SECTION 3: PREPARE & PROMOTE

Contents

Promotion of the Study Locally

Engagement of Clinical Staff

Each participating ICU will have a different organizational system and process for introducing a new study to clinical staff. The EFFORT study leaders should take some time to consider their communication strategy and which clinician groups should be engaged.

For example, if the study is running in a surgical ICU, the study leaders should consider engaging the surgeons to get their buy-in regarding the study as the care for any enrolled patient will likely be collaboration between the surgeon and ICU clinicians.

We have developed some tools that study leaders can use as part of their local EFFORT communication strategy.

In Servicing (Training) Staff

We have created training materials and support documents for the EFFORT study leaders to in service clinical staff. ICUs may download these tools using the links below.

PowerPoint Presentations **-** These slide decks may be used to conduct in service training of clinical staff as well as new study team members. They are available for download from the website.

- The ***EFFORT Trial Brief Presentation*** – This presentation may be used to engage the ICU team and succinctly explain the purpose of the trial.
- ***Overview of The EFFORT Trial*** – This presentation is longer and may be suitable for local implementation purposes as the study team sees fit.

Poster **-** A Poster template is available for sites to post around their ICU to create study awareness amongst the staff. Please note that use of this poster may require local ethics approval. If you are not sure whether this should be submitted for approval prior to use, please contact your ethics committee. They are available for download from the website.

Eligibility Criteria Pocket Cards **-** A temple for pocket size study eligibility criteria cards is available for sites to use and pass out to their attending physicians, residents and nursing staff. They are available for download from the website.

Preparing to Begin Patient Recruitment

Clinical Supplies & Nutrition Products

There are no supplies provided to the sites for this trial. Sites will use nutrition products available at their institution, as clinically indicated, to achieve the appropriate protein dose in accordance with the study group assignment.

Refer to the next section “Recruit Participants” for examples of nutrition products that can be used to achieve the study group assignment.

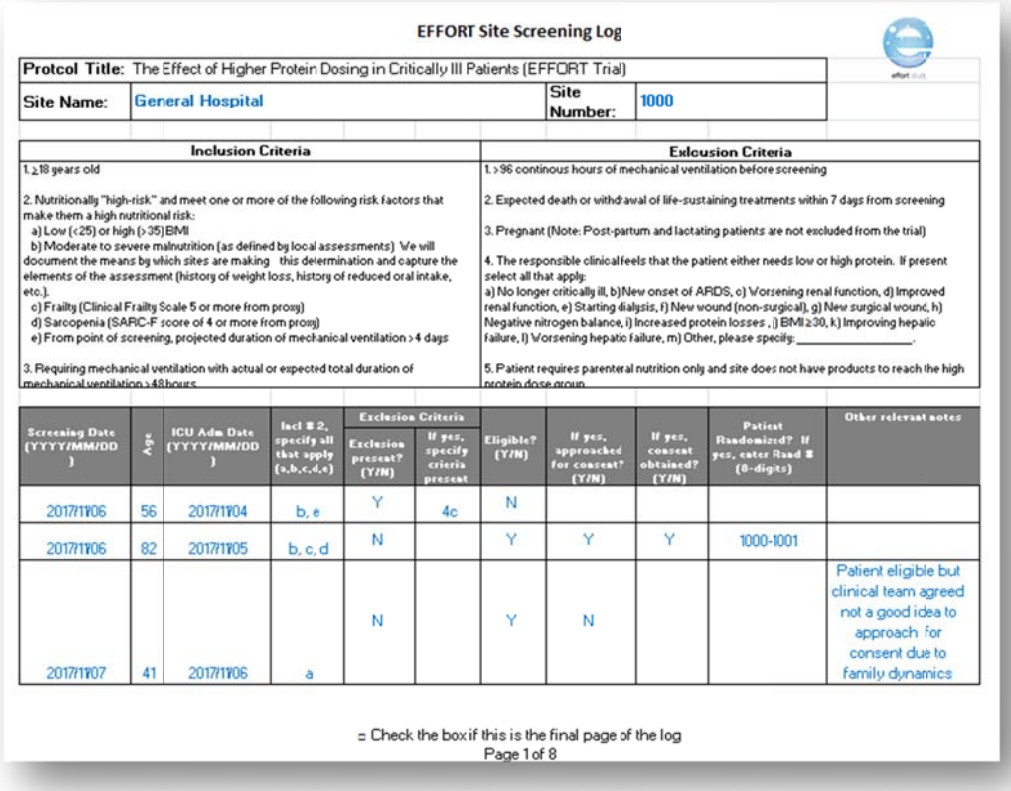
How to Keep Track of Screened and Enrolled Patients from your ICU

To make sure you are following Good Clinical Practice (GCP), an essential activity is to maintain records and tracking documents about the types of patients that have been screened for the study, and if they are found to be eligible for the study, also records about their consent and enrolment.

