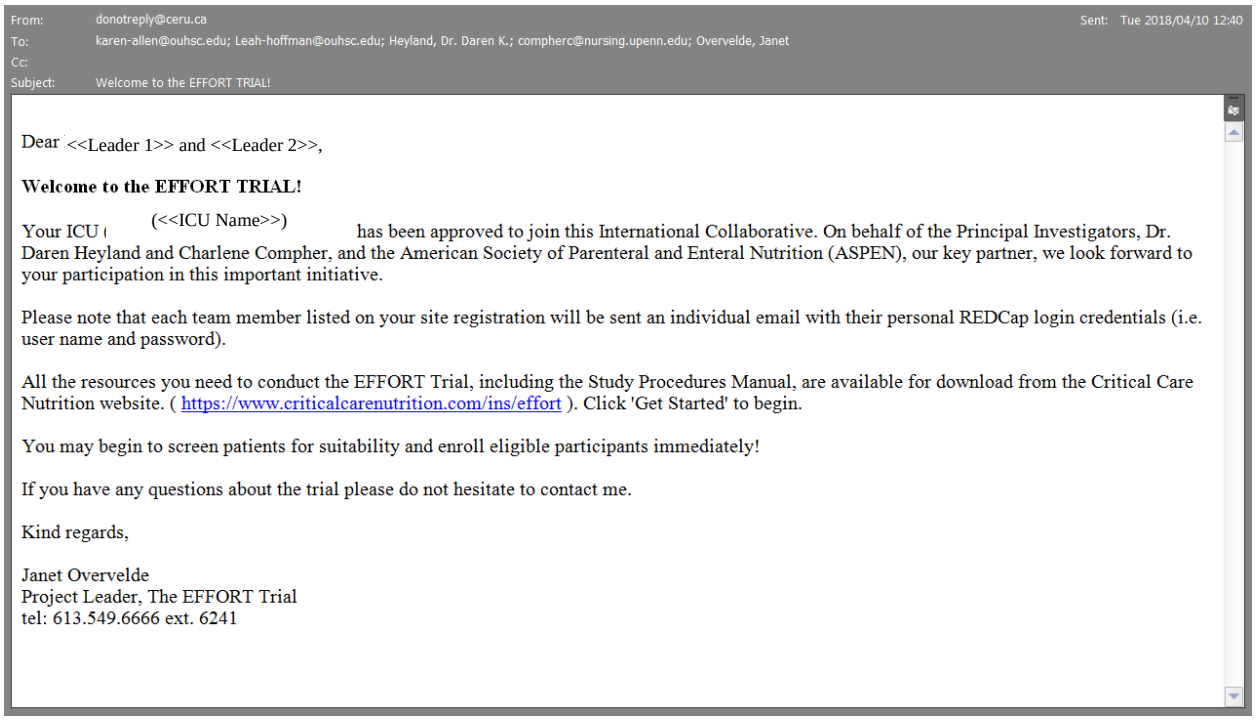
If you have any questions regarding this process, please contact Janet Overvelde: overvelj@kgh.kari.net

Registration Approval Emails

AFTER the coordinating centre has reviewed and approved your site to join, you will receive 2 emails:

1. Registration Confirmation & Welcome Message
   Note: the coordinating centre will respond to registration requests as quickly as possible. Please allow for 72h for a response before you contact them about the status of your registration.

Site Registration Form and Instructions



From: donotreply@ceru.ca
Sent: Tue 2018/04/10 12:40
To: karen-allen@ouhsc.edu; Leah-hoffman@ouhsc.edu; Heyland, Dr. Daren K.; compherc@nursing.upenn.edu; Overvelde, Janet
Cc:
Subject: Welcome to the EFFORT TRIAL!

Dear <<Leader 1>> and <<Leader 2>>,

Welcome to the EFFORT TRIAL!

Your ICU ((<<ICU Name>>) has been approved to join this International Collaborative. On behalf of the Principal Investigators, Dr. Daren Heyland and Charlene Compher, and the American Society of Parenteral and Enteral Nutrition (ASPEN), our key partner, we look forward to your participation in this important initiative.

Please note that each team member listed on your site registration will be sent an individual email with their personal REDCap login credentials (i.e. user name and password).

All the resources you need to conduct the EFFORT Trial, including the Study Procedures Manual, are available for download from the Critical Care Nutrition website. (https://www.criticalcarenutrition.com/ins/effort). Click 'Get Started' to begin.

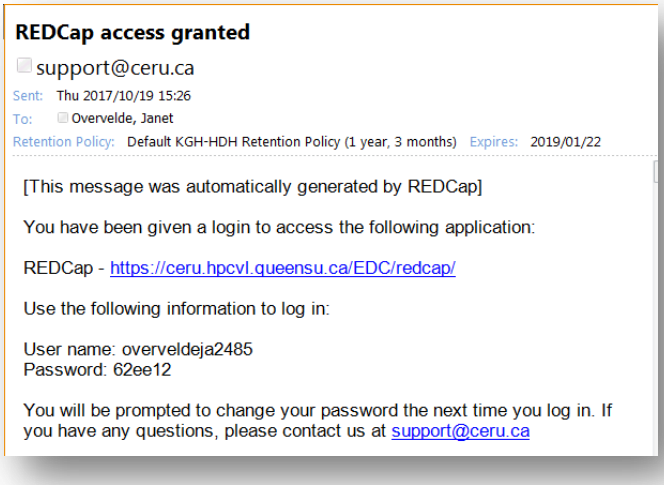
You may begin to screen patients for suitability and enroll eligible participants immediately!

