The Screening Log will be used to collect data on all patients screened for eligibility for CYCLE who meet the study inclusion criteria.

The Screening Log has 3 parts:

1. This manual (CYCLE Screening Log Manual)
2. An electronic log (Excel Document- CYCLE Electronic Screening Log) to be used for monthly electronic submissions of screening information to the study investigators
3. A paper log (Word Document- CYCLE Paper Screening Log) to be used as needed for quick manual recording of information for future input into the electronic log

NOTE: Current versions of the above documents can be downloaded from the CYCLE website

Please note that the paper log is intended as a tool to enable the completion of the electronic log. Although the data collected is the same, there are some small variations in the manner that data is recorded between the electronic log and the paper log. The electronic log has been designed to facilitate efficient data analysis while the paper log has been designed to facilitate quick and easy recording of information in clinical settings. Specific notes on how to use the paper log as a complement to the electronic log are included in the instructions below only when recording strategies are different. ***Use of the paper log is not mandatory and is at the discretion of the local site research coordinator.*** Research coordinators are welcome to use the paper log or another strategy to support completion of the electronic log.

Please find instructions for completing each column of the electronic log in the table below. Examples for each of the following screening outcomes are also provided in the table:

(1) Patient is excluded as exclusion criteria are present e.g., patient presents with leg fracture, neuromuscular blocker for 5 hrs, and is now considered palliative].
(2) Patient is eligible but is not enrolled (ENE) [e.g., patient meets all screening criteria but is not conscious and no substitute decision maker is available to give consent].
(3) Patient is included and randomized to the control group [e.g., patient meets all screening criteria and gives informed consent].
(4) Patient is excluded as inclusion criteria are not met [e.g., patient is 15 yrs of age]
Patients who do not all meet inclusion criteria do not need to be included on the log.

Column(s)		Instructions	Example
		Patient Information	
C	Pt Initials	• Enter patient's first and last initials.	**E1.** AA **E2.** AB **E3.** AC
D	Age (yrs)	• Enter patient's age in years on the date of screening.	**E1.** 50 **E2.** 60 **E3.** 70

E	Date of Screening (dd-mmm-yyyy)	• Enter the date of screening in the format dd-mmm-yyyy.	**E1, E2, E3.** 18-Jul-2018
F-AD	Indicate all exclusion criteria met (y)	• Enter "y" to indicate presence of any exclusion criterion. • If "y" for criterion 2.11 (Exemptions 4 days + (Column R)), enter "y" for each exemption criterion that is present. • Paper log instructions: Enter the numeric code of each exclusion criterion that is present. If 2.11 is present, also note the exemption code number as an extension to the exclusion criteria code.	**E1.** y for columns 2.2, 2.11, and sub-columns 2.11.6 and 2.11.9 **E2, E3.** N/A **E1.** 2.2, 2.11.6, 2.11.9 **E2, E3.** N/A
AE	Meets all screening criteria? (y/n)	• Enter "y" if patient meets all inclusion criteria and has NO exclusion criteria • Enter "n" if patient meets all inclusion criteria but has one or more exclusion criteria	**E1.** n **E2.** y **E3.** y
AF	If column AH=y, was patient enrolled? (y/n)	• Enter "y" or "n" to indicate whether the patient has been enrolled in the study or not	**E1.** N/A **E2.** n **E3.** Y
AG-AS	If column AI=n, indicate one main reason patient eligible but not enrolled (y)	• Enter "y" to indicate one main reason that the patient is eligible for the study but has not been enrolled • Paper log instructions: Enter the numeric code and brief description of one main reason the patient is not enrolled.	**E1, E3.** N/A **E2.** y to column 3.2 **E1, E3.** N/A **E2.** 3.2
AT	Date of consent (dd-mmm-yyyy)	• Enter the date that informed consent was obtained in the format dd-mmm-yyyy	**E1, E2.** N/A **E3.** 18-Jul-2018
AU	Pt randomization #	• Enter the patient's randomization # number (i.e. study ID)	**E1, E2.** N/A **E3.** 01-1-001
AV	Date of randomization (dd-mmm-yyyy)	• Enter the date that randomization occurred in the format dd-mmm-yyyy	**E1, E2.** N/A **E3.** 18-Jul-2018
AW	Treatment Arm	• Enter the treatment arm that the patient was randomized to: Routine or Cycling + Routine	**E1, E2.** N/A **E3.** Routine
AX	Date of study day 1 (dd-mmm-yyyy)	• Enter the date that patient received their first study intervention in the format dd-mmm-yyyy	**E1, E2.** N/A **E3.** 18-Jul-2018

Important Notes

- Please **submit** either the electronic log or scanned copies of your paper logs on **Friday** of **each week** to Alex Molloy at amolloy@stjosham.on.ca
- Please **r**ecord screenings for all patients that meet inclusion criteria, even if they present with exclusion criteria, or ultimately are not enrolled in the study
- Please **notify** Alex Molloy if there are **days/weeks** that you are **not screening** at amolloy@stjosham.on.ca

NOTE: Please contact Methods Centre for contact information and submission guidelines