Screening Logs

The purpose of keeping a screening log document is to record patients who entered pre-trial screening. It also serves to chronologically document the enrollment of eligible patients. And finally, it can be used to assist the site in updating their screening data in REDCap.

Screen shot of the EFFORT Trial Screening Log



EFFORT Site Screening Log

Protocol Title:	The Effect of Higher Protein Dosing in Critically Ill Patients (EFFORT Trial)		
Site Name:	General Hospital	Site Number:	1000

Inclusion Criteria	Exclusion Criteria
1. ≥18 years old 2. Nutritionally "high-risk" and meet one or more of the following risk factors that make them a high nutritional risk: a) Low (<25) or high (>35) BMI b) 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.). c) Frailty (Clinical Frailty Scale 5 or more from proxy) d) Sarcopenia (SARC-F score of 4 or more from proxy) e) From point of screening, projected duration of mechanical ventilation > 4 days 3. Requiring mechanical ventilation with actual or expected total duration of mechanical ventilation > 48 hours	1. > 96 continous hours of mechanical ventilation before screening 2. Expected death or withdrawal of life-sustaining treatments within 7 days from screening 3. Pregnant (Note: Post-partum and lactating patients are not excluded from the trial) 4. The responsible clinical feels that the patient either needs low or high protein. If present select all that apply: a) No longer critically ill, b) New onset of ARDS, c) Worsening renal function, d) Improved renal function, e) Starting dialysis, f) New wound (non-surgical), g) New surgical wound, h) Negative nitrogen balance, i) Increased protein losses , j) BMI ≥ 30, k) Improving hepatic failure, l) Worsening hepatic failure, m) Other, please specify: _____. 5. Patient requires parenteral nutrition only and site does not have products to reach the high protein dose group

Screening Date (YYYY/MM/DD)	Age	ICU Adm Date (YYYY/MM/DD)	Incl # 2, specify all that apply (a,b,c,d,e)	Exclusion Criteria: Exclusion present? (Y/N)	Exclusion Criteria: If yes, specify criteria present	Eligible? (Y/N)	If yes, approached for consent? (Y/N)	If yes, consent obtained? (Y/N)	Patient Randomized? If yes, enter Rand # (8-digits)	Other relevant notes
2017/11/06	56	2017/11/04	b, e	Y	4c	N				
2017/11/06	82	2017/11/05	b, c, d	N		Y	Y	Y	1000-1001	
2017/11/07	41	2017/11/06	a	N		Y	N			Patient eligible but clinical team agreed not a good idea to approach for consent due to family dynamics

= Check the box if this is the final page of the log

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The ***Screening Log*** template can be downloaded from the website.

1. **Record all patients that meet <u>all inclusion criteria.</u>** (NOTE: If they do not meet all inclusion criteria, then you do not need to enter them into the log).

a. Patients must meet all inclusion criteria to be eligible for the study.
b. A patient is not eligible for the study if they meet any of the exclusion criteria.
c. Where possible and appropriate, patient eligibility may be confirmed with a physician before randomizing.
d. Patients must be randomized in the trial within 96 hours of their ICU admission.

2. Record the unique ID number assigned to the patient in REDCap on the Screening Log.
Refer to SECTION 4: Recruit for details on entering patients into REDCap to obtain the unique study ID number.

3. If a patient has had several admissions to the ICU, use the **most recent** admission.
    a. If a patient you collected data on is later readmitted to the ICU, do not include them a 2nd time.
    b. If a patient you are collecting data on is discharged but readmitted within 48 hours consider it as if this patient never left the ICU. Collect data for the hours they were not in the ICU as best as possible, and continue collecting data on them once they return to the ICU.

