# **PARTICIPANT INFORMATION SHEET**

**Welfare Attorney/Welfare Guardian/Nearest Relative**

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

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

**The EFFORT Trial (“Study”)**

**You are being invited to consider giving your permission for your ward/relative/person you are consenting for to take part in a research Study. Before you decide it is important for you to understand why the research is being done and what it will involve.**

**We would then ask that you put your own views about the research aside and to consider and take into account, the past and present wishes and feelings of your ward/relative/person you are consenting for, had they been able to consent for themselves.**

**Please take time to read the following information carefully and discuss it with others if you wish.**

**Please ask me if there is anything that is not clear or if you would like more information. Thank you for reading this.**

**What is the purpose of the Study?**

We know that providing protein and calories to patients on the ICU is associated with lower rates of infection complications, more days off the ventilator, improved long-term physical recovery, and lower death rates. However, there is no agreement on how much protein a patient should receive. Recommendations vary from low to quite high amounts. There is no clear indication of the right dose of protein to provide patients in the ICU. We are conducting a research project to help us answer this question.

**Why has the patient been chosen?**

Your ward/relative/person you are consenting for has been asked to take part as they because they are mechanically ventilated (connected to a breathing machine) and expected to remain so for another 48 hours.

However, they currently lack the capacity to make an informed decision about whether they can take place in this Study. We are therefore asking you as their Welfare Attorney/Welfare Guardian/Nearest Relative, if you will give consent on their behalf to join this Study. This is permissible under the Adults with Incapacity (Scotland) Act 2000.

**Do they have to take part?**

No. It is up to you to decide whether they take part in the research or not. If you decide that they should take part you are free to change your mind at any time and without giving a reason and this will not alter their care in any way, now or at any stage in the future.

**What will happen to your ward/relative/person you are consenting for if they take part in the research?**

To find out if patients do better when given higher or usual amounts of protein, we will put each patient who agrees to take part in the Study into either a high protein group (greater than or equal to2.2g/kg/day) or a usual protein group (less than or equal to1.2g/kg/day). A computer program will choose the group based on chance (similar to tossing a coin). This ensures there is an equal chance of being placed in each group. Neither you, nor your relative will be able to choose which feeding group they will go into. All other care will be exactly the same.

Patients on the ICU who are mechanically ventilated (connected to a breathing machine) are not able to eat and drink normally. For this reason, they will usually receive their nutrition through a feeding tube (a tube inserted into the nose, down the throat and into the stomach or small bowel) or directly via the blood stream. As part of the patient’s usual care in the ICU, an ICU dietitian will check the nutritional status of the patient and create a nutrition plan to meet their individual nutritional targets. This process will be the same in the EFFORT Trial, except the individual protein targets will be decided by the computer program.

**What are the possible benefits of taking part?**

Your ward/relative/person you are consenting for may not get a direct benefit from taking part in this Study. There are no direct benefits to your ward/relative/person you are consenting for taking part in the Study. However, the information we get from this research may help to improve health care practices in the future and consequently help to improve the outcomes of future patients who are on the ICU.

**What are the possible disadvantages and risks of taking part?**

We do not anticipate any risks of taking part in the Study. We are not aware of any side-effects of the intervention as the lead investigator Dr. Daren Heyland has now conducted research on thousands of participating ICU patients in hospitals around the world, but we will collect data on these should any occur. We have also kept the demands on patient time to a minimum.

**What if there is a problem?**

If you have a concern about any aspect of this Study please contact [*name and contact details*] who will do their best to answer your questions.

This international Study is being sponsored by Queen’s University in Kingston, Ontario, Canada under the direction of Dr. Daren Heyland a renowned medical researcher in the field. As Sponsor, Queen’s University has taken on full liability for the oversight of this clinical trial in the UK and is therefore responsible for ensuring it is properly conducted by the participating hospitals that have been directed to follow standard clinical trial procedures (a “Protocol”). This Protocol includes specific processes for every clinician and hospital to follow, should anything go wrong. National Health Service complaints mechanisms are available to you (if appropriate). See the contact information below.

**What happens when the Study is finished?**

During and after the Study, all medical care will remain the same.

**Will taking part in the Study be kept confidential?**

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard the privacy of the patient at every stage. Study clinicians may need access to the medical records of participating patients to effectively carry out this research.

We will be using information from these medical records in order to undertake this Study and will act as the data controller for this Study. This means that we are responsible for looking after their information and using it properly. Once the Study has closed the Sponsor will not have access to any identifiable information as the results will be de-identified – meaning they will not contain personal information or patient medical records.

During the Study a patient’s right to access, change or move their personal and medical information are limited, as we need to manage these records in specific ways in order for the research to be reliable and accurate. If a patient withdraws from the Study, we will keep their information that we have already obtained. To safeguard patient rights, we will try to use the minimum personally-identifiable information as is possible. You can find out more about how we use their information here [Enter local site information].

[Insert local hospital name here] will use your relative’s name, date of birth and medical record number to contact them about this Study, and make sure that relevant information about this Study is recorded for their care, and to oversee the quality of this Study. Authorized clinicians from Queen’s University – (the Sponsor) and possibly regulatory organisations providing oversight may look at a patient’s medical and research records for patient safety, audit or investigations or to check the accuracy of the Study results. [Insert local hospital name here] may pass personal health information to the Sponsor along with other information collected during the Study in such situations.

The analysis of the Study results will not involve identifiable patient records such as a patient’s name, date of birth, medical record number or contact details. When the results of this Study are published, patient 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 studies and by other researchers, as determined by the Sponsor.

[Insert local hospital name here] will keep identifiable information about participants in this Study for 5 years after the Study has finished.

**What will happen to the results of the Study?**

The results of the Study will be published in a medical journal and presented at international conferences. It will not be possible to identify participating patients from the published results. Should you wish to have a copy of any papers published please contact the research team and we will be happy to forward on any publications.

**Who is organising the research and why?**

The Study is organised through Queen’s University in Kingston, Ontario, Canada through the Clinical Education Research Unit (CERU). Guy’s and St Thomas’ (GSTT) NHS Foundation Trust are the UK lead site. The research is endorsed by the American Society for Parenteral and Enteral Nutrition (ASPEN). The overall Study has received funding from the CERU, but none of the clinicians are being paid extra to undertake this Study.

**Who has reviewed the Study?**

The Study has been reviewed by ASPEN Board of Directors as well as International experts in critical care nutrition. In addition, critical care consultants and nurses at GSTT, not directly related with the Study have had an opportunity to review and comment on it. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. A favourable ethical opinion has been obtained from Scotland A REC. NHS management approval has also been obtained

**If you have any further questions about the Study please contact** xxxxx **on: (xxx xxxx) or email: xxxxx@xxxxxx**

**If you would like to discuss this Study with someone independent of the Study please contact:**

**xxxxx**

 **If you wish to make a complaint about the Study please contact NHS Lothian:**

**NHS Lothian Complaints Team**

**2nd Floor**

**Waverley Gate**

**2 - 4 Waterloo Place**

**Edinburgh**

**EH1 3EG**

**Tel: 0131 465 5708**

**craft@nhslothian.scot.nhs.uk**

**Thank you for taking the time to read this information sheet**