If you have any questions about the trial please do not hesitate to contact me.

Kind regards,

Janet Overvelde
Project Leader, The EFFORT Trial
tel: 613.549.6666 ext. 6241

2. REDCap login credentials message (user id and password)



REDCap access granted

support@ceru.ca
Sent: Thu 2017/10/19 15:26
To: Overvelde, Janet
Retention Policy: Default KGH-HDH Retention Policy (1 year, 3 months) Expires: 2019/01/22

[This message was automatically generated by REDCap]

You have been given a login to access the following application:

REDCap - https://ceru.hpcvl.queensu.ca/EDC/redcap/

Use the following information to log in:

User name: overveldeja2485
Password: 62ee12

You will be prompted to change your password the next time you log in. If you have any questions, please contact us at support@ceru.ca

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APPENDIX - Site Registration Form

Site and Study Team Member Qualifications

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	Phone	*Role in ICU	Study Leader (Y/N)

*Role in ICU options: Dietitian, Registered Nurse, Research Coordinator, Doctor, Pharmacist, Other (specify).

CVs - Upload the CVs for the two study leaders indicated above.

GCP Training Certificates - Upload the GCP training certificates for the two study leaders indicated above.

Ethics Clearance

Hospital Information

2. Did your site receive a waiver of consent for this trial?
   ☐ Yes
   ☐ No

3. A copy of your local site ethics clearance (approval) letter is a requirement for inclusion in this collaborative. Please upload your ethics clearance (approval) letter.

4. Name of Ethics Committee: _____

5. Ethics Reference Number (study unique ID): _____

Hospital Information

6. Hospital Name: _____
7. Hospital time zone: _____
8. Hospital Type: ☐Teaching ☐Non-Teaching
9. City: _____ 9. Province/State: _____ 10. Country: _____

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11. Size of Hospital (Number of Beds): _____

ICU information

12. Does your hospital have multiple ICU? ☐ Yes ☐ No
13. ICU Name: _____
14. ICU Type:
    - ☐ Open: Attending physician remain in charge, ICU physician consults.
    - ☐ Closed: Care transferred or shared with ICU physician
    - ☐ Other, *please specify*: _____
15. Case Types (select all that apply):

☐ Medical	☐ Pediatrics	☐ Cardiac Surgery
☐ Surgical	☐ Neurological	☐ Burns
☐ Trauma	☐ Neurosurgical	☐ Other, *please specify:* _____

16. Is there a designated ICU Medical Director?
    - ☐ Yes
    - ☐ No
17. Number of beds in ICU: _____
18. Do you have a Dietitian working in the ICU?
    - ☐ Yes → *If yes*: Amount of full time equivalent (FTE) dietitian: _____
    - ☐ No
19. Do you use a bedside feeding protocol/algorithm that allows the nurse to advance or withhold tube feedings as specified by the protocol/algorithm?
    - ☐ Yes – We have a feeding protocol
    - ☐ No – No systematic or standardized approach to feeding at the bedside

    If yes to "Feeding Protocol", indicate which components you are implementing in your ICU (check all that apply):
    - ☐ An initial feeding strategy that includes the use of volume based feeding
    - ☐ Prophylactic use of motility agents starting with start of enteral nutrition
    - ☐ Protein supplements starting with start of enteral nutrition

    What type of formula do you use as your initial or starting formula as part of your feeding protocol (select only one)?
    - ☐ Semi-elemental feeding formula
    - ☐ Polymeric feeding formula
    - ☐ Other type of formula , *Please Specify:* _____
20. Do you use a gastric residual volume threshold to adjust feeds?
    - ☐ Yes → *If yes*, what volume threshold do you use? _____ millilitres (ml)
    - ☐ No

Site Registration Form and Instructions

21. Do you use a protocol to monitor blood sugar control or the administration of insulin?
    ☐ Yes → *If yes*: What range do you target? -OR- What value do you target?
    ☐ No Lower:_____ ☐ mmol/L ☐mg/dL Target: _____☐ mmol/L ☐mg/dL
    Upper:_____ ☐ mmol/L ☐mg/dL

Confirmation

In order to participant in this trial, sites must confirm that:

- ❑ They have read the protocol and associated training materials on the CCN website and have adequate resources to conduct this trial; AND
- ❑ They will abide by the randomization scheme and arm assignment (high vs. low protein prescription) and avoid overfeeding for each randomized patient; AND
- ❑ They use a standardized feeding protocol in their ICU for enteral and parenteral nutrition; AND
- ❑ Have access to a range of commercial enteral and parenteral feeding products (eg. high protein EN formulas, protein supplements, parenteral nutrition formulations or amino acids) that they will use to achieve protein targets without providing excessive calories; AND
- ❑ They are committed to enrolling a minimum of 30 eligible patients within 2-3 years.

Signoff

Checking this box indicates that:

- ❑ You have had the opportunity to read information about the EFFORT Trial and understand the purpose of this international project;
- ❑ The data submitted by your site via the electronic data collection system (REDCap) allows us to disseminate and publish information and make it available for the purpose of scholarship:
    - We will compute site reports comparing statistics across all participating sites;
    - Only aggregated data will be shared. Individual patient information such as demographics and/or clinical information will NEVER be shared;
    - You are allowing us to give your site credit, when appropriate, such as on our website, in journal publications and in press releases.

_____End of Form_____