4. This document may be maintained electronically or the template may be printed and 'wet ink' entries made as needed.

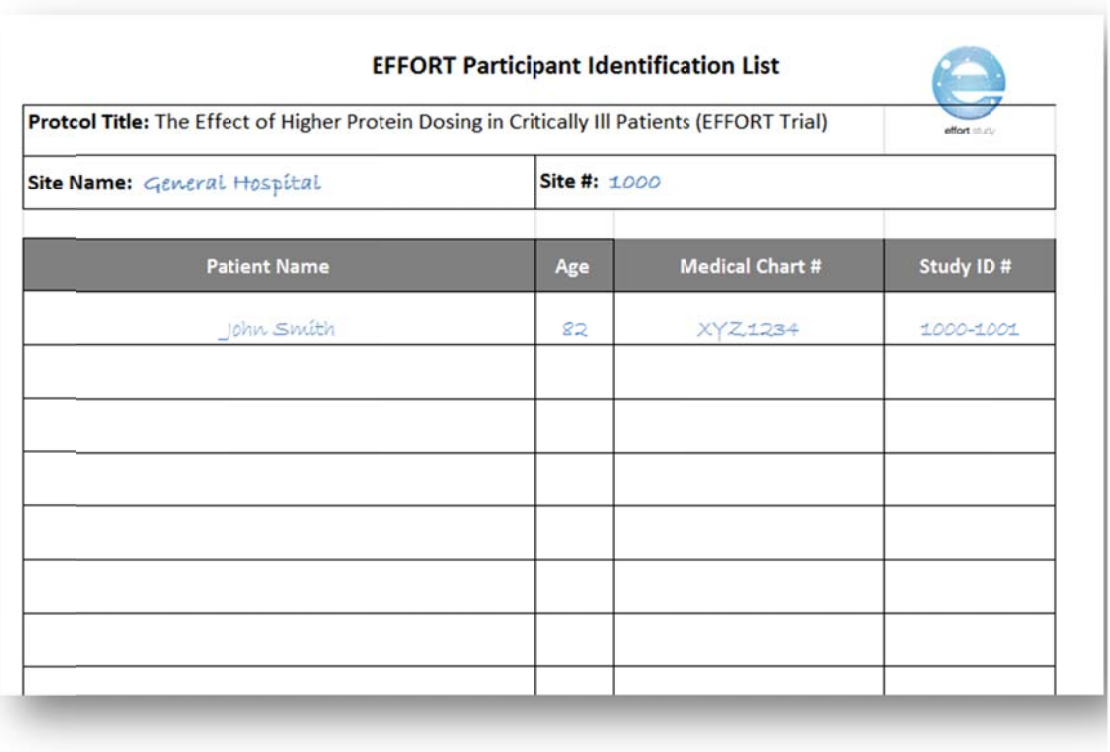
Please keep the Screening Log to help track down which patient corresponds to which patient ID number in case we have data queries at a later date, or if your site is selected for source verification. Use additional pages of the Screening Log as necessary.

Participant ID List

The purpose of the Patient ID List is to permit the identification of all participants enrolled in the trial in case follow-up is required.

This log contains personally identifying information and must be kept confidential. Do not send to CERU.

Screen shot of the EFFORT Trial Patient ID List



EFFORT Participant Identification List

Protcol Title: The Effect of Higher Protein Dosing in Critically Ill Patients (EFFORT Trial)

Site Name: General Hospital | **Site #:** 1000

Patient Name	Age	Medical Chart #	Study ID #
John Smith	82	XYZ1234	1000-1001

The ***Patient ID List*** can be downloaded from the website.

