**The Effect of Higher Protein Dosing in Critically Ill Patients:**

**A Multicenter Registry-based Randomized Trial: The EFFORT Trial**

**Why is this research being done?**

As part of the patient’s usual care in the Intensive Care Unit (ICU), an ICU nutrition specialist will do a check the nutritional status of the patient and create a nutrition plan. Providing protein and calories to critically ill patients is associated with less infectious complications, more days off the ventilator, improved long-term physical recovery, and lower death rates. The recommendations for how much protein a patient should receive vary from lower amounts to quite high amounts. We do not know the right dose of protein to provide critically ill patients so we are doing a research project where nutrition specialists are randomly told to prescribe a higher or a lower dose of protein. Other than the amount of protein patients receive, all patients will continue to receive usual care. This research study may help to clarify what the ideal amount of protein is for a critically ill patient. We expect to include 4000 patients worldwide and approximately 30 patients from your ICU in this study.

**How will my personal health information be protected?**

Information from the patient’s medical record will be collected by the researchers to look at if the higher or lower amounts of protein cause better patient outcomes. The researchers will only collect the information they need for the study from the hospital record. All information collected will be kept confidential and will not be shared with anyone outside the study unless required by law. Only de-indentified or anonymized information that is collected about the patient (called study data) will be sent electronically to the Clinical Evaluation Research Unit (CERU) in Kingston, Ontario, Canada for analysis. The research team at [Hospital name] and at CERU and the Research Ethics Board will have access to the study data. The patient’s name, birthdate, address, or other information that may directly identify you will not be used. The electronic records received by CERU will only contain a unique participant code. You will not be named in any reports, publications or presentations that may come from this study. The study records will be retained for [5 years as per local policy].

**What are the risks and benefits of this study?**

The protein critically ill patients will receive in this trial does not differ from usual care, so we do not foresee any new risks with participating. There may be risks that are currently unexpected. Receiving lower or higher amounts of protein may be beneficial. Future patients will benefit once we know the optimal amount of protein to provide critically ill patients.

**Will this study cost me anything? Will I be paid?**

Participating in this study will not cost you any money and you will not be paid for your participation.

**What if I have questions?**

You may direct your questions or concerns to the on-site study nutrition specialist and/or the doctor who sees you in the ICU for your nutrition. Further questions can be addressed by the Site Investigator, [Name], at [Telephone number] or [Email address].

If you have any questions about your rights as a research participant, please call the Chair of the Research Ethics Board, [Name], at [Phone number].