PRISM Trial: Site Feasibility Questionnaire

Date completed:		Completed by (name/role):	
Site name:			
Suggested principal investigator (PI):			
Main contact (name/role):			
Phone:			
E-mail:			

Criteria	Comments	Check
Clinical Aspects		
Does the PI have any comments to make about the trial? For example with regards safety, ethical acceptability, scientific soundness?		☐ Yes ☐ No
Are the procedures documented in the protocol consistent with the site's own standards of care?		☐ Yes ☐ No
Investigators/Site Experience		
Does the Principal Investigator have previous experience with: A. Clinical research? B. Study population? C. Trial intervention		☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No
How many studies/trials is this hospital currently recruiting from this patient population?	Total "Open and enrolling": _____ Total in "Follow-up phase": _____	
How many working hours per week do the research team estimate they have available for the PRISM trial?	____ hrs/week	

Have the site staff received relevant regulatory training (eg GCP)?		☐ Yes ☐ No
Does the site anticipate that training staff in GCP and other regulatory requirements will be a problem? What resources are in place to do this?		☐ Yes ☐ No
Trial Population and Recruitment		
What is your anticipated likely recruitment rate, having reviewed inclusion & exclusion criteria?		
Are there any circumstances that may be expected to affect recruitment?		☐ Yes ☐ No
Facilities and Equipment		
Does the site have equipment to deliver continuous positive airway pressure (CPAP) and will this be available for use in the trial?		☐ Yes ☐ No ☐ Not yet
Does the site have adequate, secure storage for study records?		☐ Yes ☐ No ☐ Not yet
Are archiving facilities available to the site?		☐ Yes ☐ No ☐ Not yet
Electronic Data		
Do site staff have experience with online case report forms?		☐ Yes ☐ No
Are there local policies in place for the storage, transfer and security of data?		☐ Yes ☐ No ☐ Not yet
Does the site have support for data entry?		☐ Yes ☐ No ☐ Not yet
Monitoring/Audit		
Are study staff willing to allow the PRISM trial manager access to the medical records and source documents to ensure compliance with good clinical practice and adherence to the protocol?		☐ Yes ☐ No