1. Record patients who are <u>randomized</u> to the study on this log.

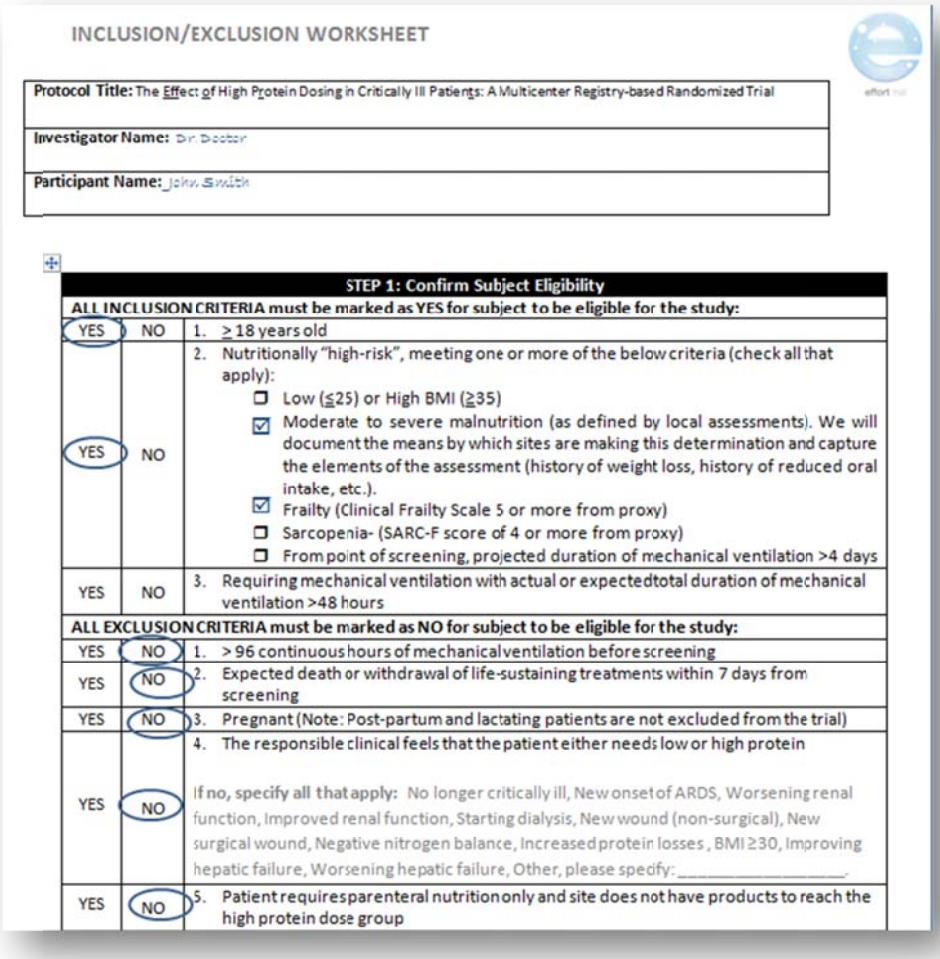
2. This document may be maintained electronically or the template may be printed and maintained as a hard copy with new entries made as needed.

Documenting Eligibility and Consent

Eligibility Worksheet

An important aspect of Good Clinical Practice is to ensure that there are records which accurately document the screening, consent and randomization processes being conducted. Use of the Eligibility Worksheet represents best practice for documenting these activities.

Screen shot of EFFORT Eligibility Worksheet



INCLUSION/EXCLUSION WORKSHEET

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

Investigator Name: Dr. Doctor

Participant Name: John Smith

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	2. 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	3. 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	2. Expected death or withdrawal of life-sustaining treatments within 7 days from screening
YES	NO	3. Pregnant (Note: Post-partum and lactating patients are not excluded from the trial)
YES	NO	4. 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	5. Patient requires parenteral nutrition only and site does not have products to reach the high protein dose group

The ***Eligibility Worksheet*** can be downloaded from the website.

1. For each patient randomized to the EFFORT Trial, an Eligibility Worksheet should be completed and filed with the patient study documents.
2. Each step in completing this form is to be completed as follows:
    a. ***STEP 1*** – Confirm the patient's eligibility by reviewing and documenting the presence of all inclusion criteria and the absence of all exclusion criteria.
    b. ***STEP 2*** – If the patient is eligible for the study proceed to engage with a physician to ensure it is medically appropriate to enroll the patient into the study. Either a site investigator or an attending physician responsible for the care of the patient can be consulted.
    c. ***STEP 3*** – When applicable (i.e. standard consent is required by the local ethics committee) consent activities should be documented.
    d. ***STEP 4*** – Once consent has been obtained (if applicable) proceed to enter the patient's screening information into REDCap and Randomize the patient.

