**Informed Consent Form for Participation in a Research Study**

**Study Title**: The Effect of Higher Protein Dosing in Critically Ill Patients: A Multicenter Registry-based Randomized Trial

**Sponsor’s Study ID:** The EFFORT Trial

**Study Doctor**: *insert name, department and telephone or pager number*

**Sponsor:** Dr. Daren Heyland, MD, FRCPC, MSc

**Emergency Contact Number** (24 hours / 7 days a week): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Non-Emergency contact numbers are noted at the end of this document under the section heading “Contacts”.

INTRODUCTION

As a Substitute Decision Maker, you are being asked to provide informed consent on behalf of a person who is unable to provide consent for him/herself. Throughout this form, “you” means the person you are representing. You are being invited to participate in a research project. Current treatments available to you are only available because previous patients like you participated in clinical trials. Future advances are dependent on participation in clinical trials. You are invited to participate in this trial because you are a critically ill patient at high nutrition risk*.* This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study. The study staff will tell you about the study timelines for making your decision.

Taking part in this study is voluntary. Deciding not to take part or deciding to leave the study later will not result in any penalty or affect current or future health care.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Critically ill mechanically ventilated patients are not able to consume a regular diet. Normally, a dietitian or other health care professional will assess the critically ill patient and determine their requirements and provide protein and calories through a feeding tube or intravenous (IV) as part of their usual care. However, there is a wide range of doses of protein provided and we do not know the optimal or best amount of protein to feed critically ill patients.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to compare the effects on you and your recovery of 2 different protein doses, both of which are commonly used for critically ill patients.

WHAT OTHER CHOICES ARE THERE?

If you choose to not take part in this study, nutrition care will be provided to you as part of the usual care in your ICU.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 4000 people will take part in this study, from at least 100 ICUs located around the world. We expect to enroll at least 30 patients locally.

WHAT WILL HAPPEN DURING THIS STUDY?

If you decide to participate then you will be "randomized" into one of the two groups described below. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will havean equal chance of being placed in either group. Neither you, the study staff, nor the study doctors can choose what group you will be in. The study doctor and study staff will know which group you are in. As a participant, you will not have any responsibilities in this study.

WHAT IS THE STUDY INTERVENTION?

Group 1: Usual ICU care plus a protein dose of >2.2 g/kg/day. If you are randomized to this group, your protein dose will be met by providing protein through tube feeding, protein supplements and/or IV protein, as determined by the doctors and/or dietitian.

Group 2: Usual ICU care plus a protein dose of <1.2 g/kg/day. If you are randomized to this group, your protein dose will be met by providing protein through tube feeding, protein supplements and/or IV protein, as determined by the doctors and/or dietitian.

The study intervention will continue for your entire time in ICU while you are receiving tube feeding and/or IV nutrition. There are no other changes to your usual care, just the amount of protein prescribed.

WHAT ARE THE STUDY PROCEDURES?

Non-Experimental Procedures

1. You will confirm this agreement by signing this consent form.
2. While you are in ICU, the clinical team will visit you daily and review your medical record to assess your medical condition.
3. The clinical team will record information about your past medical history, nutrition, and recovery during your stay in ICU.
4. The results from the blood tests that are routinely done while you are recovering in the ICU will be recorded for this study.

Experimental Procedures

1. You will be prescribed a protein dose based on your study group assignment.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

* Provide consent to participate.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

The study will last until your ICU discharge or for 28 days, whichever comes first.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

Participation in research is voluntary. You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. This will not affect their medical care in any way. Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no information will be collected or sent to the sponsor after you withdraw your permission. If you choose to withdraw from the study, you are encouraged to contact the study doctor or study staff.

CAN PARTICIPATION IN THIS STUDY END EARLY?

You will be informed, in a timely manner, of any new information which may affect your willingness to have your family member continue taking part in this study. The clinical team may stop your participation in the study early, and without your consent, for reasons such as:

* You are unable to tolerate the study intervention
* The study doctor no longer feels this is the best option for you
* The Sponsor decides to stop the study

If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form. If you are removed from this study, the study doctor will discuss the reasons with you.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

We do not expect any greater risk compared to usual care. There may be other risks that are currently unforeseeable.

WHAT ARE THE REPRODUCTIVE RISKS?

Protein dosing for critically ill pregnant women or children has not been tested, therefore, you may not take part in this research study if you are pregnant. Post-partum and lactating patients may participate.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

If you agree to take part in this study, the experimental intervention may or may not be of direct benefit to you. We anticipate a higher amount of protein may improve survival and recovery but we currently do not know for sure and that is why we are doing this trial.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the study doctors and study staff will only collect the information they need for this study from the medical record. Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

* Dr. Daren Heyland, the Sponsor of this study, and the study staff coordinating the study
* The research ethics board who oversees the ethical conduct of this study in Ontario
* *insert research site name*, to oversee the ethical conduct of research at this location

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study. Your name, address, or other information that may directly identify you will not be used. The records received by these organizations may contain your unique participant code, sex, age, and admission and discharge dates. If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be published in the medical literature and that the de-identified data collected from this study may be used in additional study questions as determined by the sponsor. Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

A copy of the consent form that you sign to enter the study may be included in your health record/hospital chart.

WILL information about this study BE available online?

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>. This website will not include information that can identify you. You can search this website at any time.

WHAT IS THE COST TO PARTICIPANTS? ARE STUDY PARTICIPANTS PAID?

Participation in this study will not involve any additional costs to you or your private health care insurance. You will not be paid for taking part in this study.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study. Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. By signing this form you do not give up any of your legal rights against the study doctor, sponsor or involved institutions for compensation, nor does this form relieve the study doctor, sponsor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, contact the study doctor [Name] at [Telephone].

If you have any concerns about your rights as a research participant please contact the Board of Record – Dr. Albert Clark, Chair of the Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics at 1-844-535-2988.

SIGNATURES

* All of my questions have been answered,
* I understand the information within this informed consent form,
* I allow access to my medical records as explained in this consent form,
* I do not give up any of my legal rights by signing this consent form,
* I agree, or agree to allow the person I am responsible for, to take part in this study.

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Signature of Participant/ PRINTED NAME Date

Substitute Decision-Maker

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Signature of Person Conducting PRINTED NAME & ROLE Date

the Consent Discussion

**Complete the following section once the patient is able to consent to participate in the study:**

* All of my questions have been answered,
* I understand the information within this informed consent form,
* I allow access to my medical records as explained in this consent form,
* I do not give up any of my legal rights by signing this consent form,
* I agree to take part in this study.

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Signature of Patient PRINTED NAME Date

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Signature of Person Conducting PRINTED NAME & ROLE Date

the Consent Discussion

**Complete the following section only if the participant is unable to read or requires an oral translation:**

* The informed consent form was accurately explained to, and apparently understood by, the participant/substitute decision maker, and
* Informed consent was freely given by the participant/substitute decision maker

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Signature of Impartial PRINTED NAME Date

Witness/Translator

*(If participant were unable to*

*read/required an oral translation)*