FREQUENTLY ASKED QUESTIONS

Sedation, **An**algesia and **D**elirium **MAN**agement: an international audit of adult medical, surgical, trauma, and neuro-intensive care patients

STUDY PLANNING and LOGISTICS		
Q1	Who can I contact if I have any questions?	Ms. Sherihane Bensemmane (sandman.oxford@gmail.com), or one of the Principal Investigators: Dr. Geeta Mehta (Geeta.mehta@utoronto.ca) and Dr. Lara Prisco (lara.prisco@ndcn.ox.ac.uk)
Q2	Who is my National Coordinator (NC)?	You can find this information and all of the SAnDMAN documents at https://www.esicm.org/research/trials/trials-group-2/sandman/
Q3	Is there any financial support for research ethics board fees or my research personnel?	We wish that we could provide financial support, however unfortunately we have no funds to support participating sites. Site investigators are encouraged to explore opportunities for local funding.
Q4	Can I participate if I work in a paediatric or neonatal ICU?	Unfortunately not. SAnDMAN includes patients aged 18 years and over only.
Q5	Can I register more than 1 ICU in my centre?	Absolutely! Please register any general (medical and surgical) or specialist ICU (e.g., neuro ICU, cardiovascular ICU) at your centre that provides care for ADULT patients. One person may serve as the local investigator for all sites, or there may be a different investigator for each ICU.
Q6	Do I need IRB (Institutional Review Board) approval?	As this is a retrospective observational study, and not an interventional study, ethics committee approval may or may not be required depending on which country your ICU is located. You must check with your local ethical committee as to whether approval is required. IRB approval must be obtained for each center if required by its local regulations. In most countries, a National Coordinator will liaise with participating centers, and will help obtain IRB approval.
Q7	Will my National Coordinator (NC) take care of my IRB approval?	In most countries, the NC will liaise with participating centres, helping them to obtain IRB approval. As this is a prospective observational study, and not an interventional study, ethical committee approval may or may not be required depending on which country your ICU is located. IRB approval must be obtained for each centre if required by its local regulations. You must check with your local ethics committee as to whether approval is required.
Q8	Does this study require informed consent?	This is an observational study, and for it to yield useful information, we must be able to include all patients in ICU during the recruitment window if they fulfil the criteria. Requiring patient informed consent makes this very difficult. Ethics committees are generally aware of this issue, and will frequently waive consent for an observational study such as this.
Q9	Can I start enrolling patients before I have IRB approval?	Centres should NOT enrol any patients prior to receiving ethics approval. It is the local investigator's responsibility to ensure that local approvals are in place at their centre prior to the initiation of the study.
Q10	When can I start enrolling patients?	If you have received local IRB approval, you may start to collect patient data on the paper CRF. Please don't send any data to the Methods Centre until the Data Contribution Agreement (DCA) is finalized.
Q11	When can I have access to the eCRF?	Within a week after all required documents are sorted out (IRB approval received and DCA is finalized)
Q12	Is the study part of the UK NIHR portfolio?	For UK centres only: The Study has been classified as Research by the CTRG at the University of Oxford. In the UK, we have obtained approval to start the study at the main study centre, and we obtained Health Research Authority (HRA) approval in July 2021, which covers England and Wales. If you are a UK centre, you can either: 1) Contact your local R&D and ask to classify the study as an audit, and then seek approval from your local Trust to conduct it as an audit. In this case you will not be eligible for NIHR CRN support. 2) Or, send the contact details of your local PI to the UK National Coordinator to be included in the main IRAS form generated by Oxford (if you do so you will be eligible for NIHR CRN support, provided our application for inclusion in the NIHR portfolio is successful).