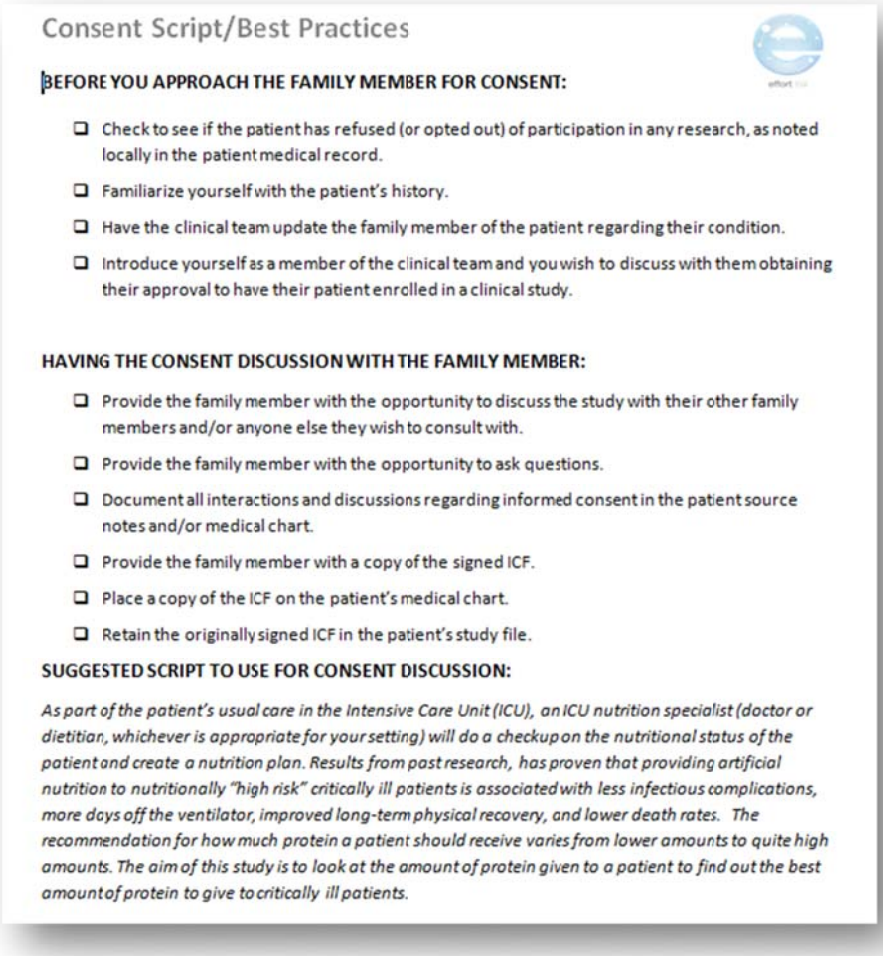
e. ***STEP 5*** – This worksheet must be signed off by the individual who conducted the screening, consent and enrollment of this patient.

Consent Tool

This tool has been created to assist the sites with the consent dialogue with a patient's family member by providing a suggested script for describing the EFFORT Trial. As well, it outlines the steps that should be followed when performing activities related to consent.

This tool may be modified by the site to ensure adherence to local practice and policies.

Screen shot of Consent Tool



Consent Script/Best Practices

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.

The ***Consent Tool*** can be downloaded from the website.

Organizing Study Paperwork

Each site must ensure that they maintain data (i.e. source documents) and records that are organized and retrievable for each study participant. This documentation should clearly note the screening, consent and study procedures performed and data collected for each participant.

Screening Packages

Tools are available to ICUs to document screening, consent and enrolment procedures followed for each patient. It is recommended that screening packages are prepared before recruitment activities start. Having packages pre-assembled and ready for use will make the process more efficient for the local study team.

It is recommended that each screening package contain the following documents:

- ✓ Eligibility Worksheet
- ✓ Ethics Approved:
  - o Consent Form (if ethics approval requires a standard consent)
  - o Patient Information Form (if ethics approval allows for waived consent)
- ✓ Consent Tool

Detailed information regarding the use of these tools is found in the next section "Recruit."

Enrolled Patient Packages

Once a patient is enrolled in EFFORT, over the course of their participation you will be creating and collecting study records to support the data you are collecting. A best practice recommendation is that you create an individual study file each patient.

Participating ICUs may use any existing practices related to maintaining individual patient study records however, if an ICU does not already have procedures in place to do this they may create a patient study file as suggested in the image on the left.

The purpose of each of the documents noted in this suggested index to the left, as well as the worksheet templates are explained in the next section "Recruit."

Are you Ready to Start Recruiting Patients?

Now that you have completed the EFFORT promotion and preparation activities let's see if you are ready to start recruiting patients.

Review the items below to see how ready your ICU is to begin patient recruitment activities EFFORT Trial.

- ❒ Have you prepared the Screening Log template for local use?
- ❒ Have you prepared the Participant ID List template for local use?
- ❒ Create screening packets (e.g. consent form/information sheet, Eligibility Worksheet, Consent Tool, etc) so you can 'grab and go' when you have a potentially eligible patient.
    - o Ensure the consent form/information sheet approved by your ethics committee is the version used.
- ❒ Create multiple copies of enrolled participant study files (e.g. blank copies of data collection worksheets, etc) so you can 'grab and go' when you have an enrolled participant.
- ❒ Review and become familiar with the procedures outlined in Sections "Recruit" and "Data Collection and Entry"
    - o Review How to Randomize a Participant Using REDCap from the "Recruit" section.

Good luck!

Please don't hesitate to contact the National Coordinator or Central Project Leader with any questions you might have as you begin your recruitment activities.