Site Screening Questionnaire

Dr. Heyland along with the Clinical Evaluation Research Unit (CERU) at Queen's University would like to assess your interest in participating as an investigator in the TOP-UP Study, a randomized clinical trial of supplemental parenteral nutrition in under and over weight critically ill patients.

We request that this questionnaire is completed by the physician or delegated research team member.

Return completed questionnaires to the CERU project office:
Email:danserem@kgh.kari.net OR Fax: 613 548 2428

PART A: Physician Contact Details			
Last Name:		First Name:	
Affiliated Hospital:		Affiliated University:	
Address:		Tel:	
City		Fax:	
Province/State:		Email:	
Postal/Zip Code:		Best Method of Contact:	

PART B: ICU Demographics		
1	Type of institution:	☐ Academic ☐ Community
2	Administrative Structure:	☐ Open ☐ Closed
3	ICU Population:	☐ Neuro ☐ Med/Surg ☐ Trauma
4	Number of ICU beds:	
5	Number of patients admitted annually:	
Part C: Clinical Trials Expertise and Resources		
1	Is the physician and research team familiar with Good Clinical Practice Guidelines for conducting clinical trials?	☐ Yes ☐ No
2	How many studies are ongoing at your site? Please list the type of studies (e.g. ARDS, Nutrition, VAP): 1) _____ ☐ Industry ☐ Academic 2) _____ ☐ Industry ☐ Academic 3) _____ ☐ Industry ☐ Academic 4) _____ ☐ Industry ☐ Academic 5) _____ ☐ Industry ☐ Academic	# studies: ____
3	Will you be available for oversight of study patients?	☐ Yes ☐ No
4	Will you be available for resolution of issues pertaining to the study?	☐ Yes ☐ No
5	Will the investigator be available for regulatory and essential document signatures?	☐ Yes ☐ No
6	Are you planning to use any sub-investigators? If yes, please list: 1) 2) 3) 4)	☐ Yes ☐ No

7	Do you have a research coordinator? If yes, please list contact details:	☐ Yes ☐ No
8	Has your site ever been audited by Health Canada, US FDA or other regulatory agency?	☐ Yes ☐ No
9	How often does your IRB/REB meet?	☐ Weekly ☐ Bi-weekly ☐ Monthly ☐ Quarterly
PART D: TOP-UP Study		
1	Based on the following Inclusion Criteria, please indicate approximately how many patients you could enroll in this study per month: 1) Critically ill adult patient (≥ 18 yrs old) admitted to ICU 2) Acute respiratory failure (expected to remain mechanically ventilated for more than 48 hrs) 3) Expected ICU dependency of ≥ 5 days 4) On or expected to initiate enteral nutrition within 7 days of ICU admission 5) BMI <25 or ≥ 35 based on pre-ICU actual or estimated dry weight	# patients: _____

Please attach a copy of the physician's CV when forwarding the questionnaire responses.

Thank you for taking the time to complete this questionnaire.