*******This document should be completed for each randomized participant and filed with the source documents*. ***DELETE*** *this highlighted instruction before use of this template.*

|  |
| --- |
| **Protocol Title:** The Effect of High Protein Dosing in Critically Ill Patients: A Multicenter Registry-based Randomized Trial |
| **Investigator Name:** |
| **Participant Name:** |

|  |  |  |  |
| --- | --- | --- | --- |
| **STEP 1: Confirm Subject Eligibility** | | | |
| **ALL INCLUSION CRITERIA must be marked as YES for subject to be eligible for the study:** | | | |
| YES | NO | 1. > 18 years old | |
| YES | NO | 1. Nutritionally “high-risk”, meeting one or more of the below criteria (check all that apply):  * Low (≤25) or High BMI (≥35) * Moderate to severe malnutrition (as defined by local assessments). We will document the means by which sites are making this determination and capture the elements of the assessment (history of weight loss, history of reduced oral intake, etc.). * Frailty (Clinical Frailty Scale 5 or more from proxy) * Sarcopenia- (SARC-F score of 4 or more from proxy) * From point of screening, projected duration of mechanical ventilation >4 days | |
| YES | NO | 1. Requiring mechanical ventilation with actual or expected total duration of mechanical ventilation >48 hours | |
| **ALL EXCLUSION CRITERIA must be marked as NO for subject to be eligible for the study:** | | | |
| YES | NO | 1. > 96 continuous hours of mechanical ventilation before screening | |
| YES | NO | 1. Expected death or withdrawal of life-sustaining treatments within 7 days from screening | |
| YES | NO | 1. Pregnant (Note: Post-partum and lactating patients are not excluded from the trial) | |
| YES | NO | 1. The responsible clinical feels that the patient either needs low or high protein   **If no, specify all that apply:** No longer critically ill, New onset of ARDS, Worsening renal function, Improved renal function, Starting dialysis, New wound (non-surgical), New surgical wound, Negative nitrogen balance, Increased protein losses , BMI ≥30, Improving hepatic failure, Worsening hepatic failure, Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. | |
| YES | NO | 1. Patient requires parenteral nutrition only and site does not have products to reach the high protein dose group | |
| **STEP 2: Is the subject eligible for the study?** | | | |
| **Yes, the subject is eligible for the study.**  Engage the investigator for confirmation of eligibility and appropriateness to proceed with consent.  Document dialogue with investigator. Enter name of investigator  ***Proceed to next steps below.*** | | | **No, the subject is not eligible for the study.**  Enter the subject into REDCap, including the exclusion criteria that were present.  **STOP** ***- No further action required.*** |

|  |  |
| --- | --- |
| To ensure it is medically appropriate for the patient to be enrolled in the study, it is necessary to review eligibility of the patient with a physician. This can be the site investigator or the attending physician responsible for the care of the patient.  Study eligibility was discussed with Dr.\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_  Physician name DD / MMM / YYYY Time  ❑ This patient meets all inclusion criteria and no exclusion criteria and is eligible to participate.  ❑ This patient is **NOT** eligible to participate. | |
| **STEP 3: What type of consent is approved for use by your ethics committee?** | |
| **Standard Consent or Third Party Consent**  **Is it appropriate to approach the SDM or third party for consent?**  If yes, the substitute decision maker (SDM) or third party should be contacted to begin the consent dialogue.  ***Proceed below to A) for Standard Consent steps***  ***Proceed below to B) for 3rd Party Consent steps*** | **Waived Consent**  Document the waived consent in accordance with local institutional policies.  Enter this information into REDCap, record the date and time of when waived consent was obtained.  NOTE: The substitute decision maker should be contacted to inform them of the patient’s enrolment in the trial and to address any questions they may have. If the SDM refuses to have the patient involved in the trial, patient should be withdrawn.  ***Proceed to randomization step.*** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. **Was the SDM/subject approached for consent?**  |  |  | | --- | --- | | ***If yes:*** | **If no:** | | ***Proceed to next step.*** | Please indicate why SDM/subject or third party was not approached for consent   * Next of kin/SDM not available * Missed subject * Language barriers * Family dynamics * REDCap not available * Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   File screening documentation as appropriate.  ***STOP - No further action required.*** | |
| 1. **Was consent obtained from the SDM/subject?**  |  |  | | --- | --- | | ***If yes:*** | **If no:** | | Enter the date and time consent was obtained into REDCap.  Consent Date (YYYY-MM-DD):­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Consent Time (HH:MM): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ***Proceed to participant randomization step.*** | Choose the most important reason why consent was not obtained   * Too overwhelmed * Not interested * Did not respond (timed out) * Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   File screening documentation as appropriate.  **STOP** ***- No further action required.*** | |
| 1. **Was 3rd party consent obtained?**  |  |  | | --- | --- | | ***If yes:*** | **If no:** | | Enter the date and time consent was obtained into REDCap.  Consent Date (YYYY-MM-DD):­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Consent Time (HH:MM): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ***Proceed to participant randomization step.*** | Enter the reason for consent being declined in REDCap.   * Missed Subject * 3rd party not available * 3rd party refused to consent * REDCap not available * Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   File screening documentation as appropriate.  **STOP** ***- No further action required.*** | |  |  | |
| **STEP 4: Randomization** |
| **Proceed to the REDCap Randomization form, select the randomization button.**  Record the assigned randomization number below and record the treatment arm the participant was randomized to.  Print a copy of the randomization confirmation form and file with this documentation.  **Treatment Arm Assigned: ­­**  **❑ LOW Protein Dose (≤ 1.2 g/kg/day) OR ❑ HIGH Protein Dose (≥ 2.2 g/kg/day)**  **Study ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  (as noted in REDCap) |
| **STEP 5: Signoff** |
| **Name:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_ **Time:**\_\_\_\_\_\_\_  Signoff from person who screened and enrolled the patient. |