This instruction should be deleted before use.

Use of this checklist is recommended. The checklist may be used by the site to standardize their consent processes. Sites may modify this as they see fit to adhere to local practice and policies.

Terms used in this document:

***Family member*** – The term ‘family member’ is being used to describe the individual that study team will engage with to obtain consent. Other terms that may be used to describe this individual are ‘next of kin’, ‘legally appointed representative,’ and ‘substitute decision maker.’

***Regained capacity*** – The term ‘regained capacity’ is used to describe the patient and their ability to grant consent for themselves once they are no longer sedated and mechanically ventilated. If a patient has regained capacity, a ‘re-consent’ process may be required. This process may not be applicable in all ICUs so please consult with local policy and procedure to determine how to proceed.

***Re-Consent*** – The term ‘re-consent’ is used to describe the activity of seeking written documentation from an ICU patient, once they have regained capacity, that was enrolled in the EFFORT Trial based on a family member consent.

**BEFORE YOU APPROACH THE FAMILY MEMBER FOR CONSENT:**

* Check to see if the patient has refused (or opted out) of participation in any research, as noted locally in the patient medical record.
* Familiarize yourself with the patient’s history.
* Have the clinical team update the family member of the patient regarding their condition.
* Introduce yourself as a member of the clinical team and you wish to discuss with them obtaining their approval to have their patient enrolled in a clinical study.

**HAVING THE CONSENT DISCUSSION WITH THE FAMILY MEMBER:**

* Provide the family member with the opportunity to discuss the study with their other family members and/or anyone else they wish to consult with.
* Provide the family member with the opportunity to ask questions.
* Document all interactions and discussions regarding informed consent in the patient source notes and/or medical chart.
* Provide the family member with a copy of the signed ICF.
* Place a copy of the ICF on the patient’s medical chart.
* Retain the originally signed ICF in the patient’s study file.

**SUGGESTED SCRIPT TO USE FOR CONSENT DISCUSSION:**

*As part of the patient’s usual care in the Intensive Care Unit (ICU), an ICU nutrition specialist (doctor or dietitian, whichever is appropriate for your setting) will do a checkup on the nutritional status of the patient and create a nutrition plan. Results from past research, has proven that providing artificial nutrition to nutritionally “high risk” critically ill patients is associated with less infectious complications, more days off the ventilator, improved long-term physical recovery, and lower death rates. The recommendation for how much protein a patient should receive varies from lower amounts to quite high amounts. The aim of this study is to look at the amount of protein given to a patient to find out the best amount of protein to give to critically ill patients.*

*Your loved one (the patient) is considered to be nutritionally ‘high risk’ (meaning that they may experience adverse complications if they do not receive optimal nutritional care). As such, they are eligible to participate in a study we are doing to determine optimal nutritional practices. This not a study of experimental nutrition products or devices. But rather, we are study health care practitioner prescribing practices. If you love one is involved in this study, they will be randomly put into one of two treatment groups. Depending on the group they are assigned to nutrition specialists will be told to prescribe a higher or a lower dose of protein. Both of these treatment groups are a reflection of usual nutrition practice for protein doses. It is not currently know whether more or less protein is better for patients; that’s why we are doing this trial.*

*Other than the amount of protein patients receive, all patients will continue to receive usual care.*

**ASSESSMENT OF THE PATIENT’S CAPACITY (REGAINING CAPACITY) FOR CONSENT:**

*If applicable, the following steps outline how to approach an enrolled patient once they are awake to obtain ongoing consent.*

* Reassess the patient on an ongoing basis to see if they have regained capacity to consent.
  + If capacity has been regained, present the study, and obtain consent from the patient.
  + If the patient does not regain capacity, document this in the medical chart and study files.
* Before the patient leaves the hospital, the research team should have clear documentation regarding their ability to consent. Such as:
  + Did the patient regain capacity to consent?
  + If so, all associated documentation regarding the consent dialogue with the patient.
  + Copy of signed ICF to patient
  + Copy of ICF on the patient’s medical chart
  + Retain original signed ICF in patient’s study file
* If not, whether assent was used, including any associated documentation.