Q13	What are the roles and responsibilities of a National Coordinator (NC)?	The roles and responsibilities of the NC are to: • Promote the study and identify participating hospitals and local investigators in your country, ensuring representation of university-affiliated, community teaching, and community non-teaching hospitals. • Serve as the main contact for local investigators regarding ethical or other queries. • Ensure that ethical IRB and other appropriate approvals are in place, where applicable. • Receive and review scanned copies of IRB approvals from all centers, and forward them to sandman.oxford@gmail.com • Distribute study material to participating centers (protocol, CRF, manual of operations, etc.) and ensure that site investigators are familiar with the study material prior to starting the study. • Assist with translation of the study protocol/CRF, and other documents where required. • Communicate with participating sites and assist local investigators to achieve optimal recruitment, data collection and data quality. • Contribute patient data from their own site(s).
Q14	As an Investigator, will I be listed as a contributor in thefinal report/paper?	All National Coordinators will be listed as collaborators, and their names will appear on Pubmed. All site investigators who recruit 20 patients with less than 20% missing data will be listed as collaborators. For further information please refer to the document **Authorship and publication** (https://www.esicm.org/research/trials/trials-group-2/sandman/)
Q15	Can I be an author?	For information on authorship please refer to the document: **Authorship and publication** (https://www.esicm.org/research/trials/trials-group-2/sandman/)
Q16	Can I have a proof of participation in the study for my CV?	Yes. We would be happy to provide a letter for National Coordinators or Investigators who have included patients in this study. Please contact sandman.oxford@gmail.com
Q17	Can I have the list of other participating centres?	A list of participating centres will be provided to the National Coordinator for your country.
Q18	Is the eCRF platform GDPR compliant?	Yes. You can find this information and all of the SAnDMAN documents at https://www.esicm.org/research/trials/trials-group-2/sandman/
Q19	Does the eCRF exist in other languages?	Study documents are available in English and Spanish. You should liaise with your National Coordinator regarding the availability of SAnDMAN documents in languages other than English and Spanish.
Q20	How can I get a Data Contribution Agreement (DCA)?	Sponsorship from the University of Oxford has been obtained. In the UK, we have obtained approval to start the study at the main study centre, and we obtained HRA approval in July 2021, which covers England and Wales. If your local R&D/Institution requires another form of DCA please send an email to sandman.oxford@gmail.com, and we will review the document with the Contract Office at theUniversity of Oxford. The DCA must be completed and signed by someone either in the contracts or legal office, or R&D department at your institution/hospital.
Q21	Can I publish my own center's data?	After the primary SANDMAN manuscript is published, site investigators may publish their own site's data which was collected locally.

PATIENT DATA COLLECTION		
Q22	Are paper Case Report Forms (CRF) available for data entry?	We prefer centres to enter data in the electronic CRF. Centres not able to do so may enter data in a paper CRF. When complete, 1) the **de-identified** paperCRF can be scanned and emailed to the methods center, or 2) a COPY of the **de-identified** CRF can be mailed to the Methods Center (address below),where the data will be entered into the eCRF. Please retain the original CRF at your centre, and do not mail the original. Dr. Lara Prisco Neurosciences Intensive Care Unit, Level 1 West WingJohn Radcliffe Hospital Headley Way – OX3 9DU Oxford - United Kingdom
Q23	Can I enrol more than 20 patients?	No. For the Main Study, each ICU should enter data for 20 consecutive mechanically ventilated patients in the 3 months prior to the COVID epidemic in their country (e.g., October 1 2019 – December 31 2019). For the COVID-19 substudy, each ICU should enter data for a maximum of 20 patients in the *COVID-19 ICU* arm and 20 patients in the *Non-COVID-19 ICU* arm (see Protocol page 5 and 14 for details).
Q24	What is considered day 1?	Day 1 is the first day of mechanical ventilation (MV) if the patient was intubated in your ICU. If the patient was intubated in another hospital and then transferred to your ICU, day 1 will be the first MV day in your ICU.
Q25	How long do I collect data foreach patient?	For each patient, ICU data will be collected until <u>one of the following</u> endpoints is reached: 1) Liberation from mechanical ventilation for ≥ 24 hours (in this case please stop collecting data after extubation); OR 2) ICU discharge if they are transferred out of ICU mechanically ventilated; OR 3) Death in ICU; OR 4) A maximum of 7 days (study days 1-7). For ICU survivors, we will record the length of ICU stay, hospital stay and vital status on discharge (including death).
Q26	For post-operative patients, does the criteria for 12 hours of mechanical ventilation include MV in the OR?	For post-operative patients admitted to the ICU, the 12-hour time frame does NOT include MV in the OR. The time window starts when the patient is admitted to the ICU.
Q27	Is a patient receiving home mechanical ventilation eligible for inclusion when admitted to the ICU?	Please exclude patients receiving INVASIVE mechanical ventilation at home, but do include those receiving home non-invasive ventilation (NIV).
Q28	Should patients admitted to ICU more than once during the study period be included once, or for each admission?	Each patient is assigned a unique identifier. Do not include individual patients more than once.
Q29	Should bed rail restraints be reported?	Please do not report bed rails as physical restraints.
Q30	Do I include patients in the COVID-19 substudy, if no COVID-19 patients were admitted to my ICU during the study period?	You can include patients for the non-COVID-19 arm of the study. You can include up to 20 non-COVID patients admitted to your ICU between January 1, 2020 (or from the date of the COVID-19 surge in your country, or the date of the first COVID-19 patient admitted to your hospital) until January 1, 2021. For UK sites, eligible patients are those who were admitted to a participating ICU from March 20, 2020 until January 1, 2021.
Q31	Should medications received during surgical procedures be included in the daily patient data?	No. Only ICU drugs should be entered in the eCRF.